FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/03/97ISR Number: 100000064Report Type:Expedited (15-DaCompany Report #971002-008012669
Age:50 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Blood Creatine	Foreign	Haloperidol Ampoule	PS		INTRAVENOUS	15 MG,	QD, IV
Initial or Prolonged	Phosphokinase Increased	Health						
	Rhabdomyolysis	Professional						
		Other						

Date:11/03/97ISR Number: 3013025-8Report Type:Periodic Company Report #001-0970-970419
Age:75 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Crying	Health	Cognex	PS		ORAL	10MG, QID,	
	Faecal Incontinence	Professional					PER ORAL	
	Thinking Abnormal		Haldol	SS		ORAL	.5 MG, QD,	
							PER ORAL	
			Calcium	C				
			Centrum	C				
			Cycrin	C				
			Hydrochlorothiazide	C				
			Naprelan	C				
			Norvasc	C				
			Ticlid	C				
			Zocor	C				
			Zoloft	C				

Date:11/04/97ISR Number: 100000136Report Type:Expedited (15-DaCompany Report #97D--10575
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Life-Threatening	Aggression	Foreign	Voltaren Suppository	PS			
RECTAL 2 DF, DAILY,							
Hospitalization -	Anaemia	Health					
RECTAL							
Initial or Prolonged	Apnoea	Professional	Amitriptyline	SS			ORAL
50MG, DAILY,							
	Coma	Other					
ORAL							
	Delirium		Haldol	SS			
INTRAMUSCULAR 5MG DAILY,							
	Depressed Level Of						
INTRAMUSCULAR							
	Consciousness		Nortriptylin	SS			ORAL
40 MG DAILY,							
	Hallucination						
ORAL							
	Paranoia		Tavor	SS			
INTRAMUSCULAR 2MG, DAILY,							
	Restlessness						
INTRAMUSCULAR							
	Vomiting		Gastrozepin	C			
			Sostril	C			
			Laxoberal	C			
			Fraxiparin	C			

Date:11/05/97ISR Number: 3029316-0Report Type:Periodic Company Report #8-97127-008J
Age:27 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Insomnia	Consumer	Ativan	PS		ORAL
ORAL						
	Nervousness		Haldol	SS		
			Xanax	SS		
			Synthroid	C		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/06/97ISR Number: 100000178Report Type:Expedited (15-DaCompany Report #970917-008012626
Age:52 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Thrombocytopenia	Foreign Health Professional	Haloperidol	PS				
			Chlorprothixene	SS				
			Carbamazepine	SS				
			Diazepam	C				

Date:11/06/97ISR Number: 3005718-3Report Type:Direct Company Report #
Age:78 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Hyponatraemia		Haloperidol	PS		ORAL	1MG BID PO	
			Aspirin	C				
			Docusate Na	C				
			Famciclovir	C				
			Humibid	C				
			Lisinopril	C				
			Multivitamin	C				
			Bactrim	C				
			Ensure Plus	C				
			Azmacort Inhaler	C				

Date:11/12/97ISR Number: 3000621-7Report Type:Expedited (15-DaCompany Report #8-97309-005C
Age:52 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Apnoea Disorientation Vomiting	Foreign Study	Ativan	PS		INTRAMUSCULAR	2MG GIVEN WITH HALDOL (HALOPERIDOL)	
						INTRAMUSCULAR		
			Haldol	SS		INTRAMUSCULAR	5MG GIVE WITH	

TAVOR (LORAZEPAM) INTRAMUSCULAR			Nortriptyline	C		
40MG DAILY			Amitriptyline	C		
50MG DAILY			Sostril	C		
300MG DAILY			Gastrozepine	C		ORAL
50 MG DAILY			Fraxiparin	C		
SUBCUTANEOUS	3 ML DAILY SC		Voltaren	C		
RECTAL	100MG DAILY		Laxoberal	C		ORAL
45 GTTS DAILY						

Date:11/14/97ISR Number: 3000745-4Report Type:Expedited (15-DaCompany Report #LACT001970020
Age:78 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Shock	Foreign	Bifiteral	PS		ORAL	45MILLILITERS , PER ORAL	
			Saroten	SS		ORAL	25MG, PER ORAL	
			Haldol (Haloperidol)	SS		ORAL	4MG, PER ORAL	
			Nivalin	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/17/97ISR Number: 3005581-0Report Type:Direct Company Report #
Age:31 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Dysphagia		Haldol Decanoate 100	PS			300 MG Q3WKS	
Hospitalization -	Neuroleptic Malignant						IM	
Initial or Prolonged	Syndrome		Haldol	SS		ORAL	90 MG PO QD	
	Pyrexia		Klonopin	C				
			Cogentin	C				
			Inderal	C				

Date:11/17/97ISR Number: 3005804-8Report Type:Direct Company Report #
Age:66 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Torsade De Pointes	Health	Haldol	PS			INTRAMUSCULAR	2 MG IM THEN
		Professional					1 MG IM	
		Other	Primacor	SS			25MG /KG THEN	
							25 MG- 1 HR	

Date:11/17/97ISR Number: 3006077-2Report Type:Direct Company Report #
Age:85 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Dry Mouth		Haloperidol	PS			5MG QD (PRN)	1 MON
Initial or Prolonged	Jaundice		Acetaminophin	C				
	Pruritus							

Date:11/18/97ISR Number: 3001346-4Report Type:Expedited (15-DaCompany Report #GB/94/00859/MEL
Age:33 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardiac Arrest	Health	Melleril	PS		ORAL	200 MG	
	Cardio-Respiratory Arrest	Professional	Leponex/Clozaril	SS		ORAL	600 MG	
	Circulatory Collapse		Haloperidol	SS			UNSPECIFIED	
	Shock		Clopixol	SS		ORAL	MG/3W	200
							ORAL	
			Lithium	C				
			Salbutamol	C				
			Ranitidine	C				
			Benzhexol	C				

Date:11/19/97ISR Number: 3001708-5Report Type:Expedited (15-DaCompany Report #B035434
Age:59 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Convulsion	Foreign	Fludecasin	PS			25MG IM	16 MON
Initial or Prolonged	Depressed Level Of	Health	Mosapramine	SS			75MG	40 MON
	Consciousness	Professional	Linton	SS		ORAL	9MG	40 MON
	Urinary Incontinence		Tasmolin	C				
	Water Intoxication		Timiperone	C			40 MON	
	Weight Increased		Vegetamin-A	C		ORAL	1 TAB	40 MON
			Levotomin	C		ORAL	50 MG	40 MON
			Pyrethia	C				
			Phenobabital	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/19/97ISR Number: 3001860-1Report Type:Expedited (15-DaCompany Report #8-97272-001C
Age:67 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Confusional State Delirium Disorientation	Foreign Study	Trevilor Tablets (Venlafaxine Hydrochloride)	PS		ORAL	37.5MG ONCE	
	Disturbance In Attention							DAILY
	Memory Impairment		Haldol	SS		ORAL	1.5 MG	DAILY
			Hypnorex (Lithium Carbonate)	SS		ORAL	1200MG	DAILY
			Tavor (Lorazepam)	SS		ORAL	3MG	DAILY

Date:11/20/97ISR Number: 3005743-2Report Type:Direct Company Report #
Age:35 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Bradycardia Intentional Misuse Suicide Attempt		Benadryl Haloperidol	PS SS			6 GMS 60MG	

Date:11/20/97ISR Number: 3005808-5Report Type:Direct Company Report #
Age:70 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Parkinsonism	Health Professional	Molindone Haloperidol	PS SS			10 MG QHS 0.5MG BID	

Date:11/25/97ISR Number: 3038666-3Report Type:Periodic Company Report #9704905
Age:34 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Abnormal Behaviour	Consumer	Sinequan	PS		ORAL		
	Akathisia		Haldol Decanoate	SS				
INTRAMUSCULAR							125.00 MG	
	Blunted Affect							
TOTAL:MONTHLY								
	Constipation		Risperdal	SS		ORAL		
4.00 MG								
	Drug Interaction							
TOTAL:BID								
	Euphoric Mood		Cogentin	C				
	Tremor							

Date:12/01/97ISR Number: 3003007-4Report Type:Expedited (15-DaCompany Report #971121-008013188
Age:82 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Hyperglycaemia	Foreign	Haldol	PS		ORAL		
ORAL								
	Hypokalaemia	Health	Risperidone	SS		ORAL		
ORAL								
	Hyponatraemia	Professional	Cisapride	SS		ORAL		
10 MG, TID,								
ORAL								
			Buflomedil	SS		ORAL		
15O MG, QD,								
ORAL								
			Propafenone	SS				
300 MG, QD								
			Zopiclone	SS		ORAL		
7.5 MG,ORAL								
			Paroxetine	SS		ORAL		
20 MG, ORAL								
			Macrogol	SS		ORAL		
ORAL								
			Gaviscon	SS		ORAL		
ORAL								

			Efferalgan	SS		ORAL
ORAL						
			Unknown	C		

Date:12/01/97ISR Number: 3003073-6Report Type:Expedited (15-DaCompany Report #971120-008013181
Age:75 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Blood Alkaline	Foreign	Haloperidol			
Hospitalization -	Phosphatase Increased	Health	Decanoate	PS		
INTRAMUSCULAR 100 MG 1X/MO						
Initial or Prolonged	Cholestasis	Professional				
IM						
	Gamma-Glutamyltransferase		Haloperidol			
	Increased		Injection	SS		
INJECTION						
	Lipids Increased					
;5MG QD IM						
	Pyrexia		Haloperidol	SS		ORAL
CONCENTRATE;						
	Sepsis					
6MG QD						
	Urinary Tract Infection		Tropatepine	SS		ORAL
10MG						
			Levomepromazine	SS		
INTRAMUSCULAR 25MG QD						
			Lactitol	SS		ORAL
30G QD						
			Amoxicillin	SS		ORAL
QD						
			Nalidixic Acid	SS		ORAL
QD						

Date:12/01/97ISR Number: 3003075-XReport Type:Expedited (15-DaCompany Report #970422-008011253
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Abortion Induced Complete	Foreign	Haloperidol			
Congenital Anomaly	Complications Of Maternal		Decanoate	PS		
INTRA-UTERINE 100 MG.1X/MO,						

		Exposure To Therapeutic					
INTRAUTERINE							
		Drugs		Glibenclamide	SS		
INTRA-UTERINE	15 MG, QD,						
		Congenital Intestinal					
INTRAUTERINE							
		Malformation		Carbamazepine	SS		
INTRA-UTERINE	400 MG, QD,						
		Facial Dysmorphism					
INTRAUTERINE							
		Finger Deformity		Trihexyphenidyl	SS		
10 MG 1X/MO,							
		Glycosylated Haemoglobin					
INTTRAUTERINE							
		Increased		Insulin	SS		
INTRA-UTERINE	INTRAUTERINE						
		Meningomyelocele		Haloperidol			
		Spine Malformation		Decanoate	SS		
INTRA-UTERINE	25 MG, 1XMO,						
INTERUTERINE							

Date:12/01/97ISR Number: 3003077-3Report Type:Expedited (15-DaCompany Report #971117-013013130
Age:73 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dysphagia	Foreign Health Professional	Haldol, Unspecified (Haloperidol)	PS			UNKNOWN, UNKNOWN, UNKNOWN	

Date:12/01/97ISR Number: 3003079-7Report Type:Expedited (15-DaCompany Report #971120-008013175
Age:31 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Pancreatitis	Foreign Health Professional	Haloperidol	PS			UNKNOWN, UNKNOWN, UNKNOWN	
			Stavudine	C				
			Lamivudin	C				

			Trihexyphenidyl	C			
			Lorazepam	C			
			Cyamemazine	C			

Date:12/01/97ISR Number: 3003095-5Report Type:Expedited (15-DaCompany Report #971112-107013077
Age:34 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged Other	Aphasia Blepharospasm Blood Pressure Increased Catatonia Coma Complications Of Maternal Exposure To Therapeutic Drugs Depression Dyskinesia Foetal Distress Syndrome Haematuria Hallucinations, Mixed Heart Rate Increased Hyporeflexia Hypotonia Lethargy Oligohydramnios Overdose Pregnancy Induced Hypertension Suicide Attempt	Literature	Haloperidol	PS		ORAL	300 MG, ONCE, ORAL

Date:12/01/97ISR Number: 3003125-0Report Type:Expedited (15-DaCompany Report #971117-013013131
Age:81 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Blood Chloride Decreased Blood Sodium Decreased Fall	Foreign Health Professional	Haldol	PS		ORAL	1 MG, QD ORAL

Urine Osmolarity
Decreased

Date:12/01/97ISR Number: 3003494-1Report Type:Expedited (15-DaCompany Report #JAFRA-36318
Age:82 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Death	Foreign	Propulsid	PS	Janssen	ORAL	10 MG 3 DAILY	
		Health					ORAL	
		Professional	Risperdal	SS	Janssen	ORAL	.5 MG DAILY	
		Other					ORAL	
			Haldol	SS		ORAL	25 DROPS/DAY	1 DAILY
			Fonzylane	SS		ORAL	150 MG DAILY	
							ORAL	
			Rythmol	SS		ORAL	150 MG 3	DAILY
			Imovane	SS		ORAL	7.5 MG 1	DAILY ORAL
			Transipeg	SS		ORAL	ORAL	

			Gaviscon	SS		ORAL
ORAL						
			Efferalgan	SS		
			Deroxat	C		ORAL
20 MG 1 DAILY						
ORAL						

Date:12/01/97ISR Number: 3003531-4Report Type:Expedited (15-DaCompany Report #DEU000155
Age:38 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain Upper Drug Interaction	Foreign Other	Akineton	PS	Knoll Pharmaceutical Co	ORAL	3MG DAILY PO	
	Intestinal Obstruction		Hiberna	SS		ORAL	150 MG DAILY PO	
	Vomiting							
			Hirnamin	SS		ORAL	150 MG DAILY PO	
			Serenace	SS		ORAL	24 MG DAILY PO	
			Vegetamin A	SS		ORAL	UNK PO	
			Vegetamin B	SS		ORAL	UNK PO	
			Silence	C				
			Navane	C				
			Pusennid	C				
			Cisapride	C				

Date:12/01/97ISR Number: 3003614-9Report Type:Expedited (15-DaCompany Report #8-97323-003D
Age:67 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Hospitalization -	Extrapyramidal Disorder	Foreign	Seresta	PS		ORAL	50MG
Initial or Prolonged		Health	Haldol	SS		ORAL	1MG
Other		Professional	Modopar	SS		ORAL	125MG
			Theralene	SS		ORAL	5MG

Date:12/01/97ISR Number: 3003733-7Report Type:Expedited (15-DaCompany Report #971002-008012669
Age:50 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Blood Creatine	Foreign	Haloperidol	PS		INTRAVENOUS	15 MG, QD, IV	
Initial or Prolonged	Phosphokinase Increased	Health				(INTRAVENOUS)		
	Rhabdomyolysis	Professional	Analgesics, Nos	C				

Date:12/02/97ISR Number: 3003678-2Report Type:Expedited (15-DaCompany Report #86854
Age:70 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Aggression	Foreign	Valium	PS		ORAL	10.0000 MG	
Initial or Prolonged	Confusional State	Study					2.0 X PER DAY	
	Hallucination	Health				ORAL		
	Phlebitis	Professional	Bromocriptine	SS		ORAL	5.0000 MG 3.0	
	Skin Ulcer					X PER DAY		
						ORAL		
			Madopar	SS		ORAL	250.0000 MG	
						5.0 X PER DAY		
						ORAL		
			Haldol	SS		ORAL	3.0 X PER DAY	
						ORAL		
			Lexomil	SS		ORAL	ORAL	

Motilium C

Date:12/02/97ISR Number: 3007008-1Report Type:Direct Company Report #
Age:26 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Constipation		Haloperidol	PS			TAB; 1 MG BID	
	Dysphonia							
	Erectile Dysfunction							
	Hypoglycaemia							
	Tachycardia							
	Urinary Retention							
	Vision Blurred							

Date:12/03/97ISR Number: 3006823-8Report Type:Direct Company Report #
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Delirium Tremens		Haldol	PS			INTRAVENOUS 5 MG IV Q4	2 DAY
Initial or Prolonged	Depressed Level Of							
Other	Consciousness							
	Neuroleptic Malignant							
	Syndrome							
	Oxygen Saturation							
	Decreased							
	Pyrexia							
	Respiratory Rate							
	Increased							
	Sepsis							

Date:12/03/97ISR Number: 3006859-7Report Type:Direct Company Report #
Age:21 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Blood Creatine		Haloperidol	PS			INTRAMUSCULAR 100 MG IM Q 2	

Phosphokinase Increased
WKS
Hyperreflexia
Neuroleptic Malignant
Syndrome
Pyrexia
Tachycardia

Date:12/03/97ISR Number: 3006945-1Report Type:Direct Company Report #
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Neuroleptic Malignant		Haloperidal	PS		INTRAVENOUS	2 MG IV Q12	
Initial or Prolonged	Syndrome						H(EVERY 12	
Other	Pyrexia						HRS)	

Date:12/04/97ISR Number: 3004147-6Report Type:Expedited (15-DaCompany Report #971120-008013183
Age:52 YR Gender:Male I/FU:I

Outcome	PT
Life-Threatening	Apnoea
	Delirium

	Depressed Level Of Consciousness Hallucination	Report Source	Product	Role	Manufacturer	Route Dose Duration
	Vomiting	Foreign	Haldol Injection	PS		INTRAMUSCULAR 5MG, IM
		Health	Lorazepam	SS		INTRAMUSCULAR 2MG; QD; IM
		Professional	Amitriptyline	SS		
			Pirenzepine	SS		
			Diclofenac	SS		
			Sodium Picosulfate	SS		
			Glycosamin	SS		
			Ranitidine	SS		
			Nortriptyline	C		

Date:12/04/97ISR Number: 3004189-0Report Type:Expedited (15-DaCompany Report #971120-008013184
Age:82 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Hospitalization - Initial or Prolonged	Coma	Foreign	Haldol	PS		ORAL 15MG, QD, ORAL
	Dyspnoea	Health				
	Lung Disorder	Professional	Meprobamate	SS		ORAL 400MG, ORAL
	Nervous System Disorder		Valproate Sodium	SS		ORAL 500MG, QD,ORAL
	Pupils Unequal					
	Tremor		Misoprostol	SS		ORAL 20MG, ORAL
			Prednisone	SS		ORAL 60MG, QD, ORAL

Date:12/04/97ISR Number: 3007602-8Report Type:Direct Company Report #
Age:30 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration

Congenital Anomaly	Cardiomegaly		Haloperidol	PS		
INTRAMUSCULAR 20 MG Q MONTH						
	Complications Of Maternal					
IM						
	Exposure To Therapeutic		Pre-Natal Vitamins	C		
	Drugs		Haldol	C		
	Congenital Eye Disorder		Zoloft	C		
	Ear Malformation					
	Heart Disease Congenital					
	Intra-Uterine Death					
	Pulmonary Artery Stenosis Congenital					
	Ventricular Hypertrophy					

Date:12/08/97ISR Number: 3004358-XReport Type:Expedited (15-DaCompany Report #971028-008012934
Age:23 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Cardio-Respiratory Arrest	Foreign Health	Haloperidol	PS	Ortho Pharmaceutical Corporation	
INTRAMUSCULAR 10 MG, ONCE,						
		Professional				
IM						
(INTRAMUSCULA						
R)						
			Droperridol	SS		
INTRAMUSCULAR 50 MG, ONCE,						
IM						
			Levomerpromazine	C		
			Zuclopenthixol	C		
			Valproate Sodium	C		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/08/97ISR Number: 3006610-0Report Type:Expedited (15-DaCompany Report #971204-008013331
Age:19 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Grand Mal Convulsion Injection Site Erythema Injection Site Oedema Raynaud'S Phenomenon Sinus Tachycardia	Foreign Health Professional	Haloperidol	PS		INTRAVENOUS (INTRAVENOUS)	2 AMP, ONCE, IV	

Date:12/09/97ISR Number: 3006611-2Report Type:Expedited (15-DaCompany Report #971204-008013314
Age:63 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Convulsion Enterococcal Bacteraemia Hyponatraemia Loss Of Consciousness Malaise Renal Impairment	Foreign Health Professional	Haldol Zopiclone Alprazolam Viloxazine Clorazepate Insulin	PS SS SS SS C C		INTRAMUSCULAR (INTRAMUSCULAR) ORAL ORAL ORAL	IM	

Date:12/11/97ISR Number: 3007722-8Report Type:Direct Company Report #
Age:34 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Crying Dyskinesia Hallucination, Visual		Haloperidol Benztropine	PS C		ORAL	1 MG / DAY TO 0 MG	

	Screaming					
	Vomiting					

Date:12/12/97ISR Number: 3006609-4Report Type:Expedited (15-DaCompany Report #971204-107056956
Age:80 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Coma	Consumer	Haldol Injection	PS		INTRAMUSCULAR (INTRAMUSCULAR); 3 TIMES	IM	
	Difficulty In Walking							
	Dysarthria							
	Pneumonia					THERAPY		
	Restless Legs Syndrome		Ativan	C				
	Tardive Dyskinesia							

Date:12/12/97ISR Number: 3006729-4Report Type:Expedited (15-DaCompany Report #971204-008013307
Age:81 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Chloride Decreased	Foreign	Haldol	PS		ORAL 1 MG QD ORAL		
	Fall	Health Professional						

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/12/97ISR Number: 3006730-0Report Type:Expedited (15-DaCompany Report #971204008013308
Age:20 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Hepatitis	Foreign	Haldol	PS		ORAL	1 MG ORAL	
Initial or Prolonged	Rhabdomyolysis	Health	Cyamemazine	SS		ORAL	100 MG ORAL	
		Professional						

Date:12/12/97ISR Number: 3006732-4Report Type:Expedited (15-DaCompany Report #971204-008013313
Age:75 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Bruxism	Foreign	Haldol	PS		ORAL	9 MG, QD,	
	Dyskinesia	Health					ORAL	
	Obsessive-Compulsive Disorder	Professional	Stimol	C				
			Acetylcysteine	C				
			Lactulose	C				
			Captopril	C				
			Lorazepam	C				
			Ferrous Sulfate	C				
			Bisacodyl	C				
			Paracetamol	C				

Date:12/12/97ISR Number: 3006737-3Report Type:Expedited (15-DaCompany Report #970624-107053914
Age:68 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Aggression	Health	Haldol	PS		ORAL	ORAL	
	Agitation	Professional						
	Catatonia							
	Confusional State							
	Depression							
	Drug Withdrawal Syndrome							
	Dysarthria							
	Dyskinesia							

	Face Oedema					
	Insomnia					
	Movement Disorder					
	Muscle Twitching					
	Restlessness					
	Sedation					
	Tardive Dyskinesia					
	Tremor					

Date:12/12/97ISR Number: 3006738-5Report Type:Expedited (15-DaCompany Report #970730-107054625
Age:85 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Amnesia	Consumer	Haldol	PS			.5 MG, QID	
Initial or Prolonged	Cerebrovascular Accident	Health	Lasix	C				
	Confusional State	Professional	Isordil	C				
	Parkinson'S Disease		Slo-Bid	C				
	Personality Change		Sinemet	C				
	Tremor							

Date:12/12/97ISR Number: 3006740-3Report Type:Expedited (15-DaCompany Report #971203-008013290
Age:60 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Pulmonary Embolism	Foreign	Haldol	PS				
		Health	Heparin Sodium	C				
		Professional						

Date:12/12/97ISR Number: 3006742-7Report Type:Expedited (15-DaCompany Report #971204-008013305
Age:52 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Asthenia	Foreign	Haldol	PS		ORAL	2 MG/ML,	
Initial or Prolonged	Purpura	Health				ORAL		
	Thrombocytopenia	Professional	Tropatepine	SS		ORAL	10 MG,QD,ORAL	

Date:12/12/97ISR Number: 3006745-2Report Type:Expedited (15-DaCompany Report #971204-008013311
Age:40 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Gynaecomastia	Foreign	Haldol	PS		ORAL	7.5 ML, QD,	
Initial or Prolonged	Hyperprolactinaemia	Health				ORAL		
		Professional	Efferalgan-Codeine (R)	C				
			Buprenorphine	C				
			Hydroxyzine	C				
			Carbamazepine	C				

Date:12/12/97ISR Number: 3006747-6Report Type:Expedited (15-DaCompany Report #971204-008013312
Age:79 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Hospitalization - 2.5 MG, QD, Initial or Prolonged ORAL	Clonic Convulsion	Foreign	Haldol	PS	ORAL
	Dysarthria	Health			
50 MG,QD	Dysphonia	Professional	Maprotiline	SS	
60 MG QD	Pain In Extremity		Mianserin	SS	
			Oxazepam	C	
			Enalapril	C	

Date:12/15/97ISR Number: 3009525-7Report Type:Direct Company Report #
Age:35 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Constipation		Haloperidol	PS	Par/Geneva/Lilly/Vanguard/Udl/Schein	
1 MG TID	Dyskinesia					
	Dystonia					
	Hypotension					
	Lethargy					
	Liver Function Test Abnormal					
	Photosensitivity Reaction					
	Torsade De Pointes					
	Vision Blurred					

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/16/97ISR Number: 3008026-XReport Type:Expedited (15-DaCompany Report #8-97342-003T
Age:82 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Amnesia	Foreign Health Professional	Temesta Haldol	PS SS		ORAL ORAL	2.5 MG DAILY 20 MG DAILY	
			Difrarel	C			ORAL	
			Dilatrane	C				
			Haldol	C				
			Sermion	C				
			Ventolin	C				

Date:12/16/97ISR Number: 3008047-7Report Type:Expedited (15-DaCompany Report #8-97341-003T
Age:35 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Akinesia Alanine Aminotransferase	Foreign Health	Trevilor	PS	Wyeth-Ayerst Laboratories	ORAL	26 TABLETS	2 DAY
Other	Increased Alcohol Withdrawal Syndrome Amnesia Apathy Aspartate Aminotransferase Increased Blood Creatine Phosphokinase Increased Blood Lactate Dehydrogenase Increased Cold Sweat Depressed Mood Grand Mal Convulsion Overdose Pallor Rhabdomyolysis	Professional	Alcohol Haloperidol	SS SS				

	Therapeutic Agent Toxicity					

Date:12/16/97ISR Number: 3008197-5Report Type:Direct Company Report #
Age:53 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Aggression	Health	Haldol	PS			INTRAVENOUS	2 MG
Hospitalization - Initial or Prolonged	Arrhythmia	Professional	Heparin	C				
	Asthenia		Coumadin	C				
	Burning Sensation							
	Dysarthria							
	Hypoventilation							
	Mental Impairment							
	Nausea							
	Sensation Of Heaviness							
	Syncope							
	Tachycardia							
	Tremor							
	Vision Blurred							
	Vomiting							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/16/97ISR Number: 3008346-9Report Type:Direct Company Report #
Age:25 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Dystonia		Prolixin	PS		INTRAMUSCULAR	5 MG	
Hospitalization -			Mellaril	SS		INTRAMUSCULAR	5 MG	
Initial or Prolonged			Congentin	SS		INTRAMUSCULAR	5 MG	
Disability			Haldol	SS			1 MG	
Other			Benadryl	C				
Required								
Intervention to								
Prevent Permanent								
Impairment/Damage								

Date:12/16/97ISR Number: 3008465-7Report Type:Expedited (15-DaCompany Report #971204-008013317
Age:83 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Blood Pressure Decreased	Foreign	Haldol	PS		ORAL	20MG/ML, QD,	
Initial or Prolonged	Hypertonia	Health						
	Malaise	Professional	Droperidol	SS		ORAL	20MG/ML, QD,	
	Pulse Abnormal							
	Sedation		Tiapride	SS		ORAL	400MG, QD,	
			Cyamemazine	SS		ORAL	20MG, QD,	
			Meprobamate	C				
			Zolpidem	C				
			Lactilol	C				

Date:12/17/97ISR Number: 3010066-1Report Type:Expedited (15-DaCompany Report #9726049
Age:19 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Drug Interaction	Health	Zoloft	PS		ORAL		
Other	Potentiation	Professional	Alprazolam	SS		ORAL		
	Overdose		Haldol	SS		ORAL		
			Cogentin	SS		ORAL		

Date:12/17/97ISR Number: 3010285-4Report Type:Expedited (15-DaCompany Report #033-0970-973002
Age:82 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Respiratory Failure	Foreign	Cognex	PS			120 MG	
Life-Threatening		Health					(,DAILY)	
		Professional	Equanil Comprimes	SS			1.2 GM (,	DAILY)
			Haldol Faible	SS				
			Cervoxan	SS				
			Moclobemide	SS				

Date:12/17/97ISR Number: 3010479-8Report Type:Expedited (15-DaCompany Report #970811-107012565
Age:43 YR Gender:Male I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Activated Partial Thromboplastin Time Prolonged

		Deep Vein Thrombosis					
		Drug Interaction					
		Haemorrhage	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
		International Normalised	Health	Haldol	PS		
1X/MO							
		Ratio Increased	Professional	Coumadin	SS		
		Muscle Spasms					
		Pain In Extremity					

Date:12/17/97ISR Number: 3010485-3Report Type:Expedited (15-DaCompany Report #971204-008013320
Age:68 YR Gender:Female I/FU:I

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Death		Alanine Aminotransferase	Foreign	Haldol Concentrate	PS		ORAL
UNKNOWN,							
Life-Threatening		Increased	Health				
UNKNOWN, ORAL							
		Aspartate	Professional				
		Aminotransferase					
		Increased					
		Blood Alkaline					
		Phosphatase Increased					
		Hepatic Function Abnormal					
		Pulmonary Embolism					
		Pyrexia					
		Urinary Tract Infection					

Date:12/17/97ISR Number: 3010885-1Report Type:Direct Company Report #
Age:60 YR Gender:Male I/FU:I

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Life-Threatening		Aphasia		Haloperidol	PS	Mcneil	ORAL
ORALLY AT							
Hospitalization -		Balance Disorder					
BEDTIME							
Initial or Prolonged		Cerebellar Ataxia		Lithium Carb	SS	Roxane	ORAL
2 X DAILY							
Disability		Difficulty In Walking					
ORALLY							
		Movement Disorder					

Visual Disturbance

Date:12/17/97ISR Number: 3011801-9Report Type:Direct Company Report #
Age:25 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Dystonia		Haldol	PS		INTRAMUSCULAR	5MG IM	

Hospitalization - Initial or Prolonged
Other
Required Intervention to Prevent Permanent Impairment/Damage

Date:12/18/97ISR Number: 3009294-0Report Type:Direct Company Report #
Age:68 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Grand Mal Convulsion		Haloperidol	PS		INTRAMUSCULAR	200 MG IM Q	4 WEEKS

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/18/97ISR Number: 3009295-2Report Type:Direct Company Report #
Age:27 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Platelet Count Decreased		Haloperidol	PS		ORAL	15 MG PO	BID 18 WK
	White Blood Cell Count Decreased							

Date:12/18/97ISR Number: 3009580-4Report Type:Expedited (15-DaCompany Report #971211-008013456
Age:82 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Amnesia	Foreign Health Professional	Haldol	PS		ORAL	1 MG UNKNOWN	
			Lorazepam	SS		ORAL		
			Theophylline	C				
			Salbutamol	C				
			Difrael	C				
			Nicergoline	C				

Date:12/18/97ISR Number: 3009626-3Report Type:Expedited (15-DaCompany Report #970624-107053914
Age:68 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Agitation	Health Professional	Haldol	PS		ORAL		
	Catatonia							
	Confusional State							
	Dementia Alzheimer'S Type							
	Depression							
	Dysarthria							
	Dyskinesia							
	Face Oedema							
	Insomnia							
	Restlessness							
	Sedation							
	Tardive Dyskinesia							

	Tic					

Date:12/19/97ISR Number: 3011686-0Report Type:Expedited (15-DaCompany Report #9726282
Age:39 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Drug Interaction	Foreign	Diflucan	PS		ORAL	50MG TOTAL:	
Initial or Prolonged	Hypertonia	Health					DAILY: ORAL	
	Neuroleptic Malignant	Professional	Haloperidol	SS		ORAL	10MG TOTAL	
	Syndrome	Other					DAILY: ORAL	
	Pyrexia		Flunitrazepam	C				
			Levomepromazine	C				

Date:12/19/97ISR Number: 3011935-9Report Type:Direct Company Report #
Age:34 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dyspepsia		Haloperidal	PS	Mcneil		0.5 MG TID	
	Erectile Dysfunction							
	Headache							
	Lethargy							
	Palpitations							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/22/97ISR Number: 3012218-3Report Type:Expedited (15-DaCompany Report #91570
Age:50 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Coma	Foreign	Cercine	PS	Hoffmann-Laroche,			
	Drug Ineffective	Health			Inc.			
INTRAVENOUS							INTRAVENOUS	
	Respiratory Arrest	Professional	Rohyphol	SS				
INTRAVENOUS							1.0000 MG	
							DAILY	
INTRAVENOUS								
			Serenace	SS				
INTRAVENOUS								

Date:12/23/97ISR Number: 3012077-9Report Type:Direct Company Report #
Age:77 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required	Blood Creatine	Health	Haldol	PS				
Intervention to	Phosphokinase Increased	Professional	Clonidine	C				
Prevent Permanent	Catatonia		Enalapril	C				
Impairment/Damage	Labile Blood Pressure		Acetaminophen	C				
	Metabolic Encephalopathy		Milk Of Magnesia	C				
	Muscle Rigidity		Tums	C				
	Neuroleptic Malignant		Cogentin	C				
	Syndrome		Trazadone	C				
	Pyrexia		Lorazepam	C				
	White Blood Cell Count		Multivitamins	C				
	Increased		Thiamine	C				
			Olanzapine	C				

Date:12/24/97ISR Number: 3042284-0Report Type:Periodic Company Report #604AD970001
Age:35 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Depression	Consumer	Haloperidol	PS		ORAL		
ORAL								
			Depakote	C				

Date:12/30/97ISR Number: 3015315-1Report Type:Direct Company Report #
Age:76 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Effect Increased Lethargy Sedation		Xanax Diazepam Versed	PS SS SS		ORAL ORAL	0.25 MG PO;1625 5MG PO 1645 INTRAVENOUS 1819; 0.5 MG IV 10/15 1833 -DURING PTCA	1 MG IV 10/15
			Lorazepam	SS			INTRAVENOUS 0400	2 MG IV 0030;
			Haloperidol	SS			INTRAVENOUS 0400	2MG IV
			Ticlid Aspirin Colace Pepcid Ntg Patch	C C C C C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/30/97ISR Number: 3043896-0Report Type:Periodic Company Report #97-030
Age:70 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dry Mouth Tardive Dyskinesia	Health Professional	Haloperidol	PS		ORAL	5 MG P.O.	B.I.D.
			Buspirone	C				
			Cyproheptadine	C				
			Sertraline	C				
			E.C. Asa	C				
			Clonidine	C				
			Cimetidine	C				
			Oxybutinin	C				
			Chlorthalidone	C				
			Kcl	C				

Date:12/31/97ISR Number: 3012884-2Report Type:Direct Company Report #
Age:24 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Creatine Phosphokinase Increased		Resperidol	PS			TITRATE 3MG	BID
	Depressed Level Of Consciousness Feeling Jittery Neuroleptic Malignant Syndrome Pyrexia		Haloperidol	SS				

Date:01/02/98ISR Number: 3013832-1Report Type:Expedited (15-DaCompany Report #JAKYO-37064
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Rhabdomyolysis	Foreign	Risperdal	PS	Janssen	ORAL	6 MG DAILY	

			Health				
ORAL							
			Professional	Haloperidol Decanoate	SS	Janssen	
INTRAMUSCULAR	100 MG						
INTRAMUSCULAR							

Date:01/07/98ISR Number: 3016066-XReport Type:Expedited (15-DaCompany Report #971223-008013561
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Congenital Anomaly	Complications Of Maternal	Foreign	Haloperidol	PS				
INTRA-UTERINE	INTRAUTERINE	142 DAY						
	Exposure To Therapeutic	Health	Fluvoxamine	SS				
INTRA-UTERINE	100 MG, QD,							
	Drugs	Professional						
INTRAUTERINE	20 DAY							
	Foetal Macrosomia		Biperiden	SS				
INTRA-UTERINE	12 MG QD							
	Pneumonia							
INTRAUTERINE	140 DAY							
	Pyloric Stenosis		Diazepam	SS				
INTRA-UTERINE	INTRAUTERINE	17 DAY						
			Lorazepam	SS				
112 DAY								
			Clopenthixol	SS				
INTRA-UTERINE	40 MG QD							
INTRAUTERINE	6 DAY							
			Promethazine	SS				
75 MG QD								
INTRAUTERINE	28 DAY							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/07/98ISR Number: 3016068-3Report Type:Expedited (15-DaCompany Report #971223-008013562
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Congenital Anomaly	Complications Of Maternal Exposure To Therapeutic Drugs Developmental Delay Foetal Growth Retardation Premature Rupture Of Membranes Psychomotor Retardation Strabismus	Foreign Health Professional	Haloperidol	PS		INTRA-UTERINE	120 MG, QD,	INTRAUTERINE 107 DAY
			Flunitrazepam	SS		INTRA-UTERINE	TIW	INTRAUTERINE 92 DAY
			Diamorphine	SS		INTRA-UTERINE	TIW,	INTRAUTERINE 90 DAY
			Levomethadone	SS		INTRA-UTERINE	10 ML, QD,	INTRAUTERINE; 7 ML QD
			Biferiden	SS		INTRA-UTERINE	2 MG, QD,	INTRAUTERINE 107 DAY
			Lorazepam	SS		INTRA-UTERINE	3 MG, QD,	INTRAUTERINE 16 DAY
			Codeine	SS		INTRA-UTERINE	300 MG. QD,	INTRAUTERINE 90 DAY
			Amitriptyline	SS		INTRA-UTERINE	75 MG, QD,	INTRAUTERINE 16 DAY

Date:01/07/98ISR Number: 3016071-3Report Type:Expedited (15-DaCompany Report #971223-008013563
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Congenital Anomaly	Complications Of Maternal	Foreign	Haloperidol	PS		INTRA-UTERINE	INTRAUTERINE	
	Exposure To Therapeutic	Health	Biperiden	SS		INTRA-UTERINE	4 MG. QD,	
	Drugs	Professional				INTRAUTERINE		
	Congenital Hip Deformity		Diazepam	SS		INTRA-UTERINE	INTRAUTERINE	

Date:01/07/98ISR Number: 3016074-9Report Type:Expedited (15-DaCompany Report #971223-008013560
Age:53 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Thyroid Neoplasm	Foreign	Haldol	PS		ORAL	1	YR
Initial or Prolonged		Health	Cyamemazine	C				
		Professional	Biperiden	C				
			Benzodiazepines	C				

Date:01/07/98ISR Number: 3016076-2Report Type:Expedited (15-DaCompany Report #971224-008013582
Age:82 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Respiratory Failure	Foreign	Haldol	PS		ORAL		
		Health	Meprobamate	SS		ORAL	1.2 MG, QD,	
		Professional				ORAL		
			Moclobemide	SS		ORAL	450 MG. QD,	
						ORAL		
			Deanol	SS		ORAL		
			Tacrine	SS			120 MG, QD,	
						ORAL		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/08/98ISR Number: 3015941-XReport Type:Expedited (15-DaCompany Report #971224-107057317
Age:82 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Diabetes Mellitus	Consumer	Haldol	PS		ORAL	5 MG, QD	1 MON
	Gangrene		Risperidone	C				
	Haemoglobin Decreased		Clonazepam	C				
	Respiratory Failure							
	Skin Ulcer							

Date:01/08/98ISR Number: 3015944-5Report Type:Expedited (15-DaCompany Report #971224-008013583
Age:46 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Foreign	Haldol	PS		INTRAMUSCULAR	50MG QD, IM	
	Depression	Health Professional	Haldol Tablets	SS		ORAL	10 MG, QD, ORAL	
			Zolpidem	C				
			Lorazepam	C				

Date:01/08/98ISR Number: 3016844-7Report Type:Expedited (15-DaCompany Report #91570
Age:50 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Coma		Cercine	PS		INTRAVENOUS	INTRAVENOUS	
	Drug Ineffective		Rohypnol	SS		INTRAVENOUS	1.0000 MG DAILY	
	Respiratory Arrest					INTRAVENOUS		
			Serenace	SS		INTRAVENOUS	INTRAVENOUS	

Date:01/12/98ISR Number: 3016069-5Report Type:Expedited (15-DaCompany Report #971211-008013452
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Complications Of Maternal Exposure To Therapeutic Drugs Foetal Growth Retardation Heart Rate Abnormal Premature Baby Sepsis	Foreign Health Professional	Haldol	PS		INTRA-UTERINE	4MG, QD,	
			Haldol	SS		INTRA-UTERINE	6 MG, QD,	INTRAUTERINE 8 WK
			Ampicillin	SS		INTRA-UTERINE	3 G, QD,	INTRAUTERINE 8 DAY
			Diazepam	SS		INTRA-UTERINE	2.5 MG, QD,	INTRAUTERINE 13 DAY
			Valerian	SS		ORAL	QD, ORAL	

Date:01/12/98ISR Number: 3016078-6Report Type:Expedited (15-DaCompany Report #971211-008013454
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Atrial Septal Defect Complications Of Maternal Exposure To Therapeutic Drugs Foetal Growth Retardation Neonatal Aspiration Patent Ductus Arteriosus	Foreign Health Professional	Haldol	PS		INTRA-UTERINE	100 MG, 1X/3WK,	INTRAUTERINE 49 DAY
			Lithium Acetate	SS		INTRA-UTERINE	450 MG, QD,	INTRAUTERINE 49 DAY

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/13/98ISR Number: 3016398-5Report Type:Direct Company Report #
Age:77 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Blood Creatine Phosphokinase Increased		Haldol	PS				
	Catatonia		Clonidine	C				
	Labile Blood Pressure		Enalapril	C				
	Mental Impairment		Acetaminophen	C				
	Metabolic Encephalopathy		Mom	C				
	Muscle Rigidity		Tums	C				
	Neuroleptic Malignant Syndrome		Cogentin	C				
			Trazadone	C				
	Pyrexia		Lorazepam	C				
	White Blood Cell Count Increased		Mvi	C				
			Thiamine	C				
			Olanbodine	C				

Date:01/14/98ISR Number: 3126231-9Report Type:Direct Company Report #
Age:37 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Ineffective		Haloperidol	PS	Silarx Pharmaceutical	ORAL	ORAL SOLUTION	5 DAY

Date:01/15/98ISR Number: 3017043-5Report Type:Expedited (15-DaCompany Report #9726282
Age:39 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Bacterial Infection	Foreign	Diflucan	PS		ORAL	50.00 MG	TOTAL:DAILY:O
	Fungal Infection	Health						
	Hypertonia	Professional						
	Hypotension	Other	Haloperidol	SS		ORAL	10.00 MG	TOTAL:DAILY:O
	Infection							

	Neuroleptic Malignant					
RAL						
	Syndrome		Flunitrazepam	C		
	Pyrexia		Levomepromazine	C		
			Antibiotic	C		

Date:01/15/98ISR Number: 3017052-6Report Type:Expedited (15-DaCompany Report #9726282
Age:39 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Hypertonia	Foreign	Diflucan	PS		ORAL	50.00 MG	
Initial or Prolonged	Neuroleptic Malignant	Other	Haloperidol	SS		ORAL	10.00 MG	
	Syndrome		Flunitrazepam	C				
	Pyrexia		Levomepromazine	C				

Date:01/15/98ISR Number: 3017087-3Report Type:Expedited (15-DaCompany Report #971204-008013319
Age:64 YR Gender:Female I/FU:I

Outcome	PT
Hospitalization -	C-Reactive Protein
Initial or Prolonged	Increased
	Haemoglobin Decreased
	Leukopenia
	Malnutrition
	Pain
	Platelet Count Decreased

	Pyrexia Sepsis Weight Decreased	Report Source	Product	Role	Manufacturer	Route	Dose Duration
		Foreign Health Professional	Haloperidol Decanoate	PS		INTRAMUSCULAR	25 MG 1X/MO,IM (INTRAMUSCULAR)
			Mallorol	SS		ORAL	250 MG QD/ORAL
			Akineton Ekvacillin Heracillin	C C C			

Date:01/15/98ISR Number: 3018777-9Report Type:Direct Company Report #
Age:32 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Blood Creatine Phosphokinase Increased Body Temperature Increased Mental Impairment Sedation		Thorazine Haldol Digoxin Allopunnol Quinapril Levothyroxine	PS SS C C C C			

Date:01/20/98ISR Number: 3017285-9Report Type:Expedited (15-DaCompany Report #980109-008010041
Age:34 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Life-Threatening Hospitalization - Initial or Prolonged	Blood Creatine Phosphokinase Increased Cardio-Respiratory Arrest	Foreign Health Professional	Haloperidol Lorazepam	PS C		ORAL	15 MG, QD, ORAL

	Confusional State		Tropatepine	C
	Extrapyramidal Disorder		Citalopram	C
	Hepatic Enzyme Increased			
	Pyrexia			

Date:01/20/98ISR Number: 3017402-0Report Type:Expedited (15-DaCompany Report #8933-AR
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Congenital Anomaly	Diabetic Relative	Other	Orap	PS		ORAL	11 MG ORAL	99 DAY
Other	Foetal Macrosomia		Haloperidol	SS		ORAL	ORAL	
	Pneumonia		Flupentixol	SS			INTRA-UTERINE	5 MG
			Biperiden	SS			INTRA-UTERINE	1 DAILY
			Amitriptyline	SS			INTRA-UTERINE	50 MG 99 DAY
			Thioridazine	SS			INTRA-UTERINE	50 MG 66 DAY
			Diclofenac	SS			INTRA-UTERINE	160 MG

Date:01/20/98ISR Number: 3017947-3Report Type:Expedited (15-DaCompany Report #JAUSA-31021
Age:82 YR Gender:Male I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Anaemia
Disability	Dehydration
	Diabetes Mellitus Insulin-Dependent

		Haematochezia Joint Stiffness Lethargy	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
		Respiratory Failure	Consumer	Risperdal	PS		
5 MG 2 DAILY							
		Sepsis					
ORAL							
				Haldol	SS		
1 MG 1 DAILY							
ORAL							
				Klonopil	C		

Date:01/21/98ISR Number: 3017914-XReport Type:Expedited (15-DaCompany Report #M35005
Age:70 YR Gender:Male I/FU:F

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Death		Aggression	Foreign	Valium	PS		ORAL
10 MG 2 X PER							
Hospitalization -		Confusional State	Study				
DAY ORAL							
Initial or Prolonged		Dysphagia	Health	Bromocriptine	SS		ORAL
5 MG 3 X PER							
		Hallucination	Professional				
DAY ORAL							
		Hypoxia		Madopar	SS		ORAL
250 MG 5 X							
		Phlebitis					
PER DAY ORAL							
		Pulmonary Embolism		Lexomil	SS		ORAL
ORAL							
		Skin Exfoliation		Haldol	SS		ORAL
3 X PER DAY							
ORAL							
				Lovenox	SS		
SUBCUTANEOUS	.4 MG 1 X PER						
DAY							
SUBCUTANEOUS							

Date:01/21/98ISR Number: 3018895-5Report Type:Direct Company Report #
Age:46 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Agitation Hyperhidrosis Neuroleptic Malignant Syndrome Pyrexia		Fluphenazine Perphenazine Haloperidol	PS SS SS		ORAL	5 MG BID PO 8 MG PO BID 5 MG PO BID	

Date:01/22/98ISR Number: 3017566-9Report Type:Expedited (15-DaCompany Report #971224-008013581
Age:73 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death Hospitalization - Initial or Prolonged	Cardiogenic Shock Pulmonary Embolism Syncope	Foreign Health Professional	Haldol Sertraline Melperone Lorazepam	PS SS SS SS		ORAL ORAL ORAL ORAL	2 MG, QD/ORAL 50 MG, QD,ORAL 25 MG, QD,ORAL 1 MG, QD,ORAL	

Date:01/22/98ISR Number: 3017567-0Report Type:Expedited (15-DaCompany Report #980101-107050009
Age:19 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Asphyxia Intentional Self-Injury Overdose	Health Professional	Haldol Decanote Haloperidol	PS SS		INTRAMUSCULAR (INTRAMUSCULAR) ORAL	200 MG, 1X/2 WK, IM 5 MG, HS,	5 YR

ORAL 5 YR

Xanax	C
Cogentin	C
Lithium	C
Zoloft	C
Risperidone	C
Ativan	C

Date:01/22/98ISR Number: 3018246-6Report Type:Direct Company Report #
Age:37 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Extrapyramidal Disorder		Haloperidol	PS	Silaix Pharmacutical ,Spring Vally Ny 10997	ORAL		

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Date:01/28/98ISR Number: 3021255-4Report Type:Expedited (15-DaCompany Report #980121-008010207
Age:82 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Anaemia	Health	Haloperidol	PS		ORAL	1 MG, QD	
Initial or Prolonged	Dehydration	Professional	Risperidone	SS		ORAL	.5 MG QD	
Disability	Faecal Occult Blood Positive		Clonazepam	C				
	Lethargy							
	Respiratory Failure							
	Sepsis							

Date:01/28/98ISR Number: 3021501-7Report Type:Direct Company Report #
Age:33 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Muscle Spasms Muscle Twitching		Haldol Prozac	PS C				

Date:01/28/98ISR Number: 3022560-8Report Type:Direct Company Report #
Age:44 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Acute Psychosis Delusion Schizophrenia		Haloperidol Haloperidol Decanoate Syringe 2.5-3ml/Ndl 22g 1.5in Valproic Acid Amantadine Hcl Albuterol Ipratropium Bromide Casanthranol Multivitamin Risperidone	PS SS C C C C C C C C		ORAL	T1T IJ	PO B 350 M

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/02/98ISR Number: 3021852-6Report Type:Direct Company Report #
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Creatine Phosphokinase Increased Depressed Level Of Consciousness Muscle Rigidity Neuroleptic Malignant Syndrome		Haloperidol Benztropine	PS C				

Date:02/03/98ISR Number: 3022394-4Report Type:Expedited (15-DaCompany Report #D/98/00292/LEX
Age:30 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Complications Of Maternal Exposure To Therapeutic Drugs Convulsion Neonatal Drug Withdrawal Syndrome Neonatal Electrolyte Imbalance Fever Neonatal Infection Leukopenia Neonatal Pyrexia	Health Professional	Leponex Haldol	PS SS		ORAL	600 MG	

Date:02/04/98ISR Number: 3024228-0Report Type:Direct Company Report #
Age:53 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Asthenia		Hydroxyzine	PS			50 MG 8 HS	
Hospitalization - Initial or Prolonged	Cough		Haldol	SS			20 MG TID	
Required Intervention to	Decreased Appetite Dyspnoea Fatigue		Azaracort Albuterol Cogentin	C C C				

Prevent Permanent Impairment/Damage	Hyponatraemia Macroglossia Pneumonia Polydipsia Tongue Oedema		Doxapin Theophylline	C C			

Date:02/04/98ISR Number: 3035888-2Report Type:Expedited (15-DaCompany Report #980123-008010272
Age:49 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Blood Creatine Phosphokinase Increased Disseminated Intravascular Coagulation Neuroleptic Malignant Syndrome Polyneuropathy Pyrexia Renal Failure Respiratory Disorder Rhabdomyolysis	Foreign Literature Health Professional	Haloperidol Thioridazine	PS C		ORAL	3 MG QD ORAL

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/05/98ISR Number: 3024084-0Report Type:Expedited (15-DaCompany Report #971121-008013188
Age:82 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Sudden Death	Foreign	Haldol	PS		ORAL	UNK, UNK,	
		Health						
		Professional	Risperidone	SS		ORAL	UNK, UNK,	
			Cisapride	SS		ORAL	10 MG, TID,	
			Buflomedil	SS		ORAL	150 MG, QD,	
			Propafenone	SS			300 MG, QD,	
			Zopiclone	SS		ORAL	7.5 MG, UNK,	
			Paroxetine	SS		ORAL	20 MG, UNK,	
			Macrogol	SS		ORAL	UNK, UNK,	
			Gaviscon	SS		ORAL	UNK, UNK,	
			Efferalgan	SS		ORAL	UNK, UNK,	

Date:02/05/98ISR Number: 3024115-8Report Type:Expedited (15-DaCompany Report #980129-107050522
Age:45 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Confusional State	Health	Haloperidol	PS			UNK, UNK, UNK	
Hospitalization - Initial or Prolonged	Delirium Neuroleptic Malignant Syndrome	Professional	Lithobid	C				

Date:02/06/98ISR Number: 3024835-5Report Type:Expedited (15-DaCompany Report #980127-008010324
Age:13 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dyskinesia Dyspnoea	Foreign Health Professional	Haldol	PS		ORAL	TAB, QD, ORAL	

Date:02/06/98ISR Number: 3024837-9Report Type:Expedited (15-DaCompany Report #980202-107050598
Age:30 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Death	Health Professional	Haldol	PS				

Date:02/09/98ISR Number: 3026303-3Report Type:Expedited (15-DaCompany Report #JAKYO-37064
Age:48 YR Gender:Male I/FU:F

Outcome	PT
Other	Blood Creatine Phosphokinase Increased Chromaturia Condition Aggravated Hallucination, Auditory

	Hepatic Necrosis Myalgia Pain In Extremity	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
	Renal Impairment	Foreign	Risperdal	PS	Janssen	ORAL
6 MG DAILY						
	Rhabdomyolysis	Health				
ORAL						
		Professional	Haloperidol	SS	Janssen	ORAL
6 MG DAILY						
ORAL						
			Flunitrazepam	C		
			Diazepam	C		
			Biperiden Hydrochloride	C		

Date:02/10/98ISR Number: 3026722-5Report Type:Expedited (15-DaCompany Report #971211-008013451
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Complications Of Maternal	Foreign	Haldol	PS		
INTRA-UTERINE 11MG, QD,						
Initial or Prolonged	Exposure To Therapeutic	Health				
INTRAUTERINE						
	Drugs	Professional	Pimozide	SS		
24MG						
	Diabetes Mellitus		Flupentixol	SS		
INTRA-UTERINE 5MG, QD						
	Foetal Macrosomia					
INTRAUTERINE						
	Pneumonia		Biperiden	SS		
INTRA-UTERINE 1TAB, QD						
INTRAUTERINE						
			Amitriptyline	SS		
INTRA-UTERINE 50 MG, QD						
INTRAUTERINE						
			Thioridazine	SS		
INTRA-UTERINE 50 MG, QD,						
INTRAUTERINE						

			Diclofenac	SS		
INTRA-UTERINE	160 MG, QD, INTRAUTERINE					
			Pimozide	SS		
INTRA-UTERINE	4MG INTRAUTERINE					

Date:02/10/98ISR Number: 3027041-3Report Type:Expedited (15-DaCompany Report #LBID002980004
Age:48 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Confusional State	Health	Lithobid	PS		ORAL	PER ORAL	YR
Hospitalization - Initial or Prolonged	Delirium Neuroleptic Malignant Syndrome Pyrexia Tachycardia	Professional	Haldol	SS		ORAL	15 MG, PER ORAL	

Date:02/10/98ISR Number: 3027421-6Report Type:Direct Company Report #
Age:84 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Agitation	Health	Colchicine	PS			0.6 MG BID	
Hospitalization - Initial or Prolonged	Confusional State	Professional						
	Convulsion		Loperamide	SS		ORAL	2 MG PRN (2 DOSE)	
	Diarrhoea							
	Dyskinesia		3 Haloperidol	SS		ORAL	0.5 MG TID	
	Nausea		Metoprolol	C				
	Status Epilepticus		Furosemide	C				
	Vomiting		Doxepin	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/13/98ISR Number: 3029882-5Report Type:Direct Company Report #
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Ineffective		Trihexyphenidyl	PS			BID	
			Haloperidol	SS			BID	
			Temazepam	SS			1T HS	

Date:02/13/98ISR Number: 3030121-XReport Type:Expedited (15-DaCompany Report #JAUSA-31021
Age:82 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Anaemia	Consumer	Risperdal	PS	Janssen	ORAL	.5 MG 2 DAILY	
Initial or Prolonged	Dehydration						ORAL	
Disability	Diabetes Mellitus		Haldol	SS	Janssen	ORAL	1 MG 1 DAILY	
	Insulin-Dependent						ORAL	
	Joint Stiffness		Klonopin	C				
	Lethargy							
	Respiratory Failure							
	Sepsis							

Date:02/17/98ISR Number: 3030513-9Report Type:Expedited (15-DaCompany Report #980203-107050655
Age:54 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Neuroleptic Malignant	Health	Haldol Decanoate	PS			INTRAVENOUS	100 MG QD, IM
	Syndrome	Professional	Haldol Tablets	SS		ORAL	10 MG BID	
			Lithium	C				
			Ativan	C				
			Serzone	C				

Date:02/17/98ISR Number: 3030514-0Report Type:Expedited (15-DaCompany Report #970227-107051351
Age:34 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Disability	Macular Cyst	Consumer	Haldol	PS				17 YR

Date:02/17/98ISR Number: 3031324-0Report Type:Expedited (15-DaCompany Report #971117-013013130
Age:73 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Apathy Cerebral Ischaemia Dysphagia Nasopharyngeal Disorder Oesophageal Disorder Pyrexia Salivary Hypersecretion	Foreign Health Professional	Haldol Furosemide	PS C		ORAL	2 MG BID ORAL	

Date:02/17/98ISR Number: 3031325-2Report Type:Expedited (15-DaCompany Report #980123-008010288
Age:40 YR Gender:Female I/FU:I

Outcome
Life-Threatening Hospitalization -

Initial or Prolonged

	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Hypokalaemia	Foreign	Haldol	PS		ORAL	30 MG QD ORAL	
	Loss Of Consciousness	Health	Chlorpromazine	C				
	Malaise	Professional	Diazepam	C				
	Torsade De Pointes		Tropatepine	C				

Date:02/18/98ISR Number: 3036412-0Report Type:Direct Company Report #
Age:64 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Respiratory Failure		Haloperidol	PS		INTRAVENOUS	5 MG IV PRN	

Date:02/19/98ISR Number: 3032362-4Report Type:Expedited (15-DaCompany Report #98037.01
Age:77 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Abnormal Behaviour	Consumer	Haloperidol	PS	Mylan	ORAL	5 MG Q HS,	
Initial or Prolonged	Agitation	Health					ORAL	
Other	Amnesia	Professional	Glipizide	C				
	Cerebral Infarction		Paxil	C				
	Chorea		Benztropine	C				
	Confusional State							
	Decreased Appetite							
	Delusion							
	Dysarthria							
	Dyskinesia							
	Dystonia							
	Eating Disorder							
	Gait Disturbance							
	Pancytopenia							
	Paranoia							
	Salivary Hypersecretion							
	Urinary Retention							
	Urinary Tract Infection							

Date:02/20/98ISR Number: 3032725-7Report Type:Expedited (15-DaCompany Report #001-0991-973214
Age:48 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Glucose Decreased	Health Professional	Rezulin	PS		ORAL	400 MG	(DAILY), PER ORAL
	Cerebrovascular Accident							
	Chills							
	Condition Aggravated		Insulin N & R	SS				
	Drug Effect Increased		Tegretol	SS				
	Dysarthria		Haloperidol	SS				
	Lethargy		Folic Acid	C				
	Nausea		Zestril	C				
	Pyrexia		Prilosec	C				
	Salivary Hypersecretion		Mevacor	C				
	Vomiting		Ticlid	C				
	White Blood Cell Count Increased		Cipro	C				
			Propine	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/23/98ISR Number: 3034742-XReport Type:Expedited (15-DaCompany Report #9802649
Age:41 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Akinesia	Foreign	Cefobid	PS		INTRAVENOUS	2000	
Required	Aphasia	Health					MG/TOTAL/BID/	
Intervention to	Convulsion	Professional					INTRAVENOUS	
Prevent Permanent	Csf Test Abnormal	Company	Haloperidol	SS				
Impairment/Damage	Depressed Level Of	Representative	Impenem/Cilastatin	SS		INTRAVENOUS	INTRAVENOUS	
	Consciousness		Stronger					
	Electroencephalogram		Neo-Minophagen C	C				
	Abnormal		Miraclid	C				
			Human Immunoglobulin (Peg Treated)	C				

Date:02/23/98ISR Number: 3036304-7Report Type:Expedited (15-DaCompany Report #8-98043-003D
Age:35 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Aggression	Foreign	Effexor	PS		TAB		
Initial or Prolonged	Drug Interaction	Health	Carbamazepine	SS				
Other	Potentiation	Professional	Doxepin	SS				
	Hypotension		Etoh	SS				
	Overdose		Flupenthixol	SS				
	Sedation		Procylidine	SS				
	Tachycardia		Haloperidol	SS				
			Zolpidem	SS				

Date:02/23/98ISR Number: 3036364-3Report Type:Expedited (15-DaCompany Report #980217-008010586
Age:31 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Coma	Foreign	Haloperidol	PS		INTRAMUSCULAR	5 MG, QD, IM	

	Hypotension	Health				
(INTRAMUSCULA						
		Professional				
R)						
			Droperidol	SS		
INTRAMUSCULAR 50 MG, QD, IM						

Date:02/23/98ISR Number: 3036368-0Report Type:Expedited (15-DaCompany Report #980217-107010580
Age:72 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Clostridium Colitis	Literature	Haloperidol	PS		
.5 MG, TID,						
Initial or Prolonged	Diarrhoea					
UNKNOWN; 1						
	Leukocytosis					
MG, QUID,						
	Pyrexia					
UNKNOWN						
			Benztropine Mesilate	SS		
.5 MG, BID,						
UNKNOWN; .5						
MG, TID,						
UNKNOWN						
			Clindamycin	C		
			Ceftazidime	C		

Date:02/23/98ISR Number: 3121212-3Report Type:Periodic Company Report #9715698
Age:30 YR Gender:Male I/FU:I

Outcome	PT
Other	Confusional State
	Coordination Abnormal

	Drug Level Above Therapeutic					
	Dysarthria	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
	Gait Disturbance	Literature	Procardia	PS		ORAL
30.00 MG						
	Sedation	Health				
TOTAL:DAILY						
	Tremor	Professional	Lithium	SS		
1500.00 MG						
TOTAL DAILY						
			Haloperidol	SS		
20.00 MG						
TOTAL:DAILY						
			Clonazepam	SS		
DAILY						

Date:02/24/98ISR Number: 3030442-0Report Type:Expedited (15-DaCompany Report #8-98033-010D
Age:70 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Death	Catatonia	Foreign	Trihexyphenidyl	PS		ORAL
2 MG DAILY						
Hospitalization -	Muscle Rigidity	Health	Haloperidol	SS		ORAL
2.0 MG DAILY						
Initial or Prolonged	Neuroleptic Malignant	Professional	Levomepromazine	SS		ORAL
20 MG DAILY						
	Syndrome		Haloperidol	C		
	Pyrexia		Levomepromazine	C		

Date:02/24/98ISR Number: 3035569-5Report Type:Expedited (15-DaCompany Report #980217-107010581
Age:50 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization -	Blood Creatine	Foreign	Haldol	PS		ORAL
5 MG, BID						
Initial or Prolonged	Phosphokinase Increased	Literature				
ORAL						
Disability	Bronchopneumonia	Health				

Required Intervention to Prevent Permanent Impairment/Damage	Cerebellar Syndrome	Professional
	Coma	
	Convulsion	
	Coordination Abnormal	
	Csf Protein Increased	
	Depressed Level Of Consciousness	
	Dysarthria	
	Dystonia	
	Heart Rate Increased	
	Hepatic Function Abnormal	
	Hyperhidrosis	
	Hyperpyrexia	
	Hyperreflexia	
	Hypotension	
	Leukocytosis	
	Muscle Rigidity	
	Mutism	
	Neuroleptic Malignant Syndrome	
	Posturing	
	Pupillary Disorder	
	Pyrexia	
	Renal Impairment	
	Respiratory Alkalosis	
	Social Avoidant Behaviour	
	Supraventricular Extrasystoles	
	Tremor	
	Ventricular Extrasystoles	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/24/98ISR Number: 3038000-9Report Type:Direct Company Report #
Age:65 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Blood Creatine	Health	Haldol	PS				
N.I.							8	DAY
Hospitalization -	Phosphokinase Increased	Professional	Digoxin	C				
Initial or Prolonged	Muscle Rigidity		Norvac	C				
	Muscle Spasms		Thorazine	C				
	Neuroleptic Malignant		Elavil	C				
	Syndrome		K-Dur	C				
	Pyrexia							

Date:02/25/98ISR Number: 3036495-8Report Type:Direct Company Report #
Age:9 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Tardive Dyskinesia		Haloperidol	PS		ORAL	2 MG PO/IM	BID

Date:02/26/98ISR Number: 3037056-7Report Type:Expedited (15-DaCompany Report #B036793
Age:87 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Abnormal Behaviour	Foreign	Lopril	PS		ORAL		
Initial or Prolonged	Blood Creatinine	Health	Parkinane	SS				
	Increased	Professional	Haldol	SS				
	Blood Urea Increased		Floxyfral	SS			100 MG	
	Confusional State							
	Disorientation							
	Pyrexia							
	Urinary Tract Infection							

Date:02/27/98ISR Number: 3043661-4Report Type:Direct Company Report #
Age:51 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Hallucination Hallucination, Auditory Intentional Self-Injury		Haldol Ativan	PS SS		ORAL		

Date:02/27/98ISR Number: 3043694-8Report Type:Direct Company Report #
Age:75 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Fall		Haloperidol	PS			5MG AM PO, 2MG PM PO	
			Lisinopril	C				
			Diaoxin	C				
			Benztropine	C				
			Timoptic	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/27/98ISR Number: 3043699-7Report Type:Direct Company Report #
Age:81 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Required	Blood Creatine		Haloperidol	PS		ORAL	1 MG BID ORAL
Intervention to Prevent Permanent Impairment/Damage	Phosphokinase Increased		Lithium	C			
	Difficulty In Walking		Thiamine	C			
	Joint Stiffness		Glyburide	C			
	Lethargy		Amantadine	C			
	Mental Impairment		L-Thyroxine	C			
	Neuroleptic Malignant Syndrome		Vitamin E	C			
			Valproic Acid	C			
			Hctz	C			

Date:03/02/98ISR Number: 3139920-7Report Type:Periodic Company Report #9727541
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Other	Drug Interaction	Health	Zoloft Tablets	PS		ORAL	ORAL
	Tremor	Professional	Haldol	SS		ORAL	ORAL
		Company Representative					

Date:03/02/98ISR Number: 3148077-8Report Type:Periodic Company Report #9612782
Age:80 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Other	Accommodation Disorder	Health	Zoloft Tablets	PS		ORAL	50.00 MG TOTAL: DAILY: ORAL
	Influenza Like Illness	Professional					
			Haldol	SS		ORAL	ORAL
			Coumadin	C			
			Diabinese	C			

			Theodur	C		
			Captopril	C		
			Entex	C		

Date:03/04/98ISR Number: 3040385-4Report Type:Expedited (15-DaCompany Report #980109-008010040
Age:48 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Chromaturia Myalgia Pain In Extremity Rhabdomyolysis	Foreign Health Professional	Haloperidol Decanoate	PS		INTRAMUSCULAR (INTRAMUSCULAR)	100MG, 1X/MO,IM	
			Risperidone	SS		ORAL	6MG, QD, ORAL	
			Biperiden Hydrochloride	C				
			Flunitrazepam	C				
			Diazepam	C				

Date:03/05/98ISR Number: 3041526-5Report Type:Expedited (15-DaCompany Report #980223-107051042
Age:83 YR Gender:Male I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Catatonia Confusional State

		Pharyngeal Oedema Rectal Haemorrhage					
			Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
			Consumer	Haldol	PS		
INTRAVENOUS	IV						
			Health				
(INTRAVENOUS)	1 DAY						
			Professional	Lorazepam	C		
1 DAY							

Date:03/05/98ISR Number: 3041529-0Report Type:Expedited (15-DaCompany Report #980202-107050598
Age:30 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Death	No Adverse Drug Effect	Health	Haldol	PS		
INTRAMUSCULAR	5 MG, ONCE,					
		Professional				
IM						
(INTRAMUSCULA						
R)	1 DAY					

Date:03/05/98ISR Number: 3046261-5Report Type:Expedited (15-DaCompany Report #9804146
Age:75 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization -	Diarrhoea	Foreign	Unasyn	PS		
INTRAVENOUS	3000.00 MG					
Initial or Prolonged	Enterocolitis	Health				
TOTAL:BID:INT						
Required	Haemorrhagic	Professional				
RAVENOUS						
Intervention to	Gastroenteritis	Company	Haloperidol	SS		
INTRAVENOUS	INTRAVENOUS					
Prevent Permanent	Clostridial	Representative	Isosorbide Dinitrate	C		
Impairment/Damage	Hypoproteinaemia		Heparin	C		
	Pyrexia		Carperitide	C		
			Buprenorphine Hydrochloride	C		

			Ticlopidine Hydrochloride	C		

Date:03/05/98ISR Number: 3047367-7Report Type:Expedited (15-DaCompany Report #9803737
Age:25 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Interaction	Foreign	Zoloft	PS		ORAL	50 MG TOTAL	
	Dysarthria	Consumer					DAILY ORAL	
	Dyskinesia	Health	Haloperidol	SS		ORAL	2 MG TOTAL	
	Extrapyramidal Disorder	Professional					DAILY ORAL	
	Joint Dislocation	Company	Clomipramine	C				
	Suicidal Ideation	Representative						

Date:03/06/98ISR Number: 3043632-8Report Type:Expedited (15-DaCompany Report #FLUV001980029
Age:87 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Blood Creatine Increased	Foreign	Floxyfral	PS		ORAL	100 MG, PER	
Initial or Prolonged	Blood Urea Increased						ORAL	
	Confusional State		Parkinane	SS		ORAL	ORAL	
	Disorientation		Haldol Faible	SS		ORAL	05 MG/ML, PER	
	Escherichia Infection						ORAL	
	Pyrexia		Lopril	SS		ORAL	50 MG PER	
	Urinary Tract Infection						ORAL	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/06/98ISR Number: 3149540-6Report Type:Periodic Company Report #970819-107054942
Age:35 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Injection Site Reaction	Health	Haloperidol	PS		INTRAMUSCULAR	300 MG, 1X/MO	
Initial or Prolonged	Pyrexia	Professional				IM		
	Sedation					(INTRAMUSCULAR)		

Date:03/09/98ISR Number: 3049588-6Report Type:Expedited (15-DaCompany Report #9802649
Age:41 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Akinesia	Foreign	Cefobid	PS		INTRAVENOUS	2000.00 MG	
Required	Aphasia	Health				TOTAL BID		
Intervention to	Convulsion	Professional				INTRAVENOUS		
Prevent Permanent	Csf Test Abnormal	Company	Haloperidol	SS				
Impairment/Damage	Depressed Level Of	Representative	Stronger					
	Consciousness		Neo-Minophagen C	C				
	Electroencephalogram		Miraclid	C				
	Abnormal		Polythyleneglycol					
			Treated Human					
			Immunoglobulin	C				

Date:03/09/98ISR Number: 3049591-6Report Type:Expedited (15-DaCompany Report #9802649
Age:41 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Akinesia	Foreign	Cefobid	PS		INTRAVENOUS	2000.00 MG	
Required	Aphasia	Health				TOTAL BID		
Intervention to	Convulsion	Professional	Haloperidol	SS				

Prevent Permanent Impairment/Damage	Csf Test Abnormal Depressed Level Of Consciousness	Company Representative	Stronger Neo-Minophagen C Miraclid Polyethyleneglycol	C C C

Date:03/10/98ISR Number: 3049101-3Report Type:Direct Company Report #
Age:77 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agitation Clonic Convulsion Muscle Rigidity Muscle Twitching Musculoskeletal Stiffness Neuroleptic Malignant Syndrome Pyrexia		Haldol	PS		INTRAVENOUS	0.5MG IV Q 4H	PRN 1 DAY

Date:03/11/98ISR Number: 3055946-6Report Type:Expedited (15-DaCompany Report #8-98033-010D
Age:70 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Catatonia	Foreign	Trihexyphenidyl	PS		ORAL	2 MG DAILY	
Hospitalization - Initial or Prolonged	Muscle Rigidity Neuroleptic Malignant Syndrome Pyrexia	Health Professional	Haloperidol Levomepromazine	SS SS		ORAL ORAL	2.0 MG DAILY 20 MG DAILY	

ORAL

		...	C	
		...	C	

Date:03/12/98ISR Number: 3052914-5Report Type:Expedited (15-DaCompany Report #980306-008010826
Age:52 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Rhabdomyolysis	Foreign	Haldol	PS				
INTRAMUSCULAR							100 MG,	QD IM
Initial or Prolonged		Health						
(INTRAMUSCULA								
		Professional						
R)								
			Haloperidol	SS				
2.3 MG								QD
			Diazepam	C				
			Lormetazepam	C				

Date:03/12/98ISR Number: 3059153-2Report Type:Direct Company Report #
Age:65 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Blood Pressure Increased		Ativan	PS				
INTRAMUSCULAR							4 MG	IM Q2-4H
	Coma							
PRN								
	Hyperhidrosis		Haloperidol	SS				
INTRAMUSCULAR							1 MG	IM Q6H
	Muscle Rigidity							
	Neuroleptic Malignant							
	Syndrome							
	Pyrexia							
	Tremor							

Date:03/12/98ISR Number: 3135230-2Report Type:Periodic Company Report #JAUSA-27780
Age:20 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hyperprolactinaemia Pituitary Tumour	Health Professional	Risperdal (Risperidone) Janssen Tablet	PS	Janssen	ORAL	6MG DAILY	
						ORAL		
			Haldol (Haloperidol) Janssen Tablet	SS	Janssen	ORAL	20MG DAILY	
						ORAL		
			Doxepin (Doxepin)	SS		ORAL	75MG DAILY	
						ORAL, 150MG		
						DAILY ORAL		
						CAPSULES		

Date:03/12/98ISR Number: 3135713-5Report Type:Periodic Company Report #JAUSA-26930
Age:76 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Tardive Dyskinesia	Health Professional	Risperdal Haldol	PS SS	Janssen Janssen	ORAL ORAL	7 MG DAILY	

Date:03/12/98ISR Number: 3139726-9Report Type:Periodic Company Report #JAUSA-29795
Age:47 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Extrapyramidal Disorder	Health Professional	Risperdal	PS	Janssen	ORAL	2 MG 2 DAILY ORAL	

				Haldol	SS	Janssen	

Date:03/12/98ISR Number: 3140255-7Report Type:Periodic Company Report #JAUSA-28779
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Asthenia	Health	Risperdal	PS	Janssen	ORAL	TABLET, ORAL	
Initial or Prolonged	Blood Creatine	Professional	Haldol	SS	Janssen	ORAL	ORAL	
	Phosphokinase Increased		Cogentin	C				
	Confusional State							
	Hypokalaemia							

Date:03/12/98ISR Number: 3146653-XReport Type:Periodic Company Report #JAUSA-27541
Age:12 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Condition Aggravated	Health	Risperdal					
	Muscle Contractions	Professional	(Risperidone)	PS	Janssen	ORAL	SEE IMAGE	
	Involuntary		Haldol (Haloperidol)	SS	Janssen	ORAL	1 MG 2 DAILY	
							ORAL	
			Zyprexa (Olanzapine)	SS		ORAL	SEE IMAGE	9 WK
			Prozac (Fluoxetine)	C				
			Depakote	C				
			Eskalith	C				
			Atenolol	C				

Date:03/12/98ISR Number: 3149419-XReport Type:Periodic Company Report #JAUSA-30291
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Mania	Consumer	Risperdal	PS	Janssen	ORAL	-, ORAL	

			Haldol	SS	Janssen	

Date:03/19/98ISR Number: 3057897-XReport Type:Direct Company Report #
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Required	Dystonia		Haloperidol	PS		
10MG, 1 QD						
Intervention to Prevent Permanent Impairment/Damage						

Date:03/19/98ISR Number: 3058216-5Report Type:Expedited (15-DaCompany Report #980312-008010887
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Atrioventricular Block	Foreign	Haldol	PS		ORAL
1 MG, QD,						
	Complete	Health				
ORAL						
	Hyperkalaemia	Professional	Lithium	C		
	Myocardial Infarction		Thioridazine	C		
			Potassium	C		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/19/98ISR Number: 3058217-7Report Type:Expedited (15-DaCompany Report #980316-008010924
Age:89 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Coma	Foreign	Haloperidol	PS		INTRAMUSCULAR	50 MG,	
	Hemiplegia	Health				UNKNOWN,		
	Peripheral Ischaemia	Professional				INTRAMUSCULAR		

Date:03/20/98ISR Number: 3057117-6Report Type:Expedited (15-DaCompany Report #980316-008010925
Age:26 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Paralysis	Health	Haloperidol	PS		ORAL	ORAL	
Hospitalization -		Professional	Risperidone	SS		ORAL	ORAL	12 MON
Initial or Prolonged								

Date:03/20/98ISR Number: 3057118-8Report Type:Expedited (15-DaCompany Report #960227-107050555
Age:57 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Condition Aggravated	Study	Haldol	PS		ORAL	15 MG, QD,	
	Fall	Health				ORAL		
	Respiratory Disorder	Professional	Haldol	SS		INTRAMUSCULAR	200 MG,	
							1X/MO, IM	
			Depakote	SS		ORAL	1000 MG, BID,	
							ORAL	
			Risperidone	SS		ORAL		

Date:03/20/98ISR Number: 3059772-3Report Type:Expedited (15-DaCompany Report #JACAN-16678
Age:26 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Paralysis	Foreign	Risperdal	PS	Janssen	ORAL	ORAL	12 MON
Hospitalization - Initial or Prolonged		Consumer	Haldol	SS	Janssen	ORAL	ORAL	
			Ativan	SS		ORAL	ORAL	

Date:03/23/98ISR Number: 3058513-3Report Type:Expedited (15-DaCompany Report #CH98030121A
Age:47 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Foreign	Haloperidol	PS			20 MG/ 2 DAY	
Life-Threatening	Diarrhoea	Study	Chloraldurat					
Hospitalization - Initial or Prolonged	Electrolyte Imbalance	Health Professional	(Chloral Hydrate)	C				
	Gastrointestinal Infection		Lorazepam	C				
	Polydipsia		Pipamperone	C				
	Vomiting		Oxazepam	C				
	Water Intoxication		Antra (Omeprazole)	C				

Date:03/30/98ISR Number: 3058391-2Report Type:Expedited (15-DaCompany Report #D/98/00292/LEX
Age:30 YR Gender:Female I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Agitation
	Clonic Convulsion
Congenital Anomaly	Complications Of Maternal Exposure To Therapeutic

	Drugs						
	Convulsion						
	Drug Withdrawal Syndrome						
	Neonatal	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Ear Malformation	Health	Leponex	PS		ORAL	900 MG ORAL
	Electroencephalogram	Professional	Haldol Deconoate	SS		INTRAMUSCULAR	100 MG
	Abnormal		....	C			
	Electrolyte Imbalance		...	C			
	Eructation						
	Feeding Problem In Newborn						
	Fever Neonatal						
	Hyperhidrosis						
	Hypertonia						
	Hypocalcaemia						
	Infection						
	Leukopenia Neonatal						
	Livedo Reticularis						
	Nervous System Disorder						
	Nervousness						
	Neuropathy Peripheral						
	Regurgitation Of Food						
	Skin Disorder						
	Sleep Disorder						
	Tremor Neonatal						

Date:03/30/98ISR Number: 3059106-4Report Type:Expedited (15-DaCompany Report #JACAN-16678
Age:26 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Life-Threatening	Cardiac Arrest	Foreign	Risperdal	PS	Janssen	ORAL	ORAL; ON FOR
Hospitalization - Initial or Prolonged	Coma	Consumer					ABOUT 1 YEAR,
	Paralysis						5 YEARS AGO 12 MON
	Tremor		Haldol	SS	Janssen	ORAL	ORAL
			Ativan	SS			TABLET; ORAL

Date:04/01/98ISR Number: 3058807-1Report Type:Expedited (15-DaCompany Report #980324-008010997
Age:44 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Respiratory Depression	Foreign	Haloperidol	PS		ORAL	ONCE, ORAL	
	Suicide Attempt	Health	Doxepin	SS		ORAL	ONCE, ORAL	
		Professional	Diclofenac	SS		ORAL	ONCE, ORAL	
			Risperidone	SS		ORAL	ONCE, ORAL	
			Alcohol	SS		ORAL	ONCE, ORAL	

Date:04/01/98ISR Number: 3058810-1Report Type:Expedited (15-DaCompany Report #980324-008010998
Age:37 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Miosis	Foreign	Haloperidol	PS		ORAL	20 MG, ONCE,	ORAL
	Sedation	Health						
	Tachycardia	Professional	Pipamerone	SS		ORAL	800MG, ONCE	ORAL
			Levomepromazine	SS		ORAL	1250 MG,	ONCE, ORAL
			Alcohol	SS		ORAL	ORAL	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/02/98ISR Number: 3064045-9Report Type:Expedited (15-DaCompany Report #980327-008011067
Age:23 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Foreign	Haldol	PS		ORAL	4.5 MG QD,	
Hospitalization - Initial or Prolonged	Drug Ineffective	Health						
	Hallucination, Auditory	Professional	Risperidone	SS		ORAL	1 MG, QD ORAL	
			Levomepromazine	SS		ORAL	15 MG, QD, ORAL	

Date:04/02/98ISR Number: 3071915-4Report Type:Direct Company Report #
Age:49 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Electrocardiogram Qt		Erythromycin	PS		INTRAVENOUS	500 MG QID IV	
	Prolonged		Haloperidol	SS		INTRAVENOUS	2 MG QIH PRN	
	Torsade De Pointes					IV		
	Ventricular Extrasystoles							
	Ventricular Tachycardia							

Date:04/03/98ISR Number: 3061341-6Report Type:Expedited (15-DaCompany Report #980316-008010925
Age:26 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Cardiac Arrest	Health	Haloperidol	PS		ORAL	ORAL	
Hospitalization - Initial or Prolonged	Paralysis	Professional	Risperidone	SS		ORAL	ORAL	12 MON
			Lorazepam	SS		ORAL	ORAL	

Date:04/07/98ISR Number: 3071743-XReport Type:Direct Company Report #
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Akathisia Gait Disturbance Muscle Rigidity Muscle Spasms Staring		Haldol	PS		ORAL	5MG PO BID	

Date:04/13/98ISR Number: 3063777-6Report Type:Expedited (15-DaCompany Report #980406-008011153
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Congenital Anomaly	Cataract Congenital	Foreign	Haloperidol	PS			INTRA-UTERINE	INTRAUTERINE
	Complications Of Maternal Exposure To Therapeutic Drugs	Health Professional	Procyclidine Loxapine	SS C				
	Foetal Growth Retardation							

Date:04/13/98ISR Number: 3063778-8Report Type:Expedited (15-DaCompany Report #980406-008011155
Age:35 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Coma	Foreign	Haloperidol	PS		ORAL	20 MG, QD, ORAL	
	Miosis	Health Professional						
	Stridor		Haloperidol Decanoate	SS			100 MG, 1X/MO, IM	

			Carbamazepine	SS		ORAL 800 MG, QD, ORAL
			Levomepromazine	SS		ORAL 100 MG, QD, ORAL
			Biperidin	C		

Date:04/13/98ISR Number: 3063779-XReport Type:Expedited (15-DaCompany Report #980406-008011156
Age:81 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Death	Parkinsonism	Foreign	Haloperidol	PS		INTRAMUSCULAR 50 MG, IM
Life-Threatening	Pneumonia	Health	Benperidol	SS		ORAL ORAL
	Pneumonia Aspiration	Professional				
	Pulmonary Embolism					
	Pyrexia					

Date:04/13/98ISR Number: 3063780-6Report Type:Expedited (15-DaCompany Report #980406-008011157
Age:20 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Other	Hairy Cell Leukaemia	Foreign	Haloperidol	PS		INTRAMUSCULAR IM
	Leukopenia	Health	Fluoxetine	SS		ORAL 20 MG, ORAL
	Platelet Count Decreased	Professional				
	Retinal Haemorrhage					

Date:04/14/98ISR Number: 3063979-9Report Type:Expedited (15-DaCompany Report #980409-008011213
Age:17 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration

Life-Threatening	Suicide Attempt	Foreign	Haloperidol	PS		ORAL 5MG/QD/ORAL
		Health	Risperidone	SS		ORAL ORAL
		Professional				

Date:04/14/98ISR Number: 3063980-5Report Type:Expedited (15-DaCompany Report #980406-008011152
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Death	Jaundice Cholestatic	Foreign	Haloperidol	PS		ORAL 10MG/QD/ORAL
		Health Professional				

Date:04/14/98ISR Number: 3063983-0Report Type:Expedited (15-DaCompany Report #980406-008011160
Age:83 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Hospitalization -	Decreased Activity	Literature	Haloperidol	PS		ORAL 2MG/QD/ORAL
Initial or Prolonged	Depressed Level Of	Health	Phenytoin	SS		
INTRAVENOUS 1000MG/QD/IV	Consciousness	Professional	Cimetidine	C		
	Difficulty In Walking		Verapamil	C		
	Drug Level Above		Timolol	C		
	Therapeutic		Dipivefrine	C		
	Medication Error		Psyllium	C		
	Middle Insomnia		Clindamycin	C		
	Stupor		Pilocarpine	C		
	Urinary Incontinence					

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/14/98ISR Number: 3063989-1Report Type:Expedited (15-DaCompany Report #980406-008011158
Age:22 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Rigidity	Foreign	Haloperidol Decanoate	PS		ORAL	150 MG/QD/ORAL	
	Disorientation	Health						
	Dysarthria	Professional						
	Extrapyramidal Disorder		Fluoxetine	SS		ORAL	80 MG/QD/ORAL	
	Hallucination		Alcohol	C				
	Hypertonia		Alcohol	C				
	Muscle Rigidity							
	Suicide Attempt							
	Tremor							

Date:04/14/98ISR Number: 3071808-2Report Type:Direct Company Report #
Age:64 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Neuroleptic Malignant Syndrome		Haloperidol	PS		ORAL	T1T PO H	
			Trihexhphenidyl Hcl	C				
			Trazodone Hcl	C				
			Risperidone	C				

Date:04/14/98ISR Number: 3071864-1Report Type:Direct Company Report #
Age:84 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Difficulty In Walking		Haloperidol Decanoate	PS			IJ 1ML	
	Fall							
	Loss Of Consciousness		Benztropine	C				
	Parkinsonism							
	Rhabdomyolysis							

Date:04/15/98ISR Number: 3066284-XReport Type:Expedited (15-DaCompany Report #001-0073-980166
Age:27 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Aspartate	Health	Dilantin	PS		ORAL	25-50	
Hospitalization -	Aminotransferase	Professional					CAPSULES X 1	
Initial or Prolonged	Increased						DOSE	
	Blood Bilirubin Increased		Haldol	SS		ORAL	25-50 TABLETS	
	Blood Creatinine						X 1 DOSE	
	Increased		Tylenol	SS		ORAL	25-50 TABLETS	
	Blood Lactate						X 1 DOSE	
	Dehydrogenase Increased							
	Cardiac Arrest							
	Coma							
	Hepatotoxicity							
	Intentional Misuse							
	Intentional Self-Injury							
	Oliguria							
	Prothrombin Time Ratio Increased							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/15/98ISR Number: 3071901-4Report Type:Direct Company Report #
Age:64 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Aphasia		Haldol	PS				
	Lethargy		Lithium	C				
	Leukocytosis		Cogentin	C				
	Pyrexia							
	Speech Disorder							

Date:04/15/98ISR Number: 3071903-8Report Type:Direct Company Report #
Age:64 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Aphasia		Haldol	PS				
	Lethargy		Lithium	C				
	Leukocytosis		Cogentin	C				
	Pyrexia							
	Speech Disorder							

Date:04/16/98ISR Number: 3064381-6Report Type:Expedited (15-DaCompany Report #980223-107051042
Age:83 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - INTRAVENOUS	Catatonia	Consumer	Haldol	PS		IV		
Initial or Prolonged (INTRAVENOUS)	Confusional State	Health						
	Medication Error	Professional	Lorazepam	C				
	Oropharyngeal Swelling		Ramipril	C				
			Propranolol	C				
			Dilitiazem	C				

Date:04/16/98ISR Number: 3064934-5Report Type:Expedited (15-DaCompany Report #8-98098-004A
Age:56 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Hospitalization - Initial or Prolonged	Extrapyramidal Disorder	Foreign	Temesta	PS		ORAL 2.5 MG ORAL
Other		Health Professional	Deroxat	SS		
			Haldol Decanoas	SS		
			Mepronizine	SS		ORAL ORAL

Date:04/16/98ISR Number: 3070780-9Report Type:Expedited (15-DaCompany Report #FR01-08971
Age:55 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Hospitalization - Initial or Prolonged	Fall	Foreign	Calsyn	PS	Rpr Specia	INTRAMUSCULAR IM
	Haematoma	Health Professional	Haldol	SS		ORAL PO
	Haemorrhage		Laroxyl	SS		ORAL PO
	Malaise		Lexomil	SS		ORAL PO
	Skull Fracture		Primperan	C		
			Estreva	C		
			Utrogestan	C		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/16/98ISR Number: 3072643-1Report Type:Direct Company Report #
Age:52 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Coma	Health	Haldol	PS			1 MG IV	ONCE
Other	Lethargy	Professional	Prograf	C				
Required	Mental Impairment		Propranolol	C				
Intervention to			Lactulose	C				
Prevent Permanent			Vit K	C				
Impairment/Damage								

Date:04/20/98ISR Number: 3065160-6Report Type:Expedited (15-DaCompany Report #96491
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Interaction	Foreign	Roaccutane	PS				
	Drug Level Above	Health	Haloperidol	SS				
	Therapeutic	Professional						

Date:04/20/98ISR Number: 3066625-3Report Type:Expedited (15-DaCompany Report #96491
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Interaction	Foreign	Roaccutane	PS				
	Drug Level Above	Health	Haloperidol	SS				
	Therapeutic	Professional						

Date:04/20/98ISR Number: 3069333-8Report Type:Expedited (15-DaCompany Report #97581
Age:35 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Alveolitis	Foreign	Bactrim	PS		ORAL	1.0000 DOSE	
Initial or Prolonged	Cryptogenic Organizing	Other						
FORM 1.0 X								

Pneumonia

PER DAY ORAL

Haldol Decanoas SS

INTRAMUSCULAR 1.0000 DOSE

FORM 1.0X PER

MON

INTRAMUSCULAR

Zithromax SS

Date:04/22/98ISR Number: 3066976-2Report Type:Expedited (15-DaCompany Report #8-98099-006N
Age:74 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Anticholinergic Syndrome	Foreign	Effexor	PS		ORAL	150MG/DAILY/O	
Initial or Prolonged	Blood Magnesium	Literature					RAL -	
Other	Delirium						75MG/DAILY	6 MON
	Drug Interaction		Alprazolam	SS			0.25MG/DAILY	5 DAY
	Ileus Paralytic		Desipramine	SS			50MG/DAILY	5 DAY
	Stupor		Haloperidol	SS		ORAL	0.5MG/DAILY	5 DAY
	Urinary Retention							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/22/98ISR Number: 3070745-7Report Type:Expedited (15-DaCompany Report #8-98099-006N
Age:74 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anticholinergic Syndrome	Foreign	Efexor	PS		ORAL	150 DAILY	
	Delirium	Literature						
ORAL							6	MON
Other	Ileus Paralytic		Alprazolam	SS			0.25 MG DAILY	5 DAY
	Stupor		Desipramine	SS			50MG DAILY	5 DAY
	Urinary Retention		Haloperidol	SS			0.5 MG DAILY	5 DAY

Date:04/23/98ISR Number: 3066818-5Report Type:Expedited (15-DaCompany Report #9810118
Age:35 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Alveolitis	Foreign	Zithromax	PS		ORAL	1.00 ORAL	
	Cryptogenic Organizing Pneumonia	Health Professional	Sulfamethoxazole Haloperidol	SS		ORAL	DAILY:ORAL	
	Obliterative Bronchiolitis	Other	Decanoate	SS			INTRAMUSCULAR	50.00 MG

TOTAL:MONTHLY

:INTRAMUSCULA

R

Date:04/23/98ISR Number: 3067551-6Report Type:Expedited (15-DaCompany Report #970227-107051351
Age:34 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Condition Aggravated	Health	Haldol	PS			INTRAMEDULLAR	

Initial or Prolonged Macular Cyst Professional (BONE MARROW) 150 MG MO IM 17 YR
Disability Macular Degeneration
Visual Acuity Reduced

Date:04/23/98ISR Number: 3072745-XReport Type:Direct Company Report #
Age:75 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Fall		Haloperidol	PS			5MG Q AN 10 MG QHS	

Date:04/24/98ISR Number: 3068815-2Report Type:Expedited (15-DaCompany Report #97581
Age:35 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Alveolitis	Foreign	Bactrim	PS		ORAL	1.0000 DOSE FORM 1.0 X PER DAY	
	Bronchiolitis	Other						
			Haldol Decanoas	SS		INTRAMUSCULAR	1.0000 DOSE FORM 1.0 X PER MON	

Date:04/24/98ISR Number: 3072185-3Report Type:Expedited (15-DaCompany Report #980421-008011345
Age:37 YR Gender:Male I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Mydriasis
	Sedation
	Suicide Attempt

	Tachycardia					
		Report Source	Product	Role	Manufacturer	Route
Dose Duration						
		Foreign	Haloperidol	PS		ORAL
100MG/ONCE/OR AL		Health				
		Professional	Clomethiazole	SS		ORAL
1200MG/ONCE/O RAL						
			Metamizole	SS		ORAL
2500MG/ONCE/O RAL						

Date:04/27/98ISR Number: 3068970-4Report Type:Expedited (15-DaCompany Report #19980400236
Age:77 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Respiratory Arrest	Foreign	Prilosec	PS		ORAL
PO						
Hospitalization -	Thrombocytopenia	Health	Allopurinol	SS		ORAL
PO						
Initial or Prolonged		Professional	Haldol	SS		ORAL
PO						

Date:04/29/98ISR Number: 3070429-5Report Type:Expedited (15-DaCompany Report #8-98111-021A
Age:88 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Confusional State	Foreign	Temesta	PS		ORAL
1 MG ONCE						
Initial or Prolonged	Dehydration	Health				
DAILY ORAL						
Other	Hepatitis Cholestatic	Professional	Anafranil	SS		ORAL
10 MG DAILY						
	Hepatocellular Damage					
ORAL						

	Jaundice		Endotelon	SS		ORAL
150 MG DAILY						
	Malnutrition					
ORAL						
			Haldol	SS		ORAL
ORAL						
			Hept-A-Myl	SS		ORAL
ORAL						
			Iskedyl	SS		ORAL
ORAL						
			Anafranil	C		
			Endotelon	C		
			Haldol	C		
			Hept-A-Myl	C		
			Iskedyl	C		
			Praxilene	C		

Date:04/29/98ISR Number: 3070550-1Report Type:Expedited (15-DaCompany Report #980421-008011344
Age:60 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Suicide Attempt	Foreign	Haloperidol	PS		ORAL	9 MG QD	
Initial or Prolonged		Health	Risperidone	SS		ORAL	3 MG QD	
		Professional	Trihexyphenidyl	SS		ORAL	3 MG QD	
			Flunitrazepam	SS		ORAL	2 MG QD	
			Mexazolam	SS		ORAL	2 MG QD	

Date:04/29/98ISR Number: 3071613-7Report Type:Expedited (15-DaCompany Report #8-98111-001A
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Agitation	Foreign	Seresta	PS		ORAL	30 MG DAILY	
Initial or Prolonged	Hypotonia	Health					DECREASED TO	
Other	Respiratory Disorder	Professional					25 MG DAILY	40 WK
			Haldol	SS			TRANSPLACENTAL	.8 MG DAILY
			Haldol	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/29/98ISR Number: 3078865-8Report Type:Direct Company Report #
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Asthenia		Haldol	PS				
	Atrial Flutter							
	Atrioventricular Block							
	Dizziness							

Date:05/06/98ISR Number: 3074110-8Report Type:Expedited (15-DaCompany Report #971013-107012819
Age:86 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Agitation	Health	Haldol	PS		ORAL	.5 MG, QD,	
Hospitalization -	Condition Aggravated	Professional						
ORAL								
Initial or Prolonged	Depressed Level Of		Aricept	SS		ORAL	5 MG, QD,	
	Consciousness							
ORAL								
	Drug Interaction		Paroxetine					
	Muscle Rigidity		Hydrochloride	C				
	Pyrexia		Risperidone	C				
	Sedation		Anticoagulant	C				
	Subdural Haematoma							
	Tremor							

Date:05/13/98ISR Number: 3079190-1Report Type:Expedited (15-DaCompany Report #8-98043-003D
Age:35 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Aggression	Foreign	Effexor	PS				
Initial or Prolonged	Hypotension	Health	Carbamazepine	SS				
Other	Overdose	Professional	Flupenthixol	SS				
	Sedation		Haloperidol	SS				
	Tachycardia		Zolpidem	SS				
			Doxepin	C				
			Etoh	C				
			Procyclidine	C				

Date:05/18/98ISR Number: 3079419-XReport Type:Direct Company Report #
Age:62 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Muscle Spasms	Health Professional	Haloperidol	PS		ORAL	2 MG TABLET AM PO	3 MON
			Haloperidol	SS		ORAL	10 MG CAP HS PO	

Date:05/18/98ISR Number: 3079993-3Report Type:Expedited (15-DaCompany Report #8-98111-021A
Age:88 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Confusional State	Foreign Health Professional	Temesta	PS		ORAL	1 MG ONCE DAILY ORAL	
	Dehydration							
Other	Hepatic Necrosis		Anafranil	SS		ORAL	10 MG DAILY ORAL	
	Hepatitis Cholestatic							
	Jaundice		Endotelon	SS		ORAL	150 MG DAILY ORAL	
	Malnutrition							
			Haldol	SS		ORAL	ORAL	
			Hept-A-Myl	SS		ORAL	ORAL	

			Iskedyl	SS		ORAL
ORAL						
			Anafranil	C		
			Endotelon	C		
			Haldol	C		
			Hept-A-Myl	C		
			Iskedyl	C		
			Praxilene	C		

Date:05/19/98ISR Number: 3081108-2Report Type:Expedited (15-DaCompany Report #980511-008011618
Age:1 DY Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Agitation	Foreign	Haloperidol	PS		INTRA-UTERINE	2 MG, QD,	
Initial or Prolonged	Benign Congenital	Health				INTRAUTERINE		
	Hypotonia	Professional	Oxazepam	SS		INTRA-UTERINE	25 MG, QD,	
	Complications Of Maternal					INTRAUTERINE		
	Exposure To Therapeutic Drugs							
	Respiratory Disorder							

Date:05/20/98ISR Number: 3080343-7Report Type:Direct Company Report #
Age:31 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Extrapyramidal Disorder		Haldol	PS			20 MG BID	

Date:05/20/98ISR Number: 3081526-2Report Type:Expedited (15-DaCompany Report #98F--10389
Age:30 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Gastrointestinal Necrosis	Foreign	Tegretol	PS		ORAL	400 MG, BID,	
Hospitalization - Initial or Prolonged		Health Professional Other	Haldol Solution (Haloperidol)	SS		ORAL	15 L, DAILY,	
			Nozinan Solution (Levomepromazine)	SS		ORAL	30 ML, DAILY,	
			Parkinane Lp Slow Release Capsules (Trihexyphenidyl Hydrochloride)	SS		ORAL	10 MG, DAILY,	

Date:05/20/98ISR Number: 3081534-1Report Type:Expedited (15-DaCompany Report #98F--10386
Age:42 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Peripheral Embolism	Foreign Health Professional Other	Tegretol	PS		ORAL	200 MG, BID,	
			Haldol Table (Haloperidol)	SS		ORAL	2.5 MG,	DAILY, ORAL
			Ludiomil Tablet					

			(Maprotiline Hydrochloride)	SS		ORAL 75 MG, DAILY, ORAL

Date:05/21/98ISR Number: 3083176-0Report Type:Expedited (15-DaCompany Report #980421-008011344
Age:60 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Hospitalization - Initial or Prolonged	Suicide Attempt	Foreign	Haloperidol	PS		ORAL 9MG QD ORAL
		Health	Risperidone	SS		ORAL 3MG QD ORAL
		Professional	Trihexyphenidyl	SS		ORAL 3MG QD ORAL
			Flunitrazepam	SS		ORAL 2MG, QD, ORAL
			Mexazolam	SS		ORAL 2MG QD ORAL

Date:05/22/98ISR Number: 3081003-9Report Type:Direct Company Report #
Age:42 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Required Intervention to Prevent Permanent Impairment/Damage	Liver Function Test		Carbamazepine	PS		T 2 BID
	Abnormal		Haloperidol	SS		2 HS
			Lithium Carbonate	C		
			Trihexyphenidyl Hcl	C		

Date:05/22/98ISR Number: 3082929-2Report Type:Expedited (15-DaCompany Report #980518-008011727
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Hospitalization -	Dry Mouth	Foreign	Haloperidol	PS		ORAL 50 MG, QD

Initial or Prolonged	Overdose	Health				ORAL
	Sedation	Professional				

Date:05/22/98ISR Number: 3082930-9Report Type:Expedited (15-DaCompany Report #980518-008011729
Age:27 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Overdose	Foreign	Haloperidol	PS		ORAL	40 MG, QD	
Initial or Prolonged		Health				ORAL		
		Professional	Paracetamol	SS			3 G	

Date:05/22/98ISR Number: 3082931-0Report Type:Expedited (15-DaCompany Report #980518-008011730
Age:74 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Death	Foreign	Haloperidol	PS			1.5 MG, TID	4 DAY
		Literature						
		Health						
		Professional						

Date:05/22/98ISR Number: 3083541-1Report Type:Expedited (15-DaCompany Report #98F-10397
Age:24 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Coma	Foreign	Ludiomil	PS		ORAL	50 MG, DAILY,	
Initial or Prolonged	Hyponatraemia	Health				ORAL		
		Professional	Haldol	SS		ORAL		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/26/98ISR Number: 3082386-6Report Type:Expedited (15-DaCompany Report #PRIUS-36259
Age:86 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Agitation	Foreign	Risperidone	PS	Janssen	ORAL	.5 MG 2 DAILY	
Hospitalization - Initial or Prolonged	Condition Aggravated	Health Professional	Haldol	SS	Janssen	ORAL	.5 MG DAILY	
	Depressed Level Of Consciousness					ORAL		
	Drug Interaction		Aricept	SS		ORAL	5MG/DAILY/ORA	
	Muscle Rigidity					L	2	DAY
	Pyrexia		Paroxetine	C				
	Sedation		Anticoagulants	C				
	Subdural Haematoma							
	Tremor							

Date:05/26/98ISR Number: 3082854-7Report Type:Expedited (15-DaCompany Report #980518-008011731
Age:23 MON Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Coma	Foreign Health Professional	Haloperidol	PS		ORAL	1 MG, ONCE, ORAL	

Date:05/26/98ISR Number: 3082858-4Report Type:Expedited (15-DaCompany Report #980518-008011726
Age:30 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Gastrointestinal Necrosis	Foreign	Haloperidol	PS		ORAL	15 ML, QD, ORAL	
Hospitalization -	Intestinal Perforation	Health						

Initial or Prolonged	Shock	Professional	Levomepromazine	SS			ORAL 30 ML, QD, ORAL
			Carbamazepine	SS			ORAL 800 MG, QD, ORAL
			Heptaminol	C			
			Trihexyphenidyl	C			ORAL 10 MG, QD, ORAL

Date:05/26/98ISR Number: 3082862-6Report Type:Expedited (15-DaCompany Report #980518-008011732
Age:20 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Hospitalization - Initial or Prolonged	Blood Prolactin Increased Galactorrhoea Pituitary Tumour Benign Psychotic Disorder Tremor	Health Professional	Haloperidol	PS		ORAL 20 MG, QD, ORAL
			Risperidone	SS		ORAL 6 MG, QD, ORAL/4 MG, QD, ORAL
			Doxepin	SS		ORAL 75 MG, QD, ORAL/100 MG, QD, ORAL
			Risperidone	SS		ORAL 4 MG, QD, ORAL
			Doxepin	SS		
			Risperidone	SS		ORAL 6 MG, QD, ORAL
			Medoxyprogesterone	C		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/26/98ISR Number: 3084410-3Report Type:Direct Company Report #
Age:22 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Dyspnoea		Lithium	PS			300 MG TID	
	Insomnia		Haloperidol	SS				
	Malaise							
	Nausea							
	Respiratory Rate Increased							
	Restlessness							
	Vomiting							

Date:05/27/98ISR Number: 3083388-6Report Type:Direct Company Report #
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Injection Site Oedema		Haldol	PS	Ortlo-Mcneil		100 MG/ICC	
	Injection Site Pruritus							

Date:05/27/98ISR Number: 3083450-8Report Type:Direct Company Report #
Age:71 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Coma		Haloperidol	PS			1 MG IV PX 12 MG X 1; 1 MG PO Q 6 H	
	Cyanosis							
	Neuroleptic Malignant Syndrome		Elavil	SS			125 MG PO X 1	
	Pyrexia						THE N 50 X 1	
	Tachycardia							
	Tachypnoea							
	White Blood Cell Count Increased							

Date:06/01/98ISR Number: 3087267-XReport Type:Direct Company Report #
Age:92 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Accident		Navane	PS				
Hospitalization - Initial or Prolonged	Blood Disorder		Respiradol	SS				
	Convulsion		Haldol	SS				
Disability	Ecchymosis		Aspirin	C				
Other	Fatigue		Nitropaste	C				
Required Intervention to Prevent Permanent Impairment/Damage	Parkinson'S Disease							
	Pulmonary Congestion							
	Sepsis							
	Urinary Tract Infection							

Date:06/01/98ISR Number: 3088557-7Report Type:Direct Company Report #
Age:33 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Neuroleptic Malignant Syndrome		Haldol	PS				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/05/98ISR Number: 3179010-0Report Type:Periodic Company Report #980114-107050221
Age:65 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Laryngospasm	Health Professional	Haldol Injection (Haloperidol)	PS				ONCE

Date:06/05/98ISR Number: 3179011-2Report Type:Periodic Company Report #970417-107052517
Age:68 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Neuroleptic Malignant Syndrome	Health Professional	Haldol Tablets (Haloperidol)	PS		ORAL	1 MG, BID,	ORAL
			Mellaril	C				
			Tamoxifen	C				
			Zoloft	C				

Date:06/05/98ISR Number: 3179012-4Report Type:Periodic Company Report #970506-107052965
Age:9 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Grand Mal Convulsion	Health Professional	Haloperidol, Unspecified (Haloperidol)	PS		ORAL	.5 MG, QD,	ORAL

Date:06/05/98ISR Number: 3179013-6Report Type:Periodic Company Report #970328-107052034
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Neuroleptic Malignant	Health	Haldol Injection					

Initial or Prolonged	Syndrome	Professional	(Haloperidol)	PS		
INTRAMUSCULAR 1.5 MG, IM						
(INTRAMUSCULA						
R)						
			Bromocriptine	C		
			Dantrolene	C		

Date:06/08/98ISR Number: 3091761-5Report Type:Expedited (15-DaCompany Report #980604-008011953
Age:61 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Pco2 Increased	Foreign	Haloperidol	PS		ORAL	1 MG,	ORAL
Initial or Prolonged	Po2 Decreased	Health	Clorazepate	SS		ORAL		
	Respiratory Failure	Professional	Cyamemazine	SS		ORAL		
ORAL								
	Sedation							

Date:06/08/98ISR Number: 3091794-9Report Type:Expedited (15-DaCompany Report #8-98147-012A
Age:51 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Dyskinesia	Foreign	Loxapac	PS		ORAL	25 MG ONCE	
Initial or Prolonged	Dystonia	Health					DAILY ORAL	
Other		Professional	Cisordinol	SS		ORAL	20 MG DAILY	
ORAL								
			Seranase	SS				
			Lithium Karbonat	C				

			Lysantin	C			

Date:06/10/98ISR Number: 3092361-3Report Type:Expedited (15-DaCompany Report #980604-008011954
Age:24 MON Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Disability	Complications Of Maternal	Foreign	Haloperidol	PS		INTRA-UTERINE	
Congenital Anomaly	Exposure To Therapeutic Drugs	Health Professional					
	Hypertonia						
	Mental Retardation						
	Severity Unspecified						

Date:06/11/98ISR Number: 3092832-XReport Type:Expedited (15-DaCompany Report #980604-008011955
Age:42 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Arterial Stenosis	Foreign	Haloperidol	PS		ORAL	2.5 MG QD
	Cardiovascular Disorder	Health Professional					
	Metabolic Disorder		Carbamazepine	SS		ORAL	ORAL 2 YR 400 MG, QD,

Date:06/11/98ISR Number: 3095975-XReport Type:Periodic Company Report #17812-037
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Other	Drug Interaction	Consumer	Lithium Carbonate Capsules Usp, 300 Mg-Roxane Laboratories, Inc.	PS		ORAL	600 MG, BID, PO
	Dysphagia						
	Gait Disturbance						
	Speech Disorder						
	Visual Disturbance						

				Haloperidol (Manufacturer Unknown)	SS		ORAL
5 MG OHS PO							

Date:06/12/98ISR Number: 3093144-0Report Type:Direct Company Report #
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Agitation		Risperdal	PS		ORAL
1.5 MG PO BID						
Initial or Prolonged	Blood Creatine		Haldol	SS		
INTRAMUSCULAR 5MG TID PRN						
	Phosphokinase Increased					
N/IM 3 DAY						
	Depressed Level Of		Rocephin	C		
	Consciousness		Doxycycline	C		
	Hypernatraemia		Zovirax	C		
	Muscle Rigidity					
	Pyrexia					
	Tachycardia					
	Tremor					

Date:06/15/98ISR Number: 3094700-6Report Type:Expedited (15-DaCompany Report #US_980604470
Age:62 YR Gender:Male I/FU:I

Outcome
Life-Threatening
Hospitalization -

Initial or Prolonged

	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Aspiration	Study	Haloperidol	PS			3 MG/DAY	
	Blood Pressure Abnormal	Health	Famotidine	C				
	Coma	Professional	Multivitamin	C				
	Condition Aggravated		Soft Clens Wound					
	Cyanosis		Cleaner	C				
	Dysphagia		Artificial Tears	C				
	Pneumonia		Divalproex Sodium	C				
	Pneumonia Aspiration		Petrolatum					
	Pulse Pressure Decreased		Ophthalmic Ointment	C				
	Vomiting							

Date:06/23/98ISR Number: 3097377-9Report Type:Expedited (15-DaCompany Report #WAES 98060809
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Heat Stroke	Health	Cogentin	PS		ORAL	UNK/ UNK/ PO	
Life-Threatening		Professional	Haloperidol	SS			UNK/ UNK/ UNK	

Date:06/23/98ISR Number: 3097572-9Report Type:Expedited (15-DaCompany Report #J / 97/ 00620 / MEL
Age:49 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Diabetes Insipidus	Health	Melleril	PS		ORAL	200 MG ORAL	
Hospitalization -	Dyskinesia	Professional	Haloperidol	SS		ORAL	6 MG ORAL	
Initial or Prolonged	Electrocardiogram		Levotomin	SS		ORAL	25 MG ORAL	
Required	Abnormal		Chlorpromazine	SS		ORAL	60 MG ORAL	
Intervention to	Extrapyramidal Disorder		Artane	C				
Prevent Permanent	Hyperhidrosis		Pyrethia	C				
Impairment/Damage	Inappropriate		Biperiden	C				
	Antidiuretic Hormone		Flunitrazepan	C				

Secretion
Loss Of Consciousness
Muscle Rigidity
Mydriasis
Neuroleptic Malignant
Syndrome
Pyrexia
Stupor
Tonic Convulsion
Tremor
Urinary Incontinence
Ventricular Extrasystoles
Ventricular Tachycardia
Vomiting Projectile
Water Intoxication

Date:06/23/98ISR Number: 3097718-2Report Type:Expedited (15-DaCompany Report #980518-008011728
Age:28 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Delusion Overdose Visual Disturbance	Foreign Health Professional	Haloperidol	PS		ORAL	120 DROP, QD, ORAL	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/23/98ISR Number: 3097773-XReport Type:Expedited (15-DaCompany Report #980518-008011728
Age:28 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Delusion	Foreign	Haloperidol	PS		ORAL	120 DROP, QD	
Initial or Prolonged	Overdose	Health				ORAL		
	Visual Disturbance	Professional						

Date:06/24/98ISR Number: 3097792-3Report Type:Expedited (15-DaCompany Report #980617-008012115
Age:29 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Aspiration	Foreign	Haloperidol	PS		ORAL	100 MG	
Initial or Prolonged	Electrocardiogram Qrs	Health	Diazepam	SS		ORAL	400 MG	
Other	Complex Prolonged	Professional	Amitriptyline	SS		ORAL	3000 MG	
	Respiratory Depression		Doxylamine	SS		ORAL	250 MG	
	Rhabdomyolysis							
	Suicide Attempt							

Date:06/24/98ISR Number: 3097793-5Report Type:Expedited (15-DaCompany Report #980617-008012141
Age:33 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Convulsion	Foreign	Haloperidol	PS		ORAL	2000 MG	
Initial or Prolonged	Intentional Misuse	Health	Levomepromazine	SS		ORAL	2500 MG	
Other	Mydriasis	Professional	Antidepressives	C				
	Sedation							
	Suicide Attempt							

Date:06/24/98ISR Number: 3097795-9Report Type:Expedited (15-DaCompany Report #980618-008012158
Age:1 DY Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Bradycardia	Foreign	Haloperidol	PS		INTRA-UTERINE	15 MG, QD	
	Complications Of Maternal Exposure To Therapeutic Drugs Sedation	Health Professional	Chlorpromazine	SS		INTRA-UTERINE	42 MG, QD	

Date:06/24/98ISR Number: 3097882-5Report Type:Expedited (15-DaCompany Report #980617-008012114
Age:60 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Amnesia	Foreign	Haloperidol	PS		ORAL	6 MG, QD, ORAL	
	Bradykinesia	Health						
	Disorientation	Professional	Haloperidol	SS		INTRAMUSCULAR	IM	
	Fatigue		Neuroleptics	SS				
	Sedation		Biperiden	C				

Date:06/24/98ISR Number: 3097886-2Report Type:Expedited (15-DaCompany Report #980617-008012135
Age:1 DY Gender:Male I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Agitation Neonatal
	Arrhythmia Neonatal
	Complications Of Maternal
	Exposure To Therapeutic

Drugs
Uterine Spasm

		Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
		Foreign	Haloperidol	PS		
INTRA-UTERINE	25 MG, QD,					
		Health				
INTRAUTERINE						
		Professional	Biperiden	SS		
INTRA-UTERINE	INTRAUTERINE					
			Flunitrazepam	SS		
INTRA-UTERINE	PRN,					
INTRAUTERINE						
			Alimemazine	SS		

Date:06/24/98ISR Number: 3097889-8Report Type:Expedited (15-DaCompany Report #980617-008012136
Age:88 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization -	Hyponatraemia	Foreign	Haloperidol	PS		ORAL
ORAL						
Initial or Prolonged	Psychomotor Retardation	Health	Phenytoin	C		
		Professional	Benazepril	C		
			Isosorbide Mononitrate	C		

Date:06/24/98ISR Number: 3098101-6Report Type:Expedited (15-DaCompany Report #980617-008012134
Age:61 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Life-Threatening	Delusion	Foreign	Haloperidol	PS		
INTRAMUSCULAR	100 M, IX/MO,					
Hospitalization -	Depressed Mood	Health				
IM						
Initial or Prolonged	Extrapyramidal Disorder	Professional				
(INTRAMUSCULA						
	Suicidal Ideation					
R)						
	Suicide Attempt		Potassium Iodide	C		

Date:06/24/98ISR Number: 3098104-1Report Type:Expedited (15-DaCompany Report #980617-008012118
Age:42 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Thrombocytopenia	Foreign Health Professional	Haloperidol	PS		INTRAMUSCULAR IM	100 MG, QD,	
			Meprobamate	SS		INTRAMUSCULAR IM	1600 MG, QD,	
			Trihexyphenidyl	C				
			Oxazepam	C				

Date:06/24/98ISR Number: 3098714-1Report Type:Direct Company Report #
Age:25 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Neuroleptic Malignant Syndrome		Haloperidol	PS		ORAL PLUS HALOPERIDOL	DECANOTE 5MG PO Q HS;	
			Inderal	C				
			Paxil	C				
			Cogentin	C				
			Ativan	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/25/98ISR Number: 3098538-5Report Type:Expedited (15-DaCompany Report #100867
Age:74 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Condition Aggravated	Foreign	Bactrim Forte	PS		ORAL	960 MG 1 X PER DAY	
	Hypokalaemia	Health Professional						
	Hyponatraemia		Bactrim	SS			INTRAVENOUS	2 DOSE FORM 1 X PER DAY
		Other					INTRAVENOUS	
			Atacand	SS		ORAL	16 MG 1 X PER DAY	
			Anafranil	SS			25 MG 1 X PER DAY	
			Haldol	SS		ORAL	2 DROP 3 X PER DAY	
			Paspertin	SS			INTRAVENOUS	30 MG DAILY 1 X PER CONTINUOUS
							INTRAVENOUS	
			Minalgin	SS			INTRAVENOUS	10 MG DAILY 1 X PER DAY CONTINUOUS
							INTRAVENOUS	
			Kytril	SS			INTRAVENOUS	1 MG 2 X PER DAY

INTRAVENOUS						
			Pethidin	SS		
INTRAVENOUS	100 MG DAILY					
1 X PER DAY						
CONTINUOUS						
INTRAVENOUS						
			Antra	C		
			Marcoumar	C		
			Tramadolor	C		
			Treuphadol	C		
			Halcion	C		
			Collunosol-N	C		

Date:06/25/98ISR Number: 3098910-3Report Type:Expedited (15-DaCompany Report #F/98/01341/MEL
Age:24 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Convulsion		Melleril	PS		ORAL	250 MG	
Initial or Prolonged	Intestinal Obstruction		Floxyfral					
Required	Mydriasis		(Fluvoxamine					
Intervention to			Maleate)	SS		ORAL	200 MG	
Prevent Permanent			Haldol (Haloperidol)	SS		ORAL	30 MG	
Impairment/Damage			Theralene	SS		ORAL	300 MG	
			Artane					
			(Trihexyphenidyl					
			Hydrochloride)	SS		ORAL	7 MG	

Date:06/25/98ISR Number: 3098911-5Report Type:Expedited (15-DaCompany Report #J/97/00411/ MEL
Age:43 YR Gender:Female I/FU:I

Outcome
Hospitalization -
Initial or Prolonged
Required
Intervention to
Prevent Permanent

Impairment/Damage

	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Akinesia	Health	Mellaril	PS		ORAL	60 MG	
	Blood Amylase Increased	Professional	Serenace	SS		ORAL	1 MG	
	Blood Creatine Phosphokinase Increased							
	Catatonia							
	Depressed Level Of Consciousness							
	Leukocytosis							
	Melaena							
	Muscle Rigidity							
	Mutism							
	Pyrexia							
	Urethritis							
	White Blood Cell Count Increased							

Date:06/25/98ISR Number: 3102007-3Report Type:Periodic Company Report #701001001
Age:77 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Bundle Branch Block Left	Foreign	Droperidol	PS		ORAL	ORAL	
Hospitalization -	Cardiac Arrest	Health	Haloperidol	SS		ORAL	ORAL	
Initial or Prolonged	Cardiac Disorder	Professional						
	Convulsion							
	Electroencephalogram Abnormal							
	Epilepsy							
	Respiratory Arrest							

Date:06/25/98ISR Number: 3102017-6Report Type:Periodic Company Report #701601001
Age:77 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Death	Bundle Branch Block Left	Foreign	Droperidol	PS		ORAL
ORAL						
Hospitalization -	Cardiac Arrest		Haloperidol	SS		ORAL
ORAL						
Initial or Prolonged	Convulsion		Enalapril	SS		ORAL
ORAL						
	Electroencephalogram Abnormal					
	Respiratory Arrest					

Date:06/25/98ISR Number: 3102034-6Report Type:Periodic Company Report #702501001
Age:52 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Akinesia	Foreign	Droperidol	PS				
INTRAVENOUS	10 MG TOTAL;							
Initial or Prolonged	Extrapyramidal Disorder							
INTRAVENOUS								
	Hyperthermia Malignant		Haloperidol	SS				
INTRAVENOUS	INTRAVENOUS							
	Hypertonia							
	Mental Impairment							
	Neuroleptic Malignant Syndrome							
	Tremor							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/29/98ISR Number: 3099478-8Report Type:Expedited (15-DaCompany Report #WAES 98066083
Age:92 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Agranulocytosis	Foreign	Vasotec	PS		ORAL	20 MG; PO	366 DAY
Hospitalization - Initial or Prolonged		Other	Haloperidol	SS		ORAL	0,75 MG; PO	22 DAY

Date:06/29/98ISR Number: 3099515-0Report Type:Expedited (15-DaCompany Report #980616-008012091
Age:62 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain Upper	Literature	Haloperidol	PS		ORAL	4.5 MG, QD,ORAL	
	Blood Creatine Phosphokinase Increased	Health Professional	Famotidine	C				
			Acetylsalicylic Acid	C				
			Glyceryl Trinitrate	C				
			Benztropine	C				
			Clorazepate	C				

Date:06/29/98ISR Number: 3099519-8Report Type:Expedited (15-DaCompany Report #980617-008012119
Age:48 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Asthenia	Foreign	Haloperidol	PS		INTRAMUSCULAR	50 MG, 1X/3WK, IM	
	Discomfort	Health Professional						
	Dyspnoea							
	Feeling Hot							
	Hallucination, Auditory							
	Malaise							
	Nausea							
	Panic Reaction							
	Psychotic Disorder							
	Syncope							

Date:06/29/98ISR Number: 3099694-5Report Type:Expedited (15-DaCompany Report #9803737
Age:23 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Condition Aggravated	Foreign	Zoloft	PS		ORAL	50.00 MG	
Initial or Prolonged	Depression	Consumer					TOTAL: DAILY:	
Required	Drug Ineffective	Health					ORAL	
Intervention to	Dysarthria	Professional	Haloperidol	SS		ORAL	1.00 MG	
Prevent Permanent	Dyskinesia	Company					TOTAL: DAILY:	
Impairment/Damage	Extrapyramidal Disorder	Representative					ORAL	
	Joint Dislocation		Clomipramine	SS		ORAL	75.00 MG	
	Muscle Contractions						TOTAL: DAILY:	
	Involuntary						ORAL	
	Suicidal Ideation							

Date:06/29/98ISR Number: 3099921-4Report Type:Direct Company Report #
Age:69 YR Gender:Male I/FU:I

Outcome	PT
	Blood Creatine Phosphokinase Increased
	Body Temperature Increased

	Confusional State						
	Muscle Rigidity						
		Report Source	Product	Role	Manufacturer		Route
Dose	Duration						
			Haloperidol	PS	Mcneil		
INTRAVENOUS	IV 1-2MG Q 2H						
PRN							
			Vancomycin	C			
			Prozofal	C			
			Laorgepam	C			
			Captopril	C			
			Cisapride	C			
			Clindamycin	C			
			Ceftriaxone	C			
			Metoprolal	C			
			Omeprazole	C			
			Neutratlas	C			
			Ntg	C			

Date:06/30/98ISR Number: 3100034-3Report Type:Direct Company Report #
Age:30 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Death	Agitation		Lithium	PS		
300MG Q AM;						
Hospitalization -	Coma					
600MG Q HS						
Initial or Prolonged	Convulsion		Prozac	SS		
20MG BID						
	Disseminated		Haldol	SS		
5MG BID						
	Intravascular Coagulation		Cogentin	SS		
2MG Q AM						
	Hypotension					
	Hypotonia					
	Lactic Acidosis					
	Multi-Organ Failure					
	Muscle Rigidity					
	Pulmonary Oedema					
	Pyrexia					
	Respiratory Failure					
	Tremor					

Date:07/01/98ISR Number: 3100515-2Report Type:Expedited (15-DaCompany Report #980625-008012257
Age:91 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Blister	Foreign	Haloperidol	PS		ORAL	QD, ORAL;	
Life-Threatening	Cardiac Failure	Health					DROPS	
	Dermatitis	Professional	Sulfamethoxazole & Trimethoprim	SS		ORAL	2 TAB, QD,	
	Psychotic Disorder						ORAL	
	Pyrexia		Oxazepam	SS		ORAL	1 TAB, QD,	
	Stevens-Johnson Syndrome						ORAL	
	Toxic Epidermal		Diazepam	SS			INTRAVENOUS	2.5 MG, QD,
	Necrolysis						IV	
	Urinary Tract Infection		Furosemide	SS		ORAL	1 TAB, QD,	
							ORAL	
			Heparin	SS			INTRAVENOUS	15000 U, QD,
							IV	
			Nisoldipine	SS		ORAL	2 TAB, QD,	
							ORAL	
			Metoclopramide	SS		ORAL	QD, ORAL	
			Caffeine	SS		ORAL	200 MG, QD,	
							ORAL	
			Isosorbide Dinitrate	SS				

			Vomex	SS			ORAL 360, MG, QD, ORAL
			Levomepromazine	C			
			Insulin	C			
			Nidfedipine	C			
			Nitrendipine	C			
			Enalapril	C			
			Chloral-Hydrate	C			

Date:07/01/98ISR Number: 3100516-4Report Type:Expedited (15-DaCompany Report #980625-008012258
Age:30 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Death	Aspiration	Foreign	Haloperidol	PS		ORAL 30 MG, QD,
Hospitalization -	Bronchopneumonia	Health				ORAL
Initial or Prolonged	Pneumonia Aspiration	Professional	Droperidol	SS		ORAL 100 MG, QD,
	Respiratory Distress					ORAL
	Sedation		Diazepam	SS		ORAL 34 MG, QD, ORAL
			Meprobamate	SS		ORAL ORAL

Date:07/01/98ISR Number: 3100634-0Report Type:Expedited (15-DaCompany Report #980625-008012256
Age:50 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Hospitalization -	Pancreatitis Acute	Foreign	Haloperidol	PS		UNKNOWN,
Initial or Prolonged	Suicide Attempt	Health				UNKNOWN
		Professional				(UNSPECIFIED)
			Neuroleptics, Nos	SS		

Date:07/01/98ISR Number: 3100636-4Report Type:Expedited (15-DaCompany Report #980304-008010807
Age:43 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Akathisia	Foreign	Haloperidol					
	Amenorrhoea	Health	Decanoate	PS				
INTRAMUSCULAR							250 MG,	
	Constipation	Professional						
1X/WK, IM								
	Dry Mouth							
(INTRAMUSCULA								
	Extrapyramidal Disorder							
R)								
	Galactorrhoea		Cyamemazine	SS		ORAL		
75 MG, QD,								
	Muscle Rigidity							
ORAL								
	Paraesthesia		Tropatepine	C				
	Tremor		Anethole Trithione	C				
			Lactitol	C				

Date:07/01/98ISR Number: 3100639-XReport Type:Expedited (15-DaCompany Report #980617-008012153
Age:27 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Overdose	Study	Haloperidol					
		Health	Decanoate	PS				
INTRAMUSCULAR							UNKNOWN,	
		Professional						
UNKNOWN, IM								
			Paroxetine	SS				
UNKNOWN,								
UNKNOWN,								
UNKNOWN								
			Diphenhydramine	SS		ORAL		
50 CAP,								
UNKNOWN, ORAL								

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/01/98ISR Number: 3104422-0Report Type:Direct Company Report #
Age:43 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Condition Aggravated		Ativan	PS				
	Medication Error		Buspar	SS				
	Psychotic Disorder		Cardura	SS				
			Depakote	SS				
			Desyrel	SS				
			Haldol	SS				
			Mellaril	SS				
			Neurontin	SS				
			Propilsid	SS				
			Risperdal	SS				

Date:07/02/98ISR Number: 3101400-2Report Type:Expedited (15-DaCompany Report #A001-002-002355
Age:71 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Condition Aggravated	Foreign	Aricept	PS		ORAL	5 MG (1 IN 1	
	Extrapyramidal Disorder	Health					D) PER ORAL	
	Gait Disturbance	Professional	Haloperidol	SS		ORAL	0.5 MG, PER	
	Muscle Rigidity						ORAL	
	Tremor		Flurazepam (Flurazepam)	C				
			Levothyroxine (Levothyroxine)	C				

Date:07/02/98ISR Number: 3101781-XReport Type:Expedited (15-DaCompany Report #980617-008012144
Age:54 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Anorexia	Foreign	Haloperidol	PS		INTRAMUSCULAR	5 MG QD, ORAL	
Hospitalization -	Body Temperature	Literature	Haloperidol	SS		ORAL	8 MG, QD,	

Initial or Prolonged	Decreased	Health			
ORAL					
	Condition Aggravated	Professional	Bromperidol	SS	ORAL
10 MG QD,					
	Heart Rate Decreased				
ORAL					
	Hypothyroidism		Levothyroxine Sodium	C	
	Loss Of Consciousness				
	Mental Impairment				

Date:07/02/98ISR Number: 3102279-5Report Type:Expedited (15-DaCompany Report #99408
Age:91 YR Gender:Female I/FU:F

Outcome	PT
Death	Blood Creatinine
	Increased
	Blood Lactate
	Dehydrogenase Increased
	Blood Urea Increased
	Cardiac Failure
	Dermatitis
	Dermatitis Bullous
	Leukocytosis
	Mental Disorder
	Pruritus
	Pyrexia
	Renal Failure Acute
	Stevens-Johnson Syndrome

		Toxic Epidermal Necrolysis Urinary Tract Infection	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
		White Blood Cell Count	Foreign	Valium	PS		
INTRAVENOUS	2.5000 MG	Increased	Health				
DAILY			Professional				
INTRAVENOUS			Other	Bactrim Forte	SS		ORAL
1.0000 DOSE							
FORM 2.0 X							
PER DAY ORAL							
				Adumbran	SS		ORAL
1.0000 DOSE							
FORM 1.0XPER							
DAY ORAL							
				Heparin-Natrium	SS		
SUBCUTANEOUS	7500.0000 IU						
2.0 X PER DAY							
SUBCUTANEOUS							
				Coffein	SS		ORAL
1.0000 DOSE							
FORM 1.0 X							
PER DAY ORAL							
				Paspertin	SS		ORAL
20.0000 DROP							
DAILY ORAL							
				Baymyard	SS		ORAL
1.0000 DOSE							
FORM 2.0 X							
PER DAY ORAL							
				Furosemid	SS		ORAL
0.2500 DOSE							

FORM 1.0XPER

DAY ORAL

Neurocil	SS	ORAL

10.0000 DROP

DAILY ORAL

Vertigo-Vomex	SS	ORAL

1.0000 DOSE

FORM 3.0 X

PER DAY ORAL

Haldol	SS	ORAL

20.0000 DOSE

FORM 3.0 X

PER DAY ORAL

Neurocil	SS	

INTRAVENOUS 1.0000 DOSE

FORM DAILY

INTRAVENOUS

Depot-H-Insulin	C
Adalat Ret	C
Bayotensin	C
Chloraldurat	C
Pres	C
Ismo	C
Urbason	C

Date:07/07/98ISR Number: 3104050-7Report Type:Direct Company Report #
Age:88 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Anxiety		Haldol	PS				
	Delusion							
	Hallucination							

Date:07/08/98ISR Number: 3103078-0Report Type:Expedited (15-DaCompany Report #800101001
Age:30 YR Gender:Female I/FU:I

Outcome
Death
Hospitalization -

Initial or Prolonged

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Acute Respiratory	Foreign	Haloperidol	PS			50 MG	
	Distress Syndrome		Droperidol	SS			100 MG	
	Bronchopneumonia		Diazepam	SS			34 MG	
	Pyrexia		Meprobamate	SS				
	Sedation							

Date:07/09/98ISR Number: 3108938-2Report Type:Direct Company Report #
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required	Tardive Dyskinesia		Haldol Decanoate	PS	Mcneil Labs		INTRAMUSCULAR	75 MG IM
Intervention to Prevent Permanent Impairment/Damage			Klonopin	C				
			Cogentin	C				
			Depakote	C				

Date:07/09/98ISR Number: 3185139-3Report Type:Periodic Company Report #JAUSA-32895
Age:47 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Dyspnoea	Health Professional	Risperdal (Risperidone), Janssen, Solution	PS	Janssen	ORAL	2 ML SINGLE	
Life-Threatening	Neuroleptic Malignant Syndrome							
Hospitalization - Initial or Prolonged	Rhabdomyolysis						ORAL	
	Stupor		Haldol (Haloperidol), Janssen, Tablet	SS	Janssen	ORAL	SINGLE ORAL	
			Benadryl	C				
			Pen-Vee K	C				
			Erythromycin	C				

Date:07/10/98ISR Number: 3108411-1Report Type:Direct Company Report #
Age:54 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Agitation		Haldol	PS			0.2 MG/0.3 MG	
Hospitalization - Initial or Prolonged	Coma		Klonopin	SS				
	Hostility		Trazodone	SS				
	Mydriasis		Depakote	SS				
	Respiratory Depth Increased							

Date:07/10/98ISR Number: 3108412-3Report Type:Direct Company Report #
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Tardive Dyskinesia		Haldol Decanoate	PS	Mcneil Labs	INTRAMUSCULAR	75 MG IM	
			Klonopin	C				
			Cogentin	C				
			Depakote	C				

Date:07/13/98ISR Number: 3105068-0Report Type:Expedited (15-DaCompany Report #980701-008012349
Age:52 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Fatigue Hypotension Hypothermia	Foreign Health Professional	Haloperidol Decanoate	PS		INTRAMUSCULAR IM	6 MG, 1X/MO,	
			Fluoxetine	C				
			Levomepromazine	C				
			Parazepam	C				

Date:07/13/98ISR Number: 3105073-4Report Type:Expedited (15-DaCompany Report #980707-008012425
Age:2 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Congenital Anomaly	Complications Of Maternal Exposure To Therapeutic Drugs Hypertonia Mental Retardation Severity Unspecified	Foreign Health Professional	Haloperidol	PS		ORAL	I MG QD, ORAL	

Date:07/13/98ISR Number: 3105075-8Report Type:Expedited (15-DaCompany Report #980707-008102396
Age:84 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Depressed Level Of Consciousness	Foreign Health Professional	Haloperidol	PS		ORAL	1 MG QD, ORAL	

Date:07/13/98ISR Number: 3105081-3Report Type:Expedited (15-DaCompany Report #980701-008012344
Age:19 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Alopecia	Foreign	Haloperidol	PS		ORAL	7 MG, QD, ORAL	6 WK
	Depression	Health						
	Disturbance In Attention	Professional	Perazine	SS		ORAL	300 MG, QD, ORAL	
	Erectile Dysfunction							
	Fatigue		Risperidone	C		ORAL	6 MG QD, ORAL	
	Gynaecomastia		Diazepam	C				
	Parkinsonism		Promethazine	C				
	Suicidal Ideation							

Date:07/13/98ISR Number: 3105083-7Report Type:Expedited (15-DaCompany Report #980707-008012397
Age:54 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Delusion	Foreign	Haloperidol	PS		ORAL	2 MG, QD, ORAL	
	Hallucination, Auditory	Health						
	Suicide Attempt	Professional	Risperidone	SS		ORAL	2 MG, QD, ORAL	

Date:07/14/98ISR Number: 3104808-4Report Type:Expedited (15-DaCompany Report #US_980606187
Age:23 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Agitation	Study	Haloperidol	PS			6 MG/HS AT BETIME
	Akathisia	Health Professional					
	Emotional Disorder		Benztropine	C			
	Ideas Of Reference		Lorazepam	C			
	Muscle Rigidity		Benztropine	C			

Date:07/14/98ISR Number: 3104867-9Report Type:Expedited (15-DaCompany Report #B038883
Age:61 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged Other	Chills	Foreign	Buspar	PS		ORAL	ORAL
	Mental Retardation	Health Professional Other	Haldol (Haloperidol)	SS			
	Severity Unspecified						
	Pyrexia						
	Tremor						

Date:07/14/98ISR Number: 3105141-7Report Type:Expedited (15-DaCompany Report #980701-008012347
Age:39 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged ORAL	Blood Creatine	Foreign	Haloperidol	PS		ORAL	12 MG, QD,
	Phosphokinase Increased	Literature					
	Blood Creatinine Increased	Health Professional	Trihexyphenidy Hydrochloride	C			
	Blood Gases Abnormal						
	Blood Urea Increased						
	Depressed Level Of Consciousness						
	Disseminated Intravascular Coagulation						
	Heart Rate Increased						

Hypotension
Muscle Rigidity
Myoglobin Blood Increased
Neuroleptic Malignant
Syndrome
Platelet Count Decreased
Pyrexia
Renal Failure Acute
Respiratory Rate
Increased
Rhabdomyolysis
Stupor
Tremor

Date:07/15/98ISR Number: 3105564-6Report Type:Expedited (15-DaCompany Report #JAFRA-39785
Age:34 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Mania	Foreign	Risperdal	PS	Janssen	ORAL	10 MG DAILY	
Hospitalization -	Vasodilatation	Health					ORAL; 12 MG	
Initial or Prolonged		Professional					DAILY ORAL	8 WK
			Haldol Decanoas (Haloperidone) Solution	SS			INTRAMUSCULAR	300 MG 3

WEEKLY							
INTRAMUSCULAR							
				Nozinan (Levomepromazine)	SS		ORAL
300 MG DAILY							
ORAL	14	MON					
				Hydrate De Chloral (Chloral-Hydrate) Syrup	SS		ORAL
SINGLE ORAL 2							
SOUP SPOONS							
				Depamide (Valpromide)	SS		ORAL
30 MG DAILY							
ORAL; 600 MG							
DAILY ORAL							
				Theralene (Alimemazine) Solution	SS		ORAL
SINGLE ORAL							
100 DROPS							
				Theralite (Lithium)	SS		ORAL
DAILY ORAL, 5							
CAPSULES/DAY	14	MON					

Date:07/16/98ISR Number: 3105875-4Report Type:Expedited (15-DaCompany Report #9721884
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Delirium	Foreign	Zoloft	PS		ORAL		
	Depression	Health Professional	Levomepromazine	SS				
	Disorientation		Haloperidol	SS				
	Drug Withdrawal Syndrome		Trihexyphenidyle	C				
	Dysphagia		Mianserine	C				
	Tachycardia							

Date:07/16/98ISR Number: 3105882-1Report Type:Expedited (15-DaCompany Report #980710-008012494
Age:29 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Foreign	Haloperidol	PS		ORAL	10 MG, QD,	
	Erectile Dysfunction	Health					ORAL	
	Poisoning Deliberate	Professional	Risperidone	SS		ORAL	2 MG, QD,	
	Thinking Abnormal						ORAL	
			Haloperidol Decanoate	SS			INTRAMUSCULAR	50 MG, QD, IM (INTRAMUSCULAR)
			Risperidone	SS		ORAL	4 MG, QD, ORAL	
			Risperidone	SS		ORAL	6 MG, QD, ORAL	
			Chlorprothixene	C				
			Biperiden	C				

Date:07/16/98ISR Number: 3105885-7Report Type:Expedited (15-DaCompany Report #980701-008012345
Age:35 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Coma	Foreign	Haldol	PS		ORAL	45 MG, ORAL	
	Depressed Level Of Consciousness	Health	Doxepin	SS		ORAL	1.7 G, ORAL	
Other		Professional	Perazine	SS		ORAL	600 MG, ORAL	
	Overdose		Olanzapine	SS		ORAL	20 MG, ORAL	
			Fluoxetine	SS		ORAL	60 MG, ORAL	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/22/98ISR Number: 3107992-1Report Type:Expedited (15-DaCompany Report #980717-008012566
Age:86 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hypotonia	Foreign	Haloperidol Solution	PS		ORAL	6 MG, QD,	ORAL
	Myalgia	Health						
	Pyrexia	Professional	Donepezil	SS		ORAL	5 MG, QD,	ORAL
	Sedation							

Date:07/23/98ISR Number: 3108213-6Report Type:Expedited (15-DaCompany Report #980720-008012574
Age:93 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardiac Disorder	Foreign	Haloperidol	PS		ORAL	ORAL	
Hospitalization - Initial or Prolonged	Jaundice	Health Professional						

Date:07/23/98ISR Number: 3109186-2Report Type:Expedited (15-DaCompany Report #980720-008012575
Age:85 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Interaction	Foreign	Haloperidol	PS		ORAL	.5 MG, PRN,	ORAL;LIQUID
	International Normalised Ratio Increased	Health Professional	Warfarin	C				
			Loperamide	C				
			Paroxetine	C				
			Co-Amilofruse	C				
			Zopiclone	C				

Date:07/27/98ISR Number: 3109792-5Report Type:Direct Company Report #
Age:78 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Coma		Haloperidol	PS		ORAL	1-2MG/ML ORAL	
							SOLN Q2H PRN	
			Vitamin C	C				
			Digoxin	C				
			Dss	C				
			Pepcid	C				
			Hyoscyamine	C				
			Mvi	C				
			Nortriptyline	C				
			Propranolol	C				
			Risperidone	C				
			Tylenol	C				
			Mom	C				
			Maalox	C				

Date:07/27/98ISR Number: 3109793-7Report Type:Direct Company Report #
Age:85 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Neuroleptic Malignant		Haloperidol	PS		ORAL	4MG Q DAY PO	
	Syndrome		Aspirin	C				
			Carbmaxepine	C				
			Gabapentin	C				
			Lorazepam	C				
			Psyllium	C				

Sertraline	C
Tylenol	C
Maalox	C
Bisacodyl	C
Lorazepam	C
Mom	C
Brimonidine	C
Despximetasone	C
Haldol	C
Triaminic Dm	C

Date:07/27/98ISR Number: 3110110-7Report Type:Expedited (15-DaCompany Report #JAFRA-37621
Age:49 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged Disability	Alanine Aminotransferase Increased Blood Creatine Phosphokinase Increased Cachexia Cerebellar Syndrome Diarrhoea Hepatocellular Damage Hypoglycaemia Malaise Mutism Neuroleptic Malignant Syndrome Pyrexia Thrombocytopenia	Foreign Health Professional	Risperdal Haldol	PS SS	Janssen Janssen	ORAL ORAL	2 MG 2 DAILY 12 MG DAILY

Date:07/30/98ISR Number: 3111432-6Report Type:Expedited (15-DaCompany Report #A044-002-000662
Age:70 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Life-Threatening Hospitalization -	Cerebrovascular Accident Hypotension	Foreign Health	Aricept	PS		ORAL	5 MG (1 IN 1 D), PER ORAL

Initial or Prolonged	Myocardial Infarction	Professional	Haldol	SS		ORAL
4.5 MG (3 IN						
	Sedation					
1 D), PER						
ORAL						

Date:07/31/98ISR Number: 3111306-0Report Type:Expedited (15-DaCompany Report #1998AP47177
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Delirium	Foreign	Meropenem	PS		
Initial or Prolonged	Depressed Level Of Consciousness	Health Professional	Haloperidol	SS		
	Lower Respiratory Tract Infection	Other				

Date:07/31/98ISR Number: 3111818-XReport Type:Direct Company Report #
Age:79 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Drug Ineffective		Haloperidol	PS		ORAL
1MG - TWO						
TABLETS QD,						

ORAL						
			Vitamin E	C		
			Aspirin	C		
			Verapamil Hcl	C		
			Lovastatin	C		
			Benztropine Mesylate	C		
			Risperidone	C		

Date:08/03/98ISR Number: 3111573-3Report Type:Direct Company Report #
Age:61 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Blood Creatine Phosphokinase Increased Blood Creatinine Increased Blood Urea Increased Muscle Rigidity Pyrexia White Blood Cell Count Increased		Haloperidol	PS		ORAL	PO 5 MG X 2	

Date:08/03/98ISR Number: 3112380-8Report Type:Expedited (15-DaCompany Report #980730-008012735
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Hospitalization - Initial or Prolonged	Cardiac Arrest	Foreign Health Professional	Haldol	PS		INTRAVENOUS (INTRAVENUOS) INJECTION	IV	
			Levomepromazine	C				
			Trihexyphenidyl	C				
			Zolpidem	C				

Date:08/03/98ISR Number: 3210016-9Report Type:Periodic Company Report #98249.01
Age:42 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Cerebral Cyst	Consumer	Haloperidol Tablets	PS		ORAL	1/2 TABLET	
	Chemical Injury						QD, ORAL	13 YR
	Laboratory Test Abnormal							
	Thermal Burn							

Date:08/03/98ISR Number: 3210022-4Report Type:Periodic Company Report #98154.01
Age:23 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Asthenia	Consumer	Haloperidol	PS		ORAL	1 MG QD THEN	
	Fatigue						2 MG QD, ORAL	
	Headache		Seroquel Tablets					
	Muscular Weakness		Zeneca	SS	Zeneca	ORAL	400 MG QD,	
	Sedation						ORAL	MON

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/03/98ISR Number: 3212353-0Report Type:Periodic Company Report #98116.01
Age:17 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dyskinesia Dystonia	Health Professional	Haloperidol Tablets 5 Mg	PS			20-25 MG	
Other (SINGLE DOSE)	Hyperhidrosis Muscle Spasms Opisthotonus	Other						

Date:08/03/98ISR Number: 3212358-XReport Type:Periodic Company Report #98116.02
Age:15 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dyskinesia Dystonia	Health Professional	Haloperidol Tablets 5 Mg	PS			20-25 MG	
Other (SINGLE DOSE)	Hyperhidrosis Muscle Spasms Opisthotonus	Other						

Date:08/03/98ISR Number: 3212366-9Report Type:Periodic Company Report #98116.03
Age:15 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dyskinesia Dystonia	Health Professional	Haloperidol Tablets 5 Mg	PS			20-25 MG	
Other (SINGLE DOSE)	Hyperhidrosis Muscle Spasms Opisthotonus	Other						

Date:08/03/98ISR Number: 3212371-2Report Type:Periodic Company Report #98116.04
Age:16 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dyskinesia Dystonia	Health Professional	Haloperidol Tablets 5 Mg	PS			20-25 MG	
Other (SINGLE DOSE)	Hyperhidrosis Opisthotonus	Other						

Date:08/03/98ISR Number: 3212379-7Report Type:Periodic Company Report #98116.05
Age:16 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dyskinesia Dystonia	Health Professional	Haloperidol Tablets 5 Mg	PS			20-25 MG	
	Hyperhidrosis Muscle Spasms Opisthotonus	Other						

Date:08/03/98ISR Number: 3212385-2Report Type:Periodic Company Report #98116.06
Age:14 YR Gender:Female I/FU:I

Outcome	PT
Other	Dyskinesia Dystonia Hyperhidrosis Muscle Spasms

	Opisthotonus						
		Report Source	Product	Role	Manufacturer	Route	Dose Duration
		Health Professional	Haloperidol Tablets 5 Mg	PS			20-25 MG
		Other					

Date:08/04/98ISR Number: 3113252-5Report Type:Direct Company Report #
Age:79 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Coordination Abnormal		Haldol	PS		ORAL	PO FOR SOME TIME
	Fall						
	Gait Disturbance		Depakote	SS			PO FOR SOME TIME
			Zoloft	C			

Date:08/05/98ISR Number: 3113407-XReport Type:Expedited (15-DaCompany Report #980730-107055144
Age:70 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Death	Dizziness	Consumer	Haldol Injection	PS		INTRAMUSCULAR	.5 MG, ONCE
Hospitalization - Initial or Prolonged	Feeling Hot					IM	
	Hyperhidrosis		Fluoxetine Hydrochloride	C			
	Metabolic Acidosis		Meperidine Hydrochloride	C			
	Muscle Rigidity		Oxycodone With Acetaminophen	C			
			Pentoxifylline	C			
			Furosemide	C			
			Alprozolam	C			
			Albuterol	C			

Date:08/06/98ISR Number: 3114199-0Report Type:Expedited (15-DaCompany Report #980611-107054096
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dermatitis	Health	Ultram	PS		ORAL	ORAL	
	Pyrexia	Professional	Haldol	SS		ORAL	ORAL	
		Company Representative	Dilantin	SS				

Date:08/07/98ISR Number: 3114195-3Report Type:Expedited (15-DaCompany Report #A044-002-00062
Age:70 YR Gender:Female I/FU:F

Outcome	PT
Death	Arrhythmia
Hospitalization - Initial or Prolonged	Cardiac Arrest
	Cardiac Failure Congestive
	Cerebrovascular Accident
	Drug Interaction
	Hypotension
	Pulmonary Congestion
	Renal Failure
	Respiratory Failure

	Sedation Ultrasound Scan Abnormal						
		Report Source	Product	Role	Manufacturer	Route	Dose Duration
		Foreign	Aricept	PS		ORAL	5 MG (1 IN 1 D);
		Health Professional	Haldol	SS		ORAL	4.5 MG (3 IN 1 D);

Date:08/10/98ISR Number: 3115036-0Report Type:Expedited (15-DaCompany Report #8-98211-025A
Age:24 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Rhabdomyolysis	Foreign	Loxapine	PS		INTRAMUSCULAR	IM
		Health Professional	Haloperidol	SS		INTRAMUSCULAR	IM
Other			Tropatepine	SS		INTRAMUSCULAR	IM
			Methotrimeprazine	SS		INTRAMUSCULAR	IM
			Haldol	C			
			Lepticur	C			
			Nozinan	C			

Date:08/10/98ISR Number: 3115096-7Report Type:Expedited (15-DaCompany Report #US_980605975
Age:19 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Decreased Activity Depression Insomnia Suicidal Ideation	Foreign Study Health Professional	Haloperidol Lorazepam Fluoxetine	PS C C			

Date:08/12/98ISR Number: 3115951-8Report Type:Expedited (15-DaCompany Report #980805-008012843
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Accidental Exposure	Foreign	Haloperidol	PS		ORAL	ONCE, ORAL	
	Blood Creatine Phosphokinase Increased	Health Professional						
	Coma							
	Disorientation							
	Dyskinesia							
	Extrapyramidal Disorder							
	Nervous System Disorder							

Date:08/12/98ISR Number: 3115989-0Report Type:Expedited (15-DaCompany Report #980805-008012840
Age:24 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Rhabdomyolysis	Foreign	Haloperidol	PS		INTRAMUSCULAR	IM; INJECTION	
		Health Professional	Levomepromazine	SS		INTRAMUSCULAR	IM	
			Loxapine	SS		INTRAMUSCULAR	IM	
			Tropatepine	SS		INTRAMUSCULAR	IM	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/12/98ISR Number: 3115992-0Report Type:Expedited (15-DaCompany Report #980805-00812841
Age:30 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Myocarditis	Foreign	Haloperidol	PS		INTRAMUSCULAR	10 MG, QD	2 DAY
Hospitalization - Initial or Prolonged	Rhabdomyolysis Tachycardia	Health Professional	Levomepromazine	C				

Date:08/13/98ISR Number: 3117223-4Report Type:Direct Company Report #
Age:21 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Convulsion Muscle Spasms		Haldol	PS	Ortho-Mcneil Pharmaceutical	INTRAMUSCULAR	INJECTION	

Date:08/13/98ISR Number: 3117389-6Report Type:Expedited (15-DaCompany Report #980811-008012917
Age:39 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Intentional Misuse	Foreign	Haloperidol	PS		ORAL	10 TA, ONCE,	
	Neuroleptic Malignant Syndrome Pyrexia Rhabdomyolysis	Health Professional	Medication (Unspecified)	C		ORAL		

Date:08/14/98ISR Number: 3117016-8Report Type:Direct Company Report #
Age:44 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Blood Creatine Phosphokinase Increased		Risperdal	PS	Janssen	ORAL	3MG PO BID	
Hospitalization -			Haloperidol	SS		INTRAMUSCULAR	5MG POOR IM Q	

Initial or Prolonged	Body Temperature					
B' PRN						
	Increased					
	Muscle Rigidity					

Date:08/14/98ISR Number: 3117383-5Report Type:Expedited (15-DaCompany Report #980617-008012153
Age:25 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Overdose	Study	Haloperidol					
		Health	Decanoate	PS				
INTRAMUSCULAR							100 MG	
		Professional						
INTRAMUSCUALR								
			Paroxetine	SS		ORAL		
40 TAB, ONCE,								
ORAL								
			Diphenhydramine	SS		ORAL		
50 CAP, ONCE								
ORAL								

Date:08/17/98ISR Number: 3117136-8Report Type:Expedited (15-DaCompany Report #1998-08-0236
Age:38 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Brain Herniation	Health	Intron A	PS				
40-2- MU								
Hospitalization -	Coma	Professional	Haloperidol	SS				
Initial or Prolonged	Convulsion							
	Electrocardiogram							
	Abnormal							
	Respiratory Arrest							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/17/98ISR Number: 3117293-3Report Type:Direct Company Report #
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Ineffective		Haldol	PS		ORAL	PO 1TAB AM 1/2 TAB AFTERNOON 1 TAB NOON , PM	

Date:08/17/98ISR Number: 3117390-2Report Type:Expedited (15-DaCompany Report #980312-008010887
Age:60 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Abdominal Pain Upper	Foreign	Haldol	PS		ORAL	1 MG QD ORAL	
	Bundle Branch Block	Health	Lithium	C				
	Cardiac Arrest	Professional	Thioridazine	C				
	Cardiac Enzymes Increased		Potassium	C				
	Electrocardiogram Change		Nitrates	C				
	Hypotension							
	Myocardial Infarction							

Date:08/19/98ISR Number: 3118763-4Report Type:Expedited (15-DaCompany Report #9824960
Age:23 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Aggression	Consumer	Vistaril	PS		ORAL	100.00 MG TOTAL:DAILY:O RAL	
	Drug Dependence							
	Drug Ineffective							
	Drug Interaction		Haldol	SS		ORAL	10.00 MG TOTAL:DAILY:O	
	Insomnia							

	Muscle Rigidity					
RAL						
	Sedation		Thorazine	SS		

Date:08/20/98ISR Number: 3119605-3Report Type:Direct Company Report #
Age:55 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Creatine Phosphokinase Increased		Haloperidol	PS	Roxane Probable Manufacturer	ORAL	4MG PO BID	
	Drug Interaction		Coseutin	C				
	Mental Impairment		Eskalith Cr	C				
	Muscle Rigidity		Prempro	C				
	Tremor							
	White Blood Cell Count Increased							

Date:08/21/98ISR Number: 3120040-2Report Type:Expedited (15-DaCompany Report #JAUK-39978
Age:54 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Torsade De Pointes	Foreign	Cisapride	PS	Janssen	ORAL	10 MG DAILY	
ORAL								
			Haloperidol	SS	Janssen			
INTRAMUSCULAR	5MG DAILY							
INTRAMUSCULAR								
			Amiodarone	SS				
INTRAVENOUS	200 MG SINGLE							
INTRAVENOUS								
			Fentanyl	C				
			Digoxin	C				

Frusemide (Furosemide)	C
Midazolam	C
Diazepam	C
Atracurium	C
Glucose	C
Ceftriaxone	C
Metronidazole	C
Potassium Chloride	C
Paracetamol	C
Amlodipine	C
Inderal La (Propranolol)	C
Diclofenac	C
Co-Proxamol	C
Clexane	C
Dobutamine Hydrochloride	C
Isoket	C
Propofol	C
Adrenaline (Epinepherine)	C
Human Actrapid (Insulin Rapid Act.)	C
Pethidine	C

Date:08/21/98ISR Number: 3120361-3Report Type:Expedited (15-DaCompany Report #B0058607
Age:76 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Confusional State	Foreign	Zantac	PS		INTRAVENOUS INJECTION	INTRAVENOUS	
	Pelvic Mass							
	Rash Erythematous		Haloperidol	SS		ORAL	ORAL	
	Ureteric Stenosis		Framycetin	SS				
			Morphine Injection	SS		INTRAVENOUS	INTRAVENOUS	
			Paracetamol	SS		INTRAVENOUS		
			Ofloxacin	SS		INTRAVENOUS		

Date:08/24/98ISR Number: 3120853-7Report Type:Expedited (15-DaCompany Report #9824960
Age:23 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Aggression	Consumer	Vistaril	PS		ORAL	100 MG	TOTAL:BID:ORAL
	Drug Dependence							
	Drug Ineffective							
	Drug Interaction		Haldol	SS		ORAL	10.00 MG	TOTAL:DAILY:ORAL
	Insomnia							
	Joint Stiffness							
	Muscle Rigidity		Thorazine	SS				
	Musculoskeletal Stiffness							
	Sedation							

Date:08/24/98ISR Number: 3120858-6Report Type:Expedited (15-DaCompany Report #980617-008012148
Age:87 YR Gender:Female I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Abnormal Behaviour
	Blood Creatinine

		Increased						
		Blood Urea Increased						
		Disorientation						
		Escherichia Infection	Report Source	Product	Role	Manufacturer	Route	Dose
Duration								
		Pyrexia	Foreign	Haloperidol Solution	PS		ORAL	ORAL
		Urinary Tract Infection	Health	Trihexyphenidyl	SS		ORAL	ORAL
			Professional	Captopril	SS		ORAL	ORAL
				Fluvoxamine	SS		ORAL	ORAL

Date:08/27/98ISR Number: 3121848-XReport Type:Expedited (15-DaCompany Report #980821-107055670
Age:68 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Cerebrovascular Accident	Consumer	Haldol (Haloperidol)	PS				
	Muscle Contractions Involuntary		Selegiline Hydrochloride	C				
	Muscle Rigidity							
	Quadriplegia							

Date:08/27/98ISR Number: 3121849-1Report Type:Expedited (15-DaCompany Report #980316-008010924
Age:89 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Coma	Foreign	Haloperidol Decanoate	PS		INTRAMUSCULAR	100 MG, ONCE	IM
	Decreased Activity	Health						
	Gastrointestinal Haemorrhage	Professional						
	Hemiplegia							
	Medication Error							
	Oesophageal Haemorrhage							
	Peripheral Ischaemia							

Date:08/27/98ISR Number: 3122988-1Report Type:Direct Company Report #
Age:61 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required	Electrocardiogram Qt		Haloperidol	PS	Mcneil Pharm	INTRAVENOUS	IV	
Intervention to Prevent Permanent Impairment/Damage	Corrected Interval Prolonged		Lorazepam	C				
	Torsade De Pointes		Furosemide	C				
	Ventricular Tachycardia		Dopamine	C				
			Heparin	C				
			Digoxin	C				
			Captopril	C				

Date:08/28/98ISR Number: 3125606-1Report Type:Expedited (15-DaCompany Report #1998-08-0236
Age:38 YR Gender:Male I/FU:F

Outcome	PT
Death	Blood Pressure Increased
Life-Threatening	Brain Herniation
Hospitalization - Initial or Prolonged	Brain Oedema
	Cardiomegaly
	Coma
	Convulsion
	Hepatic Congestion
	Hepatic Fibrosis
	Hypoxic Encephalopathy
	Liver Disorder

		Pancreatitis Pulmonary Congestion Pulmonary Oedema	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
		Respiratory Arrest	Health	Intron A	PS		
40- 20 MU*							
			Professional	Haloperidol	SS		ORAL

Date:08/31/98ISR Number: 3123301-6Report Type:Direct Company Report #
Age:41 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - 5MG Q HS	Hypertonia		Haldol	PS		
Initial or Prolonged	Muscle Rigidity Neuroleptic Malignant Syndrome		Benadryl	C		

Date:09/01/98ISR Number: 3124437-6Report Type:Direct Company Report #
Age:21 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - 2 INJECTIONS	Dyskinesia		Haldol	PS		
Initial or Prolonged	Dystonia					
Required Intervention to Prevent Permanent Impairment/Damage	Injection Site Reaction					

Date:09/02/98ISR Number: 3125011-8Report Type:Expedited (15-DaCompany Report #980828-008013160
Age:91 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Apathy	Foreign	Haloperidol	PS		ORAL
UNKNOWN QD						
Hospitalization - ORAL	Decreased Appetite	Health				

Initial or Prolonged	Dehydration	Professional	Fluoxetine	SS		ORAL
20 MG QD ORAL						
	Hyponatraemia					
	Infection					

Date:09/04/98ISR Number: 3127227-3Report Type:Direct Company Report #
Age:24 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Extrapyramidal Disorder		Haldol	PS		
INTRAMUSCULAR 1MG IM X 1						
Initial or Prolonged	Movement Disorder					

Date:09/09/98ISR Number: 3126667-6Report Type:Expedited (15-DaCompany Report #9824960
Age:23 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Required	Aggression	Consumer	Vistaril	PS		ORAL
100 MG TOTAL						
Intervention to	Drug Dependence					
BID ORAL						
Prevent Permanent	Drug Ineffective		Haldol	SS		ORAL
10 MG TOTAL						
Impairment/Damage	Drug Interaction					
DAILY ORAL						
	Joint Stiffness		Thorazine	SS		
	Muscle Rigidity					
	Musculoskeletal Stiffness					
	Parkinsonian Gait					

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/10/98ISR Number: 3127773-2Report Type:Expedited (15-DaCompany Report #980811-008012917
Age:39 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Agitation	Foreign	Haloperidol	PS		ORAL	50 MG, ONCE,	
Hospitalization -	Haemodialysis	Health				ORAL		
Initial or Prolonged	Intentional Misuse	Professional	Droperidol	SS		INTRAVENOUS	150 MG, QD,	
Other	Multi-Organ Failure					IV		
	Neuroleptic Malignant		Fluvoxamine	SS		ORAL	15 TAB, ONCE,	
	Syndrome					ORAL		
	Pyrexia		Tropatepine	C				
	Rhabdomyolysis		Alcohol	C				
	Suicide Attempt		Vasopressin	C				
			Dantrolene	C				
			Antibiotic, Nos	C				

Date:09/10/98ISR Number: 3128316-XReport Type:Direct Company Report #
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Tardive Dyskinesia	Health Professional	Haldol	PS	Mcneil	UNKNOWN		

Date:09/11/98ISR Number: 3128343-2Report Type:Expedited (15-DaCompany Report #980904-008013267
Age:21 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Arrhythmia	Foreign	Haloperidol	PS		ORAL	9 MG, QD,	
Initial or Prolonged	Hallucination, Auditory	Health				ORAL		

	Supraventricular	Professional	Risperidone	SS		ORAL
SEE IMAGE						
	Extrasystoles		Bromperidol	SS		ORAL
6 MG, QD,						
ORAL						
			Chlorpromazine	SS		ORAL
75 MG, QD,						
ORAL						
			Flunitrazepam	C		
			Biperiden Hydrochloride	C		
			Zonisamide	C		
			Pilsicainide Hydrochloride	C		

Date:09/11/98ISR Number: 3128357-2Report Type:Expedited (15-DaCompany Report #980904-008013270
Age:23 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Neuroleptic Malignant	Health	Haldol	PS		
Initial or Prolonged	Syndrome	Professional	Risperidone	SS		ORAL
ORAL						
	Respiratory Depression		Fluphenazine Hydrochloride	SS		
			Fluphenazine Decanoate	SS		
INTRAMUSCULAR IM						

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/11/98ISR Number: 3128361-4Report Type:Expedited (15-DaCompany Report #980908-008013291
Age:68 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Atrioventricular Block	Foreign	Haloperidol	PS		ORAL	4.5 MG, QD,	
Hospitalization - Initial or Prolonged	Bundle Branch Block Left	Health						
	Electrocardiogram Abnormal	Professional	Risperidone	SS		ORAL	3 MG, QD,	
	Sinus Arrhythmia		Sulpiride	SS		ORAL	600 MG, QD,	
			*	C				
			Mazaticol Hydrochloride	C				
			Pantethine	C				
			Clocapramine Hydrochloride	C				
			Pimozide	C				

Date:09/14/98ISR Number: 3129146-5Report Type:Expedited (15-DaCompany Report #JAKYO-39917
Age:68 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Atrioventricular Block	Foreign	Risperidone	PS	Janssen	ORAL	3 MG DAILY	
	Bundle Branch Block Left	Health						
	Condition Aggravated	Professional	Haloperidol	SS	Janssen	ORAL	4.5 MG DAILY	
	Electrocardiogram Delta Waves Abnormal		Sulpiride	SS		ORAL	600 MG DAILY	
	Sinus Arrhythmia							
ORAL								5 YR
			Pimozide (Pimozide)	C				
			Mazaticol (Mazaticol)	C				

			Pantethine (Pantethine)	C		

Date:09/16/98ISR Number: 3130062-3Report Type:Expedited (15-DaCompany Report #980902-107055912
Age:32 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Arthropathy	Consumer	Haldol	PS				3 DAY
	Dizziness							
	Dyskinesia							
	Headache							
	Muscle Spasms							
	Pain							
	Tongue Disorder							

Date:09/16/98ISR Number: 3130109-4Report Type:Expedited (15-DaCompany Report #980904-008013266
Age:70 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anorexia	Foreign	Haloperidol	PS		ORAL	4.5 MG, QD, ORAL	
	Convulsion	Health						
Other	Hyponatraemia	Professional	Meprobamate	C				
			Clorazepate	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/16/98ISR Number: 3130668-1Report Type:Direct Company Report #
Age:44 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Accidental Overdose Asthenia Back Pain Blood Creatine Phosphokinase Increased Bradykinesia Catatonia Cellulitis Difficulty In Walking Dystonia Injection Site Infection Lack Of Spontaneous Speech Medication Error Muscle Rigidity Pyrexia Waxy Flexibility		Haldol	PS		INTRAMUSCULAR	50 MG IM	

Date:09/16/98ISR Number: 3131123-5Report Type:Direct Company Report #
Age:84 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Parkinsonism		Haloperidol Decanoate	PS		IJ	1ML	
			Benztropine	C				

Date:09/18/98ISR Number: 3131903-6Report Type:Direct Company Report #
Age:81 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent	Drug Effect Decreased	Health Professional	Haldol	PS		1 QD		

Impairment/Damage

Date:09/21/98ISR Number: 3133414-0Report Type:Expedited (15-DaCompany Report #9824960
Age:23 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required	Aggression	Consumer	Vistaril	PS		ORAL	100.00 MG	
Intervention to	Drug Ineffective						TOTAL: BID:	
Prevent Permanent	Drug Interaction						ORAL	
Impairment/Damage	Joint Stiffness		Haldol	SS		ORAL	10.00 MG	
	Muscle Rigidity						TOTAL:	
	Musculoskeletal Stiffness						DAILY: ORAL	
	Parkinsonian Gait		Thorazine	SS				
	Posture Abnormal							
	Sedation							
	Sleep Phase Rhythm Disturbance							

Date:09/22/98ISR Number: 3134271-9Report Type:Expedited (15-DaCompany Report #980915-008013484
Age:43 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agitation	Foreign	Haloperidol	PS		INTRAMUSCULAR IM (INTRAMUSCULAR)	5 MG	UNKNOWN
	Blood Creatine Phosphokinase Increased	Literature Health Professional						
	Depressed Level Of Consciousness		Lithium	SS		UNKNOWN	UNKNOWN	
	Disorientation		Naloxone	C				
	Drug Level Above Therapeutic		Glucose	C				
	Drug Toxicity							
	Electrocardiogram T Wave Inversion							
	Electrolyte Imbalance							
	Hypokalaemia							
	Myocardial Infarction							
	Myocardial Ischaemia							
	Sedation							

Date:09/22/98ISR Number: 3134296-3Report Type:Expedited (15-DaCompany Report #980917-107056262
Age:41 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Decubitus Ulcer	Consumer	Haldol	PS		UNKNOWN		
	Mutism		Antidiabetic	C				
	Neuroleptic Malignant Syndrome		Antihypertensive	C				
	Urinary Retention							
	Weight Decreased							

Date:09/23/98ISR Number: 3133951-9Report Type:Direct Company Report #
Age:51 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Neuroleptic Malignant Syndrome		Haloperidol Benztropine Olanzapine	PS SS SS		ORAL ORAL	1 MG TAB PO/IM 5 M TAB PO	

Date:09/24/98ISR Number: 3134818-2Report Type:Expedited (15-DaCompany Report #980918-107013536
Age:45 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Abdominal Distension	Foreign	Haloperidol	PS			45 MG, QD	
Hospitalization - Initial or Prolonged	Abdominal Pain Lower Bowel Sounds Abnormal Gastrointestinal Disorder Heart Rate Decreased Hypotension Ileus Paralytic Nausea Pyrexia Shock Vomiting	Literature Health Professional	Zotepine Trihexyphenidyl Hydrochloride Biperidden Promethazine Hydrochloride Flunitrazepam	C C C C C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/24/98ISR Number: 3134819-4Report Type:Expedited (15-DaCompany Report #980917-008013515
Age:74 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Fall	Foreign Health Professional	Haloperidol Solution	PS		ORAL	QD, ORAL	
			Zopiclone	SS		ORAL	7.5 MG, QD,	ORAL
			Meprobamate	SS		ORAL	1500 MG, QD,	ORAL
			Tiapride	SS		ORAL	100 MG, QD,	ORAL
			Paroxetine	SS		ORAL	40 MG, QD,	ORAL
			Pollen	C				

Date:09/24/98ISR Number: 3134877-7Report Type:Expedited (15-DaCompany Report #980617-008012134
Age:61 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Hospitalization - Initial or Prolonged	Akathisia Delusion Depressed Mood Extrapyramidal Disorder Suicidal Ideation Suicide Attempt	Foreign Health Professional	Haloperidol Decanoate	PS		INTRAMUSCULAR (INTRAMUSCULAR)	100 MG, LX/MO, IM	
			Bromperidol	SS		ORAL	5 MG QD ORAL	
			Potassium Iodide	C				
			Isosorbide Dinitrate	C				
			Metoprolol	C				

Date:09/28/98ISR Number: 3135635-XReport Type:Direct Company Report #
Age:35 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Injection Site		Haldol Decanoate 100	PS		INTRAMUSCULAR	150MG IM Q 4	
	Inflammation							
WEEKS							4	WK

Date:09/28/98ISR Number: 3135649-XReport Type:Direct Company Report #
Age:89 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Hypoventilation		Haldol	PS	Mcneil Pharm	TABLET		
Initial or Prolonged	Medication Error		Halcion	SS	Upjohn	TAB		
	Sedation							

Date:09/28/98ISR Number: 3136068-2Report Type:Expedited (15-DaCompany Report #980922-008013592
Age:42 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Benign Ovarian Tumour	Foreign	Haloperidol	PS		ORAL	9MG QD ORAL	
Hospitalization -	Blood Creatine	Health	Levomepromazine	SS		ORAL	80MG QD ORAL	
Initial or Prolonged	Phosphokinase Increased	Professional						
	Circulatory Collapse							
	Neuroleptic Malignant							
	Syndrome							
	Pyrexia							
	Urinary Tract Infection							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/28/98ISR Number: 3136069-4Report Type:Expedited (15-DaCompany Report #980922-008013593
Age:30 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Depression	Foreign	Haloperidol	PS		ORAL	10MG QD ORAL	
	Fear	Health	Haldol	SS		INTRAMUSCULAR	100MG TIW IM	
	Intentional Misuse	Professional					50MG TIW IM	
	Suicide Attempt		Chlorprothixene	SS		ORAL	50MG QD ORAL	

Date:09/28/98ISR Number: 3136070-0Report Type:Expedited (15-DaCompany Report #980922-008013598
Age:45 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardiogenic Shock	Foreign	Haloperidol	PS		ORAL	ORAL	
	Coma	Health	Pyridoxine	C				
	Disseminated	Professional	Potassium Cluconate	C				
	Intravascular Coagulation		Netilmicin	C				
	Enzyme Abnormality		Amphotericin B	C				
	Hypertonia		Thiamine	C				
	Hypotension							
	Pelvic Pain							
	Pyrexia							
	Tachycardia							
	Urinary Tract Infection							

Date:09/30/98ISR Number: 3136914-2Report Type:Direct Company Report #
Age:86 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Anorexia		Haldol	PS			0.5 MG BID.	
Initial or Prolonged	Lethargy							
	Mental Disorder							

Date:09/30/98ISR Number: 3136967-1Report Type:Direct Company Report #
Age:57 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Congenital Anomaly	Decreased Appetite Libido Decreased		Haldol	PS		ORAL	ORAL	

Date:10/01/98ISR Number: 3137547-4Report Type:Expedited (15-DaCompany Report #980928-002013692
Age:47 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Delusional Disorder, Persecutory Type Hemiparesis	Foreign Study Health Professional	Haloperidol Topiramate Clonazepam Carbamazepine	PS SS C C		ORAL	200MG QD ORAL, 100MG QD ORAL	

Date:10/01/98ISR Number: 3137548-6Report Type:Expedited (15-DaCompany Report #980922-008013590
Age:83 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Condition Aggravated	Foreign	Haloperidol	PS			5MG TID	
	Dyskinesia	Literature	Benztropine	SS			2MG BID	
	Dyspepsia	Health	Diphenhydramine	SS			25MG BID	
	Restlessness	Professional	Metoclopramide	SS			10 MG, QID,	
	Tardive Dyskinesia							
UNKNOWN	Weight Decreased		Glyceryl Trinitrate	C				

Date:10/01/98ISR Number: 3137549-8Report Type:Expedited (15-DaCompany Report #980928-008013690
Age:19 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Abortion Induced	Foreign	Haloperidol	PS		ORAL	ORAL	
	Complications Of Maternal	Health	Paroxetine	SS		ORAL	ORAL	
	Exposure To Therapeutic Drugs	Professional						
	Multiple Cardiac Defects							

Date:10/02/98ISR Number: 3137384-0Report Type:Expedited (15-DaCompany Report #98F-10397
Age:21 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Coma	Foreign	Ludiomil	PS		ORAL	75 MG, DAILY,	
	Hyponatraemia	Health					ORAL	
		Professional	Haldol					
		Other	(Haloperidol)	SS		ORAL	15 MG, DAILY,	

ORAL

Date:10/02/98ISR Number: 3262144-XReport Type:Periodic Company Report #71132-002
Age: Gender:Not SpecifiI/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Condition Aggravated Drug Effect Decreased General Symptom	Health Professional	Haloperidol Tablets	PS	Roxane Laboratories, Inc.	ORAL PO	30 MG DAILY	

Date:10/05/98ISR Number: 3138222-2Report Type:Expedited (15-DaCompany Report #US_980910574
Age:52 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Akathisia Delusion Restlessness	Study Health Professional	Haloperidol Benztropine	PS SS			UNKNOWN BEDTIME UNKNOWN	20 MG/QHS AT 1 MG/D DAY

UNKNOWN

Date:10/05/98ISR Number: 3138301-XReport Type:Expedited (15-DaCompany Report #980925-008013676
Age:55 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Cognitive Deterioration Memory Impairment	Foreign Literature Health Professional	Haloperidol	PS			2 MG, QD,	7 YR

Date:10/05/98ISR Number: 3138313-6Report Type:Expedited (15-DaCompany Report #980925-008013662
Age:64 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Inappropriate Antidiuretic Hormone Secretion	Foreign Health Professional	Haloperidol Decanoate	PS		INTRAMUSCULAR (INTRAMUSCULAR)	1X/2WK, IM	
			Ferrous Sulfate	C				
			Lorazepam	C				
			Procyclidine	C				
			Zopiclone	C				
			Paracetamol	C				

Date:10/06/98ISR Number: 3138626-8Report Type:Expedited (15-DaCompany Report #981001-1070137359
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Haematuria	Health	Haldol	PS		UNKNOWN	UNKNOWN	
	Neuroleptic Malignant Syndrome	Professional						

Date:10/07/98ISR Number: 3139393-4Report Type:Expedited (15-DaCompany Report #DEU001068
Age:27 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Creatine Phosphokinase Increased	Foreign Literature	Akineton	PS		ORAL PO	10 MG DAILY	
	Blood Sodium Decreased	Health	Serenace	SS		ORAL PO	20 MG DAILY	
	Body Temperature Increased	Professional	Chlorpromazine Hcl	SS		ORAL	200 MG DAILY	

	Depressed Level Of					
PO						
	Consciousness		Zotepine	SS		ORAL
150 MG DAILY						
	Fall					
PO						
	Hyperhidrosis					
	Salivary Hypersecretion					
	White Blood Cell Count					
	Increased					

Date:10/07/98ISR Number: 3139396-XReport Type:Expedited (15-DaCompany Report #DEU001071
Age:49 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Life-Threatening	Abnormal Behaviour	Foreign	Akineton	PS		
INTRAMUSCULAR 5 MG DAILY IM						
Hospitalization -	Dyskinesia	Literature	Serenace	SS		
INTRAVENOUS 5 MG DAILY IV						
Initial or Prolonged	Excitability	Health	Contomin	SS		
INTRAMUSCULAR 25 MG DAILY						
	Hyponatraemia	Professional				
IM/12.5 MG						
	Insomnia					
DAILY IM						
	Joint Stiffness		Solu-Medrol	C		
	Muscle Rigidity		Parodel	C		
	Neuroleptic Malignant		Thyradin	C		
	Syndrome		Solu-Certef	C		
	Parkinsonism		Cortril	C		
	Pyrexia					

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/08/98ISR Number: 3140347-2Report Type:Expedited (15-DaCompany Report #981005-008013816
Age:17 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Creatinine Increased	Health Professional	Haloperidol	PS		ORAL	1 MG BID ORAL	
	Haematuria		Risperidone	SS		ORAL	.5 MG BID ORAL/ 1 MG	
	Kidney Infection						BID ORAL	
	Urinary Retention		Valproate Sodium	C				
			Alprazolam	C				
			Sertraline	C				
			Olanzapine	C				

Date:10/08/98ISR Number: 3140552-5Report Type:Expedited (15-DaCompany Report #981002-008013792
Age:30 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Intentional Misuse	Foreign	Haldol	PS		ORAL	ORAL	
	Sedation	Health						
	Suicide Attempt	Professional						

Date:10/08/98ISR Number: 3140555-0Report Type:Expedited (15-DaCompany Report #981002-008013793
Age:39 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Neuroleptic Malignant	Foreign	Haldol	PS		ORAL	ORAL	
Other	Syndrome	Health	Tropatepine	C				
		Professional	Flovoxamine	C				

Date:10/09/98ISR Number: 3141124-9Report Type:Expedited (15-DaCompany Report #JAUSA-34511
Age:17 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Dialysis	Health	Risperdal	PS	Janssen	ORAL	.5 MG 2 DAILY	
Initial or Prolonged	Haematuria	Professional					ORAL ; 1 MG 2	
	Kidney Infection						DAILY ORAL	
	Renal Failure		Haldol	SS	Janssen	ORAL	1 MG 2 DAILY	
	Tremor						ORAL	
	Urinary Retention		Depakote	C				
	Vesicoureteric Reflux		Xanax	C				
			Zoloft	C				
			Zyprexa	C				

Date:10/13/98ISR Number: 3142374-8Report Type:Expedited (15-DaCompany Report #981005-008013817
Age:62 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Angioneurotic Oedema	Foreign	Haloperidol	PS			INTRAMUSCULAR	TIW, IM,
	Oedema Peripheral	Health					(INTRAMUSCULA	
	Psychiatric Symptom	Professional					R)	
			Risperidone	SS		ORAL	1 TAB, QD,	
							ORAL	
			Inovane	SS		ORAL	3.75 MG,	
							BID, ORAL	
			Artane	SS		ORAL	10 MG.; QD;	
							ORAL	
			Lysanxia	SS		ORAL	40 MG; QD;	
							ORAL	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/13/98ISR Number: 3142375-XReport Type:Expedited (15-DaCompany Report #981006-008013834
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Polyneuropathy	Foreign Health Professional	Haldol	PS				

Date:10/13/98ISR Number: 3142929-0Report Type:Expedited (15-DaCompany Report #199812857HPD
Age:82 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Blister	Foreign	Lasix	PS		ORAL	40 MG QD PO	15 DAY
Life-Threatening	Multi-Organ Failure	Study	Lasix Solution For					
	Myocardial Infarction	Health	Injection	SS			INTRAVENOUS IV	3 DAY
	Paralysis	Professional	Ampicillin Solution					
	Pneumonia	Other	For Infusion	SS			INTRAVENOUS IVF	2 DAY
	Rash Erythematous		Tramal Drops	SS		ORAL	40 DROP/DAY	
	Toxic Epidermal						PO	1 DAY
	Necrolysis		Diazepam	SS			INTRAVENOUS	10 MG QD IV 1 DAY
			Tavor Solution For Injection	SS			INTRAMUSCULAR	IM 2 DAY
			Aspisol Solution For Injection	SS			INTRAVENOUS	IV 1 DAY
			Heparin Solution For Injection	SS			SUBCUTANEOUS	7500 IU BID
							SC	3 DAY
			Haldol Drops	SS		ORAL	PO	4 DAY
			Mono-Embolex Nm	SS				
			Atosil Drops	SS		ORAL	PO	2 DAY
			Atosil Solution For					

INTRAVENOUS	IV	1	DAY
40 MG QAM PO	1	DAY	
SUBCUTANEOUS	SC	3	DAY
INTRAVENOUS	IVF	2	DAY
INTRAVENOUS	IV	1	DAY
INTRAVENOUS	IV	3	DAY
PO	1	DAY	
100 MG QD PO	2	DAY	
10 MG IRR PO	25	DAY	
IRR PO	25	DAY	
TOPICAL	IRR TOP	19	DAY

Injection	SS	
Isoket	SS	ORAL
Insulin H	SS	
Glyceroinitrat Solution For Infusion	SS	
Haldol Solution For Injection	SS	
Heparin Solution For Infusion	SS	
Dytide H Tablets	SS	ORAL
Ass 100	SS	ORAL
Oxazepam	SS	ORAL
Gelonida Tablets	SS	ORAL
Septopalkette Implant	C	
Normofundin Op	C	
Psyquil	C	
Dobutrex	C	
Tutofusin Op	C	
Dopamin	C	
Morphin	C	
Kalinor	C	
Dusodril Ret.	C	
Aldactone Saltucin	C	
Nacl	C	
Amaryl	C	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/13/98ISR Number: 3142953-8Report Type:Expedited (15-DaCompany Report #981007-107013874
Age:26 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Blood Creatine	Literature	Haldol	PS		ORAL		
	Phosphokinase Increased	Health	Thioridazine	SS				
	Coma	Professional	Valproic Acid	C				
	Pyrexia		Insulin	C				
			Benztropeine	C				

Date:10/13/98ISR Number: 3267159-3Report Type:Periodic Company Report #JAUSA-32895
Age:47 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Dyspnoea	Health	Risperdal					
Life-Threatening	Neuroleptic Malignant	Professional	(Risperidone),					
Hospitalization -	Syndrome		Janssen, Solution	PS		ORAL	2 ML	SINGLE
Initial or Prolonged	Rhabdomyolysis							
ORAL								
	Stupor							

COMMENTS: ONE

DOSE TAKEN IN

P.M.

			Haldol					
			(Haloperidol),					
			Janssen, Tablet	SS	Janssen	ORAL		

SINGLE ORAL;

TAKEN ONCE

PRIOR TO

11/12/97;

PRESCRIPTION

			Prolixin					
			(Fluphenazine)	SS		ORAL		

5 MG 2 DAILY

ORAL

Benadryl (Diphenhydramine)	C
Pen-Vee K (Penicillin V Potassium)	C
Erythromycin (Erythromycin)	C

Date:10/15/98ISR Number: 3142329-3Report Type:Expedited (15-DaCompany Report #981008-008013886
Age:94 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Depressed Level Of	Foreign	Haloperidol	PS			5 MG	QD
	Consciousness	Literature	Sulpiride	C				
	Disseminated	Health	Flunitrazepam	C				
	Intravascular Coagulation	Professional						
	Neuroleptic Malignant Syndrome							
	Pyrexia							
	Renal Failure Acute							
	Respiratory Failure							
	Rhabdomyolysis							
	Thrombocytopenia							

Date:10/15/98ISR Number: 3142331-1Report Type:Expedited (15-DaCompany Report #981008-008013887
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Polyneuropathy	Foreign Health Professional	Haloperidol	PS		ORAL	ORAL	

Date:10/19/98ISR Number: 3143588-3Report Type:Expedited (15-DaCompany Report #US_980910574
Age:52 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Abnormal Behaviour	Study	Haloperidol	PS			10 MG/QHS AT	
Initial or Prolonged	Akathisia	Health Professional					BEDTIME	
	Delusion		Benztropine (Benzatropine)	SS			4 MG/D DAY	
	Psychotic Disorder							
	Restlessness							
	Schizophrenia							

Date:10/19/98ISR Number: 3144258-8Report Type:Direct Company Report #
Age:35 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Injection Site		Haldol Decanoate 100	PS			150 MG IM Q 4	
	Inflammation						WEEKS	

Date:10/19/98ISR Number: 3144314-4Report Type:Direct Company Report #
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Eyelid Function Disorder		Haldol	PS				

	Hallucination					
	Medication Error					
	Parkinson'S Disease					
	Tremor					

Date:10/21/98ISR Number: 3144494-0Report Type:Expedited (15-DaCompany Report #981008-008013886
Age:94 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Depressed Level Of	Foreign	Haloperidol	PS		ORAL	5MG QD	
	Consciousness	Literature	Sulpiride	C				
	Disseminated	Health	Flunitrazepam	C				
	Intravascular Coagulation	Professional						
	Neuroleptic Malignant Syndrome							
	Pyrexia							
	Respiratory Failure							
	Restlessness							
	Rhabdomyolysis							
	Thrombocytopenia							

Date:10/21/98ISR Number: 3144495-2Report Type:Expedited (15-DaCompany Report #981008-008013887
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Polyneuropathy	Foreign Health Professional	Haloperidol	PS		ORAL	ORAL	

Date:10/22/98ISR Number: 3145487-XReport Type:Expedited (15-DaCompany Report #980730-008012735
Age:49 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Agitation	Foreign Health Professional	Haldol	PS		ORAL	9 MG, ONCE, ORAL TABLETS	
Life-Threatening	Blood Creatine Phosphokinase Increased		Haldol	SS		ORAL	150 MG, ONCE, ORAL SOLUTION	Initial or Prolonged
Hospitalization -	Blood Sodium Increased							
	Brain Oedema		Levomepromazine	C				
	Cardiac Arrest		Trihexyphenidyl	C				
	Cardio-Respiratory Arrest		Zolpidem	C				
	Cerebral Ischaemia		Loxapine	C				
	Coma							
	Convulsion							
	Haemorrhagic Stroke							
	Heart Rate Increased							
	Hyperkalaemia							
	Hypertension							
	Red Blood Cells Csf Positive							

Date:10/22/98ISR Number: 3145493-5Report Type:Expedited (15-DaCompany Report #981015-008014025
Age:39 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Dyskinesia	Foreign	Haldol	PS		ORAL	1 MG, QD,	

Initial or Prolonged Tachycardia Paroxysmal Health
ORAL; 2MG

Professional

ORAL SEE

IMAGE

Prozac SS ORAL
20 MG, QD,

ORAL

Teralithe SS ORAL
375 MG, QD,

ORAL

Date:10/22/98ISR Number: 3145497-2Report Type:Expedited (15-DaCompany Report #981015-008014026
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Blindness	Foreign	Haloperidol	PS				
Other	Haemorrhagic Stroke	Consumer	Fentanyl	SS				
			Heparin	SS				
			Cortisone	C				

Date:10/22/98ISR Number: 3145543-6Report Type:Expedited (15-DaCompany Report #800301001
Age:39 YR Gender:Male I/FU:I

Outcome	PT
Death	Agitation
Hospitalization - Initial or Prolonged	Completed Suicide
	Intentional Misuse

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Multi-Organ Failure Neuroleptic Malignant Syndrome							
	Pyrexia	Foreign	Hapoperidol	PS			50 MG	
	Rhabdomyolysis		Droperidol	SS			150 MG	
			Fluvoxamine	SS		ORAL	ORAL	
			Oxygen	C				
			Alcohol	C				

Date:10/22/98ISR Number: 3145583-7Report Type:Expedited (15-DaCompany Report #981014-008014001
Age:32 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Alanine Aminotransferase Increased	Foreign Health Professional	Haldol	PS		ORAL	1 TAB, QD, ORAL	
	Blood Alkaline Phosphatase Increased		Biperiden	SS		ORAL	ORAL	
			Clonazepam	SS		ORAL	ORAL	
	Dermatitis Eczema Infected		Carbamazepine	SS		ORAL	600 MG, QD, ORAL	
	Eosinophilia Gamma-Glutamyltransferase Increased		Zopiclone	SS		ORAL	3.75 MG, QD, ORAL	
	Inflammation Lymphadenopathy Oedema Peripheral		Amisulpride	SS		ORAL	ORAL	

Date:10/22/98ISR Number: 3145587-4Report Type:Expedited (15-DaCompany Report #981012-008013964
Age:50 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Enteritis Necroticans	Foreign Health Professional	Haloperidol	PS		ORAL	125 MG, QD, ORAL
			Levomepromazine	SS		ORAL	100 MG, QD, ORAL
			Trihexyphenidyl	SS		ORAL	
			Tiapride	SS		ORAL	
			Valproate Sodium	C			
			Heptaminol	C			

Date:10/22/98ISR Number: 3145591-6Report Type:Expedited (15-DaCompany Report #980811-008012917
Age:39 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Death	Multi-Organ Failure	Foreign Health Professional	Haloperidol	PS		ORAL	50 MG, ONCE
Hospitalization - Initial or Prolonged	Neuroleptic Malignant Syndrome		Droperidol	SS			INTRAVENOUS 10 MG, QD, IV
Other	Pyrexia		Fluvoxamine	SS		ORAL	15 TAB, ONCE, ORAL
	Rhabdomyolysis						
	Suicide Attempt		Tropatepine	C			
			Alcohol	C			
			Vasopressin	C			
			Dantrolene	C			
			Antibiotic, Nos	C			

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/23/98ISR Number: 3146065-9Report Type:Expedited (15-DaCompany Report #981009-008013943
Age:40 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Mental Disorder	Foreign	Haloperidol	PS		ORAL	2 MG, QD,	
	Restlessness	Health					ORAL 4 MG	
	Thrombocytopenia	Professional	Zuclopenthixol	C				
			Perazine	C				
			Levomepromazine	C				
			Promethazine	C				
			Prothipendyl	C				
			Lithium Acetate	C				
			Carbamazepine	C				
			Diazepam	C				
			Zopiclone	C				
			Clorazepate	C				
			Valproic Acid	C				
			Valproate Sodium	C				
			Lithium Carbonate	C				
			Melperone	C				
			Metoprolol	C				

Date:10/23/98ISR Number: 3146066-0Report Type:Expedited (15-DaCompany Report #981012-008013963
Age:78 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Chromaturia	Foreign	Haloperidol	PS		ORAL	200 MG, QD, ORAL	
	Hepatitis Chronic Active	Health						
	Jaundice	Professional	Cyamemazine	C				
	Liver Function Test Abnormal		Alimemazine	C				
	Nausea							

Date:10/23/98ISR Number: 3146694-2Report Type:Direct Company Report #
Age:18 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Dystonia Muscle Rigidity Opisthotonus Tic		Haldol	PS			5MG QHS	

Date:10/27/98ISR Number: 3147845-6Report Type:Expedited (15-DaCompany Report #107197
Age:32 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Alanine Aminotransferase Increased Blood Alkaline Phosphatase Increased Condition Aggravated Dermatitis Exfoliative Eosinophilia Face Oedema Gamma-Glutamyltransferase Increased Lymphadenopathy Oedema Peripheral	Foreign Other	Rivotril Akineton Haldol Tegretol Imovane Solian	PS SS SS SS SS SS		ORAL ORAL ORAL ORAL ORAL ORAL	2.5 DOSE FORM 1 X PER DAY 3 DOSE FORM 1 X DAY .5 DOSE FORM 3 DOSE FORM 1 X PER DAY	ORAL ORAL ORAL ORAL ORAL ORAL

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/28/98ISR Number: 3148787-2Report Type:Expedited (15-DaCompany Report #981006-008013834
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Polyneuropathy	Foreign	Haldol	PS		ORAL	ORAL	
		Health Professional						

Date:10/29/98ISR Number: 3149323-7Report Type:Expedited (15-DaCompany Report #981015-008014026
Age:49 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Blindness	Foreign	Haloperidol Solution	PS		INTRAVENOUS	5 MG, QD, IV	
Other	Haemorrhagic Stroke	Health Professional				(INTRAVENOUS)	; 2.5 MG, PRN, IV	(INTRAVENOUS)
			Fentanyl	SS		INTRAVENOUS	100 MCG, QD, IV	
			Heparin	SS				
			Cortisone	C				
			Diazepam	C				
			Procyclidine	C				

Date:10/29/98ISR Number: 3149324-9Report Type:Expedited (15-DaCompany Report #981023-008014167
Age:40 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Pain	Foreign	Haldol	PS		ORAL	30 MG, QD, ORAL	
	Paralysis	Health						

Disability			Professional	Promethazine	C		
				Chlorpromazine	C		

Date:10/29/98ISR Number: 3151481-5Report Type:Expedited (15-DaCompany Report #981021-008014141
Age:82 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Blister	Foreign	Haldol	PS				
INTRAVENOUS	UNKNOWN,							
Life-Threatening	Diaphragmatic Paralysis	Health						
ONCE, IV								
	Multi-Organ Failure	Professional						
(INTRAVENOUS)								
	Rash Erythematous		Haldol	SS		ORAL		
UNKNOWN, QD,								
	Toxic Epidermal							
ORAL								
	Necrolysis		Oxazepam	SS		ORAL		
10 MG, QD,								
ORAL								
			Gelonida	SS		ORAL		
ORAL								
			Furosemide	SS		ORAL		
10 MG, QD,								
ORAL; 40								
MG, QD, ORAL								
			Furosemide	SS				
INTRAVENOUS	UNKNOWN, QD,							
IV								
(INTRAVENOUS)								
			Gentamicin	SS		ORAL		
10 MG, QD,								
ORAL								
			Tramadol	SS		ORAL		
UNKNOWN,								
ONCE, ORAL								
			Diazepam	SS				
INTRAVENOUS	10 MG, ONCE,							
IV								
			Lorazepam	SS				
INTRAMUSCULAR	2.5 MG, QD,							

(INTRAMUSCULAR)				
SUBCUTANEOUS	7500 U, UNKNOWN, SC (SUBCUTANEOUS)	Heparin Sodium	SS	
INTRAVENOUS	UNKNOWN, UNKNOWN, IV (INTRAVENOUS)	Heparin	SS	
INTRAVENOUS	UNKNOWN, ONCE, IV (INTRAVENOUS)	Lysine Acetylsalicylate	SS	
		Dytide H	SS	ORAL
INTRAVENOUS	UNKNOWN, BID, ORAL	Ampicillin	SS	
INTRAVENOUS	2 G, QD, IV (INTRAVENOUS)	Glycerol	SS	
INTRAVENOUS	UNKNOWN, UNKNOWN, IV (INTRAVENOUS)	Mezlocillin	SS	
SUBCUTANEOUS	10 U, QD, SC (SUBCUTANEOUS)	Isoket	SS	ORAL
	40 MG, ONCE,			

ORAL

			Promethazine	SS	

INTRAVENOUS UNKNOWN,

ONCE, IV

(INTRAVENOUS)

			Promethazine	SS	ORAL

UNKNOWN, QD,

ORAL

			Acetylsalicylic Acid	SS	ORAL

100 MG, QD,

ORAL

			Glimepiride	C	
			Naftidrofuryl	C	
			Spironolactone	C	
			Sodium Chloride	C	
			Normofundin	C	
			Kalinor	C	
			Morphine	C	
			Trifluoperazine	C	
			Dopamine	C	
			Dobutamine	C	
			Tutofusin	C	

Date:10/30/98ISR Number: 3150341-3Report Type:Expedited (15-DaCompany Report #971224-008013583
Age:46 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Foreign	Haldol Decanoate	PS				

INTRAMUSCULAR 50 MG, QD, IM

	Loss Of Employment	Health						

(INTRAMUSCULAR); 100 MG

	Marital Problem	Professional						
	Social Problem		Haldol (Haloperidol)	SS		ORAL	10 MG, QD	

,ORAL; 7.5 MG

			Zolpidem	C	
			Lorazepam	C	

Date:10/30/98ISR Number: 3150347-4Report Type:Expedited (15-DaCompany Report #981026-008014217
Age:81 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cheyne-Stokes Respiration	Foreign	Haldol	PS		INTRAVENOUS		IV
Hospitalization -	Dysphagia	Consumer				(INTRAVENOUS)		
Initial or Prolonged	Dyspnoea		Prepulsid					
	Hallucination		(Cisapride)	SS		ORAL		
ORAL								
	Hyperhidrosis		Ranitidine	C				
	Hypersensitivity		Paracetamol	C				
	Rash Macular							
	Tardive Dyskinesia							

Date:11/02/98ISR Number: 3150344-9Report Type:Expedited (15-DaCompany Report #980805-008012841
Age:40 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Blood Creatine	Foreign	Haloperidol					
Hospitalization -	Phosphokinase Increased	Health	Injection	PS		INTRAMUSCULAR	10 MG,	QD, IM
Initial or Prolonged	Myocarditis	Professional				(INTRAMUSCULA		
	Rhabdomyolysis					R)		
	Tachycardia		Levomepromazine	C				
	Thrombocytopenia		Prazepam	C				
			Sertraline	C				
			Sulpiride	C				
			Fluvoxamine	C				
			Mepronizine	C				
			Alimemazine	C				
			Nifedipine	C				
			Nitroglycerin	C				
			Heparin Sodium	C				
			Paracetamol	C				

Date:11/02/98ISR Number: 3151635-8Report Type:Expedited (15-DaCompany Report #981005-008013816
Age:17 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Creatinine Increased	Health Professional	Haloperidol	PS		ORAL	1 MG, BID, ORAL	
	Haematuria		Risperidone	SS		ORAL	.5 MG, BID ORAL	
	Kidney Infection							
	Urinary Retention		Risperidone	SS		ORAL	.5 MG, BID, ORAL	
	Vesicoureteric Reflux							
			Sertraline	SS		ORAL	25 MG, QD, ORAL	
			Valproate Sodium	C				
			Olanzapine	C				
			Benzatropine Mesilate	C				

Date:11/02/98ISR Number: 3151698-XReport Type:Expedited (15-DaCompany Report #980406-008011154
Age:65 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Circulatory Collapse	Foreign	Haloperidol	PS		ORAL	1) 5 MG, QD, ORAL 2) 10 MG, QD, ORAL	
	Fall	Health						
	Syncope	Professional						
			Citalopram	SS		ORAL	1) 20 MG, QD, ORAL	

2) 30 MG,

QD, ORAL

Lorazepam SS ORAL

1) .5 MG, QD,

ORAL 2) 1

MG, QD, ORAL

3) 2 MG, QD,

ORAL

Date:11/03/98ISR Number: 3151493-1Report Type:Expedited (15-DaCompany Report #981005-008013817
Age:62 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Angioneurotic Oedema	Health	Haloperidol	PS		INTRAMUSCULAR	UNKNOWN, TIW,	
	Mental Disorder	Professional				IM		
	Oedema Peripheral					(INTRAMUSCULAR)		
			Risperidone	SS		ORAL	1 TAB, QD,	
			Inovane	SS		ORAL	3.75 MG, BID,	
			Artane	SS		ORAL	10 MG, QD,	
			Lysanxia	SS		ORAL	40 MG, QD,	

Date:11/03/98ISR Number: 3151494-3Report Type:Expedited (15-DaCompany Report #981027-008014244
Age:13 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Death	Literature	Haloperidol	PS		INTRAVENOUS	IV	
		Health Professional	Benztropine	SS		(INTRAVENOUS)		

Date:11/04/98ISR Number: 3152006-0Report Type:Direct Company Report #
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Lethargy Medication Error Pain Tremor	Consumer	Haloperidol	PS	Mcneil Pharmaceutical	ORAL		

Date:11/05/98ISR Number: 3152432-XReport Type:Expedited (15-DaCompany Report #981102-008014325
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Ileus Paralytic	Foreign Health Professional	Haldol Decanoate, Unspecified (Haloperidol)	PS		INTRAMUSCULAR	IM	(INTRAMUSCULAR)

Date:11/05/98ISR Number: 3153026-2Report Type:Expedited (15-DaCompany Report #9824960
Age:23 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Required	Aggression	Consumer	Vistaril Cap	PS		ORAL	100.00 MG
Intervention to	Condition Aggravated	Health					TOTAL: BID:
Prevent Permanent	Drug Dependence	Professional					ORAL
Impairment/Damage	Drug Ineffective		Haldol	SS		ORAL	10.00 MG
	Drug Interaction						TOTAL: DAILY:
	Insomnia						ORAL
	Muscle Rigidity		Thorazine	SS			
	Parkinsonian Gait						
	Posture Abnormal						
	Sedation						

Date:11/09/98ISR Number: 3154345-6Report Type:Expedited (15-DaCompany Report #JACAN-16924
Age:81 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Death	Cheyne-Stokes Respiration	Foreign	Prepulsid	PS	Janssen	ORAL	ORAL
	Drug Interaction	Consumer	Haldol	SS			INTRAVENOUS -,
	Dysphagia						INTRAVENOUS
	Dyspnoea		Ranitidine	C			
	Hallucination		Acetaminophen	C			
	Hyperhidrosis						
	Hypersensitivity						
	Skin Discolouration						
	Tardive Dyskinesia						

Date:11/10/98ISR Number: 3155621-3Report Type:Expedited (15-DaCompany Report #93835
Age:31 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Blood Pressure Decreased	Foreign	Valium	PS			INTRAMUSCULAR	10 MG 2 X PER DAY
	Coma	Other					INTRAMUSCULAR /INJECTION	
	Shock		Droleptan	SS		ORAL	20 MG 1 X PER ONE DOSE ORAL	
			Droleptan	SS			INTRAMUSCULAR	50 MG 1 X PER ONE DOSE
			Haldol	SS			INTRAMUSCULAR	5 MG 1 X PER ONE DOSE

Date:11/13/98ISR Number: 3157230-9Report Type:Expedited (15-DaCompany Report #981103-008014340
Age:25 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Deep Vein Thrombosis	Foreign	Haloperidol	PS			16 MG, QD	
Initial or Prolonged		Health	Levomepromazine	SS			480 MG, QD	
		Professional					360 MG	
			Ciprofloxacin Hydrochloride	C				
			Theophylline	C				
			Heparin	C				
			Lamivudin Antivirals	C				
			Nevirapine					

			Antivirals	C		
			Paracetamol	C		

Date:11/13/98ISR Number: 3157827-6Report Type:Direct Company Report #
Age:44 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to AGITATION-IV Prevent Permanent Impairment/Damage	Torsade De Pointes		Haloperidol	PS	Mcneil	INTRAVENOUS	20MG Q15MIN	
	Ventricular Tachycardia							

Date:11/16/98ISR Number: 3158135-XReport Type:Expedited (15-DaCompany Report #981021-008014134
Age:75 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Cholestasis	Foreign	Haloperidol Solution	PS		ORAL (SEE IMAGE)		
	Hepatic Function Abnormal	Health				ORAL		
	Hepatocellular Damage	Professional	Meprobamate	C				
	Jaundice		Hydroxyzine	C				

Date:11/18/98ISR Number: 3281886-3Report Type:Periodic Company Report #8-98093-022N
Age:8 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Confusional State	Health	Tenex	PS		ORAL	1 MG ORAL	
	Coordination Abnormal	Professional	Haldol	SS			5 MG IM	
	Drug Interaction		Versed	C				
	Sedation		Allergy Medicine (Otc)	C				
			Dexedrine	C				
			Haldol	C				

Date:11/20/98ISR Number: 3160887-XReport Type:Expedited (15-DaCompany Report #A001-002-002830
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Convulsion	Foreign	Aricept	PS		ORAL	10MG (1 IN 1 D), PER ORAL	
	Drug Interaction	Health						
	Syncope	Professional	Haloperidol	SS			(1 IN 1 D)	

Date:11/23/98ISR Number: 3161769-XReport Type:Expedited (15-DaCompany Report #8-98315-028A
Age:36 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Blood Pressure Systolic	Foreign	Tavor	PS		ORAL	4 MG ONCE	
Hospitalization -	Decreased	Study					DAILY ORAL	
Initial or Prolonged	Circulatory Collapse		Haldol	SS		ORAL	20 MG DAILY	
	Depressed Level Of Consciousness		Haldol	C			ORAL	
	Heart Rate Increased		Neurocil	C				
	Pulmonary Embolism		Fragmin	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/24/98ISR Number: 3162288-7Report Type:Expedited (15-DaCompany Report #981116-008014563
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Laryngospasm	Foreign	Haloperidol	PS		ORAL	ORAL	
Hospitalization - Initial or Prolonged		Health Professional						

Date:11/25/98ISR Number: 3162292-9Report Type:Expedited (15-DaCompany Report #981027-008014244
Age:13 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardiac Arrest	Literature	Haloperidol	PS		INTRAVENOUS	2 MG, BID, IV	
Hospitalization - Initial or Prolonged		Health Professional	Benztropine	SS		(INTRAVENOUS)	3 MG, BID	
			Carbamazepine	C				
			Lorazepam	C				
			Trihexyphenidyl	C				
			Hydrocodone With Acetaminophen	C				

Date:11/27/98ISR Number: 3163637-6Report Type:Expedited (15-DaCompany Report #S98-GER-00848-01(0)
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Back Pain	Foreign	Cipramil	PS		ORAL	40 MG DAILY	PO
		Health Professional	Haloperidol	SS		ORAL	3 MG DAILY PO	
			Dimidon	C				
			Ranitic	C				

Date:11/27/98ISR Number: 3163763-1Report Type:Expedited (15-DaCompany Report #981117-008014578
Age:58 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Malaise	Foreign	Haldol	PS		ORAL	7.5 MG/ML, QD, ORAL	
	Orthostatic Hypotension	Health Professional	Gliclazide	SS		ORAL	ORAL	
	Vertigo		Lacidipine	SS		ORAL	4 MG, QD, ORAL	
			Fluoxetine	C				

Date:12/01/98ISR Number: 3163957-5Report Type:Expedited (15-DaCompany Report #DEU001235
Age:30 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hepatic Function Abnormal	Foreign	Akineton	PS		ORAL	4 MG OD PO	
		Study	Haldol	SS			INTRAMUSCULAR	10 MG DAILY
		Health Professional	Haldol	SS			IM	
			Haldol	SS			INTRAMUSCULAR	20 MG DAILY
			Haldol	SS			IM	
			Haldol	SS			20 MG DAILY	
			Haldol	SS			10 MG DAILY	
			Haldol	SS			4 MG DAILY	
			Dociton	C			2 MG DAILY	
			Zyprexa (Olanzapine)	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/01/98ISR Number: 3165171-6Report Type:Expedited (15-DaCompany Report #981124-008014689
Age:74 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Coronary Artery Disease	Consumer	Haldol	PS		ORAL		
Hospitalization -	Fracture		Risperidone	SS		ORAL	10 MG, QD,	
Initial or Prolonged	Miosis							
	Myocardial Infarction		Tamoxifen	C				
	Schizophrenia		Levothyroxine	C				
			Alcohol	C				

Date:12/02/98ISR Number: 3165767-1Report Type:Expedited (15-DaCompany Report #981125-008014718
Age:37 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Attention	Foreign	Haloperidol	PS		ORAL	20 MG, QD.	
Life-Threatening	Deficit/Hyperactivity	Health						
Hospitalization -	Disorder	Professional	Lorazepam	SS		ORAL	24 MG QD ORAL	
Initial or Prolonged	Circulatory Collapse		Levomepromazine	C				
	Cyanosis		Heparin	C				
	Depressed Level Of Consciousness							
	Pulmonary Embolism							

Date:12/02/98ISR Number: 3165769-5Report Type:Expedited (15-DaCompany Report #981125-008014717
Age:41 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Cyanosis	Foreign	Haloperidol	PS		ORAL	20 MG, QD	
	Loss Of Consciousness	Health						
	Respiratory Depression	Professional	Levomepromazine	SS		ORAL	200 MG QD	

ORAL						
			Acetylsalicylic Acid	C		

Date:12/03/98ISR Number: 3166582-5Report Type:Expedited (15-DaCompany Report #981124-008014689
Age:74 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Death	Coronary Artery Disease	Consumer	Haldol	PS		ORAL	ORAL
Hospitalization -	Hip Fracture		Risperidone	SS		ORAL	10 MG, QD,
Initial or Prolonged	Miosis						ORAL
	Myocardial Infarction		Tamoxifen	C			
	Schizophrenia		Levothyroxine	C			
			Alcohol	C			

Date:12/04/98ISR Number: 3167570-5Report Type:Expedited (15-DaCompany Report #JAUSA-35231
Age:74 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Death	Coronary Artery Disease	Consumer	Risperdal	PS	Janssen	ORAL	10 MG DAILY
	Miosis						ORAL
	Myocardial Infarction		Haldol (Haloperidol)	SS	Janssen	ORAL	ORAL
			Tamoxifen	C			
			Synthroid	C			
			Alcohol	C			

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/04/98ISR Number: 3167694-2Report Type:Expedited (15-DaCompany Report #981124-008014688
Age:27 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Biopsy Bone Marrow	Foreign	Haloperidol Tablets	PS		ORAL	3 MG, QD,	
	Abnormal	Health					ORAL; 4 MG	
	Leukopenia	Professional					QD, ORAL; 5	
	Neutropenia						MG, QD, ORAL	
	Pancytopenia							

Date:12/04/98ISR Number: 3167697-8Report Type:Expedited (15-DaCompany Report #981125-008014719
Age:32 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Acute Psychosis	Foreign	Haloperidol	PS		ORAL	ORAL	11 YR
Hospitalization - Initial or Prolonged	Cardiogenic Shock	Literature	Lithum	C				
	Coma	Health						
	Cough	Professional						
	Electroencephalogram Abnormal							
	Hyperhidrosis							
	Hyporeflexia							
	Hypotension							
	Mania							
	Muscle Rigidity							
	Nasopharyngitis							
	Neuroleptic Malignant Syndrome							
	Pallor							
	Pharyngitis							
	Pyrexia							
	Tachypnoea							
	Urinary Incontinence							
	Vasoconstriction							

Date:12/04/98ISR Number: 3167700-5Report Type:Expedited (15-DaCompany Report #981120-008014631
Age:71 YR Gender:Male I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Blood Acid Phosphatase Increased
	Blood Creatine Phosphokinase Increased
	Blood Lactate Dehydrogenase Increased
	Blood Pressure Decreased
	Bradycardia
	Bundle Branch Block Left
	Chest Pain
	Dysarthria
	Dysphagia
	Electrocardiogram Abnormal
	Extrapyramidal Disorder
	Flight Of Ideas
	Heart Rate Decreased
	Hypotension
	Muscle Rigidity
	Neuroleptic Malignant Syndrome

	Pressure Of Speech Sedation Speech Disorder	Report Source	Product	Role	Manufacturer	Route	Dose Duration
		Foreign	Haldol	PS			5 MG, BID;
		Study					2.5 MG, BID 2 DAY
		Health Professional	Isosobride Monotrate	C			
			Diltiazem	C			
			Perhexline	C			
			Acetylsalicylic Acid	C			
			Enalapril	C			
			Diazepam	C			
			Flunitrazepam	C			
			Amitriptyline	C			
			Benztropene	C			
			Thioridazine Hydrochloride	C			

Date:12/07/98ISR Number: 3167902-8Report Type:Expedited (15-DaCompany Report #981202-008014808
Age:49 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Death	Alanine Aminotransferase Increased	Foreign	Haloperidol	PS		ORAL	12 MG, QD,
Hospitalization - Initial or Prolonged	Blood Creatine Phosphokinase Increased	Health Professional	Risperidone	SS		ORAL	2 MG, QD,
	Cachexia		Perciazine	SS		ORAL	90 DROP, QD,
	Cerebellar Syndrome						
	Communication Disorder		Levomepromazine	SS			
	Depressed Level Of Consciousness		Loxapac	SS			
	Malaise		Largactil	SS		ORAL	

	Neuroleptic Malignant Syndrome Pyrexia Thrombocytopenia		Laxpine Chlorpromazine	C C		

Date:12/07/98ISR Number: 3167952-1Report Type:Expedited (15-DaCompany Report #JAUSA-35231
Age:74 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Death	Condition Aggravated	Consumer	Risperdal	PS	Janssen	ORAL	10 MG DAILY
	Coronary Artery Atherosclerosis Hip Fracture Mental Disorder Miosis Myocardial Infarction		Haldol Tamoxifen (Tamoxifen) Synthroid (Levothyroxine) Alcohol (Alcohol)	SS C C C	Janssen	ORAL	

Date:12/07/98ISR Number: 3168539-7Report Type:Direct Company Report #
Age:21 YR Gender:Male I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Abnormal Behaviour Blood Creatine Phosphokinase Increased Condition Aggravated Flat Affect Gait Disturbance

		Joint Stiffness					
		Movement Disorder					
		Neuroleptic Malignant	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
		Syndrome		Haloperidol	PS		ORAL
5MG BID PO							
		Psychotic Disorder					
		Skin Warm					
		Tremor					

Date:12/09/98ISR Number: 3169528-9Report Type:Direct Company Report #
Age: Gender:Male I/FU:I

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Hospitalization -		Angioneurotic Oedema		Haldol	PS		
INTRAMUSCULAR	10MG IM X1;						
Initial or Prolonged		Drooling					
5MG PO X1							
Other		Tongue Oedema					

Date:12/09/98ISR Number: 3169727-6Report Type:Direct Company Report #
Age: Gender:Male I/FU:I

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Hospitalization -		Apnoea		Haldol	PS		
INTRAVENOUS	5MG IV X 1T						
Initial or Prolonged		Bradycardia					
NOW							
Other		Coma					
		Hypotension					

Date:12/10/98ISR Number: 3168963-2Report Type:Direct Company Report #
Age: Gender: I/FU:I

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Death		Anoxia		Haldol	PS		
10MG PO TID							
		Coma		Seroquel	C		

	Dyspnoea		Cogentin	C		
	Electrocardiogram					
	Abnormal					
	Extrapyramidal Disorder					
	Muscle Rigidity					
	Pulmonary Oedema					
	Respiratory Arrest					
	Tetany					

Date:12/11/98ISR Number: 3170105-4Report Type:Direct Company Report #
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Delusion		Haldol	PS				
	Insomnia							
	Nervousness							

Date:12/14/98ISR Number: 3170464-2Report Type:Direct Company Report #
Age:52 YR Gender:Male I/FU:I

Outcome	PT
Other	Abnormal Behaviour
	Aggression
	Apathy
	Autoimmune Disorder

	Joint Stiffness Muscle Rigidity Psychomotor Retardation	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
			Haloperidol	PS		ORAL
4MG PO BID						
			Klonopin	C		
			Synpmoid	C		
			Zyprexa	C		
			Valmoic Acid	C		

Date:12/14/98ISR Number: 3170535-0Report Type:Expedited (15-DaCompany Report #981207-008014865
Age:89 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Agranulocytosis	Foreign Health Professional	Haloperidol	PS		

Date:12/15/98ISR Number: 3171030-5Report Type:Expedited (15-DaCompany Report #981203-008014819
Age:74 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Clonic Convulsion Encephalitis Pyrexia Speech Disorder	Foreign Health Professional	Haloperidol	PS		ORAL
15 DROP, QD, ORAL						
			Modopar	C		
			Loprazolam Mesilate	C		
			Pindolol	C		
			Ginkgo Tree Leaves Extract	C		
			Fenofibrate	C		

Date:12/15/98ISR Number: 3171032-9Report Type:Expedited (15-DaCompany Report #981207-008014864
Age:78 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						

Death	Sedation	Foreign	Haloperidol	PS		ORAL
35 DROP, QD,						
		Health				
ORAL						
		Professional	Enalapril	C		
			Sotalol	C		

Date:12/15/98ISR Number: 3171034-2Report Type:Expedited (15-DaCompany Report #981207-008014866
Age:60 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Colonic Fistula	Foreign	Haloperidol			
Initial or Prolonged		Consumer	Decanoate	PS		
INTRAMUSCULAR 150MG,	1X/MO,					
IM						
(INTRAMUSCULA						
R)						
			Chloral Hydrate	SS		ORAL
1 DROP, QD,						
ORAL						
			Meprobamate	SS		ORAL
800MG, QD,						
ORAL						
			Flunitrazepam	SS		ORAL
2MG, QD, ORAL						

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/15/98ISR Number: 3171037-8Report Type:Expedited (15-DaCompany Report #981202-107058473
Age:36 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Encephalopathy	Consumer	Haldol	PS				

Date:12/16/98ISR Number: 3170950-5Report Type:Expedited (15-DaCompany Report #981208-008014916
Age:56 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Blood Creatine	Foreign	Haloperidol Solution	PS		ORAL	20 DROP, TID	
Other	Phosphokinase Increased	Health				ORAL		
	Neuroleptic Malignant Syndrome	Professional						
	Phlebitis							
	Pulmonary Embolism							

Date:12/17/98ISR Number: 3170826-3Report Type:Direct Company Report #
Age:67 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Amnesia		Eskalith	PS			300 MG AM/ 450 MG PM	
	Blood Creatine							
	Phosphokinase Increased		Haldol	SS			IM OR PO PRN	
	Blood Pressure Fluctuation							
	Coma							
	Confusional State							
	Coordination Abnormal							
	Dysarthria							
	Dysphagia							
	Hypotonia							
	Lethargy							
	Mental Disorder							
	Muscle Rigidity							

	Muscular Weakness					
	Myocardial Infarction					
	Posturing					
	Speech Disorder					
	Urinary Incontinence					

Date:12/17/98ISR Number: 3171550-3Report Type:Expedited (15-DaCompany Report #981210-008014955
Age:24 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Amnesia	Foreign	Haloperidol	PS			20 MG	4 WK
	Brain Damage	Consumer	Risperidone	C				
			Benzatropine Mesilate	C				

Date:12/17/98ISR Number: 3171571-0Report Type:Expedited (15-DaCompany Report #JAFRA-42017
Age:59 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Cutaneous Vasculitis	Foreign	Ketoderm	PS	Janssen	TOPICAL	1 DF	WEEKLY
	Oedema					TOPICAL		
	Rash Pustular		Haldol Decanoas (Haloperidol					

				Decanoate), Janssen, Solution	SS	Janssen		
				Lamisil (Terbinafine) Tablet 250 Mg	SS		ORAL	500 MG DAILY
ORAL	8	DAY						
				Surmontil	C			
				Euphylline	C			
				Becotide	C			
				Serevent	C			
				Temesta	C			
				Parkinane	C			

Date:12/18/98ISR Number: 3171656-9Report Type:Expedited (15-DaCompany Report #981001-107013759
Age:80 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Abnormal Behaviour	Health	Haldol	PS			10 MG, BID	DAY
	Confusional State	Professional	Risperidone	SS		ORAL	.5 MG, BID	
	Depressed Level Of Consciousness		Quetiapine Fumarate	SS		ORAL	12.5 MG, BID	
	Haematuria					ORAL		
	Joint Stiffness							
	Neuroleptic Malignant Syndrome							
	Pyrexia							

Date:12/21/98ISR Number: 3172525-0Report Type:Expedited (15-DaCompany Report #US_981214565
Age:24 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abortion Spontaneous	Study	Haloperidol	PS			2 MG/DAY	
		Health Professional						

Date:12/22/98ISR Number: 3173721-9Report Type:Expedited (15-DaCompany Report #981209-008014931
Age:59 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged (INTRAMUSCULAR)	Oedema	Foreign	Haldol Decanoas	PS		INTRAMUSCULAR	IM	
	Rash Generalised	Health						
	Rash Pustular	Professional						
	Vasculitis		Ketoconazole	SS		TOPICAL	1X/WK	TOPICAL
			Terbinafine	SS		ORAL	500MG	QD ORAL
			Trimipramine	C				
			Aminophylline	C				
			Beclometasone	C				
			Salmeterol	C				
			Lorazepam	C				
			Trihexphenidyl	C				

Date:12/23/98ISR Number: 3174093-6Report Type:Expedited (15-DaCompany Report #981214-107058757
Age:17 YR Gender:Male I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Abnormal Behaviour
	Condition Aggravated
	Gastrooesophageal Reflux

	Disease					
	Pancreatitis					
		Report Source	Product	Role	Manufacturer	Route
Dose Duration						
		Consumer	Haldol	PS		ORAL
.5MG ORAL						
			Haldol	SS		
INTRAMUSCULAR IM						
			Ranitidine Hydrochloride	C		
			Cisapride	C		

Date:12/23/98ISR Number: 3174096-1Report Type:Expedited (15-DaCompany Report #981216-008015042
Age:35 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Chest Pain	Health	Haloperidol	PS		ORAL
10MG BID ORAL						
Initial or Prolonged	Myocardial Infarction	Professional				

Date:12/23/98ISR Number: 3174098-5Report Type:Expedited (15-DaCompany Report #981216-008015041
Age:74 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Jaundice Cholestatic	Foreign	Haloperidol	PS		ORAL
.5MG BID ORAL						
Initial or Prolonged		Health	Chlorpromazine	SS		ORAL
25MG HS ORAL						
		Professional	Diazepam	C		
			Fluoxetine	C		

Date:12/24/98ISR Number: 3173998-XReport Type:Expedited (15-DaCompany Report #8-98350-092A
Age:54 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Alanine Aminotransferase	Foreign	Artane Tablets			
Initial or Prolonged	Increased	Health	(Trihexphenidyl)	PS		ORAL
4 MG ONCE						

Other	Blood Creatine	Professional				
DAILY ORAL						
	Phosphokinase Increased		Haloperidol	SS		ORAL
1.5 MG TO 3MG						
	Neuroleptic Malignant					
DAILY ORAL						
	Syndrome		Chlorpromazine	C		
	Pyrexia		Etizolam	C		
			Promethazine	C		
			Flunitrazepam	C		

Date:12/28/98ISR Number: 3175952-0Report Type:Expedited (15-DaCompany Report #R037460
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Alanine Aminotransferase	Foreign	Metoclopramide	PS		ORAL
10 MG Q 6H						
Initial or Prolonged	Increased	Study	Haloperidol	SS		ORAL
1 MG BID; 1						
	Aspartate	Health				
CYCLE						
	Aminotransferase	Professional	Dppe	SS		
231 MG 1 DAY						
	Increased		Doxorubicin	SS		
INTRAVENOUS 85 MG Q3W; 1						
	Blood Alkaline					
CYCLE						
	Phosphatase Increased		Domperidone	SS		
	Dystonia		Morphine Sulfate	C		
	Headache		Clodronate	C		
	Malaise		Senokot	C		
	Pyrexia		Colace	C		
	Tongue Disorder					
	Trismus					

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/28/98ISR Number: 3176366-XReport Type:Expedited (15-DaCompany Report #981218-107058966
Age:65 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Creatine Phosphokinase Increased	Health Professional	Haldol Injection (Haloperidol)	PS		INTRAMUSCULAR (INTRAMUSCULAR)	PRN, IM	
	Catatonia							
	Muscle Rigidity							
	Neuroleptic Malignant Syndrome		Risperidal (Risperidone)	SS		ORAL	2 MG, BID, ORAL	
	Pneumonia							
	Pupils Unequal		Antibiotic, Nos	C				
	Pyrexia							
	Rhabdomyolysis							
	Urinary Tract Infection							

Date:12/28/98ISR Number: 3176367-1Report Type:Expedited (15-DaCompany Report #981216-008015039
Age:78 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Blood Creatine Phosphokinase Increased	Foreign Health	Haldol Concentrate (Haloperidol)	PS		ORAL	2 MG, QD, ORAL	
	Blood Electrolytes Abnormal	Professional	Bromperidol	SS		ORAL	2 MG, QD, ORAL	
	Dementia							
	Leukocytosis							
	Muscle Rigidity							
	Neuroleptic Malignant Syndrome							
	Pyrexia							
	Renal Failure Acute							
	Sedation							

Date:12/29/98ISR Number: 3176290-2Report Type:Expedited (15-DaCompany Report #8-98350-097A
Age:28 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Alanine Aminotransferase Increased	Foreign Health Professional	Artane	PS		ORAL	5MG ONCE	DAILY ORAL
Other	Aspartate Aminotransferase Increased		Bromperidol	SS		ORAL	3MG TO 20 MG	DAILY ORAL
	Blood Creatine Phosphokinase Increased		Chlorpromazine	SS			30 MG TO 50	MG DAILY
	Blood Lactate Dehydrogenase Increased		Flunitrazepam	SS		ORAL	1MG TO 2MG	DAILY ORAL
	Blood Urea Increased		Haloperidol	SS		ORAL	5 MG TO 12 MG	DAILY ORAL
	Neuroleptic Malignant Syndrome		Levopromazine	SS		ORAL	50MG DAILY	ORAL

Date:12/29/98ISR Number: 3176475-5Report Type:Expedited (15-DaCompany Report #981217-008015073
Age:73 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Interaction	Foreign Health Professional	Haldol	PS		ORAL	1 MG, QD, ORAL	2 YR
	Orthostatic Hypotension		Alimemazine Tartrate	SS		ORAL	25MG, QD ORAL	2 YR
	Rhabdomyolysis		Levodopa-Carbidopa	C				
			Piribedil	C				

			Alfuzosin	C		
			Citalopram	C		

Date:12/29/98ISR Number: 3176476-7Report Type:Expedited (15-DaCompany Report #981217-008015074
Age:89 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hypothermia	Foreign Health Professional	Haldol Buflomedil Hydrochloride	PS C		ORAL	ORAL	

Date:12/29/98ISR Number: 3176503-7Report Type:Expedited (15-DaCompany Report #JAUSA-35445
Age:65 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Creatine Phosphokinase Increased	Health Professional	Risperdal (Risperidone)	PS	Janssen	ORAL	2 MG 2 DAILY	
	Catatonia					ORAL		
	Muscle Rigidity		Haldol (Haloperidol)	SS	Janssen	INTRAMUSCULAR	PRN	
	Neuroleptic Malignant Syndrome					INTRAMUSCULAR		
	Pneumonia							
	Pyrexia							
	Rhabdomyolysis							
	Urinary Tract Infection							

Date:12/30/98ISR Number: 3176207-0Report Type:Direct Company Report #
Age:52 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Arrhythmia		Haloperidol	PS		INTRAVENOUS	10MG/HR IV	

Initial or Prolonged INFUSION + 15	Sleep Apnoea Syndrome					
MG PO QID	Ventricular Tachycardia					
			Gentamicin	C		
			Vancomycin	C		
			Albuterol	C		
			Rifampin	C		
			Lorazepam	C		

Date:12/30/98ISR Number: 3176253-7Report Type:Direct Company Report #
Age:16 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Cyanosis		Haldol	PS	Mcneil			
INTRAMUSCULAR							10MG,	STAT,
Required	Dyskinesia							
IM								
Intervention to Prevent Permanent Impairment/Damage	Feeling Cold		Diphenhydramine	C				
	Hyperhidrosis							
	Joint Stiffness							
	Tongue Oedema							

Date:12/30/98ISR Number: 3176656-0Report Type:Expedited (15-DaCompany Report #981222-008015134
Age: Gender: I/FU:I

Outcome	PT	Report Source
Death	Pulmonary Oedema	Foreign
		Health

Professional

			Product	Role	Manufacturer	Route
Dose	Duration					
			Haloperidol	PS		
INTRAVENOUS	2 AMP, BID,					
IV						
(INTRAVENOUS)						
			Bromazapem	SS		ORAL
ORAL						

Date:12/31/98ISR Number: 3176272-0Report Type:Direct Company Report #
Age:80 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization -	Agitation		Haloperidol	PS		
CHRONIC						
Initial or Prolonged	Blood Creatine					
THERAPY						
Required	Phosphokinase Increased		Thioridazine	SS		
Intervention to	Muscle Rigidity					
Prevent Permanent	Neuroleptic Malignant					
Impairment/Damage	Syndrome					
	Pyrexia					

Date:12/31/98ISR Number: 3177237-5Report Type:Expedited (15-DaCompany Report #981228-008015169
Age:76 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Life-Threatening	Dialysis	Foreign	Haldol Tablets			
Hospitalization -	Ileus Paralytic	Health	(Haloperidol)	PS		ORAL
ORAL						
Initial or Prolonged	Intestinal Obstruction	Professional	Tiapride	SS		ORAL
ORAL						
	Renal Failure Acute		Loxapine	SS		
INTRAMUSCULAR	IM,					
	Urinary Retention					
(INTRAMUSCULA						

R)

Date:12/31/98ISR Number: 3177238-7Report Type:Expedited (15-DaCompany Report #980518-008011725
Age:48 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Circulatory Collapse	Study	Haloperidol	PS		ORAL	1 TAB, QD, ORAL	
	Diabetes Mellitus	Health						
	Dizziness	Professional	Riseperidone	SS		ORAL	TAB, QD, ORAL	
	Hyperglycaemia							
			Benztropine	C				

Date:12/31/98ISR Number: 3177242-9Report Type:Expedited (15-DaCompany Report #981223-008015152
Age: Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Antepartum Haemorrhage	Foreign	Haloperidol					
	Complications Of Maternal	Health	Decanoate	PS		TRANSPLACENTAL	50 MG.; 1X/MO, INTRAUTERINE	
	Exposure To Therapeutic	Professional						
	Drugs							
	Foetal Growth Retardation							
	Haemorrhagic Stroke							
	Premature Baby							
	Small For Dates Baby							

Date:12/31/98ISR Number: 3177244-2Report Type:Expedited (15-DaCompany Report #981229-008015196
Age:28 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Antepartum Haemorrhage Complications Of Maternal Health Exposure To Therapeutic Drugs Foetal Growth Retardation Haemorrhagic Stroke Premature Baby Small For Dates Baby	Foreign Professional	Haloperidol Decanoate	PS		TRANSPLACENTAL (INTRAMUSCULAR)	50 MG; 1X/MO, IM	

Date:01/05/99ISR Number: 3178051-7Report Type:Expedited (15-DaCompany Report #981229-008015186
Age:29 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dysarthria Electrocardiogram Qt Prolonged Hypokinesia Tachycardia Tremor	Foreign Health Professional	Haldol	PS		INTRAMUSCULAR (INTRAMUSCULAR)	50 MG, QD, IM	

Date:01/05/99ISR Number: 3178053-0Report Type:Expedited (15-DaCompany Report #981203-008014819
Age:74 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Clonic Convulsion Encephalitis Pyrexia	Foreign Health Professional	Haloperidol Modopar	PS C		ORAL ORAL	15 DROP, QD,	

Loprazolam Mesilate	C
Pindolol	C
Ginkgo Tree Leaves Extract	C
Fenofibrate	C

Date:01/05/99ISR Number: 3390803-7Report Type:Periodic Company Report #98-017
Age:79 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Insomnia Psychomotor Hyperactivity Restlessness	Health Professional	Haloperidol Tablets, 1 Mg Par	PS	Par		1MG QID DAILY	

Date:01/06/99ISR Number: 3178014-1Report Type:Direct Company Report #
Age:24 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drooling Parkinsonism Tremor		Haloperidol	PS				

Date:01/07/99ISR Number: 3178715-5Report Type:Direct Company Report #
Age:60 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Torsade De Pointes		Haldol	PS		INTRAVENOUS	5-20MG	IVP Q Required 1H PRN; Intervention to Prevent Permanent Impairment/Damage
	Ventricular Tachycardia						5MG/ML	INJECTION

Date:01/11/99ISR Number: 3179302-5Report Type:Direct Company Report #
Age:68 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Confusional State	Health	Haloperidol	PS	Geneva	ORAL	5MG PO HS	
	Difficulty In Walking	Professional	Lithium	C				
	Drooling		Atenolol	C				
	Drug Interaction		Buspirone	C				
	Dysarthria		Lorazepam	C				
	Joint Stiffness		Premarin	C				
	Motor Dysfunction							
	Tremor							

Date:01/11/99ISR Number: 3179488-2Report Type:Expedited (15-DaCompany Report #981231-008015205
Age:86 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blister	Foreign	Haldol Solution	PS		ORAL ORAL		
	Condition Aggravated	Health	Aldactazine	SS		ORAL ORAL		
	Dermatitis Bullous	Professional	Bromazepam	SS		ORAL ORAL		
	Dermatitis Exfoliative		Amiodarone	SS		ORAL	100 MG, QD,	

	Pruritus					
ORAL						
	Toxic Epidermal Necrolysis		Iskedyl	SS		
			Vitamins	SS		

Date:01/11/99ISR Number: 3179528-0Report Type:Expedited (15-DaCompany Report #990104-107050039
Age: Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Cardiac Arrest	Health	Haldol	PS		
INTRAMUSCULAR IM						
		Professional				
(INTRAMUSCULA						
R)						
			Alprazolam	C		

Date:01/12/99ISR Number: 3179737-0Report Type:Expedited (15-DaCompany Report #8-98364-001Z
Age:22 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Movement Disorder	Foreign	Tavor	PS		ORAL
TABLETS, 3 MG						
	Spinal Disorder	Study				
DAILY ORAL						
			Haldol	SS		ORAL
TABLETS, 4.5						
- 10 MG DAILY						
ORAL						

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/12/99ISR Number: 3179819-3Report Type:Expedited (15-DaCompany Report #981229-008015186
Age:29 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Dysarthria	Foreign	Haldol Decanoate	PS		INTRAMUSCULAR	50 MG, QD, IM	
Initial or Prolonged	Dyskinesia	Health				(INTRAMUSCULAR)		
	Electrocardiogram Qt	Professional						
	Prolonged							
	Hypokinesia							
	Tachycardia							
	Tremor							

Date:01/12/99ISR Number: 3179820-XReport Type:Expedited (15-DaCompany Report #981217-008015074
Age:89 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Hypothermia	Foreign	Haldol	PS		ORAL		
Hospitalization -		Health	Buflomedil					
Initial or Prolonged		Professional	Hydrochloride	C				
			Omeprazole	C				
			Ferrous Sulfate	C				
			Ciprofloxacin	C				
			Bactrim	C				

Date:01/12/99ISR Number: 3179828-4Report Type:Expedited (15-DaCompany Report #990106-008010055
Age:59 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Blood Creatine	Health	Haloperidol	PS		ORAL		
Initial or Prolonged	Phosphokinase Increased	Professional	Risperidone	SS		ORAL		
	Sinus Tachycardia		Temazepam	C				
			Lithium Carbonate	C				
			Psyllium	C				
			Theophylline	C				

			Ipratropium Bromide	C		

Date:01/12/99ISR Number: 3180135-4Report Type:Direct Company Report #
Age:34 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Electrocardiogram Qt		Cisapride	PS			10MG QID	
	Prolonged		Haloperidol	SS			INTRAVENOUS	5MG IVP Q 1H
							PRN	

Date:01/15/99ISR Number: 3180891-5Report Type:Expedited (15-DaCompany Report #8-99011-064A
Age:29 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Hallucination	Foreign	Effexor	PS		ORAL	10 TABLETS	
Initial or Prolonged	Overdose	Health					ORAL	
		Professional	Haloperidol Tablets	SS		ORAL	ORAL	
			Procyclidine	SS		ORAL	150 MG ONE	
							TIME ORAL	
			Thioridazine Tablets	SS		ORAL	ORAL	
			Thioridazine Tablets	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/19/99ISR Number: 3182140-0Report Type:Expedited (15-DaCompany Report #990108-008010092
Age:93 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Pressure Increased	Foreign	Haloperidol	PS		ORAL	20 DROP, QD,	
	Fall	Health				ORAL		
	Femoral Neck Fracture	Professional	Theophylline	SS		ORAL	400 MG, QD,	
	Orthostatic Hypotension					ORAL		
			Furosemide	SS		ORAL	40 MG, QD,	
						ORAL		
			Potassium Chloride	SS		ORAL	1 TAB, QD,	
						ORAL		
			Digoxine	SS		ORAL	.25 MG, QD,	
						ORAL		

Date:01/19/99ISR Number: 3182790-1Report Type:Expedited (15-DaCompany Report #990111-008010106
Age:71 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Asthenia	Foreign	Haloperidol Tablets	PS		ORAL	4 MG; QD;	
	Circulatory Collapse	Health				ORAL		
	Dizziness	Professional	Jatrosom	SS		ORAL	30 MG; QD;	
	Loss Of Consciousness					ORAL		
	Syncope		Sotalol	C				

Date:01/19/99ISR Number: 3182858-XReport Type:Expedited (15-DaCompany Report #990106-008010052
Age:25 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Syncope	Foreign Health Professional	Haloperidol	PS		INTRAMUSCULAR (INTRAMUSCULAR)	.5 ML, IM	1X/MO,
			Disulfirm	C				
			Riboflavin	C				

Date:01/20/99ISR Number: 3182638-5Report Type:Expedited (15-DaCompany Report #JAKYO-37064
Age:48 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blood Creatine	Foreign	Risperidal	PS	Janssen	ORAL	6 MG DAILY	
	Phosphokinase Increased	Literature				ORAL		
	Chromaturia	Health Professional	Haloperidol Decanoate	SS	Janssen	INTRAMUSCULAR	100 MG	MONTHLY
	Confusional State							
	Hallucination					INTRAMUSCULAR		
	Hepatic Function Abnormal		Biperiden Hydrochloride	C				
	Myalgia		Flunitrazepam	C				
	Pain In Extremity		Diazepam	C				
	Renal Impairment							
	Rhabdomyolysis							

Date:01/20/99ISR Number: 3182709-3Report Type:Expedited (15-DaCompany Report #990118-107050213
Age:75 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Pyrexia	Health Professional	Levaquin	PS		INTRAVENOUS (INTRAVENOUS)	500 MG QD IV	

			Paroxetine Hydrochloride	SS		
30 MG, HS						
			Haldol	SS		
INTRAMUSCULAR	ONCE, IM					
INTRAMUSCULAR						
			Flecainide Acetate	C		
			Atorvastatin	C		
			Levothyroxine Sodium	C		
			Potassium Chloride	C		
			Metoprolol Tartrate	C		
			Oxazepam	C		

Date:01/21/99ISR Number: 3183497-7Report Type:Expedited (15-DaCompany Report #990114-008010166
Age:38 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Agitation	Foreign	Haloperidol	PS		INTRAVENOUS	20MG, QD, IV	
	Condition Aggravated	Health				(INTRAVENOUS)		
		Professional	Bromazepam	SS		ORAL	80 TAB, QD,	
						ORAL		
			Levomepromazine	SS				
			Promethazine	SS				
			Flumazenil	C				

Date:01/21/99ISR Number: 3183711-8Report Type:Expedited (15-DaCompany Report #9842002
Age:41 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required	Medication Error	Foreign	Zoloft Tablets	PS		ORAL	100.00 MG	
Intervention to	Parkinson'S Disease	Health				TOTAL;DAILY;O		
Prevent Permanent		Professional				RAL		

Impairment/Damage			Haloperidol	SS		ORAL
4.00 MG TOTAL;BID;ORA L						

Date:01/21/99ISR Number: 3183724-6Report Type:Expedited (15-DaCompany Report #981231-008015205
Age:86 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Blister	Foreign	Haldol	PS		ORAL
UNKNOWN,						
Hospitalization -	Condition Aggravated	Health				
UNKNOWN, ORAL						
Initial or Prolonged	Dermatitis Bullous	Professional	Aldactazine	SS		ORAL
UKNWON,						
	Lung Disorder					
UNKNOWN, ORAL						
	Pruritus		Bromazepam	SS		ORAL
UNKNOWN,						
	Renal Failure					
UNKNOWN, ORAL						
	Toxic Epidermal		Amiodarone	SS		ORAL
100 MG, QD,						
	Necrolysis					
ORAL						
			Iskedyl	SS		ORAL
UNKNOWN,						
UNKNWON, ORAL						
			Vitamins	SS		ORAL
UNKNWON,						
UNKNOWN, ORAL						

Date:01/21/99ISR Number: 3183725-8Report Type:Expedited (15-DaCompany Report #981216-008015039
Age:78 YR Gender:Female I/FU:F

Outcome	PT
Life-Threatening	Blood Creatine
Disability	Phosphokinase Increased

	Dementia Electrolyte Imbalance Leukocytosis	Report Source	Product	Role	Manufacturer	Route Dose Duration
	Muscle Rigidity	Foreign	Haldol	PS		ORAL 2 MG, QD,
	Neuroleptic Malignant	Health				ORAL
	Syndrome	Professional	Bromperidol	SS		ORAL 2 MG, QD,
	Pyrexia					ORAL
	Renal Cyst Renal Failure Acute Sedation					

Date:01/21/99ISR Number: 3183726-XReport Type:Expedited (15-DaCompany Report #990108-008010091
Age:53 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Other	Blister	Foreign	Haloperidol	PS		ORAL 5 MG, BID,
	Dermatitis	Health				ORAL
	Lip Ulceration	Professional	Carbamazepiine	SS		ORAL UNKNOWN,
	Mouth Ulceration					UNKNOWN, ORAL
	Nasal Ulcer		Nifedipine	SS		ORAL 10 MG, BID,
	Rash Erythematous					ORAL
	Stevens-Johnson Syndrome		Clomethiazole	SS		ORAL 350 MG, TID,
						ORAL

Date:01/21/99ISR Number: 3183727-1Report Type:Expedited (15-DaCompany Report #981130-008014767
Age:78 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration

Hospitalization -	Diabetes Mellitus	Foreign	Haldol	PS		ORAL
10 DROP, BID,						
Initial or Prolonged	Phlebitis	Health				
ORAL						
	Urinary Retention	Professional	Tropatepine	C		
	Urinary Tract Infection		Gliclazide	C		
			Furosemide	C		
			Acenocoumarol	C		
			Metoclopramide	C		
			Fluconazole	C		

Date:01/21/99ISR Number: 3184041-0Report Type:Direct Company Report #
Age:6 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Disability	Tardive Dyskinesia		Haldol	PS		ORAL
1 MG BID						

Date:01/22/99ISR Number: 3184643-1Report Type:Expedited (15-DaCompany Report #981207-008014865
Age:89 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Agranulocytosis	Foreign	Haloperidol	PS		ORAL
1 MG, BID,						
Initial or Prolonged	Fungal Infection	Health				
ORAL						
	Gastrointestinal Disorder	Professional	Isosorbide Dinitrate	C		
	Pseudomonas Infection		Piribedil	C		
	Sepsis		Hydroxyzine	C		
	Skin Candida		Paracetamol	C		
	Streptococcal Infection		Nitrendipine	C		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/22/99ISR Number: 3184645-5Report Type:Expedited (15-DaCompany Report #990106-008010055
Age:59 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Creatine Phosphokinase Increased	Health Professional	Haloperidol	PS		ORAL	ORAL	
	Muscular Weakness		Placebo	SS		ORAL	ORAL	
	Rhabdomyolysis		Risperidone	SS		ORAL	ORAL	
	Sinus Tachycardia		Temazapam	C				
			Lithium Carbonate	C				
			Psyllium	C				
			Theophylline	C				
			Ipratropium Bromide	C				
			Benztropeine	C				
			Docusate Sodium	C				
			Lorazepam	C				

Date:01/22/99ISR Number: 3184648-0Report Type:Expedited (15-DaCompany Report #981223-008015152
Age: Gender:Not SpecifiI/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Antepartum Haemorrhage	Foreign	Haloperidol Decanoate	PS		INTRA-UTERINE	50 MG, 1X/MO,	
	Complications Of Maternal Exposure To Therapeutic Drugs	Health Professional	Fluoxetine Hydrochloride	SS		INTRAUTERINE		
	Foetal Growth Retardation							
	Haemorrhage							
	Haemorrhagic Stroke							
	Respiratory Disorder							
	Small For Dates Baby							
	Staphylococcal Infection							
	Subdural Haematoma							

Date:01/22/99ISR Number: 3184650-9Report Type:Expedited (15-DaCompany Report #981229-008015196
Age:28 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Complications Of Maternal Exposure To Therapeutic Drugs Foetal Growth Retardation Haemorrhagic Stroke Small For Dates Baby	Foreign Health Professional	Haloperidol Decanoate Fluoxetine Hydrochloride	PS SS		INTRAMUSCULAR (INTRAMUSCULAR) IM	50 MG, 1X/MO,	

Date:01/26/99ISR Number: 3186044-9Report Type:Expedited (15-DaCompany Report #DEU001431
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Complications Of Maternal Exposure To Therapeutic Drugs Gastrointestinal Haemorrhage Haematemesis	Foreign Health Professional Other	Akineton Serenace Levotomin	PS SS SS				

Date:01/26/99ISR Number: 3186112-1Report Type:Expedited (15-DaCompany Report #980730-107055144
Age:70 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Disorientation	Consumer	Haldol Injection					
Hospitalization -	Feeling Hot	Health	(Haloperidol)	PS				
Initial or Prolonged	Hyperhidrosis	Professional	Fluoxetine					
	Mental Disorder		Hydrochloride	C				
	Metabolic Acidosis		Meperidine					
	Muscle Rigidity		Hydrochloride	C				
			Oxycodone With					
			Acetaminophen	C				
			Pentoxifylline	C				
			Furosemide	C				
			Alprozolam	C				
			Albuterol	C				

Date:01/26/99ISR Number: 3186113-3Report Type:Expedited (15-DaCompany Report #990119-008010239
Age:24 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Hepatitis	Foreign	Haldol Decanoate	PS		INTRAMUSCULAR	50 MG/ML,	
Initial or Prolonged		Health					TID, IM	
		Professional					(INTRAMUSCULAR)	
			Carbamazepine	SS		ORAL	600 MG, QD,	
			Lormetazepam	SS		ORAL	1 MG, QD,	
			Benzhexol Hydrochloride	SS		ORAL	ORAL	
			Clorazepate Dipotassium	SS		ORAL	125 MG, QD,	

ORAL

Date:01/26/99ISR Number: 3186114-5Report Type:Expedited (15-DaCompany Report #980109-008010040
Age:47 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Alanine Aminotransferase Increased	Foreign Literature	Haloperidol Decanoate,					
	Aspartate Aminotransferase Increased	Health Professional	Unspecified	PS		INTRAMUSCULAR (INTRAMUSCULAR)	100 MG, 1X/MO, IM	
	Blood Creatine Increased							
	Blood Creatine Phosphokinase Increased		Risperidone	SS		ORAL	6 MG, QD, ORAL	
	Blood Urea Increased		Biperiden	C				
	Chromaturia		Flunitrazepam	C				
	Movement Disorder		Diazepam	C				
	Myalgia							
	Pain In Extremity							
	Paralysis							
	Rhabdomyolysis							

Date:01/26/99ISR Number: 3186115-7Report Type:Expedited (15-DaCompany Report #981223-008015152
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Antepartum Haemorrhage	Foreign	Haloperidol					
	Complications Of Maternal	Health	Decanoate	PS				
INTRA-UTERINE	50 MG, 1X/MO,							
	Exposure To Therapeutic	Professional						
INTRAUTERINE								
	Drugs		Fluoxetine					
	Foetal Growth Retardation		Hydrochloride	SS				
	Haemorrhage							
	Haemorrhagic Stroke							
	Hyponatraemia							
	Intraventricular Haemorrhage Neonatal							
	Premature Baby							
	Red Blood Cell Count Decreased							
	Respiratory Disorder							
	Staphylococcal Infection							
	Subdural Haematoma							
	Thrombocytopenia							
	Weight Decreased							

Date:01/26/99ISR Number: 3187631-4Report Type:Direct Company Report #
Age:53 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Coma		Haldol	PS				
INTRAMUSCULAR	2MG IM Q6							
Initial or Prolonged	Neuroleptic Malignant							
HR-5MG PO Q4								
	Syndrome							
H								
	Pyrexia		Mellaril	SS		ORAL		
5MG PO Q4H								
	Tremor							

Date:01/27/99ISR Number: 3186960-8Report Type:Expedited (15-DaCompany Report #990121-008010276
Age:37 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Overdose	Study Health Professional	Haloperidol	PS		ORAL	1 TAB, BID , ORAL	
			Risperidone	SS		ORAL	1 TAB, BID, ORAL	
			Propranolol	SS		ORAL	40 TAB, ORAL	

Date:01/28/99ISR Number: 3187206-7Report Type:Expedited (15-DaCompany Report #9902207
Age:38 YR Gender:Female I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Akinesia Blood Creatine Phosphokinase Increased Bradyphrenia Depression Drug Interaction Hypokinesia Hyponatraemia Liver Function Test Abnormal Muscle Rigidity Neuroleptic Malignant

	Syndrome					
	Parkinson'S Disease					
	Pyrexia					
	Salivary Hypersecretion	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
	Scab	Foreign	Zoloft	PS		ORAL
50.00 MG						
	Tremor	Health				
TOTAL:DAILY:O						
		Professional				
RAL						
			Haloperidol	SS		
INTRAMUSCULAR	MONTHLY:INTRA					
MUSCULAR						
			Tropatepine	C		
			Valpromide	C		

Date:02/01/99ISR Number: 3189876-6Report Type:Expedited (15-DaCompany Report #990125-107010329
Age:54 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization -	Blood Creatine	Foreign	Haloperidol	PS		
27 MG, QD,						
Initial or Prolonged	Phosphokinase Increased	Literature	Carbamazepine	SS		
400 MG, QD						
	Body Temperature	Health	Levomepromazine	SS		
350 MG, QD						
	Increased	Professional	Sultopride	SS		
800 MG, QD						
	Drug Level Below		Metixene	SS		
10 MG, QD						
	Therapeutic					
	Gait Disturbance					
	Heart Rate Increased					
	Hyperhidrosis					
	Muscle Rigidity					
	Neuroleptic Malignant					
	Syndrome					
	Tremor					

Date:02/04/99ISR Number: 3192284-5Report Type:Expedited (15-DaCompany Report #9908636
Age:24 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hepatitis Liver Function Test Abnormal	Foreign Health Professional	Tranxene Haloperidol	PS SS	Abbott	ORAL ORAL	125.000 MG PO QD PO OTH	
		Other	Carbamzepine Lormetazepam Trihexyphenidyl Hydro	C C C				

Date:02/05/99ISR Number: 3192161-XReport Type:Direct Company Report #
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Effect Increased Hypotonia Sedation		Haldol	PS		ORAL	2 MG/DAY ORAL	30 DAY

Date:02/08/99ISR Number: 3193882-5Report Type:Expedited (15-DaCompany Report #110275
Age:50 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dystonia Vomiting	Foreign Study Health Professional	Capecitabine (Capecitabine) Taxotere (Docetaxel)	PS SS		ORAL INTRAVENOUS	215 MG 2 X PER DAY ORAL 130 MG 1 X	

PER 3 WEEKS

INTRAVENOUS

	Haloperidol (Haloperidol)	SS
20 MG DAILY		
	Fentanyl	C
	Oramorph	C
	Lorazepam	C
	Ciprofloxacin	C

Date:02/08/99ISR Number: 3194308-8Report Type:Expedited (15-DaCompany Report #990201-008010431
Age:32 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Depressed Mood	Foreign Study	Haloperidol Tablets	PS		ORAL	2 MG, QD, ORAL	
	Extrapyramidal Disorder							
	Fatigue	Health Professional	Risperidone	SS		ORAL	3 MG, QD, ORAL/ 2MG	
	Malaise							
	Sedation		Paroxetine	C				
	Suicidal Ideation		Lorazepam	C				

Date:02/08/99ISR Number: 3194310-6Report Type:Expedited (15-DaCompany Report #981116-008014563
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Joint Stiffness	Foreign	Haloperidol Tablets	PS		ORAL	ORAL	
Hospitalization - Initial or Prolonged	Laryngospasm	Health Professional						

Date:02/08/99ISR Number: 3194312-XReport Type:Expedited (15-DaCompany Report #990126-008010345
Age:63 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Hospitalization -	Blood Creatine Phosphokinase Increased	Foreign Health	Haldol Injection (Haloperidol)	PS		INTRAVENOUS	20 MG,	IV/ 30
Initial or Prolonged	Condition Aggravated	Professional					MG IV	
	Delirium		Haldol Decanoate					
	Depressed Level Of		(Haloperidol)	SS		INTRAMUSCULAR	1 ML,	1X/MO
	Consciousness						IM	
	Disorientation		Lorazepam	C				
	Fall		Chlorprothixene	C				
	Fatigue							
	Injury							
	Lip Disorder							
	Muscle Rigidity							
	Musculoskeletal Stiffness							
	Neuroleptic Malignant Syndrome							
	Oculogyration							
	Pleural Infection							
	Pneumonia							
	Psychotic Disorder							
	Pyrexia							
	Schizoaffective Disorder							
	Urinary Retention							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/09/99ISR Number: 3194515-4Report Type:Expedited (15-DaCompany Report #990119-008010239
Age:24 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hepatic Enzyme Increased Hepatitis	Foreign Health Professional	Haldol Decanoate	PS		INTRAMUSCULAR (INTRAMUSCULAR)	50 MG/ML, TID, IM	
			Carbamazepine	SS		ORAL	600 MG, QD, ORAL	
			Lormetazepam	SS		ORAL	1 MG, QD, ORAL	
			Trihexyphenidyl	SS		ORAL	ORAL	
			Clorazepate Dipotassium	SS		ORAL	125 MG, QD, ORAL	

Date:02/10/99ISR Number: 3195196-6Report Type:Direct Company Report #
Age:61 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Level Above Therapeutic		Dilantin 100 Mg Capsules And 50 Mg Tablets	PS		SEE ATTACHED - EVENT DESCRIPTION		
			Haloperidol Concentrate	SS		SEE ATTACHED		

- EVENT

DESCRIPTION

Date:02/10/99ISR Number: 3195517-4Report Type:Expedited (15-DaCompany Report #990204-107050809
Age:81 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardiac Failure	Health	Haldol, Tablets					
Hospitalization - Initial or Prolonged	Congestive	Professional	(Haloperidol)	PS		ORAL	1) 5 MG, QD, ORAL 2) 2.5 MG, QD, ORAL	
	Dyspnoea							
	Myocardial Infarction							
	Oxygen Saturation							
	Decreased		Risperdal					
	Pleural Effusion		(Risperidone)	SS		ORAL	1) .5 MG, BID, ORAL 2) 1MG, BID, ORAL	
	Pneumonia							
	Pulmonary Congestion							
			Benzitropine	C				
			Ramipril	C				
			Paracetamol	C				
			Digoxin	C				
			Ipratropium Bromide	C				
			Salbutamol	C				
			Vitamin C	C				
			Calcium Carbonate	C				
			Amantadine	C				
			Nitrofurantoin	C				
			Guaifenesin	C				

Date:02/10/99ISR Number: 3195588-5Report Type:Expedited (15-DaCompany Report #GB/99/00048/LEX
Age:57 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Grand Mal Convulsion	Health	Clozaril (Clozapine)	PS		ORAL	750 MG ORAL	
	Hypoglycaemia	Professional	Haloperidol					
	Loss Of Consciousness		(Haloperidol)	SS			20 MG	

Date:02/12/99ISR Number: 3197944-8Report Type:Expedited (15-DaCompany Report #JAUSA-35335
Age:81 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardiac Failure	Health	Risperdal					
Hospitalization -	Congestive	Professional	(Risperidone),					
Initial or Prolonged	Condition Aggravated		Janssen, Tablet 1 Mg	PS	Janssen	ORAL	.5 MG 2 DAILY	
	Dyspnoea Exacerbated						ORAL	
	Myocardial Infarction		Haldol					
	Oxygen Saturation		(Haloperidol),					
	Decreased		Janssen, Tablet	SS	Janssen	ORAL	.5 MG 1 DAILY	
	Pleural Effusion						ORAL	
	Pneumonia		Cogentin					
	Pulmonary Congestion		(Benztropine)	C				
	Respiratory Failure		Ramipril (Ramipril)	C				
			Acetaminophen					
			(Paracetamol)	C				
			Digoxin (Digoxine)	C				
			Atrovent					
			(Ipratropium					
			Bromide)	C				
			Albuterol					
			(Salbutamol)	C				
			Vitamine C					
			(Ascorbic-Acid)	C				
			Tums (Ca-Carbonate)	C				
			Amantadine					
			(Amantadine)	C				
			Macrobid					

				(Nitrofurantoin)	C		
				Robitussin (Guaifenesine)	C		

Date:02/16/99ISR Number: 3198486-6Report Type:Direct Company Report #
Age:20 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Musculoskeletal Stiffness	Consumer	Haloperidol	PS			10-20 MG	
	Pain							
	Torticollis		Resperidol	C				

Date:02/16/99ISR Number: 3199645-9Report Type:Expedited (15-DaCompany Report #990104-107050039
Age: Gender:Unknown I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardiac Arrest	Health Professional	Haldol Injection (Haloperidol)	PS		INTRAMUSCULAR (INTRAMUSCULAR)	IM	
			Alprazolam	C				

Date:02/17/99ISR Number: 3200518-3Report Type:Expedited (15-DaCompany Report #9908818
Age:22 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Creatine Phosphokinase Increased	Foreign Health	Abbott-Tranxene	PS	Abbott			
			Haloperidol	SS		ORAL	30.000 MG PO	QD
	Neuroleptic Malignant Syndrome	Professional Other	...	C				
	Pyrexia		Tropatepine Hydrochlo	C				
			Levomepromazine	C				
			Loxapine Succinate	C				
			Lormetazepam	C				

Date:02/18/99ISR Number: 3203025-7Report Type:Expedited (15-DaCompany Report #99J--10015
Age:48 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Binocular Eye Movement Disorder	Foreign Health	Tofranil	PS		ORAL	30 MG, DAILY,	ORAL
	Blood Creatine Phosphokinase Increased	Professional	Serenace (Haloperidol)	SS		ORAL	3 MG, DAILY,	ORAL
	Blood Lactate Dehydrogenase Increased Blood Pressure Increased Cardiovascular Disorder Dyspnoea		Tryptanol (Amitriptyline Hydrochloride)	SS		ORAL	60 MG, DAILY,	ORAL
	Haematemesis Heart Rate Increased Hyperhidrosis		Symmetrel Tablet (Aamantadine Hydrochloride)	SS		ORAL	150 MG,	DAILY, ORAL
	Neuroleptic Malignant Syndrome		Silece	C				
	Pyrexia		Ubretid	C				

	Respiratory Arrest		Pursennid	C	
	Respiratory Disorder		Biperiden	C	
	Tremor		Artane	C	
	White Blood Cell Count Increased		Gramalil	C	
			Solanax	C	
			Marzulene S	C	

Date:02/18/99ISR Number: 3203386-9Report Type:Expedited (15-DaCompany Report #990210-008010562
Age:21 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Neutropenia Thrombocytopenia	Foreign Health Professional	Haldol Tablets (Haloperidol)	PS		ORAL	6 MG, QD, ORAL; 5 MG, QD, ORAL; 2 MG, QD, ORAL
			Carbamazepine	SS		ORAL	300 MG, QD, ORAL; 600 MG, QD, ORAL
			Lorazepam	C			

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/18/99ISR Number: 3203391-2Report Type:Expedited (15-DaCompany Report #990210-008010561
Age:41 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Death	Bronchopneumonia	Foreign	Haldol Tablets				
Life-Threatening	Circulatory Collapse	Health	(Haloperidol)	PS		ORAL	10 MG, QD
	Cyanosis	Professional	Phenytoin	C			
	Immobile		Clorazepate				
	Pulmonary Embolism		Dipotassium	C			
	Pulse Absent		Cefotiam	C			
			Heparin-Fraction, Calsium Salt	C			

Date:02/18/99ISR Number: 3203395-XReport Type:Expedited (15-DaCompany Report #990210-008010560
Age:46 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Life-Threatening	Condition Aggravated	Foreign	Haldol Tablets				
Hospitalization -	Electrocardiogram	Health	(Haloperidol)	PS		ORAL	10 MG, QD
Initial or Prolonged	Abnormal	Professional					
	Fall						
	Hypotension						

Date:02/18/99ISR Number: 3203399-7Report Type:Expedited (15-DaCompany Report #990209-008010538
Age:44 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Required	Blood Pressure Decreased	Foreign	Haloperidol	PS		ORAL	5 MG, QD
Intervention to	Chest Pain	Health	Risperidone	SS		ORAL	4 MG, QD
Prevent Permanent	Cyanosis	Professional	Levomepromazine				
Impairment/Damage	Loss Of Consciousness		Maleate	C			
	Transient Ischaemic		Magnesium Oxide	C			
	Attack		Levoglutamide,				
	Urinary Incontinence		Sodium Gualenate	C			
			Biperiden Hydrochloride	C			

			Rihexyphenidyl Hydrochloride	C			
			Chlorpromazine	C			
			Bromperidol	C			
			Flunitrazepam	C			
			Triazolam	C			
			Estazolam	C			
			Hydrocyzine	C			

Date:02/18/99ISR Number: 3203457-7Report Type:Expedited (15-DaCompany Report #9908859
Age:24 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hepatitis	Foreign	Abbott-Tranxene	PS	Abbott	ORAL	125.000 MG PO QD	
	Hepatocellular Damage	Other						
Other	Liver Function Test		Haloperidol	SS		ORAL	PO OTH	
	Abnormal		Carbamazepine	C				
			Lormetazepam	C				
			Trihexyphenidyl Hydro	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/22/99ISR Number: 3204835-2Report Type:Expedited (15-DaCompany Report #JAGER-43123
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Systemic Lupus Erythematosus Thrombosis	Foreign Health Professional	Risperdal (Risperidone), Janssen, Tablet	PS	Janssen	ORAL ORAL		
			Orap (Pimozide), Janssen, Tablet	SS	Janssen	ORAL ORAL		
			Haldol (Haloperidol)	SS				

Date:02/23/99ISR Number: 3204736-XReport Type:Expedited (15-DaCompany Report #990210-107050957
Age:42 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Diabetes Mellitus Enuresis Polydipsia	Health Professional	Haldol Decanoate, Unspecified (Haloperidol)	PS		INTRAMUSCULAR IM (INTRAMUSCULAR)	200 MG 1X/MO,	4 YR
			Benzatropine Mesilate	C				

Date:02/23/99ISR Number: 3204821-2Report Type:Expedited (15-DaCompany Report #981231-008015205
Age:98 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Dermatitis Bullous	Foreign	Haldol Solution	PS		ORAL ORAL		
Hospitalization - Initial or Prolonged	Lung Disorder	Health Professional	Aldactazone	SS		ORAL ORAL		
	Pruritus		Bromazepam	SS		ORAL ORAL		

	Renal Failure		Amiodarone	SS		ORAL
100 MG, QD,						
	Toxic Epidermal					
ORAL						
	Necrolysis		Iskedyl	SS		ORAL
ORAL						
			Vitamins	SS		ORAL
ORAL						

Date:02/25/99ISR Number: 3207844-2Report Type:Periodic Company Report #9710128
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Drug Interaction	Health	Zoloft Tablets	PS		ORAL
150.00 MG						
	Dyskinesia	Professional				
TOTAL: DAILY:						
	Extrapyramidal Disorder					
ORAL						
			Haldol	SS		ORAL
DAILY: ORAL						
			Lorazepam	C		
			Trazodone	C		

Date:02/25/99ISR Number: 3207919-8Report Type:Direct Company Report #
Age:19 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Dystonia	Health	Carborator Fluid	PS		
Initial or Prolonged	Muscle Rigidity	Professional	Haldol	SS		
	Poisoning Deliberate		Phenothiazine	SS		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/25/99ISR Number: 3208169-1Report Type:Expedited (15-DaCompany Report #981207-008014865
Age:89 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agranulocytosis Fungal Infection Pseudomonas Infection Sepsis Streptococcal Infection	Foreign Health Professional	Haloperidol, Unspecified Domperidone Isosorbide Dinitrate Piribedil Hydroxyzine Paracetamol Nitrendipine	PS SS C C C C C		ORAL	1 MG, BID ORAL UNKNOWN, UNKNOWN, UNKNOWN	

Date:02/25/99ISR Number: 3208172-1Report Type:Expedited (15-DaCompany Report #990216-008010659
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Systemic Lupus Erythematosus Thrombosis	Foreign Health Professional	Haldol, Unspecified (Haloperidol) Risperdal (Risperidone) Orap (Pimozide)	PS SS SS		ORAL ORAL	UNKNOWN, UNKNOWN, UNKNOWN UNKNOWN, UNKNOWN, ORAL UNKNOWN, UNKNOWN, ORAL	

Date:02/25/99ISR Number: 3210002-9Report Type:Periodic Company Report #9828266
Age: Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Asthenia	Health	Zoloft Tablets	PS		ORAL	200.00MG	
	Catatonia	Professional					TOTAL	BID
	Hallucination	Company				ORAL		
		Representative	Haldol	SS		ORAL	10.00MG	TOTAL
							BID	ORAL
			Ambien	SS		ORAL	5.00MG	TOTAL
							DAILY	ORAL
			Cogentin	SS		ORAL	BID	ORAL

Date:02/25/99ISR Number: 3211012-8Report Type:Periodic Company Report #JAUSA-31835
Age:20 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Condition Aggravated	Study	Risperdal					
	Medication Error	Health	(Risperidone)	PS	Janssen	ORAL	3 MG	DAILY
	Psychotic Disorder	Professional					ORAL	
			Haldol (Haloperidol)	SS	Janssen	ORAL	3 MG	DAILY
							ORAL	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/25/99ISR Number: 3212023-9Report Type:Periodic Company Report #9807373
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Anxiety	Health	Zoloft Tablets	PS		ORAL	ORAL	
	Drug Withdrawal Syndrome	Professional	Haldol	SS				
	Hostility		Cogentin	SS				
	Paranoia							

Date:02/25/99ISR Number: 3212106-3Report Type:Periodic Company Report #9618882
Age:87 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Ineffective	Health	Zoloft	PS		ORAL	100.00 MG	TOTAL: DAILY:
		Professional						
			Haldol	SS		ORAL	10.00 MG	TOTAL: DAILY:

ORAL

Date:02/25/99ISR Number: 3212213-5Report Type:Periodic Company Report #JAUSA-27780
Age:20 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Condition Aggravated	Health	Risperdal (Risperidone), Janssen, Tablet	PS		ORAL	4 MG DAILY,	ORAL
	Galactorrhoea	Professional						
	Hyperprolactinaemia							
	Pituitary Tumour							
			Haldol (Haloperidol),					

			Janssen, Tablet	SS		ORAL
20 MG DAILY,						
ORAL						
			Depo-Provera	C		

Date:02/25/99ISR Number: 3212220-2Report Type:Periodic Company Report #JAUSA-34384
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Extrapyramidal Disorder		Risperdal (Risperidone), Janssen Tablet	PS		ORAL
ORAL						
			Haldol (Haloperidol), Janssen	SS		

Date:02/25/99ISR Number: 3212544-9Report Type:Periodic Company Report #JAUSA-33466
Age:30 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Hyperglycaemia	Health	Risperdal	PS	Janssen	ORAL
3 MG 2 DAILY						
ORAL		Professional				
			Haloperidol (Haloperidol), Janssen, Ampoule	SS	Janssen	
INTRAMUSCULAR	INTRAMUSCULAR					

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/25/99ISR Number: 3212779-5Report Type:Periodic Company Report #JAUSA-34077
Age:23 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dyspnoea	Health Professional	Risperdal (Risperidone)	PS	Janssen	ORAL	1MG 1 DAILY	
	Neuroleptic Malignant Syndrome					ORAL		
			Haldol (Haloperidol)	SS	Janssen	ORAL		
			Prolixin (Fluphenazine)	SS				
			Prolixin-Deconate	SS				7 DAY

Date:02/25/99ISR Number: 3216733-9Report Type:Periodic Company Report #9804018
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Sedation	Health Professional	Zoloft	PS		ORAL	TABLETS, ORAL	
			Haldol	SS		ORAL		
			Valium	SS		ORAL		

Date:02/26/99ISR Number: 3208445-2Report Type:Expedited (15-DaCompany Report #10717-AR
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Systemic Lupus Erythematosus	Foreign Health	Orap (Pimozide Tablets Usp)	PS		ORAL		
	Thrombosis	Professional Other	Risperidone Tablets	SS				
			Haloperidol	SS				

Date:03/01/99ISR Number: 3209518-0Report Type:Expedited (15-DaCompany Report #US_990217941
Age:47 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hallucination, Auditory Paranoia	Study Health Professional	Haloperidol Benztropine(Benzatropine)	PS SS			2 DSG FORM 2 DSG FROM	DAY DAY

Date:03/01/99ISR Number: 3209570-2Report Type:Expedited (15-DaCompany Report #990218-008010716
Age:62 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardiac Arrest Choking Foreign Body Trauma Obstructive Airways Disorder	Foreign Health Professional	Haldol Tablets (Haloperidol) Haldol Decanoate, Unspecified (Haloperidol) Chlorprothixene	PS SS SS		ORAL INTRAMUSCULAR	5 MG, QD, 50 MG, 250 MG, QD	 1X/3WK, IM

Date:03/01/99ISR Number: 3209574-XReport Type:Expedited (15-DaCompany Report #990222-008010775
Age:52 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Condition Aggravated Idiopathic Thrombocytopenic Purpura Increased Tendency To Bruise Medication Error Platelet Count Decreased Psychotic Disorder Red Blood Cell Count Decreased White Blood Cell Count Increased	Health Professional	Haloperidol Lithium Depakote Risperidone	PS SS SS C		ORAL ORAL ORAL ORAL	5 MG, QD, 300 MG, TID, 1250 MG, QD, 1MG, BID,	

Date:03/02/99ISR Number: 3210214-4Report Type:Expedited (15-DaCompany Report #990218-008010726
Age:62 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hypothermia Subarachnoid Haemorrhage	Foreign Health Professional	Haloperidol Injection	 PS		 INTRAVENOUS	 IV (INTRAVENOUS)	

Date:03/02/99ISR Number: 3210216-8Report Type:Expedited (15-DaCompany Report #990218-008010717
Age:39 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Blood Creatine	Foreign	Haldol Injection					

Initial or Prolonged	Phosphokinase Increased	Health	(Haloperidol)	PS			
INTRAVENOUS 10 MG,	QD, IV						
	Dehydration	Professional					
(INTRAVENOUS)							
	Rhabdomyolysis		Haldol Concentrate				
			(Haloperidol)	SS			ORAL
SEE IMAGE,							
QD, ORAL							
			Diazepam	C			

Date:03/03/99ISR Number: 3211589-2Report Type:Expedited (15-DaCompany Report #990224-008010805
Age:56 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Deep Vein Thrombosis	Foreign	Haloperidol	PS		ORAL
2MG, QD,						
	Pain In Extremity	Health				
ORAL; 4MG,						
		Professional				
QD, ORAL						
TABLETS						
			Olanzapine	SS		ORAL
10MG, QD,						
ORAL						
			Mirtazapine	SS		ORAL
15MG, QD,						
ORAL;						
30MG,QD, ORAL						
			Lorazepam	SS		ORAL
2MG, QD, ORAL						
			Levothyroxine	C		
			Buspirone	C		
			Pindolol	C		

Date:03/04/99ISR Number: 3212757-6Report Type:Expedited (15-DaCompany Report #981229-008015196
Age:27 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Antepartum Haemorrhage Cerebral Haemorrhage Neonatal Complications Of Maternal Exposure To Therapeutic Drugs Death Neonatal Foetal Growth Retardation Haemorrhagic Stroke Premature Baby	Foreign Health Professional	Haloperidol Decanoate Fluoxetine Hydrochloride	PS SS		ORAL	50 MG, 1X/IM (INTRAMUSCULAR) ORAL	

Date:03/04/99ISR Number: 3212759-XReport Type:Expedited (15-DaCompany Report #990122-008010303
Age:91 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Condition Aggravated Confusional State Dementia Liver Function Test Abnormal Psychiatric Symptom	Foreign Health Professional	Haloperidol Ranitidine Nicardipine Hydrochloride Hydroxyzine Hydrochloride Meprobamate Furosemide Ferrous Sulfate Fluoxetine Hydrochloride Molsidomine	PS C C C C C C I		ORAL	15 DROP, UNKNOWN, ORAL	

Date:03/08/99ISR Number: 3214910-4Report Type:Expedited (15-DaCompany Report #107197
Age:32 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dermatitis Exfoliative Eczema	Foreign Other	Rivotril (Clonazepam)	PS		ORAL	.25 DOSE FORM	1 PER DAY
	Eosinophilia							
	Face Oedema							
	Liver Function Test Abnormal		Akineton Retard (Biperiden Hydrochloride)	SS		ORAL		
	Lymphadenopathy							
	Oedema Peripheral		Haldol (Haloperidol)	SS		ORAL	2.5 DOSE FORM	1 PER DAY
	Skin Inflammation							
			Tegretol (Carbamazepine) 200 Mg	SS		ORAL	600 MG 1 PER	DAY
			Imovane (Zopiclone)	SS		ORAL	.5 DOSE FORM	
			Solian (Amisulpride) 200 Mg	SS		ORAL	600 MG 1 PER	DAY

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/08/99ISR Number: 3214965-7Report Type:Expedited (15-DaCompany Report #JAUSA-36247
Age:52 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Condition Aggravated Idiopathic Thrombocytopenic Purpura Increased Tendency To Bruise Medication Error Platelet Count Decreased Psychotic Disorder Red Blood Cell Count Decreased White Blood Cell Count Increased	Health Professional	Risperdal (Risperidone), Janssen, Tablet 1 Mg	PS	Janssen	ORAL	1 MG 2 DAILY ORAL 2 MG 2 DAILY	
			Haldol (Haloperidol), Janssen, Tablet	SS	Janssen	ORAL	5 MG 1 DAILY ORAL	
			Lithium (Lithium)	SS		ORAL	300 MG 3 DAILY ORAL	8 DAY
			Depakote (Valproate Sodium)	SS		ORAL	1250 MG DAILY ORAL 500 MG AT 8 AM AND 8 PM, 250 MG AT 12 N	8 DAY
			Nifedipine	C				
			Klonopin	C				
			Prednisone	C				

Date:03/09/99ISR Number: 3215395-4Report Type:Expedited (15-DaCompany Report #8-99060-110A
Age:56 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Thrombosis	Foreign	Tavor	PS		ORAL	2 MG ONCE	

		Study					
DAILY ORAL							
			Buspar	SS			ORAL
15 MG TO 30							
MG DAILY ORAL							
			Haldol	SS			ORAL
2 MG TO 4 MG							
DAILY ORAL							
			Renergil (Mirtazapine)	SS			ORAL
15 MG TO 30							
MG DAILY ORAL							
			Zyprexa	SS			ORAL
10 MG DAILY							
ORAL							
			Levothyroxine	C			
			Visken	C			

Date:03/09/99ISR Number: 3215419-4Report Type:Expedited (15-DaCompany Report #990223-008010798
Age:80 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Pyrexia Renal Failure Rhabdomyolysis	Foreign Health Professional	Haloperidol Solution	PS		ORAL	ORAL	

Date:03/09/99ISR Number: 3217822-5Report Type:Direct Company Report #
Age:81 YR Gender:Male I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Dystonia Immobile Masked Facies Musculoskeletal Stiffness

	Parkinsonian Gait Parkinsonism					
		Report Source	Product	Role	Manufacturer	Route
Dose Duration						
			Haldol	PS	Mcneil Pharm	ORAL
0.5 MG BID PO						

Date:03/10/99ISR Number: 3216805-9Report Type:Expedited (15-DaCompany Report #9907576
Age:89 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Agranulocytosis	Foreign	Atarax Tablets	PS		
50.00 MG						
Initial or Prolonged	Anal Ulcer	Health				
TOTAL: DAILY						
	Pseudomonas Infection	Professional	Piribedil	SS		
50.00 MG						
	Sepsis					
TOTAL						
	White Blood Cell Count		Haloperidol	SS		
2.00 MG						
	Increased					
TOTAL: DAILY						
			Isosorbide Dinitrate	C		
			Paracetamol	C		
			Nitrendipine	C		
			Domperidone	C		

Date:03/15/99ISR Number: 3221572-9Report Type:Expedited (15-DaCompany Report #JASWE-43549
Age:59 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Convulsion	Foreign	Durogesic (Fentanyl)	PS	Janssen	
TRANSDERMAL 25 MCG/HR						
Initial or Prolonged	Electroencephalogram					
DAILY						
	Abnormal					
TRANSDERMAL						
	Fatigue		Haldol (Haloperidol)	SS	Janssen	ORAL
1 MG DAILY						

	Lethargy						
ORAL							
	Loss Of Consciousness		Norfin (Morphine)	SS			ORAL
ORAL 1 DAY							
	Metastases To Central Nervous System		Panodil	C			
	Sedation						

Date:03/16/99ISR Number: 3224644-8Report Type:Expedited (15-DaCompany Report #990310-008011033
Age:57 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Grand Mal Convulsion	Foreign	Haloperidol	PS		ORAL	20 MG, QD,	
	Hypoglycaemia	Health						
ORAL, TAB								
	Loss Of Consciousness	Professional	Clozapine	C				
	Sedation							

Date:03/19/99ISR Number: 3223715-XReport Type:Expedited (15-DaCompany Report #990315-008011096
Age:67 YR Gender:Male I/FU:I

Outcome	PT
Death	Cachexia
	Delirium
	Eosinophilia
	Gastric Cancer Stage Iv
	Hypochloraemia
	Hypokalaemia
	Liver Function Test Abnormal
	Lymphopenia
	Metastases To Lung

Neutrophilia
Pneumonia
Urobilinuria

Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Foreign Health	Haloperidol, Unspecified	PS		ORAL	SEE IMAGE	
Professional	Risperidone	SS		ORAL	SEE IMAGE	
	Biperiden Hydrochloride	SS		ORAL	5 MG, QD,	
					ORAL	
	Nitrazepam	SS		ORAL	5 MG, QD,	
					ORAL	
	Flunitrazepam	SS		ORAL	2 MG, QD,	
					ORAL	
	Flurazepam Hydrchloride	SS		ORAL	20 MG, QD,	
					ORAL	
	Cilastatin Soduim W/Imipenem	SS				
					INTRAVENOUS	500 MG, QD,
					IV	
					(INTRAVEOUS)	
	Piperacillin Sodium	SS				
					INTRAVENOUS	2 MG, QD, IV
	Desozopram Hydrochloride	SS				
					INTRAVENOUS	2 G, QD, IV
					(INTRAVEOUS)	
	Oxiracetam	C				
	Cefozopran Hydrochloride	C				
	Cefotiam Hydrochloride	C				
	Clindamycin	C				

			Isepamicin Sulfate	C		

Date:03/22/99ISR Number: 3224308-0Report Type:Expedited (15-DaCompany Report #JAKYO-42852
Age:67 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Blood Creatine Phosphokinase Increased	Foreign Health	Risperidone (Risperidone)	PS	Janssen	ORAL	2 MG DAILY	
	Cachexia	Professional				ORAL		
	Delirium Eosinophilia		Haloperidol (Haloperidol)	SS	Janssen	ORAL	2.25 MG DAILY	
	Gastric Cancer					ORAL		
	Gastric Polyps Gastritis Erosive		Risperidone (Risperidone) Tablet	SS		ORAL	3 MG DAILY	
	Hypocalcaemia					ORAL	9 DAY	
	Hypochloraemia Hypokalaemia		Haloperidol (Haloperidol)	SS		ORAL	6 MG DAILY	
	Liver Function Test					ORAL		
	Abnormal Lymphopenia Metastases To Lung Neutrophilia		Biperiden Hydrochloride (Biperiden Hydrochloride)	SS		ORAL	3 MG DAILY	
	Pneumonia					ORAL		
	Urobilinuria		Nitrazepam (Nitrazepam)	SS		ORAL	5 MG DAILY	
						ORAL	10 MON	
			Flunitrazepam (Flunitrazepam)	SS		ORAL	2 MG DAILY	
						ORAL	6 MON	
			Flurazepam					

				Hydrochloride (Flurazepam)	SS		ORAL
20 MG DAILY							
ORAL	6	MON					
				Tienam (Tienam (R))	SS		
500 MG DAILY							
INTRAJEJUNAL	4	DAY					
				Piperacillin Sodium (Piperacillin)	SS		
2 G DAILY							
INTRAJEJUNAL	10	DAY					
				Cefozopran Hydrochloride (Cefozopran)	SS		
2 G DAILY							
INTRAJEJUNAL							
2 G DAILY							
INTRAJEJUNAL	10	DAY					
				Aniracetam	C		
				Cefotiam Hydrochloride	C		
				Clindamycin	C		
				Isepamicin Sulfate	C		

Date:03/23/99ISR Number: 3224635-7Report Type:Expedited (15-DaCompany Report #990310-008011031
Age:59 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Convulsion	Foreign	Haloperidol	PS		ORAL	1 MG, HS,	
	Electroencephalogram	Health Professional						
	Abnormal		Fentanyl	SS		INTRADERMAL	25 MCG, HR,	
	Fatigue							
	Lethargy							

DERMAL; 100 MCG, HR,

	Loss Of Consciousness						
DERMAL							
	Metastases To Central Nervous System		Morphine Sulfate	SS			ORAL
30 MG, PRN, ORAL							
			Paracetamol	C			

Date:03/23/99ISR Number: 3224640-0Report Type:Expedited (15-DaCompany Report #981014-008014001
Age:32 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dermatitis Exfoliative	Foreign	Haldol Tablets					
	Drug Eruption	Health	(Haloperidol)	PS		ORAL	1 TAB, QD,	
	Eczema	Professional				ORAL		
	Eosinophilia		Clonazepam	SS		ORAL		
ORAL								
	Liver Function Test Abnormal		Carbamazepine	SS		ORAL	600 MG, QD,	
ORAL								
	Lymphadenopathy		Amisulpride	SS		ORAL		
ORAL								
	Oedema Peripheral		Zopiclone	SS		ORAL	3.75 MG, QD,	
ORAL								
	Skin Exfoliation							
ORAL								
			Biperiden	C		ORAL		
ORAL								

Date:03/23/99ISR Number: 3224841-1Report Type:Expedited (15-DaCompany Report #FRA000979
Age:32 YR Gender:Female I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Condition Aggravated
	Dermatitis Exfoliative
	Eczema
	Eosinophilia
	Liver Function Test Abnormal

	Lymphadenopathy						
	Oedema						
	Skin Inflammation	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Skin Lesion	Foreign	Akineton	PS			
	Toxic Skin Eruption		Tegretol	SS		ORAL	200 MG TID PO
			Haldol	SS		ORAL	50 MG DAILY PO
			Rivotril	SS		ORAL	0.5 MG OD PO
			Imovane	SS		ORAL	3.75 MG NOCTE PO
			Solian	SS		ORAL	200 MG TID PO

Date:03/23/99ISR Number: 3225634-1Report Type:Direct Company Report #
Age:61 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Other	Dysarthria	Health	Haloperidol	PS		ORAL	10 MG HS PO 1 WK
	Dysphagia	Professional					
	Immobile						
	Muscle Rigidity						
	Tongue Oedema						

Date:03/24/99ISR Number: 3225929-1Report Type:Expedited (15-DaCompany Report #9908859
Age:24 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Hepatitis	Foreign	Abbott-Tranxene	PS	Abbott	ORAL	1125.000 MG
Initial or Prolonged	Liver Function Test	Other					PO QD
Other	Abnormal		Haloperidol	SS		ORAL	PO

Carbamazepine	C	
Lormetazepam	C	
Trihexyphenidyl		
Hydro	C	

Date:03/25/99ISR Number: 3226616-6Report Type:Expedited (15-DaCompany Report #990316-008011102
Age:32 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Blood Creatine	Foreign	Halomonth					
Hospitalization -	Phosphokinase Increased	Literature	(Haloperidol					
Initial or Prolonged	Bradycardia	Health	Decanoate)	PS				
INTRAMUSCULAR	Cardiac Arrest	Professional					100 MG	1X/2W
IM	Depressed Level Of Consciousness							
	Dyspnoea							
	Hyperglycaemia							
	Hyperhidrosis							
	Hypotension							
	Malaise							
	Neuroleptic Malignant Syndrome							
	Oliguria							
	Pyrexia							
	Renal Failure Acute							
	Respiratory Arrest							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/25/99ISR Number: 3226618-XReport Type:Expedited (15-DaCompany Report #970203-107050730
Age:24 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Difficulty In Walking	Consumer	Haldol, Unspecified					
	Dysarthria		(Haloperidol)	PS				
	Joint Stiffness		Chlorpromazine					
	Memory Impairment		Hydrochloride	C				
	Muscle Twitching		Lithium	C				
	Oculogyration							
	Pain In Extremity							
	Paraesthesia							

Date:03/25/99ISR Number: 3226619-1Report Type:Expedited (15-DaCompany Report #990318-008011142
Age:53 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agranulocytosis	Foreign	Haldol Tablets					
	Candidiasis	Health	(Haloperidol)	PS		ORAL	ORAL	
	Pneumonia	Professional	Ethosuximide	SS		ORAL	750 MG QD	
	Pyrexia						ORAL	
	Urinary Tract Infection		Carbamazepine	SS		ORAL	600 MG QD PO	
			Paracetamol	C				
			Citalopram	C				
			Folic Acid	C				
			Oxazepam	C				
			Levomepromazine	C				
			Cyanocobalamine	C				

Date:03/26/99ISR Number: 3227918-XReport Type:Expedited (15-DaCompany Report #990323-008011173
Age:42 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Anticholinergic Syndrome	Foreign	Haloperidol Tablets	PS		ORAL	80 MG, ONCE,	

Initial or Prolonged	Blood Pressure Systolic	Literature				ORAL
	Decreased	Health	Clozapine	SS		10 G, ONCE,
	Coma	Professional				ORAL
	Heart Rate Increased		Prothipendyl	C		
	Hypokalaemia		Bromazepam	C		

Date:03/31/99ISR Number: 3230694-8Report Type:Direct Company Report #
Age:78 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Sluggishness	Health	Risperdal 1 Mg	PS		ORAL	1/2 MG, BID,	
Initial or Prolonged	Tardive Dyskinesia	Professional				PO		
			Haldol	SS		INTRAMUSCULAR	5 MG, X 1	
							DOSE, IM	
			Asa	C				
			Kcl	C				
			Glucotrol	C				
			Lopressor	C				
			Florinef	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/31/99ISR Number: 3230950-3Report Type:Expedited (15-DaCompany Report #990323-008011174
Age:74 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Coma Confusional State Depressed Level Of Consciousness Dyskinesia Hyporeflexia Sedation	Foreign Health Professional	Haloperidol Solution Cyamemazine Glimepiride Metformin Hydrochloride	PS C C C		ORAL	60 MG QD ORAL	

Date:03/31/99ISR Number: 3232495-3Report Type:Periodic Company Report #980212-107050838
Age:52 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Attention Deficit/Hyperactivity Disorder Drug Effect Increased Orthostatic Hypotension	Health Professional	Haldol Decanoate, Unspecified (Haloperidol) Amantadine Clonidine	PS C C		INTRAMUSCULAR IM (INTRAMUSCULAR)	250 MG, ONCE,	

Date:03/31/99ISR Number: 3232497-7Report Type:Periodic Company Report #980717-107054851
Age:30 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Confusional State Dry Mouth Extrapyramidal Disorder Oculogyration	Health Professional	Haldol Decanoate, Unspecified (Haloperidol)	PS		INTRAMUSCULAR	200 MG, 1X/2WK,IM	

(INTRAMUSCULA

R)

				Trihexyphenidyl Hydrochloride	C		

Date:03/31/99ISR Number: 3418440-6Report Type:Periodic Company Report #971212-107057143
Age:52 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Anxiety Bruxism Dyskinesia Flushing	Consumer	Haldol Decanoate, Unspecified (Haloperidol)	PS		INTRAMUSCULAR	3 MG, 1X/MO,IM	

(INTRAMUSCULA

R) 10 MON

Date:03/31/99ISR Number: 3418448-0Report Type:Periodic Company Report #980129-107050527
Age:50 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Weight Decreased	Health Professional	Haldol Decanoate 50 (Haloperidol)	PS		INTRAMUSCULAR	75 MG, 1X/2WK, IM	

(INTRAMUSCULA

R)

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/31/99ISR Number: 3418453-4Report Type:Periodic Company Report #980203-107050656
Age:38 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Injection Site Reaction	Health Professional	Haldol Decanoate, Unspecified (Haloperidol)	PS		INTRAMUSCULAR	IM	(INTRAMUSCULAR)
			Lithium	C				
			Trihexyphanidyl Hydrochloride	C				

Date:03/31/99ISR Number: 3418456-XReport Type:Periodic Company Report #980205-107050678
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Injection Site Reaction	Health Professional	Haldol Decanoate, Unspecified (Haloperidol)	PS		INTRAMUSCULAR	400 MG, 1X/MO, IM	(INTRAMUSCULAR)
			Haldol (Haloperidol)	C				
			Benzatropine Mesilate	C				
			Fluphenazine Hydrochloride	C				

Date:03/31/99ISR Number: 3418459-5Report Type:Periodic Company Report #980206-107050703
Age:50 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

	Injection Site Reaction	Health Professional	Haldol Decanoate, Unspecified (Haloperidol)	PS			
INTRAMUSCULAR (INTRAMUSCULAR)	IM						

Date:03/31/99ISR Number: 3418462-5Report Type:Periodic Company Report #980219-107051006
Age:52 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Depression Dyskinesia Weight Increased	Consumer	Haldol Decanoate, Unspecified (Haloperidol)	PS				
INTRAMUSCULAR (INTRAMUSCULAR)	IM						.5 CC, 1X/MO,	1 YR

Date:03/31/99ISR Number: 3418465-0Report Type:Periodic Company Report #980313-107051532
Age: Gender: I/FU:I

Outcome	PT
	Chest Pain Dyskinesia Gait Disturbance Headache

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Hypertonia Hypotension Pyrexia	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Speech Disorder Thinking Abnormal	Consumer	Haldol Decanoate 50 (Haloperidol)	PS				
INTRAMUSCULAR	1X/2WK, IM (INTRAMUSCULAR)							
							1	YR

Date:03/31/99ISR Number: 3418469-8Report Type:Periodic Company Report #980317-107051588
Age:43 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Amnesia	Consumer	Haldol Decanoate, Unspecified (Haloperidol)	PS				
INTRAMUSCULAR	IM (INTRAMUSCULAR)							
			Thorazine	C				
			Amitriptyline	C				

Date:03/31/99ISR Number: 3418471-6Report Type:Periodic Company Report #980325-107051789
Age:64 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Depression Hypertension Sedation	Consumer	Haldol Decanoate, Unspecified (Haloperidol)	PS				
INTRAMUSCULAR	IM (INTRAMUSCULAR)							

Date:03/31/99ISR Number: 3418475-3Report Type:Periodic Company Report #980414-107052242
Age:39 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Injection Site Reaction	Health Professional	Haldol Decanoate, Unspecified (Haloperidol)	PS		INTRAMUSCULAR (INTRAMUSCULAR)	IM	

Date:03/31/99ISR Number: 3418482-0Report Type:Periodic Company Report #980501-107053211
Age:22 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Alopecia	Consumer	Haldol Decanoate, Unspecified (Haloperidol)	PS		INTRAMUSCULAR (INTRAMUSCULAR)	IM	
			Valproic Acid	C			1	YR
			Olanzapine	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/31/99ISR Number: 3418489-3Report Type:Periodic Company Report #980518-107053642
Age:25 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Injection Site Reaction	Health Professional	Haldol Decanoate 100 (Haloperidol)	PS		INTRAMUSCULAR	200 MG, 1X/2WK, IM (INTRAMUSCULAR)	
			Clozapine	SS			1000 MG,	

Date:03/31/99ISR Number: 3418497-2Report Type:Periodic Company Report #980522-107053745
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Injection Site Reaction	Health Professional	Haldol Decanoate 100 (Haloperidol)	PS		INTRAMUSCULAR	IM (INTRAMUSCULAR)	

Date:03/31/99ISR Number: 3418503-5Report Type:Periodic Company Report #980522-107053753
Age:50 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Asthenia Gait Disturbance Retinal Disorder	Health Professional	Haldol Decanoate, Unspecified (Haloperidol)	PS		INTRAMUSCULAR	IM (INTRAMUSCULAR)	1 YR

				Benztropine Mesylate	C		

Date:03/31/99ISR Number: 3418508-4Report Type:Periodic Company Report #980529-107053858
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Effect Decreased	Health Professional	Haldol Decanoate 50 (Haloperidol)	PS		INTRAMUSCULAR	50 MG, IM	(INTRAMUSCULAR)

Date:03/31/99ISR Number: 3418512-6Report Type:Periodic Company Report #980602-107053917
Age:35 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Constipation Speech Disorder Urinary Retention	Consumer	Haldol Decanoate 50 (Haloperidol)	PS		INTRAMUSCULAR	50 MG, 1X/MO, IM	(INTRAMUSCULAR)

Date:03/31/99ISR Number: 3418519-9Report Type:Periodic Company Report #980605-107011963
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Injection Site Reaction	Health Professional	Haldol Decanoate, Unspecified (Haloperidol)	PS		INTRAMUSCULAR	IM	

(INTRAMUSCULA

R)

Date:03/31/99ISR Number: 3418522-9Report Type:Periodic Company Report #980605-107054011
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Injection Site Reaction	Health Professional	Haldol Decanoate, Unspecified (Haloperidol)	PS		INTRAMUSCULAR	IM	

(INTRAMUSCULA

R)

Date:03/31/99ISR Number: 3418529-1Report Type:Periodic Company Report #980605-107054013
Age:82 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Sedation	Consumer	Haldol Decanoate, Unspecified (Haloperidol)	PS		INTRAMUSCULAR	25 MG, 1X/MO, IM	

(INTRAMUSCULA

R)

Date:03/31/99ISR Number: 3418538-2Report Type:Periodic Company Report #980612-107012032
Age:28 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Injection Site Reaction	Health	Haldol Decanoate 100					

			Professional	(Haloperidol)	PS		
SUBCUTANEOUS	1X/MO, SC						
(SUBCUTANEOUS							
)							
				Fluphenazine Decanoate	C		
				Benzteopine Mesylate	C		
				Lorazepam	C		
				Venlafaxine Hydrochloride	C		
				Theophylline	C		

Date:03/31/99ISR Number: 3418666-1Report Type:Periodic Company Report #980612-107054107
Age:49 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
	Menstrual Disorder	Health Professional	Haldol Decanoate, Unspecified (Haloperidol)	PS		
INTRAMUSCULAR	IM					
(INTRAMUSCULA						
R)						

Date:03/31/99ISR Number: 3418670-3Report Type:Periodic Company Report #980612-107054136
Age:46 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
	Injection Site Reaction	Health Professional	Haldol Decanoate 100 (Haloperidol)	PS		
SUBCUTANEOUS	1X/WK, SC					
(SUBCUTANEOUS						

)

	Fluphenazine Decanoate	C
	Fluoxetine Hydrochloride	C
	Benztropine Mesylate	C

Date:03/31/99ISR Number: 3418673-9Report Type:Periodic Company Report #980617-107054219
Age:30 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Injection Site Reaction	Health Professional	Haldol Decanoate, Unspecified (Haloperidol)	PS		INTRAMUSCULAR	IM	

(INTRAMUSCULA

R)

Date:03/31/99ISR Number: 3418676-4Report Type:Periodic Company Report #980622-107054309
Age:65 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Injection Site Reaction	Health Professional	Haldol Decanoate, Unspecified (Haloperidol)	PS		INTRAMUSCULAR	IM	

(INTRAMUSCULA

R)

Date:03/31/99ISR Number: 3418680-6Report Type:Periodic Company Report #980710-107054682
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Oedema	Health	Haldol Decanoate,					

Salivary Hypersecretion Professional Unspecified
Therapeutic Response (Haloperidol) PS
INTRAMUSCULAR 250 MG,
Increased
1X/2WK, IM

(INTRAMUSCULA

R) 4 (N)

TIMES

Date:03/31/99ISR Number: 3418683-1Report Type:Periodic Company Report #980717-107054862
Age:57 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
	Injection Site Reaction	Health Professional	Haldol Decanoate 50 (Haloperidol)	PS		
INTRAMUSCULAR	50 MG, 1X/MO,					

IM

(INTRAMUSCULA

R) 1 YR

Date:03/31/99ISR Number: 3418685-5Report Type:Periodic Company Report #980722-107054930
Age:45 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
	Injection Site Reaction	Health Professional	Haldol Decanoate 100 (Haloperidol)	PS		
INTRAMUSCULAR	300 MG,					

1X/MO, IM

(INTRAMUSCULA

R)

Lithium Carbonate	C
Divalproex Sodium	C
Benzatropine	C
Paroxetine Hydrochloride	C
Thioridazine Hydrochloride	C
Carbamazepine Xr	C

Date:03/31/99ISR Number: 3418689-2Report Type:Periodic Company Report #980820-107055638
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Injection Site Reaction	Health Professional	Haldol Decanoate, Unspecified (Haloperidol)	PS		INTRAMUSCULAR	IM	

(INTRAMUSCULA

R)

Date:03/31/99ISR Number: 3418695-8Report Type:Periodic Company Report #980826-107055764
Age:51 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Tooth Disorder	Health Professional	Haldol Decanoate, Unspecified (Haloperidol)	PS		INTRAMUSCULAR	IM	

(INTRAMUSCULA

R)

Thioridazide Hydrochloride	C
Lithium	C
Benzatropine Mesylate	C
Hydroxyzine	

Hydrochloride	C
Thyroid Supplement, Nos	C
Omeprazole	C
Cisapride	C

Date:03/31/99ISR Number: 3418698-3Report Type:Periodic Company Report #980923-107056407
Age:33 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Dystonia	Health Professional	Haldol Decanoate 100 (Haloperidol)	PS		INTRAMUSCULAR (INTRAMUSCULAR)	100 MG, 1X/MO, IM	

Date:03/31/99ISR Number: 3418703-4Report Type:Periodic Company Report #981009-107056815
Age:50 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Injection Site Reaction	Health Professional	Haldol Decanoate, Unspecified (Haloperidol)	PS		INTRAMUSCULAR	IM	

(INTRAMUSCULA

R)

Albuterol Sulfate	C	
Flunisolide	C	
Theophylline	C	
Ipratropium Bromide	C	
Nedocromil	C	

Date:03/31/99ISR Number: 3418705-8Report Type:Periodic Company Report #981116-107058001
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Injection Site Reaction Pyrexia	Consumer	Haldol Decanoate, Unspecified (Haloperidol)	PS				

INTRAMUSCULAR IM

(INTRAMUSCULA

R)

Date:03/31/99ISR Number: 3418709-5Report Type:Periodic Company Report #981125-107058367
Age:39 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Asthenia Catatonia Erectile Dysfunction	Consumer	Haldol Decanoate, Unspecified (Haloperidol)	PS				

IM

	Hypertonia							

(INTRAMUSCULA

	Malaise							

R)

	Speech Disorder		Lithium	SS		ORAL		

ORAL

	Urinary Incontinence							

Date:03/31/99ISR Number: 3418714-9Report Type:Periodic Company Report #981125-107058380
Age:45 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Agitation	Consumer	Haldol Decanoate 100					
	Insomnia		(Haloperidol)	PS				
INTRAMUSCULAR	Salivary Hypersecretion						5 MG, BID, IM	
(INTRAMUSCULA	Speech Disorder							
R) (SEE	Tachycardia							
IMAGE)								
			Lithium	C				

Date:03/31/99ISR Number: 3418717-4Report Type:Periodic Company Report #981203-107058506
Age:29 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Oedema	Consumer	Haldol Decanoate 100					
	Pruritus		(Haloperidol)	PS				
INTRAMUSCULAR	Urticaria						100 MG, IM	
(INTRAMUSCULA								
R)								
			Bupropion Hydrochloride	C				
			Benzatropine Mesilate	C				

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Freedom Of Information (FOI) Report

Date:03/31/99ISR Number: 3418719-8Report Type:Periodic Company Report #981229-107059169
Age:40 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Injection Site Reaction	Health Professional	Haldol Decanoate, Unspecified (Haloperidol)	PS		INTRAMUSCULAR	200 MG, 1X/2WK, IM (INTRAMUSCULAR) 4 (N)	TIMES
			Benzatropine Mesilate	C				

Date:03/31/99ISR Number: 3418720-4Report Type:Periodic Company Report #990119-107010243
Age:43 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Attention Deficit/Hyperactivity Disorder	Consumer	Haldol Decanoate, Unspecified (Haloperidol)	PS		INTRAMUSCULAR	IM (INTRAMUSCULAR)	
	Dermatitis Bullous							
	Insomnia							
			Benzodiazpines	C				

Date:04/02/99ISR Number: 3232141-9Report Type:Expedited (15-DaCompany Report #046-0366-990001
Age:52 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agranulocytosis Candidiasis	Foreign Health	Suxinutin (Ethosuximide)	PS		ORAL	750 MG	

Other	Pneumonia	Professional					
(DAILY) PER							
	Pyrexia						
ORAL							
			Haldol (Haloperidol)	SS			ORAL
PER ORAL							
			Tegretol (Carbamazepine)	SS			ORAL
600 MG							
(DAILY) PER							
ORAL							
			Alvedon	C			
			Cipramil	C			
			Folacin	C			
			Sobril	C			
			Nozinan	C			
			Behepan	C			
			Polyfarmaci	C			

Date:04/07/99ISR Number: 3234475-0Report Type:Direct Company Report #
Age:40 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Cough		Haloperidol	PS			5MG BID, 1-5	
Hospitalization -	Dyspnoea						PRN	
Initial or Prolonged	Movement Disorder						AGITATION;	
	Nervous System Disorder						PRIOR TO	
	Neuroleptic Malignant						ADMIT	
	Syndrome		Lithium	SS			300MG BID	
	Pyrexia						PRIOR TO	
							ADMIT	

Date:04/07/99ISR Number: 3234656-6Report Type:Expedited (15-DaCompany Report #990325-008011210
Age:74 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Death	Foreign	Serenace Tablets					
Hospitalization - Initial or Prolonged		Health Professional	(Haloperidol)	PS		ORAL	1 MG, QD, ORAL	
			Risperidone	SS		ORAL	1 MG, QD, ORAL	
			Chlorprothixene Hydrochloride	SS		ORAL	30 MG, QD, ORAL	
			Metoprolol Succinate	C				
			Amlodipine Besilate	C				
			Propranolol Hydrochloride	C				
			Calcium Carbonate	C				
			Citalopram	C				
			Epoetin Alfa	C				
			Beko Forte	C				
			Ascorbic Acid	C				

Date:04/07/99ISR Number: 3234909-1Report Type:Expedited (15-DaCompany Report #2553/12541
Age:20 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Aggression	Health Professional	Depo-Provera Suspension	PS		INTRAMUSCULAR	200-400 MG-1Q3WK, IM	
	Balance Disorder							
	Clonic Convulsion							
	Condition Aggravated		Lithium	SS		ORAL		
	Convulsion		Depakote (Divalproex)	SS		ORAL		
	Drug Interaction							
	Psychotic Disorder		Haldol (Haloperidol)	SS				

			Ritalin (Methylphenidate Hcl)	C		

Date:04/08/99ISR Number: 3234973-XReport Type:Expedited (15-DaCompany Report #990329-008011259
Age:45 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Hospitalization - Initial or Prolonged	Depressed Level Of Consciousness	Foreign Health	Haloperidol Tablets	PS		ORAL 10 MG, QD, ORAL
	Syncope	Professional	Lithium Acetate	SS		ORAL 900 MG, QD ORAL
			Lorazepam	SS		ORAL 1.5 MG, QD,ORAL
			Diclofenac Sodium	SS		ORAL 150 MG, QD, ORAL
			Flunitrazepam	SS		ORAL QD ORAL
			Valproic Acid	C		
			Lorazepam	C		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/08/99ISR Number: 3234976-5Report Type:Expedited (15-DaCompany Report #990329-008011260
Age:41 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Life-Threatening	Arrhythmia	Foreign	Haldol Tablets				
Hospitalization - Initial or Prolonged	Chest Discomfort	Health	(Haloperidol)	PS		ORAL	35 MG, QD, ORAL
	Conduction Disorder	Professional					
	Myocardial Infarction		Melperone	SS		ORAL	50 MG, QD ORAL
	Nausea						
			Haldol Tablets (Haloperidol)	SS		ORAL	15 MG, QD ORAL
			Tiapride	C			

Date:04/08/99ISR Number: 3234978-9Report Type:Expedited (15-DaCompany Report #990330-008011268
Age:23 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Dysarthria	Foreign	Haloperidol				
	Gait Disturbance	Health	Decanoate	PS			INTRAMUSCULAR 3 ML/2 ML, QD, IM (INTRAMUSCULAR)
	Visual Disturbance	Professional					
			Carbamazepine	C			
			Fluoxetine	C			
			Diazepam	C			

Date:04/09/99ISR Number: 3236636-3Report Type:Expedited (15-DaCompany Report #199910462NHMR
Age:46 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Creatine Phosphokinase Increased	Foreign Health Professional	Furosemide (Lasix) Tablets	PS		ORAL	60 MG/DAY PO	
	Blood Lactate Dehydrogenase Increased		Haloperidol (Linton) Tablets	SS		ORAL	12 MG/DAY PO	
	Hypokalaemia Myoglobin Blood Increased		Pravastatin Sodium (Mevalotin) Tablets	SS		ORAL	10 MG/DAY PO	
	Rhabdomyolysis		Bezafibrate (Bezatol-Slow Release) Tablets	SS		ORAL	400 MG/DAY PO	
			Biperiden Hydrochloride	C				
			Bromperidol	C				

Date:04/09/99ISR Number: 3237694-2Report Type:Direct Company Report #
Age:64 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Neuroleptic Malignant Syndrome	Health Professional	Haloperidol	PS		ORAL	10MG, 2MG AM/P, ORAL	
			Benztropine Mesylate	C				
			Haloperidol	C				
			Oxazepam	C				
			Milk Of Magnesia	C				
			Lorazepam Inj	C				
			Acetaminophen	C				
			Trazodone Hcl	C				
			Multivitamin	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/12/99ISR Number: 3238079-5Report Type:Expedited (15-DaCompany Report #US_990217941
Age:47 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Agitation	Study	Haloperidol	PS			2 DSG FORM	
Initial or Prolonged	Blood Creatine	Health						DAY
	Phosphokinase Increased	Professional	Benztropine(Benzatro					
	Blood Pressure Increased		pine)	SS			4 DSG FORM	
	Bronchitis							DAY
	Bronchospasm		Valium(Diazepam)	C				
	Condition Aggravated		Colace(Docusate					
	Depressed Level Of		Sodium)	C				
	Consciousness		Amoxicillin	C				
	Hallucination, Auditory		Benadryl(Diphenhydra					
	Heart Rate Increased		mine Hydrochloride)	C				
	Neuroleptic Malignant		Acetaminophen	C				
	Syndrome		Trilafon(Perphenazin					
	Paranoia		e)	C				
	Rhinorrhoea		Lorazepam	C				
	Tachycardia							

Date:04/12/99ISR Number: 3240206-0Report Type:Periodic Company Report #802703002
Age:49 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Blindness		Haloparidol	PS			INTRAVENOUS	2.5MG PRN,
	Haemorrhagic Stroke						INTRAVENOUS	
			Fentanyl	SS			INTRAVENOUS	100MCG,
							INTRAVENOUS	
			Heparin	SS				
			Cortisone	C				
			Diazepam	C				
			Antineopl	C				

Date:04/13/99ISR Number: 3239105-XReport Type:Expedited (15-DaCompany Report #990402-008011335
Age: Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Brain Damage	Foreign	Haloperidol Tablets	PS		ORAL	5 MG, BID,	
	Medication Error	Health					ORAL	
	Respiratory Depression	Professional	Diazepam	C				
			Gabapentin	C				
			Topiramate	C				
			Carbamazepine	C				

Date:04/15/99ISR Number: 3240452-6Report Type:Direct Company Report #
Age:30 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Joint Stiffness		Haldol	PS				
	Migraine		Mellaril	SS				
	Pain							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/19/99ISR Number: 3242920-XReport Type:Expedited (15-DaCompany Report #990416-008011434
Age:17 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Attention	Foreign	Haloperidol	PS		ORAL	6 MG, QD,	
Hospitalization -	Deficit/Hyperactivity	Health						
Initial or Prolonged	Disorder	Professional	Bromperidol	SS		ORAL	6 MG, QD,	
	Dehydration							
	Depressed Level Of		Zotepine	SS		ORAL	50 MG, QD,	
	Consciousness							
	Fall		Chlorpromazine	SS		ORAL	50 MG, QD,	
	Heat Stroke							
	Myoglobinuria		Trihexyphenidyl	C				
	Oliguria		Nitrazepam	C				
	Pyrexia		Senna Extract	C				
	Stupor							

Date:04/19/99ISR Number: 3242921-1Report Type:Expedited (15-DaCompany Report #990416-008011435
Age:30 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Schizoaffective Disorder	Health	Haloperidol					
Initial or Prolonged	Schizophrenia	Professional	Decanoate	PS		INTRAMUSCULAR	100 MG,	
							1X/MO, IM	
							(INTRAMUSCULAR)	
			Risperidone	SS		ORAL	4 MG, QD,	
							ORAL	
			Carbamazepine	C				

			Benzotropine	C		
			Fluoxetine	C		

Date:04/19/99ISR Number: 3246158-1Report Type:Periodic Company Report #71130-001
Age:40 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Confusional State	Health Professional	Haloperidol Tablets Usp - Roxane Laboratories Inc	PS	Roxane Laboratories Inc	ORAL
5MG PO AM / 20MG PO HS						
			Dalmane	C		
			Dilantin	C		
			Actifed	C		
			Phenobarbital	C		
			Paxil	C		

Date:04/19/99ISR Number: 3246162-3Report Type:Periodic Company Report #71130-002
Age:17 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Confusional State	Health Professional	Haloperidol Tablets Usp, 2mg - Roxane Laboratories	PS	Roxane Laboratories	ORAL
2MG TID PO						
			Benztropine	C		
			Benadryl	C		
			Thorazine	C		
			Lorazepam	C		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/19/99ISR Number: 3246167-2Report Type:Periodic Company Report #71128-001
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Alopecia	Consumer	Haloperidol Tablets					
	Amnesia		Roxane Laboratories	PS	Roxane Laboratories			
UNKNOWN							UNK	
	Visual Disturbance							

Date:04/19/99ISR Number: 3246171-4Report Type:Periodic Company Report #71128-002
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dystonia	Consumer	Haloperidol Tablets					
			Roxane Laboratories	PS	Roxane Laboratories			
UNKNOWN							UNK	

Date:04/19/99ISR Number: 3246175-1Report Type:Periodic Company Report #71128-003
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Neuroleptic Malignant	Health	Haloperidol Roxane					
Hospitalization -	Syndrome	Professional	Laboratories, Inc.	PS	Roxane Laboratories			
UNKNOWN							UNK	
Initial or Prolonged								
Other								

Date:04/20/99ISR Number: 3243387-8Report Type:Expedited (15-DaCompany Report #990218-008010717
Age:39 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Blood Creatine	Foreign	Haldol Injection					
Initial or Prolonged	Phosphokinase Increased	Health	(Haloperidol)	PS				
INTRAVENOUS							10MG QD IV	
	Condition Aggravated	Professional						
(INTRAVENOUS)								
	Dehydration		Haldol Concentrate					

	Injury		(Haloperidol)	SS		ORAL
20MG QD ORAL,						
	Rhabdomyolysis					
10MG QD ORAL						
			Diazepam	C		

Date:04/21/99ISR Number: 3244473-9Report Type:Expedited (15-DaCompany Report #M095506
Age:48 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Drug Interaction	Study	Videx	PS		ORAL
PO 16 DAY						
Initial or Prolonged	Loose Associations	Health	Zerit	SS		ORAL
PO 16 DAY						
Other	Psychotic Disorder	Professional	Mkc442	SS		
16 DAY						
	Schizophrenia		Viracept	SS		
16 DAY						
			Placebo	SS		
16 DAY						
			Valproic Acid	SS		
			Haloperidol	SS		
			Benztropine Mesylate	C		

Date:04/22/99ISR Number: 3244849-XReport Type:Expedited (15-DaCompany Report #9902207
Age:38 YR Gender:Female I/FU:F

Outcome
Hospitalization -
Initial or Prolonged
Required
Intervention to

Prevent Permanent
Impairment/Damage

	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Akinesia	Foreign	Zoloft Tablets	PS		ORAL	50.00 MG	
	Blood Creatine Phosphokinase Increased	Health Professional					TOTAL: DAILY:	
	Depression		Haloperidol	SS		ORAL		
	Drug Interaction					INTRAMUSCULAR		MONTHLY;
	Hypokinesia		Tropatepine	C		INTRAMUSCULAR		
	Hyponatraemia		Valpromide	C				
	Liver Function Test Abnormal							
	Mental Impairment							
	Muscle Rigidity							
	Neuroleptic Malignant Syndrome							
	Parkinson'S Disease							
	Pyrexia							
	Salivary Hypersecretion							
	Tremor							

Date:04/23/99ISR Number: 3245972-6Report Type:Expedited (15-DaCompany Report #99HQ-10157
Age:33 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Agitation	Foreign	Clomipramine	PS			75 MG, DAILY,	
Initial or Prolonged	Blood Creatine	Literature	Haloperidol	SS			2 MG, DAILY	
	Phosphokinase Increased	Health	Sulpiride	SS			150 MG, DAILY	
	Cold Sweat	Professional	Trazodone	SS			150 MG, DAILY	
	Confusional State	Other	Disulfiram	SS			.5 G, DAILY	
	Depressed Level Of		Biperiden	SS			3 MG, DAILY	

	Consciousness		Etizolam	SS		
3 MG, DAILY						
	Dyskinesia					
	Hypotension					
	Neuroleptic Malignant					
	Syndrome					
	Pyrexia					
	Shock					
	Tachycardia					
	Tremor					

Date:04/27/99ISR Number: 3247962-6Report Type:Expedited (15-DaCompany Report #980928-002013692
Age:47 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Dystonia	Foreign	Haloperidol	PS		ORAL	2.5MG, HS,
Initial or Prolonged	Gait Disturbance	Study					ORAL
	Musculoskeletal Disorder	Health	Topiramate	SS		ORAL	200MG, QD,
	Sedation	Professional					ORAL/100MG QD
							ORAL
			Clonazepam	C			
			Carbamazepine	C			

Date:04/28/99ISR Number: 3248426-6Report Type:Direct Company Report #
Age:20 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Anxiety Decreased Appetite Dizziness Hair Growth Abnormal Headache Impulsive Behaviour Insomnia Libido Decreased Vision Blurred		Haldol Tabs Cogentin	PS C		ORAL	PO QID	

Date:04/30/99ISR Number: 3250790-9Report Type:Expedited (15-DaCompany Report #9916656
Age:50 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Cognitive Disorder Confusional State Disorientation Drug Interaction	Foreign Health Professional Company Representative	Zoloft Tablets Haloperidol	PS SS		ORAL	200.00 MG TOTAL; DAILY; ORAL	

Date:05/03/99ISR Number: 3252053-4Report Type:Expedited (15-DaCompany Report #001-0073-990070
Age:61 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Drug Interaction Drug Level Changed Schizoaffective Disorder	Health Professional	Dilantin (Phenytoin Sodium)	PS			100 MG TID, 50 MG QHS,	

UNKNOWN 3 YR

			Haldol (Haloperidol)	SS		
SEE TEXT,						
UNKNOWN						
			Risperdal (Risperidone)	C		

Date:05/05/99ISR Number: 3253954-3Report Type:Expedited (15-DaCompany Report #980604-008011956
Age:22 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Delusion	Foreign	Haloperidol Tablets					
Hospitalization -	Hallucination, Auditory	Study	(Haloperidol)	PS		ORAL	10 MG, 1 IN 1	
Initial or Prolonged	Schizophrenia	Health					DAY(S), ORAL	
	Suicidal Ideation	Professional	Risperidone (Risperidone)	SS		ORAL	10 MG, 1 IN 1	
							DAY(S), ORAL	

Date:05/07/99ISR Number: 3256554-4Report Type:Expedited (15-DaCompany Report #R039797
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Agitation	Study	Endocet	PS		ORAL	PRN PO	5 MON
Initial or Prolonged	Confusional State	Health	Oxycontin	SS		ORAL	60 MG Q8H PO	5 MON
	Disorientation	Professional	Ativan	SS		ORAL	0.5 MG PRN PO	
	Neutropenia		Xanax	SS		ORAL	1 G PRN PO	
			Restoril	SS		ORAL	15 MG PRN PO	
			Haldol	SS		ORAL	0.5 MG PRN PO	

			Cyclophosphamide	SS			
INTRAVENOUS	IV; 2 CYCLES						
			Lupron	C			
			Glucotrol	C			
			Lipitor	C			
			Trilisate	C			
			Rezulin	C			

Date:05/07/99ISR Number: 3256630-6Report Type:Expedited (15-DaCompany Report #JAFIN43776
Age:74 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardiac Arrest	Foreign	Serenase(Haloperidol					
Required	Condition Aggravated	Health	)	PS		ORAL	0.5 MG, 2 IN	
Intervention to	Electrocardiogram Qt	Professional						1 DAY(S),
Prevent Permanent	Prolonged							ORAL
Impairment/Damage	Glomerulonephritis		Risperdal(Risperidon					
	Chronic		e)	SS				
	Haematemesis		Truxal(Chlorprothixe					
	Haemodialysis		ne)	SS		ORAL	15 MG, 2 IN 1	
	Tachycardia							DAY(S), ORAL
	Torsade De Pointes		Seloken Zoc					
	Ventricular Fibrillation		(Metoprolol)	C				
	Ventricular Tachycardia		Norvasc(Tablet)					
			(Amlodipine)	C				
			Furesis(Tablet)					
			(Furosemide)	C				
			Obsidan(Capsules)					
			(Propranolol)	C				
			Calcium					
			Carbonate(Tablet)					
			(Calcium Carbonate)	C				
			Cipramil(Tablet)(Cit					
			alopram)	C				
			Eprex(Ampoule)(Epoet					
			in Alfa)	C				
			Beko Forte(Tablet)					
			(Vitamine B Complex)	C				
			Ascorbin (Tablet)					

			(Ascorbic Acid)	C		

Date:05/07/99ISR Number: 3256637-9Report Type:Expedited (15-DaCompany Report #JRFBEL1999000112
Age:63 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Apathy Autism	Foreign Literature	Haldol(Unspecified) (Haloperidol)	PS			DAILY,	
Required Intervention to Prevent Permanent Impairment/Damage	Cervix Carcinoma Gastrointestinal Necrosis Genital Haemorrhage Hysterectomy Inflammation Intestinal Obstruction Large Intestine Perforation Malaise Mental Impairment Necrosis Oedema Pyrexia	Health Professional	Levomepromazine(Levomepromazine) Nitrazepam(Nitrazepam) Picosulfate(Sodium Picosulfate)	C C C			UNKNOWN	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/10/99ISR Number: 3257909-4Report Type:Expedited (15-DaCompany Report #JAFIN43776
Age:74 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Death	Electrocardiogram Qt	Foreign	Risperdal				
Required	Prolonged		(Risperidone)	PS			(.5 MG 2
Intervention to	Haemodialysis						DAILY
Prevent Permanent	Tachycardia						01-JUL-97)
Impairment/Damage	Torsade De Pointes		Serenase				
			(Haloperidol)	SS		ORAL	0.5 MG, 2 IN
							1 DAY (S),
							ORAL
			Truxal				
			(Chlorprothixene)	SS		ORAL	15 MG, 2 IN 1
							DAY (S) ORAL
			Seloken	C			
			Norvasc	C			
			Furesis	C			
			Obsidan	C			
			Calcium Carbonate	C			
			Cipramil	C			
			Eprex	C			
			Beko Forte	C			
			Ascorbin	C			

Date:05/13/99ISR Number: 3261089-9Report Type:Expedited (15-DaCompany Report #970611-008011932
Age:18 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Restlessness	Foreign	Haloperidol	PS		ORAL	2 MG, QD,
Initial or Prolonged	Suicidal Ideation	Study					ORAL
		Health	Risperidone	SS		ORAL	2 MG, QD,

		Professional				
ORAL						

Date:05/13/99ISR Number: 3261092-9Report Type:Expedited (15-DaCompany Report #971202-008013270
Age:35 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Suicidal Ideation	Foreign	Haloperidol Tablets	PS		ORAL	4 MG, QD,	
		Study				ORAL		
		Health	Risperidone	SS		ORAL	2 MG, QD,	
		Professional				ORAL		

Date:05/13/99ISR Number: 3261095-4Report Type:Expedited (15-DaCompany Report #JACFRA1999000008
Age:84 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Colonic Obstruction	Foreign	Haldol (Unspecified)					
	Oral Intake Reduced	Health	(Haloperidol)	PS		ORAL		
ORAL								
Required	Vomiting	Professional	Nootropyl					
Intervention to			(Piracetam)	SS		ORAL		
ORAL								
Prevent Permanent			Lepticur					
Impairment/Damage			(Tropatepine					
			Hydrochloride)	SS		ORAL	10 MG, 1 IN 1	
DIALY, ORAL								
			Polaramine	C				
			Prozac	C				
			Stilnox	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/14/99ISR Number: 3262914-8Report Type:Expedited (15-DaCompany Report #980616-008012087
Age:52 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anxiety Lethargy Schizophrenia Social Avoidant Behaviour Weight Decreased	Foreign Study Health Professional	Haloperidol Risperidone	PS SS		ORAL ORAL	10 MG, QD, 5 MG, QD,	ORAL ORAL

Date:05/17/99ISR Number: 3266269-4Report Type:Periodic Company Report #9-002-772
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Injection Site Reaction	Health Professional	Haloperidol, 100 Mg	PS		INTRAMUSCULAR	350MG IM	MONTHLY

Date:05/17/99ISR Number: 3266270-0Report Type:Periodic Company Report #9-038-0772
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Injection Site Nodule	Health Professional	Haloperidol, 500 Mg (100 Mg/Ml) Multi-Dose	PS		INTRAMUSCULAR	200MG IM X 14	DAYS 14 DAY

Date:05/17/99ISR Number: 3266271-2Report Type:Periodic Company Report #9-033-0772
Age:45 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Injection Site Nodule	Health Professional	Haloperidol, 500 Mg (100 Mg/Ml) Multi-Dose	PS		INTRAMUSCULAR	225MG IM X 14	DAYS 14 DAY

Date:05/18/99ISR Number: 3264139-9Report Type:Expedited (15-DaCompany Report #9908636
Age:24 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hepatitis	Foreign	Abbott-Tranxene	PS	Abbott	ORAL	125.000 MG PO	QD
	Liver Function Test Abnormal	Health Professional	Haloperidol	SS		ORAL	PO OTH	
		Other	Carbamazepine	C				
			Lormetazepam	C				
			Trihexyphenidyl Hydro	C				

Date:05/18/99ISR Number: 3266275-XReport Type:Periodic Company Report #980611-107012017
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dermatitis Pyrexia	Health Professional Company Representative	Haldol, Unspecified (Haloperidol)	PS				
			Ultram Tablets	C				
			Phenytoin	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/18/99ISR Number: 3266276-1Report Type:Periodic Company Report #980821-107055648
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Pneumonia	Health Professional	Haldol Injection (Haloperidol)	PS		INTRAMUSCULAR (INTRAMUSCULAR)	ONCE, IM	1 (N) TIMES

Date:05/18/99ISR Number: 3266277-3Report Type:Periodic Company Report #980911-107013385
Age:42 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Condition Aggravated	Health Professional	Haldol, Unspecified (Haloperidol)	PS				
			Diazepam	C				

Date:05/18/99ISR Number: 3266278-5Report Type:Periodic Company Report #981028-107057410
Age:18 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Muscle Contractions Involuntary	Consumer	Haldol, Unspecified (Haloperidol)	PS			5 MG	
			Methylphenidate Hydrochloride	C				
			Paroxetine Hydrochloride	C				
			Buspirone Hydrochloride	C				
			Amitriptyline Hydrochloride	C				

Date:05/18/99ISR Number: 3266279-7Report Type:Periodic Company Report #981119-107058136
Age:87 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Pneumonia	Consumer Health Professional	Haldol Tablets (Haloperidol)	PS		ORAL	.5 MG, BID, ORAL	
			Verapamil	C				
			Levothyroxine Sodium	C				
			Venlafaxine Hydrochloride	C				
			Digoxin	C				

Date:05/18/99ISR Number: 3266280-3Report Type:Periodic Company Report #990122-107010288
Age:70 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Confusional State Hypernatraemia	Health Professional	Haldol Injection (Haloperidol)	PS		INTRAVENOUS	IV (INTRAVENOUS)	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/18/99ISR Number: 3266281-5Report Type:Periodic Company Report #990223-107051314
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Neuroleptic Malignant Syndrome	Health Professional	Haldol Injection (Haloperidol)	PS		INTRAVENOUS	IV	
		Company Representative				(INTRAVENOUS)		

Date:05/18/99ISR Number: 3266282-7Report Type:Periodic Company Report #990316-107011103
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Condition Aggravated	Consumer	Haloperidol Tablets, Generic Manufacturer Unspecified	PS		ORAL		YR

Date:05/18/99ISR Number: 3266283-9Report Type:Periodic Company Report #990325-107011212
Age:75 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agitation	Consumer	Haldol, Unspecified (Haloperidol)	PS			4 (N) TIMES	
	Confusional State							
	Insomnia							

Date:05/21/99ISR Number: 3267934-5Report Type:Expedited (15-DaCompany Report #R039797
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agitation	Study	Endocet	PS		ORAL	PRN PO	5 MON
	Confusional State	Health	Ativan	SS		ORAL	0.5 MG PRN PO	

	Disorientation	Professional	Xanax	SS			ORAL
1 G PRN PO							
	Haematocrit Decreased		Restoril	SS			ORAL
15 MG PRN PO							
	Haemoglobin Decreased		Haldol	SS			ORAL
0.5 MG PRN PO							
	Mental Disorder		Cyclophosphamide	SS			
INTRAVENOUS	1344-1290 MG						
	Neutropenia						
IV/2 CYCLES							
	Platelet Count Decreased		Oxycontin	SS			ORAL
60 MG Q8H PO	5 MON						
			Lupron	C			
			Glucotrol	C			
			Lipitor	C			
			Trilisate	C			
			Rezulin	C			

Date:05/24/99ISR Number: 3269092-XReport Type:Expedited (15-DaCompany Report #JRFBEL1999000134
Age:82 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Death	Anorexia	Foreign	Risperdal			
Hospitalization -	Delirium	Health	(Unspecified)			
Initial or Prolonged	Dysarthria	Professional	(Risperidone)	PS		ORAL
MG, DAILY ,						
	Dysphagia					
ORAL						
	Muscle Rigidity		Haloperidol (Tablet)			
	Muscle Spasms		(Haloperidol)	SS		ORAL
MCG, DAILY ,						
	Pyrexia					
ORAL						
	Renal Failure		Lofepramine			
	Respiratory Arrest		Hydrochloride	C		
	Tremor		Nicergoline	C		
			Amantadine Hcl	C		

			Etilozam	C		
			Zopiclone	C		
			Bromazepam	C		
			Aniracetam	C		
			Neurovitan	C		

Date:05/25/99ISR Number: 3269496-5Report Type:Expedited (15-DaCompany Report #JRFBEL1999000134
Age:82 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Abnormal Behaviour	Foreign	Haloperidol (Tablet)					
Hospitalization -	Anorexia	Health	(Haloperidol)	PS		ORAL	MCG, DAILY	
Initial or Prolonged	Condition Aggravated	Professional					ORAL	
	Decreased Appetite		Risperdal					
	Delirium		(Unspecified)					
	Dysarthria		(Risperidone)	SS		ORAL	MG DAILY ORAL	
	Dysphagia		Lofepramine					
	Malnutrition		Hydrochloride	C				
	Muscle Rigidity		Nicergoline	C				
	Musculoskeletal Stiffness		Amantadine Hcl	C				
	Pyrexia		Zopiclone	C				
	Respiratory Arrest		Bromazepam	C				
	Tremor		Aniracetam	C				
			Neurovitan	C				

Date:05/25/99ISR Number: 3269778-7Report Type:Expedited (15-DaCompany Report #US_981113683
Age:43 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Hostility	Study	Haloperidol	PS			15 MG/QHS AT	
Initial or Prolonged	Psychiatric Symptom	Health					BEDTIME	
		Professional	Benztropine					
			(Benzatropine)	SS			1 MG/BID DAY	
			Methocarbamol	C				
			Guaifenesin	C				

Date:05/27/99ISR Number: 3271033-6Report Type:Direct Company Report #
Age:95 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Medication Error		Haloperidol	PS	Mylan			
			Haloperidol	SS	Mylan			

Date:05/27/99ISR Number: 3271080-4Report Type:Direct Company Report #
Age:35 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Electrolyte Imbalance		Haloperidol	PS			CONTINOUS	
Initial or Prolonged	Hypokalaemia						INFUSION 7 MG	
	Torsade De Pointes		Flagyl	C				
	Ventricular Tachycardia		Lasix	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/27/99ISR Number: 3271255-4Report Type:Direct Company Report #
Age:51 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Drug Hypersensitivity		Haldol	PS				
FLUCUATES								
Life-Threatening								
BIRTH TO MAY								
Hospitalization -								
1999								
Initial or Prolonged			Penicillin	C				
Disability								
Congenital Anomaly								
Other								
Required								
Intervention to								
Prevent Permanent								
Impairment/Damage								

Date:05/27/99ISR Number: 3271261-XReport Type:Direct Company Report #
Age:56 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Blood Electrolytes		Haloperidol Drip 100					
Required	Abnormal		Mg (100 Ml D5w)	PS				
20 MG/HR CONT							2	DAY
Intervention to	Torsade De Pointes							
Prevent Permanent	Ventricular Tachycardia							
Impairment/Damage								

Date:06/01/99ISR Number: 3274966-XReport Type:Direct Company Report #
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Blood Sodium Decreased		Haloperidol	PS				
Initial or Prolonged	Confusional State							

Date:06/01/99ISR Number: 3275287-1Report Type:Expedited (15-DaCompany Report #JRFBEL1999000108
Age:58 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain Hepatitis Liver Function Test Abnormal	Foreign Health Professional	Haloperidol (Tablet) (Haloperidol)	PS		ORAL	MG, DAILY, ORAL	
			Risperidone (Tablet) (Risperidone)	SS		ORAL	MG, DAILY, ORAL	
			Nitrazepam	C				
			Tocopherol Acetate	C				
			Clotiazepam	C				

Date:06/01/99ISR Number: 3275290-1Report Type:Expedited (15-DaCompany Report #JRFBEL1999000092
Age:48 YR Gender:Male I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Anxiety Blood Chloride Decreased Blood Creatine Phosphokinase Increased Blood Sodium Decreased Confusional State Hyperhidrosis

		Leukocytosis Lymphopenia Muscle Rigidity Neutrophilia Salivary Hypersecretion Thrombocythaemia	Report Source Foreign Health Professional	Product	Role	Manufacturer	Route
Dose	Duration						
				Haloperidol (Unspecified) (Haloperidol)	PS		ORAL
MG, DAILY,							
ORAL							
				Risperidone (Tablet) (Risperidone)	SS		ORAL
MG DAILY,							
ORAL							
				Pipamperone Dihydrochloride (Unspecified) (Pipamperone)	SS		ORAL
MG, DAILY,							
ORAL							
				Sultopride Hydrochloride (Sultopride Hydrochloride)	SS		ORAL
MG, DAILY,							
ORAL							
				Levomepromazine Hydrochloride (Levomepromazine)	SS		ORAL
MG, DAILY,							
ORAL							
				Promethazine Hydrochloride (Promethazine Hydrochloride)	SS		ORAL
MG, DAILY,							
ORAL							
				Sennosides (Sennosides)	SS		ORAL
MG, DAILY,							
ORAL							

	Famotidine (Famotidine)	SS	ORAL
MG, DAILY,			
ORAL			
	Cetilo	SS	ORAL
DAILY, ORAL			
	Teprenone (Teprenone)	SS	ORAL
MG, DAILY,			
ORAL			
	Vegetamin-A (Vegetamin A)	SS	ORAL
ORAL			
	Zotepine (Zotepine)	SS	ORAL
MG, DAILY,			
ORAL			
	Flunitrazepam (Flunitrazepam)	SS	ORAL
MG, DAILY,			
ORAL			
	Biperiden Hydrochloride (Biperiden Hydrochloride)	SS	ORAL
MG, DAILY,			
ORAL			

Date:06/01/99ISR Number: 3275353-0Report Type:Expedited (15-DaCompany Report #JACGBR1999000078
Age:53 YR Gender:Female I/FU:I

Outcome
Hospitalization -
Initial or Prolonged
Required
Intervention to

Prevent Permanent
Impairment/Damage

	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Cardiac Arrest Torsade De Pointes	Foreign	Haldol Decanoat (Unspecified) (Haloperidol Decanoate)	PS			INTRAMUSCULAR	1 IN 1 MONTH(S), IM
			Aspirin(Acetylsalicylic Acid)	C				
			Oxybutynin(Oxybutynin)	C				
			Procyclidine(Procyclidine)	C				
			Metformin(Metformin)	C				
			Gliclazide(Gliclazide)	C				

Date:06/03/99ISR Number: 3275224-XReport Type:Direct Company Report #
Age:45 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Hypertensive Crisis		Haloperidol Decanoate 200mg Iv	PS			INTRAMUSCULAR	Q MONTH IM
			Zyprexa 10mg	SS		ORAL	QHS PO	

Date:06/04/99ISR Number: 3276568-8Report Type:Expedited (15-DaCompany Report #001-0073-990070
Age:61 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Drug Interaction	Health	Dilantin (Phenytoin					

Initial or Prolonged		Drug Level Above	Professional	Sodium)	PS			
100 MG TID,								
Other		Therapeutic						
50 MG QHS	3 YR							
		Drug Level Below		Haldol (Haloperidol)	SS			
SEE TEXT								
		Therapeutic		Risperdal				
		Drug Level Changed		(Risperidone)	C			
		Schizoaffective Disorder						

Date:06/07/99ISR Number: 3277665-3Report Type:Expedited (15-DaCompany Report #JRFBEL1999000227
Age:14 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Other	Blood Creatine	Literature	Haldol (Unspecified)			
	Phosphokinase Increased	Health	(Haloperidol)	PS		ORAL
MG, DAILY,						
	Coma	Professional	Haldol (Solution)			
	Delirium		(Haloperidol)	SS		
INTRAMUSCULAR	5 MG, 1 TIME					
	Depressed Level Of					
(S)						
	Consciousness					
	Muscle Rigidity					
	Neuroleptic Malignant					
	Syndrome					
	Pyrexia					

Date:06/08/99ISR Number: 3278016-0Report Type:Expedited (15-DaCompany Report #JRFBELI999000230
Age:55 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Aggression Condition Aggravated Delusion Depression Hallucination Irritability Nervousness Persecutory Delusion Psychiatric Symptom	Foreign Health Professional	Haldol (Unspecified) (Haloperidol) Chlorpromazine And Preparations (Chlorpromazine) Amoxapine (Amoxapine) Impromen (Unspecified) (Bromperidol) Mosapramine Hydrochloride (Mosapramine Hydrochloride)	PS C C C			MG, DAILY,	UNKNOWN

Date:06/09/99ISR Number: 3279039-8Report Type:Expedited (15-DaCompany Report #JRFBEL1999000134
Age:82 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death Hospitalization - Initial or Prolonged	Anorexia Cardiac Failure Cardiovascular Disorder Condition Aggravated Decreased Appetite Delirium Dysarthria Dysphagia Hallucination Hypertonia Insomnia	Foreign Health Professional	Haloperidol (Tablet) (Haloperidol) Risperdal (Unspecified) (Risperidone) Aniracetam (Aniracetam0 Lofepramine	PS SS SS		ORAL ORAL ORAL	MCG, DAILY, MG, DAILY, MG, DAILY,	ORAL ORAL ORAL

	Malnutrition		Hydrochloride	C		
	Muscle Rigidity		Nicergoline	C		
	Pyrexia		Amantadine Hcl	C		
	Renal Failure		Bromazepam	C		
	Respiratory Arrest		Neurovitan	C		
	Tremor					

Date:06/09/99ISR Number: 3279040-4Report Type:Expedited (15-DaCompany Report #JACFRA1999000059
Age:16 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Confusional State Hypertonia Mydriasis	Foreign	Haldol (Tablet) (Haloperidol)	PS		ORAL	15 MG, 1 IN 1	DAY(S), ORAL
	Neuroleptic Malignant Syndrome Restlessness Vomiting		Anafranil Lepticur Teralithe	C C C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/09/99ISR Number: 3279042-8Report Type:Expedited (15-DaCompany Report #JACFRA1999000062
Age:57 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Alkaline Phosphatase Increased	Foreign	Haldol (5 Mg Tablet) (Haloperidol)	PS		ORAL		
	Eosinophilia		Rulid					
	Gamma-Glutamyltransferase Increased		(Roxithromycin)	SS		ORAL	400 MG, 3 IN	1 DAILY, ORAL
	Rash Maculo-Papular		Tegretol (Carbamazepine)	SS		ORAL	50 MG, 2 IN 1	DAILY, ORAL
			Quintaxon (Doxepin Hydrochloride)	SS		ORAL		
			Dafalgan (Paracetamol)	SS		ORAL		

Date:06/09/99ISR Number: 3279046-5Report Type:Expedited (15-DaCompany Report #JRFBEL1999000275
Age:45 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Loss Of Consciousness	Foreign	Haldol (Unspecified)					
	Overdose	Health Professional	(Haloperidol)	PS		ORAL		
			Risperdal (Unspecified) (Risperidone)	SS		ORAL		

Date:06/09/99ISR Number: 3279155-0Report Type:Expedited (15-DaCompany Report #8-99153-144A
Age:56 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Other	Thrombocytopenia Tremor	Foreign Health Professional	Tavor Tablets (Lorazepam) Haldol (Haloperidol)	PS SS	ORAL 3 MG ORAL ORAL 6 MG DAILY DECREASED TO 3 MG DAILY ORAL
			Madopar (Levodopa / Benserazide)	SS	1 TABLET TWO TIMES DAILY (UNKNOWN IF INITIAL OR REDUCED
			Solinan	C	
			Haldol	C	
			Madopar	C	
			Stangyl	C	
			Diblocin	C	
			Rantil	C	
			Allohexal	C	

Date:06/09/99ISR Number: 3279319-6Report Type:Expedited (15-DaCompany Report #JRFBEL1999000134
Age:82 YR Gender:Female I/FU:F

Outcome	PT
Death	Anorexia
Hospitalization - Initial or Prolonged	Condition Aggravated
	Decreased Appetite
	Delirium

		Dysarthria Dysphagia Eating Disorder	Report Source	Product	Role	Manufacturer	Route	Dose Duration
		Fall Hypertonia Malnutrition	Foreign Health Professional	Risperdal (Unspecified)(Risperidone)	PS		ORAL	MG, DAILY,
		Muscle Rigidity						ORAL
		Pyrexia Respiratory Arrest Speech Disorder		Haloperidol (Tabler)(Haloperidol)	SS		ORAL	MCG, DAILY,
		Tremor						ORAL
				Aniracetam (Aniracetam)	SS		ORAL	MG, DAILY,
								ORAL
				Lofepramine Hydrochloride	C		ORAL	MG, DAILY,
								ORAL
				Nicergoline	C			
				Amantadine Hcl	C			
				Bromazepam	C			
				Neurovitan	C			

Date:06/11/99ISR Number: 3281269-6Report Type:Direct Company Report #
Age:31 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Required Intervention to Prevent Permanent Impairment/Damage	Muscle Spasms	Health Professional	Haloperidol 20 Mg Tablet	PS			ONE DOSE AT NIGHT

Date:06/11/99ISR Number: 3281721-3Report Type:Expedited (15-DaCompany Report #PRIUSA1999002038
Age:29 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Haemorrhage	Health	Haldol (Injection)					
	Internal Injury	Professional	(Haloperidol)	PS				
INTRAMUSCULAR							10 MG,	1
	Respiratory Arrest							
TIME(S), IM								
			Seroquel	C				
			Paxil	C				
			Trazadone	C				

Date:06/14/99ISR Number: 3282777-4Report Type:Expedited (15-DaCompany Report #B0066990
Age:27 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Conversion Disorder	Foreign	Zovirax Sterile					
	Decreased Appetite	Literature	Powder	PS				
INTRAVENOUS							250 MG	THREE
	Dehydration							
TIMES PER DAY								
	Excitability							
INTRAVENOUS								
	Fatigue		Haloperidol					
	Neuroleptic Malignant		(Formulation					
	Syndrome		Unknown)	SS				
SEE TEXT								
	Prostration							
	Psychiatric Symptom							
	Restlessness							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/16/99ISR Number: 3284290-7Report Type:Direct Company Report #
Age:58 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dystonia Mental Impairment Muscle Rigidity Neuroleptic Malignant Syndrome Tremor	Health Professional	Haloperidol	PS		INTRAMUSCULAR	HALOPERIDOL (UNKNOWN DOSE), HALOPERIDOL	IM Q 3 WEEKS

Date:06/16/99ISR Number: 3285127-2Report Type:Expedited (15-DaCompany Report #JACFRA1999000079
Age:6 DY Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Malaise	Foreign Health Professional	Haldol (1 Mg Tablet) (Haloperidol)	PS		ORAL	ORAL	

Date:06/16/99ISR Number: 3285130-2Report Type:Expedited (15-DaCompany Report #JACGBR1999000125
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Neuroleptic Malignant Syndrome Suicidal Ideation	Foreign Health Professional	Haldol (Unspecified) (Haloperidol)	PS				

Date:06/16/99ISR Number: 3285133-8Report Type:Expedited (15-DaCompany Report #JRFBEL1999000311
Age:32 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

	Extrapyramidal Disorder	Foreign	Haldol (Unspecified)		
	Irritability	Health	(Haloperidol)	PS	ORAL
MG, DAILY,					
	Suicidal Ideation	Professional			
ORAL					
			Risperidone (Tablet)		
			(Risperidone)	SS	ORAL
MG, DAILY,					
ORAL					
			Biperiden Hydrochloride (Biperiden Hydrochloride)	C	
			Vegetamin A	C	
			Zopiclone (Zopiclone)	C	
			Ruefrien (Ruefrien)	C	
			Vegetamin B (Vegetamin B (R))	C	

Date:06/18/99ISR Number: 3286510-1Report Type:Expedited (15-DaCompany Report #JRFBEL1999000134
Age:82 YR Gender:Female I/FU:F

Outcome	PT
Death	Abnormal Behaviour
Hospitalization - Initial or Prolonged	Anorexia
	Cardiac Failure
	Condition Aggravated
	Delirium
	Dysarthria

	Dysphagia Hypertonia Malnutrition	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Muscle Rigidity Musculoskeletal Stiffness Oral Intake Reduced	Foreign Health Professional	Risperdal (Unspecified) (Risperidone)	PS		ORAL	MG, DAILY,
	Pyrexia						ORAL
	Respiratory Arrest Tremor		Haloperidol (Tablet) (Haloperidol)	SS		ORAL	MCG, DAILY,
							ORAL
			Aniracetam (Aniracetam)	SS		ORAL	MG, DAILY,
							ORAL
			Lofepramine Hydrochloride (Lofepramine Hydrochloride)	C			
			Nicergoline (Nicergoline)	C			
			Amantadine Hcl (Amantadine Hydrochloride)	C			
			Bromazepam (Bromazepam)	C			
			Neurovitan (Neurovitan)	C			

Date:06/22/99ISR Number: 3288558-XReport Type:Expedited (15-DaCompany Report #JACFRA1999000096
Age:90 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Confusional State Fall Tremor	Foreign Health Professional	Haldol (2 Mg/Ml Solution) (Haloperidol)	PS		ORAL	DAILY, ORAL

Date:06/23/99ISR Number: 3289887-6Report Type:Expedited (15-DaCompany Report #JAKY043538
Age:59 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Akathisia Dyskinesia Salivary Hypersecretion Stomatitis	Foreign Health Professional	Risperidone (Tablet) (Risperidone)	PS		ORAL	6 MG, DAILY, ORAL	
			Bromperidol (Unspecified) (Bromperidol)	SS		ORAL	3 MG, DAILY, ORAL (SEE IMAGE)	
			Haloperidol Decanoate (Injection) (Haloperidol Decanoate)	SS		INTRAVENOUS DRIP	(100 MG DAILY 24-AUG-98) (50 MG DAILY 14-OCT-98)	
			Biperiden Hydrochloride	C				
			Sennoside (Tablet)	C				

			Tolbutamide (Tablet)	C			

Date:06/25/99ISR Number: 3291838-5Report Type:Expedited (15-DaCompany Report #JACFRA1999000102
Age:85 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agitation Confusional State Drug Withdrawal Syndrome Dysphagia Sedation	Foreign Health Professional	Haldol (2 Mg/Ml Solution) (Haloperidol)	PS		ORAL	20 MG, DAILY, ORAL	
			Melleril (Thioridazine Hydrochloride)	SS		ORAL	600 MG, DAILY, ORAL	
			Equanil	C				
			Digoxine	C				
			Innohep	C				
			Duphalac	C				

Date:06/25/99ISR Number: 3291840-3Report Type:Expedited (15-DaCompany Report #JAUK43769
Age:53 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Cardiac Arrest Cardiac Output Decreased Chest Pain Extrapyramidal Disorder Torsade De Pointes	Foreign Health Professional	Haldol Decanoate (Unspecified) (Haloperidol Decanoate)	PS			( ): ASSUMED FORM	
			Aspirin	C				
			Oxybutynin	C				
			Metformin	C				
			Gliclazide	C				

Date:06/25/99ISR Number: 3291842-7Report Type:Expedited (15-DaCompany Report #JACGER1999000133
Age:86 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death Other	Akinesia	Foreign Health Professional	Haldol (5 Mg/Ml Injection) (Haloperidol)	PS		INTRAVENOUS	IV	
			Digimerck (Digitoxin)	SS		INTRAVENOUS	DAILY, IV	
			Lasix (Furosemide)	SS		INTRAVENOUS	1 AMP, 2 IN 1	DAY(S), IV
			Xanef-Cor	C				
			Kalinor	C				
			Ben-U-Ron	C				
			Augmentan	C				

Date:06/25/99ISR Number: 3292012-9Report Type:Expedited (15-DaCompany Report #B0067655
Age:63 YR Gender:Male I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Depressed Level Of Consciousness Drug Level Above Therapeutic

Hypersensitivity

		Report Source	Product	Role	Manufacturer	Route	Dose Duration
		Foreign	Fortaz Injection	PS			
INTRAVENOUS	1 GRAMS/TWICE PER DAY/INTRAVENO US	Health Professional Company Representative	Haloperidol (Formuation Unknowna)	SS			
			Ranitidine Hydrochloride	C			
			Flunitrazepam	C			
			Alprazolam	C			

Date:06/25/99ISR Number: 3292065-8Report Type:Expedited (15-DaCompany Report #JACGER1999000123
Age:68 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged SEE IMAGE Required Intervention to Prevent Permanent Impairment/Damage	Cardiac Failure	Foreign	Haldol (Tablet)				
	Chills	Health	(Haloperidol)	PS		ORAL	
	Disorientation	Professional	Rulid				
	Neuroleptic Malignant Syndrome		(Roxithromycin)	C			
	Parkinsonism		Acc (Acetylcysteine)	C			
	Pneumonia		Concor (Bisoprolol Fumarate)	C			
	Pyrexia		...	C			
	Respiratory Failure		...	C			
	Tremor		...	C			
	Urinary Tract Infection		...	C			

Date:06/25/99ISR Number: 3292069-5Report Type:Expedited (15-DaCompany Report #JRFBEL1999000347
Age:25 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration

Hospitalization - Initial or Prolonged	Aggression	Foreign Health Professional	Haloperidol (Unspecified) (Haloperidol)	PS
	Akathisia			
	Akinesia			
SEE IMAGE				
	Eye Movement Disorder		Perphenazine	C
	Malaise		Mosapramine	C
	Suicide Attempt		Diazepam	C
			Sulpiride	C
			Biperiden	C

Date:06/25/99ISR Number: 3292078-6Report Type:Expedited (15-DaCompany Report #JRFBEL1999000121
Age:20 YR Gender:Female I/FU:I

Outcome	PT
Life-Threatening	Athetosis
Hospitalization - Initial or Prolonged	Dystonia
	Febrile Convulsion
	Loss Of Consciousness
	Muscle Rigidity
	Neuroleptic Malignant Syndrome
	Opisthotonus
	Prostration
	Pyrexia

Speech Disorder

		Report Source	Product	Role	Manufacturer	Route	Dose	Duration
		Foreign Health Professional	Haldoperidol (5 Mg Tablet) (Haloperidol)	PS		ORAL	MG, DAILY,	ORAL
			Clonazepam	C				
			Promethazine	C				
			Chlorpromazine	C				
			Trifuloperazine	C				
			Biperiden	C				

Date:06/25/99ISR Number: 3293277-XReport Type:Expedited (15-DaCompany Report #PRIUSA1999002550
Age:87 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Death	Literature Health Professional	Haldol (Unspecified) (Haloperidol)	PS		ORAL	ORAL	
			Mesoridazine (Mesoridazine)	SS		ORAL	ORAL	

Date:06/25/99ISR Number: 3293280-XReport Type:Expedited (15-DaCompany Report #PRIUSA1999002549
Age:74 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Death	Literature Health Professional	Haldol (Unspecified) (Haloperidol)	PS		ORAL	ORAL	

Date:06/25/99ISR Number: 3293287-2Report Type:Expedited (15-DaCompany Report #PRIUSA1999002548
Age:49 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Death	Literature	Haldol (Unspecified)					
		Health	(Haloperidol)	PS		ORAL		
ORAL								
		Professional						

Date:06/25/99ISR Number: 3293294-XReport Type:Expedited (15-DaCompany Report #PRIUSA1999002547
Age:47 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Overdose	Literature	Haldol (Unspecified)					
		Health	(Haloperidol)	PS		ORAL		
ORAL								
		Professional	Tranylcypromine					
			(Tranlcypromine)	SS		ORAL		
ORAL								

Date:06/25/99ISR Number: 3293302-6Report Type:Expedited (15-DaCompany Report #PRIUSA1999002546
Age:30 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Overdose	Literature	Haldol (Unspecified)					
		Health	(Haloperidol)	PS		ORAL		
ORAL								
		Professional	Fluoxetine					
			(Fluoxetine)	SS		ORAL		
ORAL								
			Lithium (Lithium)	SS		ORAL		
ORAL								

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/28/99ISR Number: 3292847-2Report Type:Expedited (15-DaCompany Report #WAES 99061391
Age:26 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anticholinergic Syndrome	Literature	Tab Cogentin 1 Mg	PS		ORAL	1 MG/TID/PO	1 DAY
	Bowel Sounds Abnormal	Health Professional	Tab Cogentin Unk	SS		ORAL	UNK / UNK / PO	3 DAY
	Bradykinesia		Sertraline 200 Mg	SS			UNK / UNK / UNK	
	Confusional State		Haloperidol 0.5 Mg	SS			0.5 MG / BID / UNK	2 WK
	Coordination Abnormal		Haloperidol 9 Mg	SS			UNK / UNK / UNK	
	Delirium		Lithiumco3 600 Mg	SS			UNK / UNK / UNK	2 DAY
	Disorientation		Lithiumco3 900 Mg	SS			UNK / UNK / UNK	3 DAY
	Drug Interaction							
	Dry Mouth							
	Dry Skin							
	Gastrointestinal Motility Disorder							
	Hallucination, Visual							
	Masked Facies							
	Muscle Rigidity							
	Mydriasis							
	Neurotoxicity							
	Parkinsonism							
	Skin Warm							
	Speech Disorder							
	Tremor							

Date:06/28/99ISR Number: 3292864-2Report Type:Expedited (15-DaCompany Report #WAES 99061391
Age:26 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Hospitalization -	Anticholinergic Syndrome	Literature	Cogentin	PS		ORAL
1 MG TID						
Initial or Prolonged	Bowel Sounds Abnormal	Health				
PO 3 DAY						
	Bradykinesia	Professional	Sertraline	SS		
	Coordination Abnormal		Haloperidol	SS		
0.5 MG BID						
	Delirium		Lithium	SS		
3 DAY						
	Disorientation					
	Drug Interaction					
	Dry Mouth					
	Dry Skin					
	Gastrointestinal Motility Disorder					
	Hallucination					
	Masked Facies					
	Muscle Rigidity					
	Mydriasis					
	Parkinsonism					
	Skin Warm					
	Speech Disorder					
	Tremor					

Date:06/28/99ISR Number: 3293380-4Report Type:Expedited (15-DaCompany Report #US_990623575
Age:71 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Abnormal Behaviour	Study	Haldol (Haloperidol)	PS		
4 DSG FORM/ 1						
Initial or Prolonged	Bipolar Disorder	Health				
AT BEDTIME						
	Condition Aggravated	Professional	Lansoprazole	C		
	Mania		Furosemide	C		
			Calcium Carbonate	C		
			Glipizide	C		

Lisinopril	C
Hexavitamin	C
Acetylsalicylic Acid	C
Magnesium Gluconate	C
Simvastatin	C
Darvocet-N	C
Lorazepam	C
Naproxen	C

Date:06/29/99ISR Number: 3294475-1Report Type:Direct Company Report #
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Interaction	Health Professional	Haldol	PS	Mcneil	INTRAMUSCULAR	HALDOL 5MG-IM	
			Cogentin	SS	Msd	INTRAMUSCULAR	COGENTIN 1MG-IM	
			...	C				
			Zoloft	C				

Date:06/29/99ISR Number: 3295220-6Report Type:Expedited (15-DaCompany Report #JRFBEL1999000275
Age:45 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Intentional Misuse Loss Of Consciousness Suicide Attempt	Foreign Health Professional	Haldol (Tablet) (Haloperidol)	PS		ORAL	MG, DAILY, ORAL	
			Risperdal (Tablet) (Risperidone)	SS		ORAL	MG, DAILY, ORAL	
			Brotizolam	C				
			Zopiclone	C				
			Nitrazepam	C				

			Promethazine Hydrochloride	C		

Date:06/29/99ISR Number: 3295222-XReport Type:Expedited (15-DaCompany Report #JACFRA1999000059
Age:16 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Blood Creatine Phosphokinase Increased	Foreign Health	Haldol (5 Mg Tablet) (Haloperidol)	PS		ORAL	15 MG, 1 IN 1 DAY(S), ORAL
	Confusional State	Professional					
	Hypertonia		Anafranil	C			
	Leukocytosis		Lepticur	C			
	Mydriasis		Teralithe	C			
	Neuroleptic Malignant Syndrome		Anafranil	C			
	Restlessness						
	Vomiting						

Date:07/01/99ISR Number: 3294896-7Report Type:Direct Company Report #
Age:39 YR Gender:Male I/FU:I

Outcome	PT
Death	Cold Sweat
	Coma

	Condition Aggravated Cyanosis Delusion	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
	Dermatitis		Haloperidol	PS		
5MG BID, 10MG						
	Respiratory Distress					
HS						
	Stridor		Lithium	SS		ORAL
900MG PO BID						
	Tremor					

Date:07/07/99ISR Number: 3298523-4Report Type:Expedited (15-DaCompany Report #JACFRA1999000149
Age:19 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Confusional State	Foreign	Haldol Decanoas (50			
Initial or Prolonged	Intentional Misuse	Health	Mg/Ml Injection)			
	Suicide Attempt	Professional	(Haloperidol			
			Decanoate)	PS		
INTRAMUSCULAR						
			Risperdal			
			(Unspecified)			
			(Risperidone)	SS		ORAL

Date:07/07/99ISR Number: 3298641-0Report Type:Expedited (15-DaCompany Report #JACFRA1999000139
Age:21 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Intentional Misuse	Foreign	Haldol (5 Mg Tablet)			
Initial or Prolonged	Pancreatitis Acute	Health	(Haloperidol)	PS		ORAL
MG, TOTAL,						
	Suicide Attempt	Professional				
ORAL						
			Risperdal (2 Mg			
			Tablet)			
			(Risperidone)	SS		ORAL
MG, TOTAL,						
ORAL						
			Aspirine			

		(Acetylsalicylic Acid)	SS	ORAL
G, TOTAL, ORAL				
		Solian (Amisulpride)	SS	ORAL
G, TOTAL, ORAL				
		Augmentin (Augmentin Injection)	SS	
INTRAVENOUS	G, TOTAL, IV			
		Athymil	C	
		Temesta	C	
		Rohypnol	C	
		Valium	C	
		Tercian	C	
		Equanil	C	
		Tranxene	C	
		Mopral	C	

Date:07/12/99ISR Number: 3301836-0Report Type:Expedited (15-DaCompany Report #B0066990
Age:27 YR Gender:Male I/FU:F

Outcome	PT
Other	Condition Aggravated
	Conversion Disorder
	Decreased Appetite
	Dehydration
	Excitability
	Fatigue

	Neuroleptic Malignant Syndrome Prostration Restlessness	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
		Foreign Literature	Zovirax Sterile Powder	PS		
INTRAVENOUS 250 MG / THREE TIMES PER DAY / INTRAVENOUS						
			Haloperidol (Formulation Unknown)	SS		

Date:07/12/99ISR Number: 3301930-4Report Type:Expedited (15-DaCompany Report #JACFRA1999000152
Age:59 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Myocardial Infarction	Foreign Health Professional	Haldol (5 Mg Tablet) (Haloperidol)	PS		ORAL
5 MG, 1 IN 1 DAY(S), ORAL						
		Company Representative	Risperdal (2 Mg Tablet) (Risperidone)	SS		ORAL
MG, DAILY, ORAL						
			Temesta (Lorazepam)	SS		ORAL
ORAL						

Date:07/13/99ISR Number: 3302484-9Report Type:Expedited (15-DaCompany Report #PRIUSA1999003040
Age:42 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Aggression	Literature	Haldol (Injection)			

	Agitation	Consumer	(Haloperidol)	PS			
, 1 TIME (S),							
	Loss Of Consciousness						
	Pulse Pressure Decreased						
	Vomiting						

Date:07/13/99ISR Number: 3302490-4Report Type:Expedited (15-DaCompany Report #JACFRA1999000153
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Thirst	Foreign	Haldol (Solution)				
	Weight Decreased	Health	(Haloperidol)	PS		ORAL	
ORAL							
		Professional	Risperdal				
		Company	(Tablet)(Risperidone				
		Representative	)	SS		ORAL	
MG, DAILY,							
ORAL							
			Nozinan	C			
			Depakine	C			

Date:07/13/99ISR Number: 3302733-7Report Type:Expedited (15-DaCompany Report #FLUV00399000533
Age:63 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Other	Neuroleptic Malignant	Foreign	Depromel 25mg	PS		ORAL	
25 MG BID PO,							
	Syndrome	Health	Tryptanol	SS		ORAL	
PO							
	Pyrexia	Professional	Serenace	SS		ORAL	
PO							
			Benzalin	SS		ORAL	
PO							
			Hirunamin	C		ORAL	
PO							

			Meilax	C		ORAL	PO
			Depas	C		ORAL	PO

Date:07/14/99ISR Number: 3303922-8Report Type:Expedited (15-DaCompany Report #JACFRA1999000157
Age:66 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death Life-Threatening	Hallucination	Foreign Health Professional	Haldol (2 Mg/Ml Solution) (Haloperidol)	PS		ORAL	10 MG, 3 IN 1	DAY (S), ORAL
			Motilium (10 Mg Tablet) (Domperidone)	SS		ORAL	DAILY, ORAL	
			Solu-Medrol (Methylprednisolone Sodium Succinate)	SS		INTRAVENOUS	IV	
			Antalvic (Dextropropoxyphene Hydrochloride)	SS		ORAL	MG, DAILY,	ORAL
			Tazocilline (Pip/Tazo)	SS		INTRAVENOUS	4 G, 3 IN 1	DAY(S), IV
			Duphalac	C				
			Maalox	C				

Date:07/15/99ISR Number: 3304653-0Report Type:Expedited (15-DaCompany Report #1998-002044 (0)
Age:48 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Hospitalization - Initial or Prolonged	Acute Psychosis Drug Interaction Loose Associations Thinking Abnormal	Study Health Professional Company	Viracept (Nelfinavir Mesylate) 250 Mg Tablets	PS		ORAL	1000MG TID, PER ORAL
		Representative Other	Mkc-442 250mg Or Placebo Tablets	SS		ORAL	750MG BID, PER ORAL
INTRAMUSCULAR	100MG Q 2WKS, INTRA-MUSCULAR		Haloperidol (Haldol)	SS			
			Valproic Acid (Depakote)	SS			360MG
			Furosemide	C			
			Verapamil	C			
			Benztropine	C			
			Stavudine	C			
			Didanosine	C			

Date:07/15/99ISR Number: 3304662-1Report Type:Expedited (15-DaCompany Report #B0067655
Age:63 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Blood Urea Decreased Depressed Level Of Consciousness Dyspnoea	Foreign Health Professional	Fortaz Injection	PS		INTRAVENOUS	PER DAY / INTRAVENOUS
			Flunitrazepam (Formulation Unknown)	SS		ORAL	PER DAY /

ORAL							
			Haloperidol (Formulation Unknown)	SS			ORAL
ORAL							
			Alprazolam (Formulation Unknown)	SS			ORAL
PER DAY /							
ORAL							
			Zonisamide (Formulation Unknown)	SS			ORAL
ORAL							
			Valporate Sodium (Formulation Unknown)	SS			ORAL
ORAL							

Date:07/15/99ISR Number: 3304731-6Report Type:Expedited (15-DaCompany Report #PRIUSA1999003302
Age:80 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Coma Confusional State	Foreign Health Professional	Ultram (50 Mg Tablet) (Tramadol Hydrochloride)	PS		ORAL	300, DAILY,	
ORAL								
			Depakine Crono (Valproate Sodium)	SS		ORAL	1000 MG, 1 IN	
1 DAILY, ORAL								
			Haldol (Tablet) (Haloperidol)	SS		ORAL	10, DAILY,	
ORAL								
			Colchicine (Colchicine)	C				
			Lopril (Captopril)	C				
			Loxen (Nicardipine					

			Hydrochloride)	C		

Date:07/16/99ISR Number: 3305839-1Report Type:Expedited (15-DaCompany Report #JACGBR1999000184
Age:30 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Circulatory Collapse Movement Disorder Simple Partial Seizures Tongue Oedema	Foreign Health Professional	Haldol (Unspecified)(Haloperidol)	PS		ORAL	1.5 MG, 1 IN 1 DAY(S), ORAL
			Diazepam	C			
			Cipramil	C			
			Omeprazole	C			
			Fybogel	C			

Date:07/16/99ISR Number: 3305843-3Report Type:Expedited (15-DaCompany Report #JACFRA1999000139
Age:21 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Intentional Self-Injury Necrosis Pancreatitis Acute Pancreatitis Relapsing	Foreign Health Professional	Haldol (5 Mg Tablet) (Haloperidol)	PS		ORAL	MG, TOTAL, ORAL
			Risperdal (2 Mg Tablet) (Risperidone)	SS		ORAL	MG, TOTAL,

ORAL			Aspirine (Acetylsalicylic Acid)	SS		ORAL
G, TOTAL,						
ORAL			Solian (Amisulpride)	SS		ORAL
G, TOTAL,						
ORAL			Augmentin (Augmentin Injection)	SS		
INTRAVENOUS	G, TOTAL, IV					
			Athymil	C		
			Temesta	C		
			Rohypnol	C		
			Valium	C		
			Terican	C		
			Equanil	C		
			Tranxene	C		
			Mopral	C		

Date:07/16/99ISR Number: 3312563-8Report Type:Periodic Company Report #800401001
Age:31 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Life-Threatening	Coma	Foreign	Droperidol	PS		
50 MG TOTAL						
		Health	Haloperidol	SS		
5MG TOTAL						
		Professional				

Date:07/19/99ISR Number: 3305833-0Report Type:Direct Company Report #
Age:45 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Feeling Abnormal		Haldol	PS		
	Sensory Disturbance					

Date:07/19/99ISR Number: 3306668-5Report Type:Expedited (15-DaCompany Report #US_981112682
Age:39 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Depression	Study	Haloperidol	PS			10 MG/HS AT	BEDTIME
	Hallucination	Health						
	Medication Error	Professional	Benztropine (Benzatropine)	SS			1 MG/D DAY	
	Psychiatric Symptom							
	Schizophrenia		Calan Sr	C				
	Suicidal Ideation		Aspirin	C				
			Tylenol	C				
			Restoril	C				
			Ativan	C				
			Dilantin	C				

Date:07/20/99ISR Number: 3307537-7Report Type:Expedited (15-DaCompany Report #PRIUSA1999002549
Age:74 YR Gender:Male I/FU:F

Outcome	PT
Death	Blood Creatine Phosphokinase Increased
Hospitalization - Initial or Prolonged	Blood Pressure Systolic Increased
	Cardiac Arrest
	Coma

	Confusional State						
	Heart Rate Increased						
	Hypertonia	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Hypotension	Literature	Haldol	PS		PARENTERAL	30 MG DAILY,
	Muscle Rigidity	Health				PARENT	2 DAY
	Myocardial Infarction	Professional					
	Pyrexia						
	Respiratory Failure						

Date:07/20/99ISR Number: 3307542-0Report Type:Expedited (15-DaCompany Report #PRIUSA1999002546
Age:30 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Death	Anticholinergic Syndrome	Literature	Haldol	PS		ORAL	ORAL
Hospitalization - Initial or Prolonged	Coma	Health	Fluoxetine				
	Convulsion	Professional	(Fluoxetine)	SS		ORAL	ORAL
	Disseminated		Lithium (Lithium)	SS		ORAL	ORAL
	Intravascular Coagulation		Cogentin				
	Drug Level Above		(Benzatropine				
	Therapeutic		Mesilate)	SS			
	Electrocardiogram Qrs		Amoxicillin				
	Complex Prolonged		(Amoxicillin)	SS			
	Epistaxis						
	Heart Rate Increased						
	Hypotension						
	Neuroleptic Malignant						
	Syndrome						
	Paralysis Flaccid						
	Pulmonary Oedema						
	Pupil Fixed						
	Pyrexia						
	Respiratory Rate						
	Decreased						
	Serotonin Syndrome						

Date:07/20/99ISR Number: 3307608-5Report Type:Expedited (15-DaCompany Report #PRIUSA1999002550
Age:87 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Agitation	Literature	Haldol (Unspecified)					
Hospitalization - Initial or Prolonged	Blood Creatine Phosphokinase Increased	Health Professional	(Haloperidol)	PS		ORAL	1 MG, DAILY, ORAL	
	Cardiac Failure		Serentil					
	Congestive		(Mesoridazine)	SS				
	Chronic Obstructive		Hytrin	C				
	Pulmonary Disease		Aricept	C				
	Dementia		Prevacid	C				
	Mental Impairment		Ventolin	C				
	Muscle Rigidity		Oxybutynin	C				
	Neuroleptic Malignant Syndrome							
	Pneumonia							
	Pyrexia							
	Renal Impairment							
	Respiratory Distress							
	Respiratory Rate Decreased							
	Tremor							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/21/99ISR Number: 3308187-9Report Type:Direct Company Report #
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Psychotic Disorder Thinking Abnormal		Haldol (Halperidol)	PS				

Date:07/21/99ISR Number: 3308344-1Report Type:Expedited (15-DaCompany Report #PRIUSA1999002548
Age:49 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death Hospitalization - Initial or Prolonged	Abdominal Pain Upper Back Pain Cardiac Arrest Chest X-Ray Abnormal Escherichia Infection Mental Impairment Metabolic Acidosis Muscle Rigidity Pyrexia	Literature Health Professional	Haldol (Unspecified) (Haloperidol) Benztropine (Benztropeine)	PS SS		ORAL ORAL		

Date:07/21/99ISR Number: 3308350-7Report Type:Expedited (15-DaCompany Report #PRIUSA1999002547
Age:47 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death Hospitalization - Initial or Prolonged	Blood Creatine Phosphokinase Increased Blood Ph Decreased Coma Haemorrhage Hyperglycaemia Hyperhidrosis Hyperpyrexia Hypotension Muscle Rigidity Neuroleptic Malignant Syndrome	Literature Health Professional	Haldol (Unspecified) (Haloperidol) Parnate (Tranylcypromine Sulfate)	PS SS		ORAL ORAL		10 MG, ORAL

	Tachycardia					

Date:07/22/99ISR Number: 3310396-XReport Type:Direct Company Report #
Age:18 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Insomnia		Haloperidol	PS		ORAL	10MG BID ORAL	
	Restless Legs Syndrome		Olanzapine	SS		ORAL	30MG QHS ORAL	

Date:07/23/99ISR Number: 3310009-7Report Type:Expedited (15-DaCompany Report #JRFBEL1999000541
Age:36 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Akathisia	Foreign	Haloperidol					
	Drug Eruption	Literature	(Unspecified)					
	Dyskinesia	Health	(Haloperidol)	PS			MG, DAILY,	
	Hallucination, Auditory	Professional					UNKNOWN	9 DAY
	Irritability		Risperidone					
	Malaise		(Unspecified)					
	Restlessness		(Risperidone)	SS		ORAL	MG, DAILY,	
							ORAL	

			Bromperidol (Unspecified) (Bromperidol)	SS			
MG, DAILY							
			Haloperidol (Unspecified) (Haloperidol)	SS			
MD, DAILY,							
UNKNOWN							
			Sulpiride (Sulpiride)	SS			
MG, DAILY							
			Risperidone (Unspecified) (Risperisone)	SS			ORAL
MG, DAILY,							
ORAL							
			Sulpiride (Sulpiride)	SS			
MG, DAILY							
			Biperiden (Biperiden)	C			
			Promethazine (Promethazine)	C			
			Etizolam (Etizolam)	C			
			Periciazine (Periciazine)	C			

Date:07/23/99ISR Number: 3310010-3Report Type:Expedited (15-DaCompany Report #JRFBEL1999000121
Age:20 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Athetosis	Foreign	Haldoperidol (5 Mg Tablet)					
Hospitalization - Initial or Prolonged	Dystonia	Health Professional	(Haloperidol)	PS		ORAL	MG, DAILY,	
	Febrile Convulsion						ORAL	
	Hereditary Cerebral Degeneration		Clonazepam	C				
	Loss Of Consciousness		Promethazine	C				
	Multiple Sclerosis		Chlorpromazine	C				
	Muscle Rigidity		Trifluoperazine	C				

	Neuroleptic Malignant Syndrome Opisthotonus Prostration Pyrexia Speech Disorder Tetanus		Biperiden	C			

Date:07/23/99ISR Number: 3310011-5Report Type:Expedited (15-DaCompany Report #JACFRA1999000187
Age:64 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Toxicity Electrocardiogram Abnormal Electrocardiogram Qt Prolonged	Foreign Health Professional	Haldol Decanoas (50 Mg/Ml Injection) (Haloperidol Decanoate)	PS		INTRAMUSCULAR	50 MG, MONTHLY, IM	
	Electrocardiogram T Wave Inversion		Seropram (Citalopram Hydrobromide)	SS		ORAL	ORAL	
	Sedation		Lexomil (Bromazepam)	SS		ORAL	ORAL	
	Sinus Bradycardia		Athymil (Mianserin Hydrochloride)	SS		ORAL	ORAL	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/23/99ISR Number: 3310437-XReport Type:Direct Company Report #
Age:21 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Erectile Dysfunction		Quetiapine	PS		ORAL	400 MG BID	
			Haloperidol	SS		ORAL	10 MG Q HS	

Date:07/26/99ISR Number: 3310669-0Report Type:Expedited (15-DaCompany Report #PRIUSA1999003733
Age:40 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Hepatitis Cholestatic	Health	Haldol (Tablet)					
Hospitalization - Initial or Prolonged	Jaundice	Professional	(Haloperidol)	PS		ORAL	5 MG, 2 IN 1	DAILY
	Lethargy							
			Haldol Decanoate (Injection) (Haloperidol Decanoate)	SS		INTRAMUSCULAR	50 MG, 1 TIME	(S)

Date:07/26/99ISR Number: 3311092-5Report Type:Expedited (15-DaCompany Report #US_981112682
Age:39 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Aggression	Study	Haloperidol	PS			10 MG/HS AT	BEDTIME
	Depression	Health						
	Hallucination	Professional	Benztropine					

	Hallucination, Auditory		(Benzatropine)	SS		
1 MG/D DAY						
	Medication Error		Calan Sr	C		
	Schizophrenia		Aspirin	C		
	Suicidal Ideation		Tylenol	C		
	Suicide Attempt		Restoril	C		
			Ativan	C		
			Dilantin	C		

Date:07/28/99ISR Number: 3312764-9Report Type:Expedited (15-DaCompany Report #210470
Age:21 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Gastric Ulcer	Foreign	Valium (Diazepam) 5 Mg	PS		ORAL	ORAL
	Overdose	Other					
	Suicide Attempt		Aspirine (Aspirin) 500 Mg	SS		ORAL	ORAL
			Rohypnol (Flunitrazepam)	SS		ORAL	ORAL
			Temesta (Lorazepam) 1 Mg	SS		ORAL	ORAL
			Solian (Amisulpride) 200 Mg	SS		ORAL	ORAL
			Haldol (Haloperidol) 5 Mg	SS		ORAL	ORAL
			Athymil (Mianserin Hydrochloride) 60 Mg	SS		ORAL	ORAL
			Risperdal (Risperidone) 2 Mg	SS		ORAL	ORAL
			Tercian (Cyamemazine) 100 Mg	SS		ORAL	ORAL

			Equanil (Meprobamate) 400 Mg	SS		ORAL	ORAL
			Tranxene (Clorazepate Dipotassium) 10 Mg	SS		ORAL	ORAL

Date:07/28/99ISR Number: 3312887-4Report Type:Expedited (15-DaCompany Report #DEU001912
Age:44 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Blood Creatine Phosphokinase Increased	Foreign Health	Akineton Serenace	PS SS		ORAL ORAL	3 MG DAILY PO 18 MG DAILY
	Blood Pressure Increased	Professional					PO
	Dysphagia		Levotomin	C			
	Epistaxis		Hiberna	C			
	Hyperhidrosis		Silece	C			
	Hypokinesia		Lendormin	C			
	Increased Appetite		Cremin	C			
	Neuroleptic Malignant Syndrome						
	Oral Intake Reduced						
	Parkinsonism						
	Pyrexia						
	Tremor						
	Vomiting						

Date:07/29/99ISR Number: 3313935-8Report Type:Expedited (15-DaCompany Report #S99-FRA-01339-01
Age:64 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Electrocardiogram Qt	Foreign	Seropram	PS			
Initial or Prolonged	Prolonged	Health	Athymil	SS			60 MG ONCE
	Electrocardiogram T Wave	Professional	Lexomil	SS			MG QD

	Inversion	Other	Haldol Decanoate	SS			
INTRAMUSCULAR	MG ONCE						
	Sedation						
	Sinus Bradycardia						

Date:07/30/99ISR Number: 3315577-7Report Type:Direct Company Report #
Age:29 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Creatine Phosphokinase Increased		Haldol	PS			5MG BID	
	Dysarthria							
	Mental Impairment							
	Muscle Rigidity							
	Neuroleptic Malignant Syndrome							
	Vision Blurred							

Date:07/30/99ISR Number: 3317792-5Report Type:Periodic Company Report #98403.01
Age:26 YR Gender:Male I/FU:I

Outcome	PT
Other	Fatigue
	Increased Appetite
	Lethargy

Weight Increased

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
		Consumer	Haloperidol Tablets 0.5 Mg Mylan	PS	Mylan	ORAL	0.5 MG BID,	ORAL

Date:07/30/99ISR Number: 3317796-2Report Type:Periodic Company Report #98565.01
Age:68 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dermatitis Pruritus	Consumer	Haloperidol Tablets 0.5 Mg Mylan	PS	Mylan	ORAL	0.25 MG QHS,	ORAL
			Combivent And Tylenol	C				

Date:07/30/99ISR Number: 3317802-5Report Type:Periodic Company Report #98378.01
Age:85 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Torticollis Tremor	Consumer	Haloperidol Tablets 5 Mg Mylan	PS	Mylan	ORAL	5 MG QD, ORAL	
			Tenormin	C				
			Cardura	C				
			Plendil	C				
			Synthroid	C				
			Enteric-Coated Aspirin	C				
			Multi-Vitamin	C				
			Prozac	C				

Date:07/30/99ISR Number: 3317803-7Report Type:Periodic Company Report #98468.01
Age:23 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Interaction Hostility	Consumer	Haloperidol Tablets 5 Mg Mylan	PS	Mylan	ORAL	10 MG QAM,	
	Insomnia						ORAL	
	Musculoskeletal Stiffness Sedation		Hydroxyzine 50 Mg Zenith Goldline	SS	Zenith Goldline	ORAL	10 MG QAM,	
							ORAL	

Date:07/30/99ISR Number: 3317805-0Report Type:Periodic Company Report #98858.01
Age:31 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Anorexia Insomnia	Consumer	Haloperidol Tablets 5 Mg Mylan	PS	Mylan	ORAL	10 MG Q AM &	
	Vomiting						10 MG QHS,	
							ORAL	
			Zyprexa 15 Mg Q Hs	C				
			Clonazepam 1 Mg Qam And 0.5mg Qhs	C				
			Trihexiphenydyl 2 Mg Qhs	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/30/99ISR Number: 3317808-6Report Type:Periodic Company Report #990049.01
Age:59 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blepharitis Keratoconjunctivitis Sicca	Consumer	Haloperidol Tablets 1 Mg Mylan	PS	Mylan	ORAL	1 MG QD, ORAL	

Date:07/30/99ISR Number: 3317810-4Report Type:Periodic Company Report #990427.01
Age:48 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Anorexia Arthralgia Dizziness Dry Mouth	Consumer	Haloperidol Tablets 1 Mg Mylan	PS	Mylan	ORAL	0.5 MG QD; THEN 0.25 MG QD, ORAL	
	Headache		Nortriptyline Capsules 50 Mg Danbury	SS	Danbury			

Date:08/02/99ISR Number: 3316370-1Report Type:Expedited (15-DaCompany Report #JACFRA1999000208
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Oedema Peripheral	Foreign Health Professional	Haldol Decanoas (50 Mg/Ml Injection) (Haloperidol Decanoate)	PS			INTRAMUSCULAR	1 IN 1 MONTH(S), IM
			Akineton Lp (Biperiden Hydrochloride) Tercian	C				

			(Cyamemazine)	C		
			Imovane (Zopiclone)	C		
			Cycloteriam (Cyclteriam)	C		

Date:08/02/99ISR Number: 3316374-9Report Type:Expedited (15-DaCompany Report #JACFRA1999000187
Age:64 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Toxicity	Foreign Health Professional	Haldol Decanoas (50 Mg/Ml Injection) (Haloperidol Decanoate)	PS		INTRAMUSCULAR	50 MG, MONTHLY, IM	
	Electrocardiogram Abnormal							
	Electrocardiogram Qt Prolonged							
	Sedation		Seropram (Citalopram Hydrobromide)	SS		ORAL		
	Sinus Bradycardia					ORAL		
			Lexomil (Bromazepam)	SS		ORAL	TABLE, DAILY,	
						ORAL		
			Athymil (Mianserin Hydrochloride)	SS		ORAL	TABLE, DAILY,	
						ORAL		

Date:08/02/99ISR Number: 3317161-8Report Type:Expedited (15-DaCompany Report #JACFRA1999000209
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Life-Threatening	Cardiac Index Increased	Foreign	Haldol (2 Mg/Ml				
Hospitalization -	Cardiomegaly	Health	Solution)				
Initial or Prolonged	Congenital Cardiovascular	Professional	(Haloperidol)	PS		ORAL	300 DROP,
Congenital Anomaly	Anomaly						DAILY, ORAL
Required	Cyanosis Neonatal		Haldol (2 Mg/Ml				
Intervention to	Dilatation Ventricular		Solution)				
Prevent Permanent	Echography Abnormal		(Haloperidol)	SS	R W Johnson	ORAL	150 DROP
Impairment/Damage	Hypoglycaemia Neonatal						DAILY ORAL
	Hypotonia Neonatal		Haldol Decanoas (50				
	Maternal Drugs Affecting		Mg/Ml Injection)				
	Foetus		(Haloperidol				
	Neonatal Disorder		Decanoate)	SS			
INTRAMUSCULAR	50 MG, 1 IN 1						
	Oxygen Saturation						MONTH (S),
	Decreased						IM; UTERINE
	Supraventricular		Imovane (Zopiclone)	SS		ORAL	1 TABLE,
	Tachycardia						DAILY, ORAL;
	Ventricular Septal Defect						UTERINE

Date:08/02/99ISR Number: 3317165-5Report Type:Expedited (15-DaCompany Report #JACFRA1999000198
Age:84 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Abnormal Faeces	Foreign	Haldol Faible (0.5				
Initial or Prolonged	Anorexia	Health	Mg/Ml Solution)				
Required	Intestinal Obstruction	Professional	(Haloperidol)	PS		ORAL	5 MG, DAILY,
Intervention to							ORAL
Prevent Permanent							

Impairment/Damage

Date:08/04/99ISR Number: 3319408-0Report Type:Expedited (15-DaCompany Report #8-99210-164A
Age:46 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hypercapnia Intentional Misuse	Foreign Health Professional	Seresta Capsules (Oxazepam)	PS		ORAL	750 MG ONE	
Other	Sedation							TIME
Required			Athymil (Mianserin)	SS		ORAL	180 MG ONE	
Intervention to Prevent Permanent Impairment/Damage			Haldol (Haloperidol) Tablets	SS		ORAL	200 MG ONE	
								TIME
			Imovane (Zopiclone)	SS		ORAL	112.5 MG ONE	
								TIME
			Tegretol Lp (Carbamazepine)	SS		ORAL	2 GRAMS ONE	
								TIME
			Valium (Diazepam)	SS		ORAL	80 MG ONE	
								TIME
			Potassium	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/05/99ISR Number: 3322028-5Report Type:Direct Company Report #
Age:41 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Tardive Dyskinesia	Health Professional	Haloperidol	PS		ORAL	2MG X3 (6MG) PO QHS	19 MON
			Neurontin	C				
			Zoloft	C				
			Tegretol	C				
			Gabitril	C				
			Thiamine	C				

Date:08/06/99ISR Number: 3321524-4Report Type:Direct Company Report #
Age:41 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Brain Oedema		Haloperidol	PS				
	Cardio-Respiratory Arrest							
	Cerebral Ischaemia							
	Circulatory Collapse							
	Coma							
	Drug Abuser							
	Encephalopathy							
	Hypertension							
	Injury							
	Laboratory Test Abnormal							
	Miosis							
	Myocardial Infarction							
	Nervous System Disorder							
	Pulse Pressure Increased							
	Pyrexia							
	Toxicologic Test Abnormal							
	Urine Analysis Abnormal							

Date:08/09/99ISR Number: 3321511-6Report Type:Direct Company Report #
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Other	Speech Disorder		Haldol	PS		
INTRAMUSCULAR 10 MG IM	Tongue Oedema					

Date:08/09/99ISR Number: 3321838-8Report Type:Expedited (15-DaCompany Report #99F--10702
Age:84 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Coronary Artery Disease Drug Interaction Fall	Foreign Health Professional	Anafranil Tablet (Clomipramine Hydrochloride)	PS		ORAL	45 MG, DAILY,	
	Guillain-Barre Syndrome	Other					ORAL	
	Myocardial Infarction Nervous System Disorder		Haldol Solution (Haloperidol)	SS		ORAL	15 DF, DAILY,	
	Pulmonary Embolism						ORAL	
	Sedation		Diamox	C				
	Serotonin Syndrome		Speciafoldine	C				
	Syncope							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/09/99ISR Number: 3322624-5Report Type:Direct Company Report #
Age:73 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hypotension		Haloperidol	PS				
			Magnesium Hydroxide	C				
			Ipratropium Bromide	C				
			Morphine Sr	C				
			Docusate Na	C				
			Hydrocodone 5/Apap	C				
			Atenolol	C				
			Nifedipine Cc	C				
			Multivitamin	C				
			Prochlorperazine	C				
			Famotidine	C				
			Oxychicine	C				
			Milk Of Magnesia	C				
			Fexofenadine	C				
			Cefazolin	C				
			Nitroglycerin 0.2mg/Hr Patch	C				
			Saslate	C				
			Aspirin Enteric Coated	C				

Date:08/12/99ISR Number: 3324836-3Report Type:Expedited (15-DaCompany Report #8-99216-204A
Age:60 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hypotension Malaise	Foreign Health Professional	Seresta Capsules (Oxazepam)	PS		ORAL	50 MG ONCE	
Other	Medication Error						DAILY ORAL	
			Haldol (Haloperidol) Tablets	SS		ORAL	ORAL	
			Prothiaden (Dosulepine)	SS		ORAL	ORAL	
			Xanax (Alprazolam) Tablets	SS		ORAL	ORAL	

Date:08/13/99ISR Number: 3325391-4Report Type:Direct Company Report #
Age:55 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Torsade De Pointes	Health	Haldol 20mg Dose; 75					
Hospitalization -	Ventricular Tachycardia	Professional	Mg/24 Hr	PS				
						INTRAVENOUS	75 MG/24 HR	
Initial or Prolonged								
IV							2	DAY
Required			Versed	C				
Intervention to			Ativan	C				
Prevent Permanent			Valium	C				
Impairment/Damage			Vecuronium	C				
			Fentanyl	C				
			Propotol	C				
			Labertalol	C				
			Thiamine	C				
			Mg So4	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/13/99ISR Number: 3325546-9Report Type:Expedited (15-DaCompany Report #S99-FRA-01339-01
Age:64 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Depressed Level Of Consciousness	Foreign Health Professional	Seropram (Citalopram)	PS			60 MG ONCE	
	Electrocardiogram Qt Prolonged	Other	Athymil	SS			MG QD	
	Electrocardiogram T Wave Inversion		Lexomil	SS		INTRAMUSCULAR	MG ONCE IM	
	Sedation		Haldol Decanoate	SS				
	Sinus Bradycardia							

Date:08/13/99ISR Number: 3326079-6Report Type:Expedited (15-DaCompany Report #JACFRA1999000221
Age:60 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hypotension	Foreign	Haldol	PS		ORAL	ORAL	
	Malaise	Health Professional	Prothiaden	C				
	Medication Error		Xanax	C				
			Seresta	C				

Date:08/16/99ISR Number: 3326503-9Report Type:Direct Company Report #
Age:90 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agitation	Health Professional	Haldol 5mg Injection	PS			1MG/M Q 3-4 HRS PRN	2 DAY
	Condition Aggravated							
Required	Delirium		Risperdal 1mg Tab	SS		ORAL	1MG 1 PO QHS	2 DAY
Intervention to Prevent Permanent Impairment/Damage	Hallucination							

Date:08/16/99ISR Number: 3326765-8Report Type:Expedited (15-DaCompany Report #JACFRA1999000232
Age:65 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death Life-Threatening	Hepatitis Fulminant Renal Failure Acute	Foreign Health Professional	Haldol (Unspecified) (Haloperidol)	PS		ORAL	MG, DAILY, ORAL	
			Mepronizine (Mepronizine)	SS		ORAL	MG, DAILY, ORAL	
			Noctran	SS		ORAL	TABLE, DAILY, ORAL	
			Theralene (Alimemazine Tartrate)	SS		ORAL	MG, DAILY, ORAL	
			Cholstat (Cerivastatin)	SS		ORAL	0.3 MG, DAILY, ORAL	

Date:08/16/99ISR Number: 3330351-3Report Type:Expedited (15-DaCompany Report #US_980910574
Age:52 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Aggression Akathisia Condition Aggravated Delusion Psychotic Disorder Restlessness Schizophrenia Suicidal Ideation	Study Health Professional	Haloperidol Benztropine (Benzatropine) Clozapine	PS SS C			10 MG/QHS AT BEDTIME 4 MG/D DAY	

Date:08/17/99ISR Number: 3327380-2Report Type:Expedited (15-DaCompany Report #JACFRA1999000242
Age:80 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hepatitis Cholestatic Hepatomegaly Knee Arthroplasty	Foreign Health Professional	Haldol Faible (0.5mg/Ml Solution) (Haloperidol) Dafalgan (Paracetamol) Zyloric (Allopurinol) Diamicron (Gliclazide) Zocor (Simvastatin)	PS SS SS SS SS		ORAL ORAL ORAL ORAL ORAL	DROP, DAILY, 3 G, DAILY, 300 MG, DAILY, 0.5 TABLE, DAILY, 20 MG, 1 IN 1	

DAY(S), ORAL

			Fraxiparine (Heparin-Fraction, Calcium Salt)	SS		
SUBCUTANEOUS	SUBCU					

Date:08/17/99ISR Number: 3327402-9Report Type:Expedited (15-DaCompany Report #JRFBEL1999000663
Age:26 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dysphonia Dyspnoea Dystonia Emotional Distress Laryngeal Disorder Pharyngolaryngeal Pain Stridor Vocal Cord Disorder	Literature Health Professional	Haloperidol (Unspecified) (Haloperidol)	PS				

Date:08/17/99ISR Number: 3327407-8Report Type:Expedited (15-DaCompany Report #JACFRA1999000227
Age:1 DY Gender:Male I/FU:I

Outcome	PT
Disability Congenital Anomaly	Complications Of Maternal Exposure To Therapeutic Drugs Hemivertebra Hypospadias Induced Labour

	Kyphosis Spine Malformation Synostosis	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
		Foreign Health Professional	Haldol (5 Mg Tablet) (Haloperidol)	PS		ORAL
5 MG, 2 IN 1 DAY (S), ORAL						
			Haldol (5 Mg Tablet) (Haloperidol)	SS		
UTERINE						
			Depamide (Valpromide)	SS		ORAL
300 MG, 3 IN 1 DAY (S), ORAL						
			Depamide (Valpromide)	SS		
UTERINE						
			Nozinan (Levomepromazine)	SS		ORAL
2 IN 1 DAY (S), ORAL						
			Nozinan (Levomepromazine)	SS		
UTERINE						

Date:08/18/99ISR Number: 3328686-3Report Type:Expedited (15-DaCompany Report #PRIUSA1999004653
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Other	Aggression Confusional State	Consumer	Haldol (Tablets) (Haloperidol)	PS		ORAL
10 MG ORAL						
	Constipation		Prozac	C		
	Drug Abuser		Serzone	C		
	Dry Mouth					
	Medication Error					
	Memory Impairment					

Date:08/19/99ISR Number: 3329450-1Report Type:Direct Company Report #
Age:15 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required	Agitation		Seroquel	PS			100 BID	
Intervention to	Blood Prolactin Increased		Haloperidol	SS			5 BID	4-26-99
Prevent Permanent	Dyskinesia						DECREASE 5	
Impairment/Damage	Feeling Abnormal						QHS	5-3-99
	Galactorrhoea						D/C	
	Psychomotor Hyperactivity							

Date:08/23/99ISR Number: 3332049-4Report Type:Expedited (15-DaCompany Report #033-0906-990020
Age:71 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Cerebral Atrophy	Foreign	Acuitel (Quinapril)	PS		ORAL	PER ORAL	
Initial or Prolonged	Confusional State	Health	Stilnox (Zolpidem)	SS		ORAL	PER ORAL	
	Disorientation	Professional	Prozac (Fluoxetine Hydrochloride)	SS		ORAL	PER ORAL	
	Electroencephalogram Abnormal		Equanil (Meprobamate)	SS		ORAL	800 MG	
	Fall						(DAILY), PER	
	Gait Disturbance						ORAL	
	Nervous System Disorder		Haldol (Haloperidol)	SS		ORAL	0.25 MG	
							(DAILY), PER	
							ORAL	

			Di-Actane (Naftidrofuryl Oxalate)	SS		ORAL	PER ORAL
			Efferalgan (Paracetamol)	SS		ORAL	1000 MG (DAILY), PER ORAL
			Oropivalone (Chlormethine Hydrochloride, Trientine, Bacitracin Zinc,	SS			

Date:08/24/99ISR Number: 3333686-3Report Type:Expedited (15-DaCompany Report #JACGER1999000437
Age:60 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Death	Convulsion	Foreign	Haldol (2 Mg/Ml				
Life-Threatening	Foreign Body Aspiration	Health	Drops) (Haloperidol)	PS		ORAL	4 MG, 3 IN
Required	Reflexes Abnormal	Professional					1DAY(S), ORAL
Intervention to			Taxilan (Perazine)	SS			100 MG, 3 IN
Prevent Permanent							1 DAY(S)
Impairment/Damage			Remergil (Mirtazapine)	SS		ORAL	30 MG, 1 IN 1 DAY(S), ORAL
			Valiquid (Diazepam)	SS		ORAL	3.3 MG, 2 IN 1 DAY(S), ORAL

Date:08/24/99ISR Number: 3333690-5Report Type:Expedited (15-DaCompany Report #JACFRA1999000248
Age:91 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Required	Intestinal Obstruction Pneumonia	Foreign Health Professional	Haldol (2 Mg/Ml Solution) (Haloperidol)	PS		ORAL	10 MG, 3 IN 1	Intervention to DAY(S), ORAL
Prevent Permanent Impairment/Damage			Largactil (Chlorpromazine Hydrochloride)	SS		ORAL	5 DROP, 3 IN	1 DAY(S), ORAL

Date:08/24/99ISR Number: 3333709-1Report Type:Expedited (15-DaCompany Report #PRIUSA1999004793
Age:83 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death Hospitalization - Initial or Prolonged	Coma Decreased Appetite Respiratory Disorder	Consumer	Haldol (Injection) (Haloperidol)	PS		INTRAMUSCULAR	5 MG, 3 TIME(S), IM	

Date:08/25/99ISR Number: 3335461-2Report Type:Expedited (15-DaCompany Report #JRFBEL1999000751
Age: Gender:Male I/FU:I

Outcome	PT
Other	Abnormal Behaviour Aggression

	Condition Aggravated Drug Interaction Medication Error	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Parkinson'S Disease Sedation	Literature Health	Haldol (Unspecified) (Haloperidol)	PS			MG, DAILY,
		Professional	Olanzapine (Olanzapine)	SS			DAILY
			Cogentin	C			
			Depakote	C			
			Axid	C			
			Nitroglycerin	C			
			Metoprolol	C			
			Lisinopril	C			
			Aspirin	C			

Date:08/26/99ISR Number: 3334565-8Report Type:Direct Company Report #
Age:17 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Required Intervention to Prevent Permanent Impairment/Damage	Drooling	Health Professional	Haldol 2mg	PS		ORAL	2MG PO BID

Date:08/26/99ISR Number: 3334572-5Report Type:Direct Company Report #
Age:13 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Other	Musculoskeletal Stiffness Neck Pain	Health Professional	Haloperidol 5 Mg Im (For Immediate Release)	PS		INTRAMUSCULAR	5MG IM X1 1 DAY

Date:08/26/99ISR Number: 3335025-0Report Type:Expedited (15-DaCompany Report #8-99196-033A
Age:58 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Adenoidectomy	Foreign	Effexor Tablets (					
Hospitalization -	Condition Aggravated	Health	Venlafaxine					
Initial or Prolonged	Dysuria	Professional	Hydrochloride)	PS		ORAL	150 MG ONCE	
Required	Hyperkalaemia						DAILY ORAL	
Intervention to	Renal Failure Acute						350 MG ONCE	
Prevent Permanent	Urinary Retention						DAILY	
Impairment/Damage			Haldol (Haloperidol)	SS		ORAL	ORAL	
			Tercian (Cyamemazine)	SS		ORAL	ORAL	
			Imovane	C				

Date:08/30/99ISR Number: 3337805-4Report Type:Expedited (15-DaCompany Report #US_990725841
Age:29 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Neck Pain	Study	Haloperidol	PS			6MG	
Initial or Prolonged	Road Traffic Accident		Propranolol	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/30/99ISR Number: 3339775-1Report Type:Expedited (15-DaCompany Report #JAOCAN199000274
Age:19 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anxiety Fear Hallucination Hallucination, Auditory Schizophrenia Suicidal Ideation	Foreign Study Health Professional	Haldol (1 Mg Tablet) (Haloperidol) Risperdal (1 Mg Tablet) (Risperidone)	PS SS		ORAL ORAL	3 MG, DAILY, 3 MG, DAILY,	

Date:08/31/99ISR Number: 3338257-0Report Type:Expedited (15-DaCompany Report #US_980910574
Age:52 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Akathisia Condition Aggravated Delusion Psychotic Disorder Restlessness Schizophrenia	Study Health Professional	Haloperidol Benztropine (Benzatropine) Clozapine	PS SS C			10 MG/QHS AT BEDTIME 4 MG/D DAY	

Date:09/01/99ISR Number: 3339128-6Report Type:Expedited (15-DaCompany Report #FLUV00399000533
Age:63 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Constipation Neuroleptic Malignant Syndrome	Foreign Health Professional	Depromel 25 Mg Tryptanol	PS SS		ORAL ORAL	25 MG BID PO, 50 MG BID PO QD PO	

	Pyrexia	Other	Serenace	SS		ORAL
QD PO						
			Hirunamin	SS		ORAL
QD PO						
			Meilax	SS		ORAL
QD PO						
			Benzalin	SS		ORAL
QD PO						
			Depas	SS		ORAL
QD PO						
			Pentona	SS		ORAL
QD PO						
			Sennoside	C		

Date:09/02/99ISR Number: 3339866-5Report Type:Expedited (15-DaCompany Report #199920508RHF
Age:93 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Fall	Foreign	Furosemide (Lasilix Faible) Tablets	PS		ORAL	20 MG QD PO	
	Loss Of Consciousness	Other						
	Orthostatic Hypotension		Nicardipine Hydrochloride (Loxen 20 Mg) Tablets	SS		ORAL	10 MG TID PO	
			Haloperidol (Haldol) Drops	SS		ORAL	5 U TID PO	

Date:09/03/99ISR Number: 3339746-5Report Type:Direct Company Report #
Age: Gender:Male I/FU:I

Outcome
Life-Threatening
Hospitalization -
Initial or Prolonged
Required

Intervention to
Prevent Permanent
Impairment/Damage

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Hyperpyrexia		Haloperidol	PS		INTRAVENOUS	1 MG IV EVERY	
	Muscle Rigidity						HOUR	

Date:09/03/99ISR Number: 3341911-8Report Type:Expedited (15-DaCompany Report #JRFBEL1999000921
Age:24 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Coma	Foreign	Haloperidol					
	Restlessness	Literature	(Unspecified)					
	Resuscitation	Health	(Haloperidol)	PS			30 MG, 4 IN 1	
	Sedation	Professional					DAY(S),	3 DAY
			Chlorpromazine					
			(Chlorpromazine)	SS			100 MG, 3 IN	
							1 DAY(S);	
							300 MG, 4 IN	
							1 DAY(S),	5 DAY
			Methadone					
			(Methadone)	C				
			Procyclidine					
			(Procyclidine)	C				

Date:09/07/99ISR Number: 3342051-4Report Type:Expedited (15-DaCompany Report #9937194
Age:72 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Apraxia	Foreign	Lithane Tablets	PS		ORAL	800.00 MG	
Initial or Prolonged	Bipolar Disorder	Literature					ORAL	

	Blepharospasm	Health	Amlodipine	SS	ORAL
ORAL					
	Clonic Convulsion	Professional	Haloperidol	SS	ORAL
ORAL 6 YR					
	Confusional State		Enalapril	C	
	Difficulty In Walking		Levothyroxine	C	
	Disorientation		Levodopa/Benserazide	C	
	Drug Toxicity		Pergolide	C	
	Eyelid Function Disorder				
	Fall				
	Gait Disturbance				
	Hyperreflexia				
	Memory Impairment				
	Muscle Rigidity				
	Poverty Of Speech				
	Tremor				
	Vomiting				

Date:09/08/99ISR Number: 3342598-0Report Type:Direct Company Report #
Age:44 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Gait Disturbance		Haloperidol			
Initial or Prolonged	Hypertonia		Decanoate	PS		
	Movement Disorder					
	Muscle Rigidity					
	Speech Disorder					
	Tremor					

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/08/99ISR Number: 3343952-3Report Type:Expedited (15-DaCompany Report #JACFRA1999000275
Age:93 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Fall Loss Of Consciousness Orthostatic Hypotension	Foreign Health Professional	Haldol (2mg/Ml Solution) (Haloperidol)	PS		ORAL	10MG 3 IN1	DAY (S) ORAL
			Loxen (Nicardipine Hydrochloride)	SS		ORAL	10MG 3 IN 1	DAY (S) ORAL
			Lasilix (Furosemide)	SS		ORAL	20MG DAILY	ORAL

Date:09/09/99ISR Number: 3343540-9Report Type:Direct Company Report #
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Ineffective		Haloperidol	PS			1MG TID	
	Hypoaesthesia		Hydroxyzine	C				
	Oral Pain		Lisinopril	C				
	Stomatitis		Simvastatin	C				
	Vertigo		Ticlopidine	C				
			Oxazepam	C				
			Sertraline	C				
			Atenolol	C				
			Beconace Nasal	C				

Date:09/09/99ISR Number: 3344535-1Report Type:Expedited (15-DaCompany Report #B0069716A
Age:80 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Hospitalization - Initial or Prolonged	Blood Bilirubin Increased Hepatic Function Abnormal Hepatomegaly Liver Disorder	Foreign	Zyloprim Tablet Paracetamol (Forulation Unknown) Glicazide (Formulation Unknown) Simvastatin (Formulation Unknown) Haloperidol (Formulation Unknown) Nadroparine Calcium (Formulation Unknown)	PS SS SS SS SS SS	ORAL 300MG DAILY ORAL ORAL 20MG DAILY ORAL

Date:09/11/99ISR Number: 3345432-8Report Type:Direct Company Report #
Age:43 YR Gender:Male I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Bradykinesia Drooling Muscle Rigidity Parkinsonian Gait Parkinsonism

	Tremor					
		Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
			Haldol	PS		
30 MG QD						

Date:09/13/99ISR Number: 3344746-5Report Type:Direct Company Report #
Age:26 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization -	Difficulty In Walking		Haloperidol			
Initial or Prolonged	Heart Rate Increased		Decanoate 100 Mg			
Required	Hyperhidrosis		American			
Intervention to	Muscle Rigidity		Pharmaceutical Inc.	PS	American Pharmacists	
Prevent Permanent	Neuroleptic Malignant				Inc	
INTRAVENOUS 0.8MG IM						
Impairment/Damage	Syndrome					
0.4MG/M						
	Schizophrenia		Thioridazine?			
	Tremor		Risperdal?	SS		

Date:09/13/99ISR Number: 3346674-8Report Type:Expedited (15-DaCompany Report #JRFBEL1999000898
Age:47 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Life-Threatening	Blood Creatine	Foreign	Risperidone (Tablet)			
Hospitalization -	Blood Creatine Increased	Health	(Risperidone)	PS		ORAL
MG, DAILY,						
Initial or Prolonged	Blood Creatine	Professional				
ORAL						
Disability	Phosphokinase Increased		Haloperidol			
Required	Blood Urea Increased		(Unspecified)			
Intervention to	C-Reactive Protein		(Haloperidol)	SS		ORAL
MG, DAILY,						
Prevent Permanent	Increased					
ORAL						
Impairment/Damage	Clonic Convulsion		Levodopa			
	Condition Aggravated		(Benserazide			
	Convulsion		Hhydrochloride)	SS		ORAL
ORAL						

	Dialysis	Trihexyphenidyl		
	Difficulty In Walking	Hydrochloride		
	Dyskinesia	(Trihexyphenidyl		
	Eye Movement Disorder	Hydrochloride)	SS	ORAL
MG, DAILY,				
	Fall			
ORAL				
	Muscle Rigidity	Amantadine		
	Nasopharyngitis	Hydrochloride		
	Psychotic Disorder	(Amantadine		
	Pyrexia	Hydrochloride)	SS	ORAL
MG, DAILY,				
	Renal Failure			
ORAL				
	Respiratory Rate	Bromocryptine		
	Increased	Mesylate		
	Serotonin Syndrome	(Bromocriptine		
	Upper Respiratory Tract	Mesilate)	SS	ORAL
MG, DAILY,				
	Infection			
ORAL				
		Amitriptyline		
		Hydrochloride		
		(Amitriptyline		
		Hydrochloride)	SS	ORAL
MG, DAILY,				
ORAL				
		Biperiden And		
		Preparations	C	
		Sennosides	C	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/13/99ISR Number: 3347002-4Report Type:Expedited (15-DaCompany Report #10097871
Age:55 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blood Creatine Phosphokinase Increased	Foreign Literature	Fluphenazine Hcl	PS			20 MILLIGRAM,	1/1 DAY
	Electroencephalogram Abnormal	Health Professional	Levomepromazine (Methotrimeprazine)	SS			850 MILLIGRAM,	1/1
	Grand Mal Convulsion							
	Hyperhidrosis							
	Hypertension		Carbamazepine	SS			800 MILLIGRAM,	1/1 DAY
	Muscle Rigidity							
	Neuroleptic Malignant Syndrome		Flunitrazepam	SS			2 MILLIGRAM,	1/1 DAY
	Pyrexia							
	Staring		Haloperidol	SS			INTRAVENOUS 5 MILLIGRAM,	1/1 DAY, IV 3 DAY
	Status Epilepticus							
	Stupor							
	Tachycardia							
	Tardive Dyskinesia							
	Tremor							

Date:09/15/99ISR Number: 3348482-0Report Type:Expedited (15-DaCompany Report #JRFBEL1999001152
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Congenital Anomaly	Complications Of Maternal Exposure To Therapeutic Drugs	Foreign Literature Health	Haldol (Unspecified) (Haloperidol)	PS			TAKEN BY MOTHER DURING	

	Limb Reduction Defect	Professional				

PREGNANCY.

			Fluphenazine Decanoate (Fluphenazine Decanoate)	SS		

TAKEN BY

MOTHER DURING

PREGNANCY.

			Trifluoperazine (Trifluoperazine)	SS		

TAKEN BY

MOTHER DURING

PREGNANCY.

Date:09/20/99ISR Number: 3351835-8Report Type:Expedited (15-DaCompany Report #S/97/00025/LEX
Age:26 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Foreign	Leponex	PS		ORAL	SEE IMAGE	
Other	Overdose Sudden Death Suicide Attempt	Health Professional Other	Haldol	SS				

Date:09/20/99ISR Number: 3351888-7Report Type:Expedited (15-DaCompany Report #F/97/00899/MEL
Age:74 YR Gender:Female I/FU:I

Outcome
Hospitalization -
Initial or Prolonged
Required
Intervention to
Prevent Permanent

Impairment/Damage

	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Fall	Foreign	Melleril	PS		ORAL	20 MG, ORAL;	
	Femoral Neck Fracture	Health	Haldol	SS		ORAL	.75 MG ORAL;	
	Fracture	Professional Other						

Date:09/20/99ISR Number: 3351945-5Report Type:Periodic Company Report #1999UW00562
Age:46 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Muscle Twitching	Health Professional	Seroquel Mellaril Haldol Depakote Tegretol Neurontin	PS SS SS C C C		ORAL	200 MG DAILY PO	

Date:09/20/99ISR Number: 3365157-2Report Type:Periodic Company Report #1999UW00304
Age:46 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Interaction	Health	Seroquel	PS		ORAL	400 MG QD PO	
	Tremor	Professional	Haldol Decanoate Mellaril Neurontin Depakote Tegretol	SS C C C C				

Date:09/21/99ISR Number: 3352972-4Report Type:Direct Company Report #
Age:84 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Body Temperature Decreased Body Temperature Increased Mental Impairment Muscle Rigidity Neuroleptic Malignant Syndrome		Haloperidol Olanzapine	PS C				

Date:09/21/99ISR Number: 3353315-2Report Type:Direct Company Report #
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Cognitive Deterioration		Haldol	PS			22 MG QD	

Date:09/21/99ISR Number: 3353537-0Report Type:Expedited (15-DaCompany Report #PRIUSA1999005912
Age:87 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source
Death	Completed Suicide	Literature Health

Professional

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
			Haldol (Unspecified) (Haloperidol)	PS		ORAL	ORAL	
			Amitriptyline (Amitriptyline)	SS		ORAL	ORAL	
			Barbiturates	SS		ORAL	ORAL	

Date:09/21/99ISR Number: 3353538-2Report Type:Expedited (15-DaCompany Report #PRIUSA1999005952
Age:20 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Blood Creatinine Increased	Literature Health	Haldol (Unspecified) (Haloperidol)	PS		ORAL	10 MG, 4 IN 1	
	Blood Potassium Increased	Professional					DAILY, ORAL	
	Blood Pressure Systolic Decreased		Lithium	SS		ORAL	600 MG, 3 IN 1 DAILY, ORAL	
	Cardiac Arrest Circulatory Collapse Coma Dehydration Drug Level Above Therapeutic Haemodialysis Heart Rate Increased Hypernatraemia Medication Error							

Date:09/21/99ISR Number: 3353539-4Report Type:Expedited (15-DaCompany Report #PRIUSA1999005953
Age:25 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Death	Overdose	Literature	Haldol (Unspecified)			
	Vomiting	Health	(Haloperidol)	PS		ORAL
20 MG, 30 IN						
		Professional				
1 TIME(S),						
ORAL						

Date:09/21/99ISR Number: 3353540-0Report Type:Expedited (15-DaCompany Report #PRIUSA1999005954
Age:96 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Death	Literature	Haldol (Unspecified)			
		Health	(Haloperidol)	PS		ORAL
ORAL						
		Professional				

Date:09/21/99ISR Number: 3353541-2Report Type:Expedited (15-DaCompany Report #PRIUSA1999005955
Age:41 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Death	Literature	Haldol (Unspecified)			
		Health	(Haloperidol)	PS		ORAL
ORAL						
		Professional	Amitriptyline			
			(Amitriptyline)	SS		ORAL
ORAL						
			Amphetamines	SS		ORAL
ORAL						

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/21/99ISR Number: 3353565-5Report Type:Expedited (15-DaCompany Report #PRIUSA1999005956
Age:43 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Literature	Haldol (Unspecified)					
		Health	(Haloperidol)	PS		ORAL	ORAL	
		Professional	Benzatropine (Benzatropine Mesilate)	SS		ORAL	ORAL	

Date:09/21/99ISR Number: 3353566-7Report Type:Expedited (15-DaCompany Report #PRIUSA1999005957
Age:52 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Literature	Haldol (Unspecified)					
		Health	(Haloperidol)	PS		ORAL	ORAL	
		Professional	Oxazepam (Oxazepam)	SS		ORAL	ORAL	
			Thiothixene (Tiotixene)	SS		ORAL	ORAL	

Date:09/21/99ISR Number: 3353574-6Report Type:Expedited (15-DaCompany Report #PRIUSA1999005966
Age:33 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardiac Arrest	Literature	Haldol (Unspecified)					
	Completed Suicide	Health	(Haloperidol)	PS		ORAL	ORAL	
		Professional	Amitriptyline (Amitriptyline)	SS		ORAL	ORAL	
			Benzotropine (Benzatropine Mesilate)	SS		ORAL	ORAL	

Date:09/21/99ISR Number: 3353575-8Report Type:Expedited (15-DaCompany Report #PRIUSA1999005968
Age:92 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Death	Literature	Haldol (Unspecified)					
		Health	(Haloperidol)	PS		ORAL	ORAL	
		Professional	Thioridazine (Thioridazine)	SS		ORAL	ORAL	

Date:09/21/99ISR Number: 3353576-XReport Type:Expedited (15-DaCompany Report #PRIUSA1999005958
Age:35 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Literature	Haldol (Unspecified)					
		Health	(Haloperidol)	PS		ORAL	ORAL	
		Professional	Imipramine (Imipramine)	SS		ORAL	ORAL	

Date:09/21/99ISR Number: 3353577-1Report Type:Expedited (15-DaCompany Report #PRIUSA1999005959
Age:68 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Literature	Haldol (Unspecified)					
	Drug Level Above Therapeutic	Health	(Haloperidol)	PS		ORAL	ORAL	
		Professional	Imipramine					

			(Imipramine)	SS		ORAL
ORAL						
			Theophylline (Theophylline)	SS		ORAL
ORAL						

Date:09/21/99ISR Number: 3353578-3Report Type:Expedited (15-DaCompany Report #PRIUSA1999005960
Age:38 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Blood Creatine Phosphokinase Increased	Literature Health	Haldol (Unspecified) (Haloperidol)	PS		ORAL
DAILY, ORAL						
	Blood Pressure Decreased	Professional	Ranitidine (Ranitidine)	C		
	Cardiac Arrest					
	Depressed Level Of Consciousness		Amantadine (Amantadine)	C		
	Heart Rate Increased		Lithium (Lithium)	C		
	Pyrexia		Baclofen (Baclofen)	C		
	Respiratory Rate Increased					
	Supraventricular Tachycardia					

Date:09/21/99ISR Number: 3353579-5Report Type:Expedited (15-DaCompany Report #PRIUSA1999005961
Age:36 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Completed Suicide	Literature Health	Haldol (Unspecified) (Haloperidol)	PS		ORAL
ORAL						
		Professional	Amitriptyline (Amitriptyline)	SS		

Date:09/21/99ISR Number: 3353580-1Report Type:Expedited (15-DaCompany Report #PRIUSA1999005962
Age:20 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Completed Suicide	Literature	Haldol (Unspecified)			

	Drug Level Above Therapeutic	Health Professional	(Haloperidol)	PS		ORAL ORAL
			Acetaminophen (Paracetamol)	SS		ORAL ORAL
			Aspirin (Acetylsalicylic Acid)	SS		ORAL ORAL

Date:09/21/99ISR Number: 3353784-8Report Type:Expedited (15-DaCompany Report #PRIUSA1999005967
Age:31 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Drug Level Above Therapeutic	Literature Health Professional	Haldol (Unspecified) (Haloperidol)	PS		PARENTERAL	INJECT	

Date:09/21/99ISR Number: 3353790-3Report Type:Expedited (15-DaCompany Report #PRIUSA1999005967
Age:31 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardio-Respiratory Arrest Lethargy	Literature Health Professional	Haldol (Injection) (Haloperidol)	PS		INTRAMUSCULAR	10 MG, 1 IN 4 HOUR(S), IM	24 HR

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/21/99ISR Number: 3353817-9Report Type:Expedited (15-DaCompany Report #PRIUSA1999005963
Age:30 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Literature	Haldol (Unspecified)					
		Health	(Haloperidol)	PS		ORAL	ORAL	
		Professional	Desipramine					
			(Desipramine)	SS		ORAL	ORAL	

Date:09/21/99ISR Number: 3353820-9Report Type:Expedited (15-DaCompany Report #PRIUSA1999005964
Age:62 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Literature	Haldol (Unspecified)					
	Drug Level Above	Health	(Haloperidol)	PS		ORAL	ORAL	
	Therapeutic	Professional	Imipramine					
			(Imipramine)	SS		ORAL	ORAL	
			Lorazepam					
			(Lorazepam)	SS		ORAL	ORAL	

Date:09/21/99ISR Number: 3353823-4Report Type:Expedited (15-DaCompany Report #PRIUSA1999005965
Age:17 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardio-Respiratory Arrest	Literature	Haldol (Unspecified)					
	Completed Suicide	Health	(Haloperidol)	PS		ORAL	ORAL	
	Drug Level Above Therapeutic	Professional						

Date:09/22/99ISR Number: 3355481-1Report Type:Expedited (15-DaCompany Report #214613
Age:30 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hepatocellular Damage Liver Function Test Abnormal	Foreign Health Professional	Rivotril (Clonazepam) Haldol (Haloperidol) Haldol (Haloperidol) Tercian (Cyamemazine)	PS SS SS SS		ORAL ORAL INTRAMUSCULAR INTRAMUSCULAR	20 DROP DAILY	

Date:09/23/99ISR Number: 3356032-8Report Type:Expedited (15-DaCompany Report #D/96/02814/LEX
Age:41 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Diarrhoea Eosinophilia Fungal Infection Leukocytoclastic Vasculitis Leukocytosis Multi-Organ Failure Pneumonia Pyrexia Rash Erythematous Sepsis	Foreign Health Professional	Leponex Timonil Retard Decentan Haldol	PS SS SS SS		ORAL ORAL	600 MG, ORAL 300 MG, ORAL	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/23/99ISR Number: 3356982-2Report Type:Expedited (15-DaCompany Report #JACFRA1999000297
Age:78 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Coma	Foreign Health Professional	Haldol (Unspecified) (Haloperidol)	PS		ORAL	DAILY, ORAL	
	Respiratory Disorder							
	Sedation		Equanil (Meprobamate)	SS			3 IN 1 DAY	
			Deroxat (Paroxetine Hydrochloride)	SS			(S), , DAILY,	
			Stilnox (Zolpidem)	SS		ORAL	5 MG, DAILY,	ORAL
			Triatec	C				

Date:09/28/99ISR Number: 3359651-8Report Type:Expedited (15-DaCompany Report #PRIUSA1999006024
Age:70 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Health Professional	Haldol Decanoate (Injection) (Haloperidol Decanoate)	PS		INTRAMUSCULAR	100 MG, IM	5 YR
	Poisoning Deliberate		Haldol Decanoate (Injection) (Haloperidol Decanoate)	SS		INTRAMUSCULAR	50 MG, 1 IN 6 WEEK (S), IM	
			Thyroid Medication Nos	C				

Date:09/28/99ISR Number: 3359670-1Report Type:Expedited (15-DaCompany Report #JACFRA1999000208
Age:71 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Antinuclear Antibody Positive Arthralgia Inflammation	Foreign Health Professional	Haldol Decanoas (50 Mg/Ml Injection) (Haloperidol Decanoate)	PS		INTRAMUSCULAR	1 IN 1 MONTH	
	Musculoskeletal Pain					(S) IM		
	Oedema Peripheral		Akineton Lp	C				
	Pain In Extremity		Tercian	C				
	Red Blood Cell Sedimentation Rate Increased		Imovane	C				
			Cycloteriam	C				
			Kardegic	C				

Date:09/28/99ISR Number: 3360220-4Report Type:Expedited (15-DaCompany Report #PRIUSA1999003733
Age:43 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death Hospitalization - Initial or Prolonged	Cardiac Arrest Coma Hepatitis Cholestatic Hepatorenal Failure Jaundice Lethargy Medication Error Vomiting	Health Professional	Haldol (Tablet) (Haloperidol)	PS		ORAL	15 MG, DAILY, ORAL	
			Haldol Decanoate (Injection) (Haloperidol Decanoate)	SS		INTRAMUSCULAR	50 MG, 1 TIME(S), IM	
			Haldol Decanoate					

			(Injection) Haloperidol Decanoate)	SS		
INTRAMUSCULAR 200 MG, 1 TIME(S), IM						

Date:09/29/99ISR Number: 3361149-8Report Type:Expedited (15-DaCompany Report #1999UW03396
Age:83 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Hip Fracture	Study	Haloperidol	PS		ORAL
25 MG QD PO						
		Health Professional	Metipranolol	C		
			Terazosin Hydrochloride	C		
			Latanoprost	C		
			Methazolamide	C		

Date:09/30/99ISR Number: 3360921-8Report Type:Direct Company Report #
Age:69 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Coma	Health Professional	Haldol Decanoate	PS		
INTRAMUSCULAR 50 MG IM						
Hospitalization - Initial or Prolonged	Neuroleptic Malignant Syndrome		Aspirin	C		
	Pyrexia					
	Renal Failure Acute					
	Rhabdomyolysis					

Date:09/30/99ISR Number: 3361988-3Report Type:Expedited (15-DaCompany Report #JACFRA1999000319
Age:31 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Pulmonary Embolism	Foreign	Haldol (5 Mg/Ml			
Life-Threatening	Sickle Cell Anaemia	Health	Injection)			
	Spleen Disorder	Professional	(Haloperidol)	PS		
INTRAMUSCULAR IM						

			Nozinan (Levomepromazine)	SS		
INTRAMUSCULAR	IM					

Date:10/05/99ISR Number: 3363261-6Report Type:Direct Company Report #
Age:48 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required	Dyspnoea	Health	Haldol 4mg Bid	PS		ORAL	4MG PO BID	
Intervention to Prevent Permanent Impairment/Damage	Joint Stiffness	Professional						

Date:10/05/99ISR Number: 3363622-5Report Type:Direct Company Report #
Age:55 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Depression	Health	Haloperidol 100mg					
	Difficulty In Walking	Professional	Inj	PS				
	Tremor		Haloperidol 5mg Tab	SS				
	Urinary Retention		Levodopa	C				
	Visual Disturbance							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/05/99ISR Number: 3364456-8Report Type:Expedited (15-DaCompany Report #PRIUSA1999006454
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Literature	Haldol (Unspecified)					
		Health	(Haloperidol)	PS		ORAL		
ORAL								
		Professional	Metoprolol					
			(Metoprolol)	SS		ORAL		
ORAL								

Date:10/05/99ISR Number: 3364459-3Report Type:Expedited (15-DaCompany Report #PRIUSA1999006278
Age:18 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Carbon Monoxide Poisoning	Literature	Haldol (Unspecified)					
	Completed Suicide	Health	(Haloperidol)	PS		ORAL		
ORAL								
		Professional						

Date:10/06/99ISR Number: 3366056-2Report Type:Expedited (15-DaCompany Report #JACFRA1999000333
Age:85 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Intestinal Obstruction	Foreign	Haldol (2 Mg/Ml					
Initial or Prolonged	Vomiting	Health	Solution)					
Required		Professional	(Haloperidol)	PS		ORAL		
DROP, DAILY,								
Intervention to								
ORAL								
Prevent Permanent			Efferalgan					
Impairment/Damage			(Paracetamol)	SS		ORAL		
ORAL								
			Equanil					
			(Meprobamate)	SS		ORAL		
MG, DAILY,								
ORAL								

Date:10/07/99ISR Number: 3367585-8Report Type:Expedited (15-DaCompany Report #PRIUSA1999006614
Age:37 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardiac Arrest	Literature	Haldol (Unspecified)					
Hospitalization -	Completed Suicide	Health	(Haloperidol)	PS		ORAL		
Initial or Prolonged	Drug Level Above Therapeutic	Professional	Acetaminophen (Paracetamol)	SS		ORAL		
	Intentional Self-Injury							
	Respiratory Arrest							

Date:10/07/99ISR Number: 3367586-XReport Type:Expedited (15-DaCompany Report #PRIUSA1999006615
Age:29 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardiac Arrest	Literature	Haldol (Unspecified)					
Hospitalization -	Completed Suicide	Health	(Haloperidol)	PS		ORAL		
Initial or Prolonged	Intentional Self-Injury	Professional	Desipramine (Desipramine)	SS		ORAL		
	Respiratory Arrest							

Date:10/07/99ISR Number: 3367587-1Report Type:Expedited (15-DaCompany Report #PRIUSA1999006616
Age:29 YR Gender:Unknown I/FU:I

Outcome
Death
Hospitalization -

Initial or Prolonged

	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Cardiac Arrest	Literature	Haldol (Unspecified)					
	Completed Suicide	Health	(Haloperidol)	PS		ORAL	ORAL	
	Intentional Self-Injury	Professional	Desipramine					
	Respiratory Arrest		(Desipramine)	SS		ORAL	ORAL	
			Nortriptyline					
			(Nortriptyline)	SS		ORAL	ORAL	

Date:10/07/99ISR Number: 3367588-3Report Type:Expedited (15-DaCompany Report #PRIUSA1999006617
Age:25 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardiac Arrest	Literature	Haldol (Unspecified)					
Hospitalization -	Completed Suicide	Health	(Haloperidol)	PS		ORAL	ORAL	
Initial or Prolonged	Intentional Self-Injury	Professional	Diphenhydramine					
	Respiratory Arrest		(Diphenhydramine)	SS		ORAL	ORAL	
			Cyclobenzaprine					
			(Cyclobenzaprine)	SS		ORAL	ORAL	

Date:10/07/99ISR Number: 3367589-5Report Type:Expedited (15-DaCompany Report #PRIUSA1999006591
Age:73 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Unevaluable Event	Literature	Haldol (Unspecified)					
		Health	(Haloperidol)	PS		ORAL	ORAL	
		Professional						

Date:10/07/99ISR Number: 3367590-1Report Type:Expedited (15-DaCompany Report #PRIUSA1999006589
Age:33 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Unevaluable Event	Literature	Haldol (Unspecified)					
		Health	(Haloperidol)	PS		ORAL		
ORAL								
		Professional						

Date:10/07/99ISR Number: 3367591-3Report Type:Expedited (15-DaCompany Report #PRIUSA1999006588
Age:89 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Literature	Haldol (Unspecified)					
	Intentional Self-Injury	Health	(Haloperidol)	PS		ORAL		
ORAL								
		Professional	Butalbital					
			(Butalbital)	SS		ORAL		
ORAL								
			Lorazepam					
			(Lorazepam)	SS		ORAL		
ORAL								

Date:10/07/99ISR Number: 3367592-5Report Type:Expedited (15-DaCompany Report #PRIUSA1999006587
Age:47 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Literature	Haldol (Unspecified)					
	Intentional Self-Injury	Health	(Haloperidol)	PS		ORAL		
ORAL								
		Professional	Doxepin (Doxepin)	SS		ORAL		
ORAL								

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/07/99ISR Number: 3367605-0Report Type:Expedited (15-DaCompany Report #PRIUSA1999006510
Age:53 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Literature	Haldol (Unspecified)					
	Intentional Self-Injury	Health	(Haloperidol)	PS		ORAL	ORAL	
		Professional	Captopril					
			(Captopril)	SS		ORAL	ORAL	
			Benztropine					
			(Benztropeine)	SS		ORAL	ORAL	

Date:10/07/99ISR Number: 3367609-8Report Type:Expedited (15-DaCompany Report #PRIUSA1999006523
Age:38 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardiac Arrest	Literature	Haldol (Unspecified)					
Hospitalization -	Completed Suicide	Health	(Haloperidol)	PS				
Initial or Prolonged	Intentional Self-Injury	Professional	Chloral Hydrate					
	Respiratory Arrest		(Chloral Hydrate)	SS		ORAL	ORAL	
			Temazepam					
			(Temazepam)	SS		ORAL	ORAL	

Date:10/07/99ISR Number: 3367613-XReport Type:Expedited (15-DaCompany Report #PRIUSA1999006543
Age:31 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Literature	Haldol (Unspecified)					
	Drug Level Above	Health	(Haloperidol)	PS		ORAL	ORAL	
	Therapeutic	Professional	Lithium (Lithium)	SS		ORAL	ORAL	
	Intentional Self-Injury		Fluoxetine					
			(Fluoxetine)	SS		ORAL	ORAL	

Date:10/07/99ISR Number: 3367614-1Report Type:Expedited (15-DaCompany Report #PRIUSA1999006544
Age:33 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardiac Arrest	Literature	Haldol (Unspecified)					
Hospitalization -	Completed Suicide	Health	(Haloperidol)	PS		ORAL		
ORAL								
Initial or Prolonged	Intentional Self-Injury	Professional	Amantadine					
	Respiratory Arrest		(Amantadine)	SS		ORAL		
ORAL								
			Benztropine					
			(Benztropeine)	SS		ORAL		
ORAL								

Date:10/07/99ISR Number: 3367616-5Report Type:Expedited (15-DaCompany Report #PRIUSA1999006545
Age:35 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardiac Arrest	Literature	Haldol (Unspecified)					
Hospitalization -	Completed Suicide	Health	(Haloperidol)	PS		ORAL		
ORAL								
Initial or Prolonged	Intentional Self-Injury	Professional	Trazodone					
	Respiratory Arrest		(Trazodone)	SS		ORAL		
ORAL								
			Clonazepam					
			(Clonazepam)	SS		ORAL		
ORAL								

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/07/99ISR Number: 3367617-7Report Type:Expedited (15-DaCompany Report #PRIUSA1999006613
Age:30 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Literature	Haldol (Unspecified)					
	Intentional Self-Injury	Health	(Haloperidol)	PS		ORAL		
ORAL								
		Professional	Amoxapine					
			(Amoxapine)	SS		ORAL		
ORAL								

Date:10/07/99ISR Number: 3367674-8Report Type:Expedited (15-DaCompany Report #PRIUSA1999006585
Age: Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Literature	Haldol	PS		ORAL		
ORAL								
	Intentional Self-Injury	Health	Desipramine					
		Professional	(Desipramine)	SS		ORAL		
ORAL								
			Propranolol(Proprano					
			lol)	SS		ORAL		
ORAL								

Date:10/07/99ISR Number: 3373371-5Report Type:Periodic Company Report #JRFUSA1999002037
Age:23 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Agitation	Consumer	Risperdal (1 Mg/Ml					
			Solution)					
			(Risperidone)	PS		ORAL		
2 MG/ML, 2 IN								
1 DAY(S) ORAL								
			Haldol (Tablet)					
			(Haloperidol)	SS		ORAL		
5 MG, 2 IN 1								
DAY(S) ORAL								
			Cogentin					

			(Benzatro-Pine Mesilate)	C		

Date:10/08/99ISR Number: 3369009-3Report Type:Expedited (15-DaCompany Report #PRIUSA1999006684
Age:35 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide Intentional Self-Injury	Literature Health	Haldol (Unspecified) (Haloperidol)	PS		ORAL	ORAL	
		Professional	Aspirin (Acetylsalicylic Acid)	SS		ORAL	ORAL	
			Bupropion (Amfebutamone)	SS		ORAL	ORAL	

Date:10/08/99ISR Number: 3369012-3Report Type:Expedited (15-DaCompany Report #PRIUSA1999006685
Age:22 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide Intentional Self-Injury	Literature Health	Haldol (Unspecified) (Haloperidol)	PS		ORAL	ORAL	
		Professional	Desipramine (Desopramine)	SS		ORAL	ORAL	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/08/99ISR Number: 3369015-9Report Type:Expedited (15-DaCompany Report #PRIUSA1999006686
Age:16 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Attention	Literature	Haldol (Unspecified)					
Required	Deficit/Hyperactivity	Health	(Haloperidol)	PS			8MG, 3 IN 1	
Intervention to	Disorder	Professional					DAY (S)	
Prevent Permanent	Blood Creatine						PARENT	2 WK
Impairment/Damage	Phosphokinase Increased		Anticonvulsants, Nos	C				
	Cardiac Arrest							
	Disseminated							
	Intravascular Coagulation							
	Dystonia							
	Haemorrhage							
	Hyperkalaemia							
	Pyrexia							

Date:10/08/99ISR Number: 3369018-4Report Type:Expedited (15-DaCompany Report #PRIUSA1999006687
Age:51 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardiac Arrest	Literature	Haldol (Unspecified)					
Hospitalization -	Completed Suicide	Health	(Haloperidol)	PS		ORAL	ORAL	
Initial or Prolonged	Intentional Self-Injury	Professional						
	Respiratory Arrest							

Date:10/08/99ISR Number: 3369020-2Report Type:Expedited (15-DaCompany Report #PRIUSA1999006688
Age:24 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardiac Arrest	Literature	Haldol (Unspeicied)					
Hospitalization -	Completed Suicide	Health	(Haloperidol)	PS		ORAL	ORAL	
Initial or Prolonged	Intentional Self-Injury	Professional	Benztropsine					
	Respiratory Arrest		(Benztropeine)	SS		ORAL	ORAL	

			Naproxen (Naproxen)	SS		ORAL
ORAL						

Date:10/08/99ISR Number: 3369023-8Report Type:Expedited (15-DaCompany Report #PRIUSA1999006689
Age:70 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Completed Suicide	Literature	Haldol (Unspecified)			
	Intentional Self-Injury	Health	(Haloperidol)	PS		ORAL
ORAL						
		Professional	Hydrochlorothiazide / Troamterence			
			(Dyazide)	SS		ORAL
ORAL						
			Lithium (Lithium)	SS		ORAL
ORAL						

Date:10/08/99ISR Number: 3369027-5Report Type:Expedited (15-DaCompany Report #PRIUSA1999006690
Age:42 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Death	Literature	Haldol (Unspecified)			
		Health	(Haloperidol)	PS		
PARENTERAL PARENT						
		Professional	Perphenazine			
			(Perphenazine)	SS		
PARENTERAL PARENT						

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/08/99ISR Number: 3369173-6Report Type:Expedited (15-DaCompany Report #PRIUSA1999006658
Age:89 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Drug Level Above Therapeutic	Literature Health	Haldol (Unspecified) (Haloperidol)	PS		ORAL	ORAL	
	Medication Error	Professional	Digoxin (Digoxin)	SS		ORAL	ORAL	
			Carbidopa / Levodopa (Sinemet)	SS		ORAL	ORAL	

Date:10/08/99ISR Number: 3369179-7Report Type:Expedited (15-DaCompany Report #PRIUSA1999006657
Age:62 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Literature	Haldol (Unspecified)					
	Drug Level Above Therapeutic	Health	(Haloperidol)	PS		ORAL	ORAL	
		Professional	Nortriptyline (Nortriptyline)	SS		ORAL	ORAL	

Date:10/08/99ISR Number: 3369184-0Report Type:Expedited (15-DaCompany Report #PRIUSA1999006659
Age:76 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Unevaluable Event	Literature	Haldol (Unspecified)					
		Health	(Haloperidol)	PS		PARENTERAL	PARENT	
		Professional						

Date:10/08/99ISR Number: 3369189-XReport Type:Expedited (15-DaCompany Report #PRIUSA1999006660
Age:53 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Death	Death	Literature	Haldol (Unspecified)			
		Health	(Haloperidol)	PS		ORAL
ORAL						
		Professional	Carbamazepine			
			(Carbamazepine)	SS		ORAL
ORAL						
			Nortriptyline			
			(Nortriptyline)	SS		ORAL
ORAL						

Date:10/08/99ISR Number: 3369217-1Report Type:Expedited (15-DaCompany Report #99-00350
Age:47 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Death	Shock	Foreign	Solu-Medrol	PS		
INTRAVENOUS	1500 TO 5600					
		Health				
MG; ONCE						
		Professional				
DAILY;						
INTRAVENOUS						
			Haloperidol	SS		
INTRAVENOUS	5 MG; ONCE					
DAILY;						
INTRAVENOUS						
			Biperiden	SS		ORAL
5 MG; ORAL						

Date:10/12/99ISR Number: 3370066-9Report Type:Expedited (15-DaCompany Report #PRIUSA1999006812
Age:22 YR Gender: I/FU:I

Outcome
Death
Hospitalization -

Initial or Prolonged

	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Cardio-Respiratory Arrest	Literature	Haldol (Unspecified)					
	Completed Suicide	Health	(Haloperidol)	PS		ORAL	ORAL	
	Overdose	Professional	Benztropine (Benztropine)	SS		ORAL	ORAL	

Date:10/12/99ISR Number: 3370826-4Report Type:Expedited (15-DaCompany Report #JRFBEL1999001438
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Blood Creatine Phosphokinase Increased	Foreign Health	Risperidone (Unspecified)					
	Rhabdomyolysis	Professional	(Risperidone)	PS		ORAL	ORAL	
			Haldol (Unspecified) (Haloperidol)	SS				

Date:10/12/99ISR Number: 3370909-9Report Type:Expedited (15-DaCompany Report #JACFRA1999000208
Age:71 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Antinuclear Antibody Positive	Foreign Health	Haldol Decanoas (50 Mg/Ml Injection)					
	Arthralgia	Professional	(Haloperidol Decanoate)	PS		INTRAMUSCULAR	1 IN 1 MONTH(S), IM	
	Laboratory Test Abnormal							
	Musculoskeletal Pain							
	Oedema Peripheral		Akineton Lp (Biperiden Hydrochloride)	C				
	Pain In Extremity							
	Red Blood Cell Sedimentation Rate Increased		Tercian (Cyamemazine)	C				
			Imovane (Zopiclone)	C				
			Cycloteriam (Cycloteriam)	C				

				Kardegic (Acetylsalicylate Lysine)	C		

Date:10/13/99ISR Number: 3371580-2Report Type:Expedited (15-DaCompany Report #JRFBEL1999001438
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Blood Creatine Phosphokinase Increased Rhabdomyolysis	Foreign Health Professional	Haldol (Unspecified) (Haloperidol)	PS				
			Risperidone (Unspecified) (Risperidone)	SS		ORAL		

Date:10/15/99ISR Number: 3373536-2Report Type:Expedited (15-DaCompany Report #JRFBEL1999001438
Age:43 YR Gender:Male I/FU:F

Outcome
Hospitalization - Initial or Prolonged
Other
Required

Intervention to Prevent Permanent Impairment/Damage

PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Acidosis Anuria Blood Creatine Phosphokinase Increased Blood Creatinine Increased Blood Urea Increased Chromaturia Pyelonephritis Renal Failure Rhabdomyolysis Urinary Retention	Foreign Health Professional	Risperidone (Unspecified) (Risperidone)	PS		ORAL	MG, DAILY, ORAL	
		Haldol (Unspecified) (Haloperidol)	SS		ORAL	DAILY, ORAL	
		Pravastatin (Pravastatin Sodium)	SS		ORAL	MG, DAILY, ORAL	
		Fluphenazine Maleate	SS		ORAL	DAILY, ORAL	
		Carbamazepine (Carbamazepine)	C				
		Promazine Hydrochloride (Promazine Hydrochloride)	C				
		Levopromazine Maleate (Levopromazine Maleate)	C				

Date:10/18/99ISR Number: 3374805-2Report Type:Expedited (15-DaCompany Report #EWC991004519
Age:29 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Bipolar I Disorder Suicide Attempt	Foreign Study Health Professional Other	Haloperidol Lorazepam	PS C			10 MG	

Date:10/18/99ISR Number: 3375063-5Report Type:Expedited (15-DaCompany Report #JRFBEL1999001569
Age:43 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Aggression	Foreign	Haldol Depot					
Hospitalization - Initial or Prolonged	Cerebral Ischaemia		(Injection)					
	Convulsion		(Haloperidol)	PS		INTRAMUSCULAR	150MG WEEKLY	
Required Intervention to Prevent Permanent Impairment/Damage	Depressed Level Of Consciousness					IM		
	Status Epilepticus		Tegretol (Carbamazepine)	C				

Date:10/21/99ISR Number: 3378155-XReport Type:Expedited (15-DaCompany Report #JRFBEL1999001438
Age:43 YR Gender:Male I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Acidosis
	Anuria
Other	Blood Creatine Phosphokinase Increased
Required Intervention to Prevent Permanent Impairment/Damage	Blood Creatinine Increased
	Blood Urea Increased
	Chromaturia

		Haemodialysis Pyelonephritis Renal Failure	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
		Rhabdomyolysis	Foreign	Haldol	PS		ORAL
DAILY, ORAL							
		Urinary Retention	Health				
(SEE IMAGE)							
			Professional	Risperidone (Risperidone)	SS		ORAL
MG, DAILY,							
ORAL							
				Pravastatin (Pravastatin Sodium)	SS		ORAL
MG, DAILY,							
ORAL							
				Fluphenazine Maleate	SS		ORAL
MG, DAILY,							
ORAL							
				Carbamazepine (Carbamazepine)	C		
				Promazine Hydrochloride (Promazine Hydrochloride)	C		
				Levomepromazine Maleate (Levomepromazine Maleate)	C		

.

Date:10/25/99ISR Number: 3381315-5Report Type:Expedited (15-DaCompany Report #PRIUSA1999005968
Age:92 YR Gender:Female I/FU:F

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Death		Attention	Literature	Haldol (Unspecified)			
Hospitalization -		Deficit/Hyperactivity	Health	(Haloperidol)	PS		ORAL
ORAL							
Initial or Prolonged		Disorder	Professional	Thioridazine			

	Cardiac Arrest		(Thioridazine)	SS		ORAL
ORAL						
	Emotional Disorder					
	Hypotonia					
	Nervous System Disorder					
	Pneumonia Aspiration					
	Pyrexia					
	Suicidal Ideation					
	Vaginal Infection					

Date:10/25/99ISR Number: 3381321-0Report Type:Expedited (15-DaCompany Report #PRIUSA1999005966
Age:33 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Blood Ph Decreased	Literature	Haldol (Unspecified)			
Hospitalization -	Cardiac Arrest	Health	(Haloperidol)	PS		ORAL
ORAL						
Initial or Prolonged	Completed Suicide	Professional	Elavil			
Required	Depressed Level Of		(Amitriptyline			
Intervention to	Consciousness		Hydrochloride)	SS		ORAL
ORAL						
Prevent Permanent	Haematemesis		Cogentin			
Impairment/Damage	Mydriasis		(Benzatropine			
	Overdose		Mesilate)	SS		ORAL
ORAL						
	Pupil Fixed					
	Pyrexia					
	Respiratory Disorder					

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/25/99ISR Number: 3381326-XReport Type:Expedited (15-DaCompany Report #PRIUSA1999005965
Age:17 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Angiopathy	Literature	Haldol (Unspecified)					
	Apnoea	Health	(Haloperidol)	PS			(60-100 PILLS	
	Blood Creatinine	Professional					INGESTED)	
	Increased		Lithium (Lithium)	C				
	Cardiac Arrest		Benzotropine					
	Coma		(Benzatropine					
	Completed Suicide		Mesilate)	C				
	Cyanosis		Clonazepam					
	Drug Level Above		(Clonazepam)	C				
	Therapeutic							
	Hyperglycaemia							
	Hyperkalaemia							
	Hypotension							
	Hypoxia							
	Intentional Misuse							
	Lung Infiltration							
	Pulse Absent							
	Respiratory Arrest							
	Sinus Tachycardia							
	Tachycardia							
	Vascular Resistance							
	Systemic							
	Ventricular Fibrillation							

Date:10/25/99ISR Number: 3381329-5Report Type:Expedited (15-DaCompany Report #PRIUSA1999005964
Age:62 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardiac Arrest	Literature	Haldol (Unspecified)					
	Completed Suicide	Health	(Haloperidol)	PS		ORAL	ORAL	
	Drug Level Above	Professional	Imipramine					
	Therapeutic		(Imipramine)	SS		ORAL	ORAL	
	Hypotension		Lorazepam					
	Lethargy		(Lorazepam)	SS		ORAL	ORAL	

	Renal Failure						
	Sedation						
	Ventricular Arrhythmia						

Date:10/25/99ISR Number: 3381330-1Report Type:Expedited (15-DaCompany Report #PRIUSA1999005963
Age:30 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Blood Bicarbonate Decreased	Literature Health	Haldol (Unspecified) (Haloperidol)	PS		ORAL		
Hospitalization - Initial or Prolonged	Blood Gases Abnormal	Professional	Desipramine (Desipramine)	SS		ORAL		
	Blood Pressure Decreased							
	Cardiac Arrest							
	Coma							
	Completed Suicide							
	Heart Rate Decreased							
	Status Epilepticus							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/25/99ISR Number: 3381341-6Report Type:Expedited (15-DaCompany Report #PRIUSA1999005962
Age:20 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Blood Creatine Phosphokinase Increased	Literature Health	Haldol (Unspecified) (Haloperidol)	PS		ORAL	ORAL	
	Blood Lactate Dehydrogenase Increased	Professional	Acetaminophen (Paracetamol)	SS		ORAL	ORAL	
	Coma Completed Suicide Decubitus Ulcer		Aspirin (Acetylsalicylic Acid)	SS		ORAL	ORAL	
	Disseminated Intravascular Coagulation Drug Level Above Therapeutic Electrolyte Imbalance Haemodialysis Hepatic Function Abnormal Liver Function Test Abnormal Movement Disorder Multi-Organ Failure Pco2 Decreased Prothrombin Time Prolonged Renal Failure Acute Skin Injury Toxicologic Test Abnormal Vomiting							

Date:10/25/99ISR Number: 3381367-2Report Type:Expedited (15-DaCompany Report #PRIUSA1999005961
Age:36 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide Convulsion	Literature Health	Haldol (Unspecified) (Haloperidol)	PS		ORAL	ORAL	
	Depressed Level Of Consciousness	Professional	Amitriptyline (Amitriptyline)	SS		ORAL	ORAL	

Respiratory Arrest
Sinus Tachycardia

Date:10/25/99ISR Number: 3381368-4Report Type:Expedited (15-DaCompany Report #PRIUSA1999005959
Age:68 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Acidosis	Literature	Haldol (Unspecified)					
	Anuria	Health	(Haloperidol)	PS		ORAL	22 TABLE, 1	
	Cardiac Arrest	Professional					DAY(S), ORAL	
	Coma		Imipramine					
	Completed Suicide		(Imipramine)	SS		ORAL	44 TABLE, 1	
	Dyspnoea						DAY(S), ORAL	
	Grand Mal Convulsion		Theophylline					
	Hypotension		(Theophylline)	SS		ORAL	60 TABLE, 1	
	Ileus Paralytic						DAY(S), ORAL	
	Overdose		Klotrix (Potassium					
	Respiratory Depression		Chloride)	C				
	Sinus Tachycardia		Lasix (Furosemide)	C				
	Toxicologic Test Abnormal		Methyldopa					
			(Methyldopa)	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/25/99ISR Number: 3381370-2Report Type:Expedited (15-DaCompany Report #PRIUSA1999005958
Age:35 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Blood Ph Decreased	Literature	Haldol (Unspecified)					
	Cardio-Respiratory Arrest	Health	(Haloperidol)	PS		ORAL	ORAL	
	Completed Suicide	Professional	Imipramine					
	Convulsion		(Imipramine)	SS		ORAL	ORAL	

Date:10/25/99ISR Number: 3381373-8Report Type:Expedited (15-DaCompany Report #PRIUSA1999005957
Age:52 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Blood Chloride Increased	Literature	Haldol (Unspecified)					
Hospitalization -	Blood Sodium Increased	Health	(Haloperidol)	PS		ORAL	ORAL	
Initial or Prolonged	Brain Herniation	Professional	Serax (Oxazepam)	SS		ORAL	ORAL	
Required	Brain Oedema		Navane (Tiotixene)	SS		ORAL	ORAL	
Intervention to	Cardiac Arrest							
Prevent Permanent	Coma							
Impairment/Damage	Completed Suicide							
	Hypotension							
	Mydriasis							
	Respiratory Arrest							

Date:10/25/99ISR Number: 3381376-3Report Type:Expedited (15-DaCompany Report #PRIUSA1999005955
Age:41 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Apnoea	Literature	Haldol (Unspecified)					
Hospitalization -	Atrioventricular Block	Health	(Haloperidol)	PS		ORAL	ORAL	
Initial or Prolonged	First Degree	Professional	Amitriptyline					
Required	Coma		(Amitriptyline)	SS		ORAL	ORAL	

Intervention to	Convulsion		Amphentamines	SS		ORAL	
ORAL							
Prevent Permanent	Electrocardiogram Qrs		Nortriptyline				
Impairment/Damage	Complex Prolonged		(Nortriptyline)	SS		ORAL	
ORAL							
	Loss Of Consciousness						
	Toxicologic Test Abnormal						

Date:10/25/99ISR Number: 3381377-5Report Type:Expedited (15-DaCompany Report #PRIUSA1999005954
Age:96 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Death	Convulsion	Literature	Haldol (Unspecified)				
Hospitalization -	Muscle Rigidity	Health	(Haloperidol)	PS		ORAL	0.5 MG, 2 IN
Initial or Prolonged	Neuroleptic Malignant	Professional					1 DAILY, ORAL
	Syndrome						
	Pyrexia						

Date:10/25/99ISR Number: 3381378-7Report Type:Expedited (15-DaCompany Report #PRIUSA1999005912
Age:87 YR Gender:Female I/FU:F

Outcome
Death
Hospitalization -
Initial or Prolonged
Required
Intervention to
Prevent Permanent

Impairment/Damage

	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Coma	Literature	Haldol (Unspecified)					
	Completed Suicide	Health	(Haloperidol)	PS		ORAL	ORAL	
	Hypoventilation	Professional	Elavil					
	Miosis		(Amitriptyline					
	Respiratory Arrest		Hydrochloride)	SS		ORAL	ORAL	
			Tuinal (Tuinal)	SS		ORAL	ORAL	
			Phenobarbital					
			(Phenobarbital)	SS		ORAL	ORAL	
			Darvocet (Darvocet)	SS		ORAL	ORAL	
			Restoril (Temazepam)	SS		ORAL	ORAL	
			Halcion (Triazolam)	SS		ORAL	ORAL	
			Dalmane (Flurazepam					
			Hydrochloride)	SS		ORAL	ORAL	

Date:10/26/99ISR Number: 3381333-7Report Type:Direct Company Report #
Age:76 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Angioneurotic Oedema		Haloperidol	PS				
Initial or Prolonged			Depakote	C				
			Lisinopril	C				
			Felodipine	C				

Date:10/26/99ISR Number: 3381411-2Report Type:Direct Company Report #
Age:63 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Asthenia		Haloperidol /5 Mg	PS		ORAL	5MG Q PM	ORAL

Initial or Prolonged	Decreased Activity Extrapyramidal Disorder Tremor					

Date:10/26/99ISR Number: 3382391-6Report Type:Expedited (15-DaCompany Report #JRFBEL1999001678
Age: Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Death	Foreign Health Professional	Haldol (Unspecified) (Haloperidol)	PS				

Date:10/26/99ISR Number: 3382552-6Report Type:Expedited (15-DaCompany Report #217761
Age:93 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Fall Loss Of Consciousness Orthostatic Hypotension	Foreign Other	Loxen (Nicardipine Hydrochloride)	PS		ORAL	30 MG DAILY	ORAL
			Haldol (Haloperidol)	SS				
			Lasilix (Furosemide)	SS				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/27/99ISR Number: 3381921-8Report Type:Direct Company Report #
Age:52 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Torsade De Pointes	Health	Haloperidol	PS			DOSE	
		Professional					PROGRESSIVELY	
							INCREASED	
							MAX=160MG~9H	
							BEFORE EVENT	
			Ativan	C				
			Heparin	C				
			Thiamine	C				
			Mvi	C				
			Lansoprazole	C				
			Clindamicin	C				
			Acetaminophen	C				
			Famotidine	C				
			Folate	I				

Date:10/28/99ISR Number: 3384034-4Report Type:Expedited (15-DaCompany Report #JACFRA1999000297
Age:78 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Apnoeic Attack	Foreign	Haldol (Unspecified)					
	Coma	Health	(Haloperidol)	PS		ORAL	DAILY ORAL	
	Drug Interaction	Professional	Equanil					
	Sedation		(Meprobamate)	SS			3 IN 1 DAY	
							(S)	
			Deroxat (Paroxetine Hydrochloride)	SS			DAILY	
			Stilnox (Zolpidem)	SS		ORAL	5 MG DAILY	
							ORAL	

			Triatec (Ramipril)	C			

Date:10/28/99ISR Number: 3384036-8Report Type:Expedited (15-DaCompany Report #JACFRA1999000232
Age:65 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Confusional State	Foreign	Haldol (Unspecified)					
Life-Threatening	Hepatitis	Health	(Haloperidol)	PS		ORAL	MG, DAILY,	
	Jaundice	Professional				ORAL		
	Renal Failure Acute		Mepronizine (Mepronizine)	SS		ORAL	MG, DAILY,	
						ORAL		
			Noctran (Noctran)	SS		ORAL	TABLE, DAILY,	
						ORAL		
			Theralene (Alimemazine Tartrate)	SS		ORAL	MG, DAILY,	
						ORAL		
			Cholstat (Cerivastatin)	SS		ORAL	0.3 MG,	
						DAILY, ORAL		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/02/99ISR Number: 3387349-9Report Type:Direct Company Report #
Age:15 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Aphasia Catatonia Joint Stiffness Musculoskeletal Stiffness Neuroleptic Malignant Syndrome Pyrexia Tachycardia Urinary Incontinence		Haloperidol	PS				

Date:11/02/99ISR Number: 3388250-7Report Type:Expedited (15-DaCompany Report #JACGER1999000696
Age:73 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Akinesia Difficulty In Walking Fall Motor Dysfunction Parkinsonism Salivary Hypersecretion	Foreign Health Professional	Haldol (Tablet) (Haloperiodl) Lopirin(Captopril) Ass(Acetylsalicylic Acid)	PS C C		ORAL	4 MG, DAILY, ORAL	

Date:11/02/99ISR Number: 3388252-0Report Type:Expedited (15-DaCompany Report #JRFBEL1999001763
Age:48 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Blood Creatine Phosphokinase Increased Depressed Level Of Consciousness Drug Interaction Fall	Foreign Health Professional	Haldol (Unspecified) (Haloperidol) Akineton Retard(Biperiden Hydrochloride)	PS SS			MG, DAILY, UNK MG, DAILY,	

	Hyponatraemia						
UNK							
	Injury			Trileptal(Oxcarbazep			
	Neuroleptic Malignant			ine)	SS		
MG, DAILY,							
	Syndrome						
UNK							
	Pyrexia			Urbanyl(Clobazam)	SS		
MG, DAILY,							
	Serotonin Syndrome						
UNK							
				Aurorix(Moclobemide)	SS		
MG, DAILY,							
UNK							

Date:11/02/99ISR Number: 3388556-1Report Type:Expedited (15-DaCompany Report #HQ3488125OCT1999
Age:54 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hypotension Hypothermia	Health Professional	Effexor (Venlafaxine Hydrochloride)	PS		ORAL	1200 MG	
Other	Overdose	Other						
OVERDOSE								
	Sedation							
AMOUNT ORAL								1 DAY
			Haloperidol(Haloperidol)	SS		ORAL	45 MG	
OVERDOSE								
AMOUNT ORAL								1 DAY
			Lorametazepam (Lorametazepam)	SS		ORAL	30 MG	
OVERDOSE								

AMOUNT ORAL 1 DAY

Propranolol
(Propranolol) SS ORAL
550 MG

OVERDOSE

AMOUNT ORAL 1 DAY

Date:11/02/99ISR Number: 3412667-5Report Type:Direct Company Report #
Age:58 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Bradycardia		Dopamine Hci Wc Labs	PS	Wc Labs	INTRAVENOUS	VARIOUS	
Hospitalization - Initial or Prolonged	Cardiac Arrest					INFUSION IV		
	Hypotension		Haloperidol Goldline	SS	Goldine	INTRAVENOUS	VARIOUS	
Required	Ventricular Tachycardia					VARIOUS IV		
Intervention to Prevent Permanent Impairment/Damage			Lorazepam	C				

Date:11/03/99ISR Number: 3388592-5Report Type:Direct Company Report #
Age:54 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Injection Site Mass Injection Site Oedema		Haloperidol Decanoate 100mg/Ml 5ml Vial	PS	Ben Venue/Bed Ford Labs	INTRAMUSCULAR	150MG IM Q	
						28D		
			Docusate	C				
			Ranitidine	C				
			Medroxyprogesterone	C				
			Cephalexin	C				
			Allopurinal	C				

Haloperidol Conc	C
Therapeutic Vitamin	C
Lorazepam	C
Doxopin	C
Nifedipine	C
Estrogens	C
Acarbase	C
Benztropine	C
Depakote	C
Doxazosin	C
Lithium Carbonate	C

Date:11/03/99ISR Number: 3388593-7Report Type:Direct Company Report #
Age:58 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Injection Site Mass		Haloperidol			
	Injection Site Oedema		Decanoate 100mg/Ml			
			5ml Vial	PS	Ben Venue/Bedford Labs	
INTRAMUSCULAR 75MG IM Q 14D 1 YR						
			Valproic Acid	C		
			Ativan	C		
			Docusate	C		
			Clonazepam	C		
			Benztropine	C		
			Enalapril	C		
			Haloperidol Conc	C		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/03/99ISR Number: 3388595-0Report Type:Direct Company Report #
Age:61 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Injection Site Mass Injection Site Oedema		Haloperidol Decanoate 100mg/Ml 5ml Vial	PS	Ben Venue/Bedford Labs		100MG Q 14 D	1 YR
			Celecoxib	C				
			Lorazepam	C				
			Docusate	C				
			Docusate With Cassanthranol	C				
			Ferrous Gluconate	C				
			Selenium Sulfide Shampoo	C				
			Benztropine	C				
			Fluoxetine	C				
			Fluoxetine	C				
			Vitamin B Complex With C	C				
			Bisacodyl	C				

Date:11/03/99ISR Number: 3389001-2Report Type:Expedited (15-DaCompany Report #JRFBEL1999001752
Age:48 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Blood Creatine Phosphokinase Increased Blood Pressure Increased Body Temperature Increased Bradyphrenia Catatonia Cold Sweat Delusion	Foreign Health Professional	Haldol (Unspecified) (Haloperidol)	PS			100MG, TOTAL, UNKNOWN STARTED IN EARLY 1999.	
			Fluanxol (Flupentixol Dihydrochloride)	SS				
			Zyprexa (Olanzapine)	SS			10 MG, DAILY, UNKNOWN	

	Hallucination, Auditory		
MG, 2 IN 1			
	Hypotension		
DAY(S),			
	Leukocytosis		
UNKNOWN			
	Lung Infiltration	Temesta (Lorazepam)	SS
MG, TOTAL,			
	Motor Dysfunction		
UNKNOWN/ MG,			
	Mutism		
TOTAL,			
	Neuroleptic Malignant		
UNKNOWN/ 1			
	Syndrome		
MG, 3 IN 1			
	Pleural Effusion	Dalmadorm	
	Pulmonary Embolism	(Flurazepam	
	Sinus Tachycardia	Hydrochloride)	SS
MG, DAILY,			
	Stereotypy		
UNKNOWN			
	Stupor	Akineton (Biperiden	
	Syncope	Hydrochloride)	SS
2 MG, 4 IN 1			
DAY(S),			
UNKNOWN			
		Tenormin (Atenolol)	SS
100 MG, 1 IN			
1 DAY(S),			
UNKNOWN			

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/03/99ISR Number: 3389115-7Report Type:Expedited (15-DaCompany Report #JRFBEL1999001602
Age:52 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Blood Creatine	Foreign	Risperidone					
Hospitalization -	Phosphokinase Increased	Health	(Unspecified)					
Initial or Prolonged	Blood Creatinine	Professional	(Risperidone)	PS		ORAL	MG, DAILY,	
Required	Increased						ORAL	
Intervention to	Blood Urea Increased		Haldol Decanoate					
Prevent Permanent	Myoglobinuria		(Unspecified)					
Impairment/Damage	Oral Intake Reduced		(Haloperidol					
	Paralysis		Decanoate)	SS				
INTRAMUSCULAR	Pyrexia						50 MG, 1 IN 1	MONTH(S), IM
	Rhabdomyolysis							

Date:11/03/99ISR Number: 3389116-9Report Type:Expedited (15-DaCompany Report #JRFBEL1999001438
Age:43 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Acidosis	Foreign	Risperidone					
Initial or Prolonged	Anuria	Health	(Unspecified)					
Other	Blood Creatine Increased	Professional	(Risperidone)	PS		ORAL	MG, DAILY,	
Required	Blood Creatine						ORAL	
Intervention to	Phosphokinase Increased		Haloperidol					
Prevent Permanent	Blood Urea Increased		(Unspecified)					
Impairment/Damage	Chromaturia		(Haloperidol)	SS		ORAL	G, DAILY,	
	Haemodialysis						ORAL (SEE	
	Myocardial Infarction						IMAGE)	
	Pyelonephritis		Pravastatin Sodium					
	Renal Failure		(Pravastatin Sodium)	SS		ORAL	MG, DAILY,	
	Rhabdomyolysis						ORAL	

	Urinary Retention		Fluphenazine Maleate	SS		ORAL
MG, DAILY,						
ORAL						
			Carbamazepine (Carbamazepine)	C		
			Promazine Hydrochloride (Promazine Hydrochloride)	C		
			Levomepromazine Maleate (Levomepromazine Maleate)	C		

Date:11/04/99ISR Number: 3389065-6Report Type:Expedited (15-DaCompany Report #JACFRA1999000400
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Dialysis Hiccups Injection Site Thrombosis Medication Error	Foreign Health Professional	Haldol Decanoas (50 Mg/Ml Injection) (Haloperidol Decanoate)	PS		
INTRAVENOUS MG, TOTAL, IV						
	Renal Failure Acute		Tegretol (Carbamazepine)	C		
			Mopral (Omeprazole)	C		
			Tranxene (Clorazepate Dipotassium)	C		
			Loxen (Nicardipine Hydrochloride)	C		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/05/99ISR Number: 3389424-1Report Type:Direct Company Report #
Age:34 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Hyperthermia Malignant		Haldol	PS				
	Muscle Rigidity		Risperidal	SS				
	Neuroleptic Malignant Syndrome							

Date:11/05/99ISR Number: 3390038-8Report Type:Expedited (15-DaCompany Report #J/94/00042/TER
Age:33 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Muscle Necrosis	Foreign	Sanorex	PS				
	Rhabdomyolysis	Health Professional	Gamma-Oryzanol	SS				
			Prazosin	SS				
			Haloperidol	SS				
			Biperiden	SS				
			Nitrendipine	C				
			Zotepine	C				
			Bromperidol	C				

Date:11/05/99ISR Number: 3390079-0Report Type:Expedited (15-DaCompany Report #GB/94/00859/LEX
Age:33 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Aggression	Foreign	Clozaril	PS		ORAL	150 MG; 300	
Required	Cardiac Arrest	Health					MG, TWICE A	
Intervention to	Cardio-Respiratory Arrest	Professional					DAY, ORAL	
Prevent Permanent	Circulatory Collapse		Clopixol	SS			200MG	
Impairment/Damage	Shock		Haloperidol	SS			2 MIN	
			Melleril	SS				
			Lithium	C				
			Salbutamol	C				
			Ranitidine	C				

			Benzhexol	C		

Date:11/05/99ISR Number: 3390115-1Report Type:Expedited (15-DaCompany Report #DEU002247
Age:18 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Abdominal Pain	Foreign	Akineton	PS		ORAL	3 MG DAILY PO	
Initial or Prolonged	Acute Respiratory	Other	Serenace	SS		ORAL	6 MG DAILY PO	
	Distress Syndrome		Contomin	SS		ORAL	300 MG DIALY	
	Blood Pressure Decreased						PO; 100 MG	
	C-Reactive Protein						DAILY PO	
	Increased		Pyrethia	SS		ORAL	25 MG DAILY	
	Cardio-Respiratory Arrest						PO	
	Constipation							
	Dialysis							
	Flatulence							
	Hypoventilation							
	Hypovolaemia							
	Ileus Paralytic							
	Oliguria							
	Sepsis							
	White Blood Cell Count Decreased							

Date:11/05/99ISR Number: 3390116-3Report Type:Expedited (15-DaCompany Report #DEU002248
Age:56 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Abdominal Distension	Foreign	Akineton	PS		ORAL	6 MG DAILY PO
	Abdominal Pain	Other	Serenace	SS		ORAL	24 MG DAILY PO
	Blood Pressure Decreased						
	Depressed Level Of Consciousness		Hirnamin	SS		ORAL	400 MG DAILY PO
	Depression		Neuleptil	SS		ORAL	150 MG DAILY PO
	Faeces Hard						
	Haemodialysis		Pyrethia	SS		ORAL	75 MG DAILY PO
	Ileus Paralytic						
	Nausea		Popon S	C			
	Renal Failure		Cinal	C			
	Shock		Isomytal	C			
	Ventricular Fibrillation		Brovarin	C			
			Vegetamin A	C			
			Dalmate	C			
			Magnesium	C			
			Sennaride	C			

Date:11/08/99ISR Number: 3390791-3Report Type:Expedited (15-DaCompany Report #JRFBEL1999001438
Age:43 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Acidosis	Foreign	Haloperidol(Unspecified)(Haloperidol)	PS		ORAL	MG, DAILY, Other ORAL
	Anuria	Health					
	Blood Creatine Phosphokinase Increased	Professional	Risperidone (Unspecified)				
Required Intervention to	Blood Creatinine						

Prevent Permanent Impairment/Damage	Increased Blood Urea Increased Chromaturia Haemodialysis Pyelonephritis Renal Failure Rhabdomyolysis Urinary Retention	(Risperidone) Pravastatin Sodium (Pravastatin Sodium) Fluphenazine Maleate (Fluphenazine Maleate) Carbamazepine (Carbamazepine) Promazine Hydrochloride (Promazine Hydrochloride) Levomepromazine Maleate (Levomepromazine Maleate)	SS SS SS C C C	ORAL MG, DAILY, ORAL ORAL MG, DAILY, ORAL ORAL MG, DAILY, ORAL

Date:11/08/99ISR Number: 3391463-1Report Type:Expedited (15-DaCompany Report #JRFBEL1999001602
Age:52 YR Gender:Male I/FU:I

Outcome
Life-Threatening
Hospitalization - Initial or Prolonged
Required Intervention to

Prevent Permanent
Impairment/Damage

	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Blood Creatine Phosphokinase Increased Blood Creatinine Increased Blood Urea Increased Haemodialysis Myoglobin Blood Increased Myoglobinuria Oral Intake Reduced Paralysis Pyrexia Rhabdomyolysis	Foreign Health Professional	Haldol Decanoate (Unspecified) (Haloperidol Decanoate) Risperidone (Unspecified) (Risperidone)	PS SS		INTRAMUSCULAR ORAL	50 MG, 1 IN 1 MONTH(S), IM MG, DAILY, ORAL	

Date:11/10/99ISR Number: 3391381-9Report Type:Direct Company Report #
Age:14 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Extrapyramidal Disorder		Haldol	PS		INTRAVENOUS	5MG IV X 2-19 MIN APART (2 DOSES)	
			Cogentin	C				

Date:11/10/99ISR Number: 3393986-8Report Type:Expedited (15-DaCompany Report #JACFRA1999000411
Age:71 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Akinesia	Foreign	Haldol (5 Mg Tablet)					

Initial or Prolonged	Condition Aggravated	Health	(Haloperidol)	PS		ORAL
MG, DAILY,						
	Hypoaesthesia	Professional				
ORAL						

Date:11/12/99ISR Number: 3396868-0Report Type:Expedited (15-DaCompany Report #PRIUSA1999007947
Age:15 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Amnesia	Health	Haldol (Unspecified)			
	Encephalopathy	Professional	(Haloperidol)	PS		
	Neuroleptic Malignant		Thorazine			
	Syndrome		(Chlorpromazine			
			Hydrochloride)	SS		

Date:11/12/99ISR Number: 3397070-9Report Type:Expedited (15-DaCompany Report #JRFBEL1999001477
Age:18 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Dysuria	Foreign	Haloperidol			
Initial or Prolonged		Health	(Injection)			
Required		Professional	(Haloperidol)	PS		
INTRAVENOUS MG, DAILY, IV						
Intervention to			Haloperidol			
Prevent Permanent			(Unspecified)			
Impairment/Damage			(Haloperidol)	SS		ORAL
MG, DAILY,						
ORAL						
			Risperidone			
			(Unspecified)			

			(Risperidone)	SS			ORAL
MG, DAILY,							
ORAL							
			Chlorpromazine Hydrochloride (Chlorpromazine Hydrochloride)	SS			ORAL
MG, DAILY,							
ORAL							
			Bromazepam (Bromazepam)	SS			ORAL
MG, DAILY,							
ORAL							
			Trihexyphenidyl Hydrochloride (Trihexyphenidyl Hydrochloride)	SS			ORAL
MG, DAILY,							
ORAL							

Date:11/16/99ISR Number: 3397781-5Report Type:Expedited (15-DaCompany Report #M1999.0779
Age:51 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Withdrawal Syndrome Headache Tremor	Other	Haloperidol 2 Mg Tablet, Geneva Manufacture	PS		ORAL	2 MG, QID, PO	
			Lorazepam 2 Mg Tablet. Mylan Distributed	SS		ORAL	2 MG, QID, PO	

Date:11/16/99ISR Number: 3398294-7Report Type:Expedited (15-DaCompany Report #PRIUSA1999007835
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Neuroleptic Malignant	Health	Haldol (Injection)					

Hospitalization - Initial or Prolonged	Syndrome	Professional	(Haloperidol)	PS		INTRAMUSCULAR IM

Date:11/16/99ISR Number: 3398525-3Report Type:Expedited (15-DaCompany Report #PRIUSA1999006523
Age:38 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Death	Cardiac Arrest	Literature	Haldol (Unspecified)				
Hospitalization - Initial or Prolonged	Completed Suicide	Health Professional	(Haloperidol)	PS			
	Drug Level Above Therapeutic		Chloral Hydrate (Chloral Hydrate)	SS		ORAL	ORAL
	Respiratory Arrest		Temazepam (Temazepam)	SS		ORAL	ORAL

Date:11/16/99ISR Number: 3398530-7Report Type:Expedited (15-DaCompany Report #PRIUSA1999006510
Age:53 YR Gender:Female I/FU:F

Outcome	PT
Death	Atrioventricular Block Complete
Hospitalization - Initial or Prolonged	Cardiogenic Shock
	Grand Mal Convulsion
	Heart Rate Decreased
	Heart Rate Increased
	Hypotension
	Myocardial Infarction

		Pyromania Ventricular Fibrillation					
			Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
			Literature	Haldol (Unspecified)			
			Health	(Haloperidol)	PS		ORAL
ORAL							
			Professional	Captopril			
				(Captopril)	SS		ORAL
ORAL							
				Benztropine			
				(Benztropeine)	SS		ORAL
ORAL							
				Theo-Dur			
				(Theophylline)	C		
				Hydrochlorothiazide			
				(Hydrochlorothiazide			
				)	C		
				Diazepam (Diazepam)	C		

Date:11/16/99ISR Number: 3398533-2Report Type:Expedited (15-DaCompany Report #PRIUSA1999006509
Age:52 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Death	Agitation	Literature	Haldol (Unspecified)			
Hospitalization -	Anion Gap Increased	Health	(Haloperidol)	PS		ORAL
ORAL						
Initial or Prolonged	Anuria	Professional	Doxepin (Doxepin)	SS		ORAL
ORAL						
Required	Blood Creatine		Ethylene Glycol	SS		ORAL
ORAL						
Intervention to	Phosphokinase Increased		Chlorpropamide			
Prevent Permanent	Blood Glucose Increased		(Chlorpropamide)	SS		ORAL
ORAL						
Impairment/Damage	Bronchospasm					
	Cardio-Respiratory Arrest					
	Completed Suicide					
	Dialysis					
	Disseminated					
	Intravascular Coagulation					
	Haematuria					
	Hypotension					
	Liver Function Test					
	Abnormal					

Loss Of Consciousness
Metabolic Acidosis
Mydriasis
Myoglobinuria
Prothrombin Time
Prolonged
Pyrexia
Tachypnoea

Date:11/16/99ISR Number: 3399067-1Report Type:Expedited (15-DaCompany Report #7399439
Age: Gender:Male I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Blood Creatine Phosphokinase Increased
	Difficulty In Walking
	Excoriation
	Fall
	Feeling Jittery
	Neuroleptic Malignant Syndrome
	Oliguria
	Parkinson'S Disease

Pyrexia

		Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
		Health Professional	Abbott- Depakote	PS	Abbott	
			Haldol	SS		ORAL
PO						

Date:11/16/99ISR Number: 3399186-XReport Type:Expedited (15-DaCompany Report #M1999.0779
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization - Initial or Prolonged	Drug Withdrawal Syndrome Headache Tremor	Other	Haloperidol 2mg Tablet, Geneva Manufacture	PS	Geneva Manufacture	ORAL
2 MG, QID, PO						
			Lorazepam 2 Mg Tablet. Mylan Distributed	SS	Mylan	ORAL
2 MG QID, PO						

Date:11/17/99ISR Number: 3398638-6Report Type:Direct Company Report #
Age:66 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization - Initial or Prolonged	Torsade De Pointes Ventricular Fibrillation		Imipramine 100 Mg	PS		ORAL
100MG PO QHS ; 1ST DOSE Other AFTER 10 DAYS	10 DAY					
			Haldol 2mg Im	SS		
INTRAMUSCULAR	2MG IM; PRN					

Date:11/17/99ISR Number: 3399502-9Report Type:Expedited (15-DaCompany Report #M0672-99
Age:61 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					

Life-Threatening	Cardiac Murmur	Foreign	Remeron	PS		ORAL
30 MG/DAY						
Required	Delirium	Health				
PO						
Intervention to	Pain In Extremity	Professional	Haloperidol	SS		
Prevent Permanent	Venous Thrombosis Limb		Amitriptyline	SS		
Impairment/Damage			Presomen (Extract			
			Frm Pregnant Mare			
			Urine)	SS		
			Amlodipine	C		
			Fenoterol/Lipratropi			
			um	C		
			Flurazepam	C		
			Fluticasone	C		
			Lorazepam	C		

Date:11/18/99ISR Number: 3401313-2Report Type:Expedited (15-DaCompany Report #JACFRA1999000429
Age:35 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Alanine Aminotransferase	Foreign	Haldol (Unspecified)					
Initial or Prolonged	Increased	Health	(Haloperidol)	PS		ORAL		
ORAL								
	Aspartate	Professional	Tranxene					
	Aminotransferase		(Clorazepate					
	Increased		Dipotassium)	SS		ORAL		
MG, TOTAL,								
	Intentional Misuse							
ORAL								
	Suicide Attempt		Deroxate (Paroxetine					
			Hydrochloride)	SS		ORAL		
MG, TOTAL,								
ORAL								

			Claradol (Paracetamol)	SS		ORAL	G, TOTAL, ORAL

Date:11/18/99ISR Number: 3401407-1Report Type:Expedited (15-DaCompany Report #7399439
Age:57 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Anuria	Health	Abbott-Depakene	PS	Abbott	ORAL	500.000 MG PO TID
	Blood Creatine Phosphokinase Increased	Professional	Haldol	SS		ORAL	0.500 MG PO BID
	Blood Creatinine Increased		Lithium	C			
	Blood Urea Increased		Inderal	C			
	Excoriation		Wellbutrin	C			
	Extrapyramidal Disorder		Paxil	C			
	Fall		Inh	C			
	Neuroleptic Malignant Syndrome						
	Parkinson'S Disease						
	Pyrexia						
	Renal Failure						

Date:11/19/99ISR Number: 3402997-5Report Type:Expedited (15-DaCompany Report #JRFBEL1999001857
Age:20 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Abdominal Pain Anxiety Blood Pressure Increased	Foreign Literature Health	Risperidone (Unspecified) (Risperidone)	PS		ORAL	1 MG 2 IN 1 DAY(S) ORAL
	Condition Aggravated Decreased Activity	Professional					

		Decreased Appetite	Haldol (Unspecified)					
		Depressed Mood	(Haloperidol)	SS			ORAL	MG DAILY
		Dyspnoea						
ORAL	6 YR							
		Dystonia	Buspirone					
		Hyperhidrosis	(Buspirone)	C				
		Intraocular Pressure Increased	Timolol (Timolol)	C				
		Lethargy						
		Movement Disorder						
		Panic Reaction						
		Polydipsia						
		Polyuria						
		Posture Abnormal						
		Respiratory Disorder						
		Tachycardia						

Date:11/19/99ISR Number: 3403270-1Report Type:Direct Company Report #
Age: Gender:Male I/FU:I

Outcome
Death
Life-Threatening
Hospitalization -
Initial or Prolonged
Disability
Other

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Blood Pressure Decreased		Haloperidol (Haldol)	PS			5 MG HALDOL	
	Cerebral Cyst		Any Or All Fluorine Based Drugs	SS			DAILY	
	Fungal Infection							
	Gastrointestinal Neoplasm							
	Weight Increased							

Date:11/22/99ISR Number: 3403230-0Report Type:Direct Company Report #
Age:48 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Catatonia	Health Professional	Haloperidol	PS				
	Drooling							
	Dyskinesia							
	Feeling Jittery							
	Hypoaesthesia							
	Movement Disorder							
	Muscle Rigidity							
	Parkinsonism							
	Salivary Hypersecretion							
	Speech Disorder							

Date:11/22/99ISR Number: 3404802-XReport Type:Expedited (15-DaCompany Report #PRIUSA1999006587
Age:47 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardiac Arrest	Literature	Haldol(Unspecified)					
Required	Coma	Health	(Haloperidol)	PS		ORAL		
Intervention to	Completed Suicide	Professional	Doxepin (Doxepin)	SS		ORAL		
Prevent Permanent Impairment/Damage	Cyanosis		Toradol (Ketorolac Tromethamine)	SS		ORAL		
	Pulse Pressure Decreased							
	Status Epilepticus		Ethanol (Ethanol)	C		ORAL		

Date:11/22/99ISR Number: 3404804-3Report Type:Expedited (15-DaCompany Report #PRIUSA1999006585
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Agitation	Literature	Haldol(Unspecified0					
Hospitalization -	Arrhythmia	Health	(Haloperidol)	PS		ORAL		
ORAL								
Initial or Prolonged	Blood Ph Increased	Professional	Desipramine					
Required	Bradycardia		(Desipramine)	SS				
Intervention to	Coma		Propranolol					
Prevent Permanent	Completed Suicide		(Propranolol)	SS		ORAL		
ORAL								
Impairment/Damage	Convulsion							
	Hypotension							
	Intestinal Gangrene							
	Pupil Fixed							
	Pyrexia							
	Shock							
	Tachycardia							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/22/99ISR Number: 3404805-5Report Type:Expedited (15-DaCompany Report #PRIUSA1999006545
Age:35 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Death	Aspiration	Literature	Haldol(Unspecified)				
Hospitalization -	Brain Oedema	Health	(Haloperidol)	PS		ORAL	
ORAL							
Initial or Prolonged	Bronchopneumonia	Professional	Trazodone				
Required	Cardiac Arrest		(Trazodone)	SS		ORAL	
ORAL							
Intervention to	Coma		Clonazepam				
Prevent Permanent	Completed Suicide		(Clonazepam)	SS		ORAL	
ORAL							
Impairment/Damage	Convulsion		Clonidine				
	Coronary Artery Disease		(Clonidine)	SS		ORAL	
ORAL							
	Hypertension						
	Hypoxic Encephalopathy						
	Overdose						
	Pco2 Decreased						
	Po2 Increased						
	Pupil Fixed						
	Pyrexia						
	Respiratory Arrest						
	Tachycardia						

Date:11/22/99ISR Number: 3404806-7Report Type:Expedited (15-DaCompany Report #PRIUSA1999006544
Age:33 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Death	Blood Pressure Increased	Literature	Haldol(Unspecified)				
Hospitalization -	Cardio-Respiratory Arrest	Health	(Haloperidol)	PS		ORAL	
ORAL							
Initial or Prolonged	Completed Suicide	Professional	Amantadine				
Required	Convulsion		(Amantadine)	SS		ORAL	
ORAL							
Intervention to	Mydriasis		Benztropine				
Prevent Permanent	Pupil Fixed		(Benztropeine)	SS		ORAL	
ORAL							
Impairment/Damage	Tachycardia						

Date:11/22/99ISR Number: 3404807-9Report Type:Expedited (15-DaCompany Report #PRIUSA1999006543
Age:31 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Anuria	Literature	Haldol (Unspecified)					
Hospitalization - Initial or Prolonged	Blood Creatine Increased	Health	(Haloperidol)	PS		ORAL	ORAL	
Required Intervention to Prevent Permanent Impairment/Damage	Blood Urea Increased	Professional	Lithium (Lithium)	SS		ORAL	ORAL	
	Body Temperature Increased		Prozac (Fluoxetine Hydrochloride)	SS		ORAL	ORAL	
	Coma		Cogentin (Benzatropine Mesilate)	SS		ORAL	ORAL	
	Completed Suicide							
	Convulsion							
	Drug Level Above Therapeutic							
	Electroencephalogram Abnormal							
	Haemodialysis							
	Hypotension							
	Nervous System Disorder							

Date:11/22/99ISR Number: 3405757-4Report Type:Expedited (15-DaCompany Report #PRIUSA1999008169
Age:77 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Coma Hyperpyrexia Tachycardia	Consumer	Haldol (Injection) (Haloperidol)	PS		INTRAVENOUS	2MG PRN IV	1 WK

Date:11/22/99ISR Number: 3406025-7Report Type:Expedited (15-DaCompany Report #PRIUSA1999006617
Age:25 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Acute Respiratory Distress Syndrome	Literature	Haldol (Unspecified)					
Hospitalization - Initial or Prolonged	Cardio-Respiratory Arrest	Health Professional	(Haloperidol) Diphenhydramine	PS		ORAL		
Required Intervention to Prevent Permanent Impairment/Damage	Coma Completed Suicide Convulsion Diabetes Insipidus Hypertension Nervous System Disorder Pneumonia Haemophilus Pneumothorax Po2 Decreased Posturing Pyrexia Tachycardia Toxicologic Test Abnormal		(Diphenhydramine)	SS		ORAL		

Date:11/22/99ISR Number: 3406095-6Report Type:Expedited (15-DaCompany Report #PRIUSA1999006616
Age:29 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardio-Respiratory Arrest	Literature	Haldol(Unspecified)					
Hospitalization - Initial or Prolonged	Completed Suicide Depressed Level Of	Health Professional	(Haloperidol) Desipramine(Desipram	PS		ORAL		

	Consciousness	ine)	SS	ORAL
ORAL				
	Drug Level Above Therapeutic	Nortriptyline(Nortriptyline)	SS	ORAL
ORAL				
	Hypotension Overdose	Cogentin(Benzatropine Mesilate)	SS	ORAL
ORAL				
	Toxicologic Test Abnormal			
	Ventricular Tachycardia			

Date:11/22/99ISR Number: 3406096-8Report Type:Expedited (15-DaCompany Report #PRIUSA1999006615
Age:29 YR Gender:Male I/FU:F

Outcome	PT
Death	Activated Partial
Hospitalization -	Thromboplastin Time
Initial or Prolonged	Prolonged
Required	Acute Respiratory
Intervention to	Distress Syndrome
Prevent Permanent	Agitation
Impairment/Damage	Atrioventricular Block
	First Degree
	Blood Bicarbonate
	Decreased
	Blood Bilirubin Increased

	Blood Ph Decreased Cardiac Arrest Completed Suicide	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Convulsion Depressed Level Of Consciousness Electrocardiogram Abnormal Oxygen Saturation Decreased Pco2 Decreased Po2 Decreased Prothrombin Time Prolonged Renal Failure Respiratory Arrest Sinus Tachycardia Ventricular Tachycardia	Literature Health Professional	Haldol(Unspecified) (Haloperidol) Desipramine(Desipramine)	PS SS		ORAL ORAL	ORAL ORAL

Date:11/22/99ISR Number: 3406098-1Report Type:Expedited (15-DaCompany Report #PRIUSA1999006614
Age:37 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Death Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Cardio-Respiratory Arrest Coma Completed Suicide Drug Level Above Therapeutic Electroencephalogram Abnormal Intentional Misuse Mydriasis	Literature Health Professional	Haldol(Unspecified) (Haloperidol) Acetaminophen(Paracetamol)	PS SS		ORAL ORAL	ORAL ORAL

Date:11/22/99ISR Number: 3406100-7Report Type:Expedited (15-DaCompany Report #PRIUSA1999006613
Age:30 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Literature	Haldol(Unspecified)					
	Intentional Misuse	Health	(Haloperidol)	PS		ORAL	10 MG, 20 IN	1 TIME(S),
	Vomiting	Professional						
			Asendin (Amoxapine)	SS		ORAL	100 MG, 20 IN	1 TIME(S),

Date:11/22/99ISR Number: 3406101-9Report Type:Expedited (15-DaCompany Report #PRIUSA1999006612
Age:47 YR Gender:Unknown I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Literature	Haldol(Unspecified)					
Required	Convulsion	Health	(Haloperidol)	PS		ORAL		
Intervention to	Dissociation	Professional	Amitriptyline(Amitri					
Prevent Permanent	Electrocardiogram		ptyline)	SS		ORAL		
Impairment/Damage	Abnormal		Chlordiazepoxide(Chl					
	Heart Rate Increased		ordiazepoxide)	SS		ORAL		
	Respiratory Arrest							
	Vomiting							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/22/99ISR Number: 3406102-0Report Type:Expedited (15-DaCompany Report #PRIUSA1999006591
Age:73 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Coma	Literature	Haldol(Unspecified)					
Hospitalization -	Hypotension	Health	(Haloperidol)	PS		ORAL		
ORAL								
Initial or Prolonged	Ileus Paralytic	Professional						
Required	Muscle Rigidity							
Intervention to	Pyrexia							
Prevent Permanent	Respiratory Arrest							
Impairment/Damage								

Date:11/22/99ISR Number: 3406104-4Report Type:Expedited (15-DaCompany Report #PRIUSA1999006589
Age:33 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Blood Creatine	Literature	Haldol(Unspecified)					
Hospitalization -	Phosphokinase Increased	Health	(Haloperidol)	PS		ORAL		
ORAL								
Initial or Prolonged	Blood Pressure Diastolic	Professional						
Required	Increased							
Intervention to	Blood Sodium Increased							
Prevent Permanent	Blood Urea Increased							
Impairment/Damage	Brain Damage							
	Brain Hypoxia							
	Coma							
	Feeling Jittery							
	Muscle Rigidity							
	Pyrexia							
	Tachycardia							

Date:11/22/99ISR Number: 3406107-XReport Type:Expedited (15-DaCompany Report #PRIUSA1999006588
Age:89 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Bradycardia	Literature	Haldol(Unspecified)					
Hospitalization -	Coma	Health	(Haloperidol)	PS		ORAL		
ORAL								
Initial or Prolonged	Completed Suicide	Professional	Butalbital(Butalbita					

Required	Electrocardiogram Qt		l)	SS	ORAL
ORAL					
Intervention to	Prolonged		Lorazepam(Lorazepam)	SS	ORAL
ORAL					
Prevent Permanent	Overdose				
Impairment/Damage	Toxicologic Test Abnormal				

Date:11/23/99ISR Number: 3405366-7Report Type:Direct Company Report #
Age:86 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Agitation		Ativan 1mg Tid	PS		
Initial or Prolonged	Balance Disorder		Haldol 1mg Tid	SS		
	Dry Mouth		Ecasa	C		
	Hallucination, Visual		Hydroxyzine	C		
	Mental Impairment		Norvasc	C		
			Ativan	C		

Date:11/24/99ISR Number: 3408994-8Report Type:Expedited (15-DaCompany Report #JRFBEL1999001602
Age:52 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Blood Creatine	Foreign	Haldol Decanoate					
Hospitalization -	Phosphokinase Increased	Health	(Unspecified)					
Initial or Prolonged	Blood Creatinine	Professional	(Haloperidol					
Required	Increased		Decanoate)	PS				
Intervention to	Blood Urea Increased							
Prevent Permanent	Immobile		Risperidone					
Impairment/Damage	Myoglobinuria		(Unspecified)					
	Oral Intake Reduced		(Risperidone)	SS				
	Paralysis							
	Pyrexia							
	Rhabdomyolysis							

Date:11/24/99ISR Number: 3409002-5Report Type:Expedited (15-DaCompany Report #JRFBEL1999001894
Age:31 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Condition Aggravated	Foreign	Haloperidol(Unspecif					
Initial or Prolonged	Disinhibition	Literature	ied) (Haloperidol)	PS				
	Euphoric Mood	Health						
	Hypomania	Professional	Olanzapine					
	Insomnia		(Olanzapine)	SS				
	Persecutory Delusion							
	Pressure Of Speech							
	Psychotic Disorder							

Date:11/24/99ISR Number: 3409003-7Report Type:Expedited (15-DaCompany Report #JACFRA1999000429
Age:35 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Hospitalization - Initial or Prolonged, TOTAL, ORAL	Liver Function Test Abnormal Overdose Suicide Attempt	Foreign Health Professional	Haldol (Unspecified) (Haloperidol)	PS		ORAL
			Tranxene (Clorazepate Dipotassium) MG, TOTAL, ORAL	SS		ORAL
			Deroxat (Paroxetine Hydrochloride) MG, TOTAL, ORAL	SS		ORAL
			Claradol (Paracetamol) G, TOTAL, ORAL	SS		ORAL

Date:11/24/99ISR Number: 3409957-9Report Type:Expedited (15-DaCompany Report #PRIUSA1999006602
Age:28 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death Required Intervention to Prevent Permanent Impairment/Damage	Bradycardia Cardiac Arrest Completed Suicide Depressed Level Of Consciousness Hypoventilation Pulse Absent	Literature Health Professional	Tylenol W/Codeine No. 4 (Tablet) (Acetaminophen/Codeine)	PS		ORAL
			Percocet (Tylox)	SS		ORAL
			Fiorinal With Codeine (Fiorinal-C 1/4)	SS		ORAL
			Haldol (Unspecified)			

			(Haloperidol)	SS		ORAL	ORAL

Date:11/26/99ISR Number: 3408918-3Report Type:Expedited (15-DaCompany Report #JRFBEL1999001747
Age:19 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardio-Respiratory Arrest	Foreign	Risperidone(Unspecified) (Risperidone)	PS		ORAL	MG, DAILY,	ORAL
	Choking	Health						
	Dyskinesia	Professional						
	Epilepsy		Haloperidol (Haloperidol)	SS		ORAL	MG, DAILY,	ORAL
	Injury Asphyxiation							
	Stupor							
	Vomiting		Sodium Valproate (Valproic Acid)	SS		ORAL	MG, DAILY,	ORAL
			Chlorpromazine Hydrochloride (Chlorpromazine Hydrochloride)	SS		ORAL	MG, DAILY,	ORAL
			Carbocisteine (Carbocisteine)	C				
			Polaramine (Dexchlorpheniramine Maleate)	C				
			Biperiden Hydrochloride (Biperiden Hydrochloride)	C				
			Flunitrazepam (Flunitrazepam)	C				
			Bacampicillin Hydrochloride (Bacampicillin Hydrochloride)	C				
			Teprenone					

			(Teprenone)	C		
			Lithium Carbonate (Lithium Carbonate)	C		
			Clonazepam (Clonazepam)	C		

Date:11/26/99ISR Number: 3409541-7Report Type:Expedited (15-DaCompany Report #99HQ-10458
Age:58 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Liver Function Test Abnormal Muscle Rigidity Neuroleptic Malignant Syndrome Pyrexia Tachycardia Tremor	Foreign Literature Health Professional Other	Clomipramine Hydrochloride Unknown (Clomipramine Hydrochloride)	PS		ORAL	DAILY, ORAL	
			Haloperidol Unknown (Haloperidol)	SS				
			Chlorpromazine Unknown (Chlorpromazine)	SS				
			Promethazine Unknown (Promethazine)	SS				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/26/99ISR Number: 3409847-1Report Type:Expedited (15-DaCompany Report #JRFBEL1999001747
Age:19 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardio-Respiratory Arrest	Foreign	Haloperidol (Unspecified)					
	Choking	Health						
	Dyskinesia	Professional	(Haloperidol)	PS		ORAL	MG, DAILY,	
	Epilepsy						ORAL	
	Injury Asphyxiation		Risperidone (Unspecified)					
	Stupor							
	Tongue Disorder		(Risperidone)	SS		ORAL	NG, DAILY,	
	Vomiting						ORAL	
			Sodium Valproate (Valproic Acid)	SS		ORAL	MG, DAILY,	
							ORAL	
			Chlorpromazine Hydrochloride (Chlorpromazine Hydrochloride)	SS		ORAL	MG, DAILY,	
							ORAL	
			Carbocisteine (Carbocisteine)	C				
			Polaramine (Dexchlorpheniramine Maleate)	C				
			Biperiden Hydrochloride (Hydrochloride (Biperiden Hydrochloride)	C				
			Flunitrazepam (Flunitrazepam)	C				
			Bacampicillin Hydrochloride (Bacampicillin Hydrochloride)	C				
			Teprenone (Teprenone)	C				

				Lithium Carbonate (Lithium Carbonate)	C		
				Clonazepam (Clonazepam)	C		

Date:12/02/99ISR Number: 3413291-0Report Type:Expedited (15-DaCompany Report #JRFBEL1999001609
Age:78 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Interaction	Literature	Haldol (Injection)					
	Heart Rate Decreased	Health	(Haloperidol)	PS				
INTRAVENOUS							0.5 MG, 1	
	Hypotension	Professional						
TIME(S), IV								
			Primaxin (Imipenem)	SS				
INTRAVENOUS							500 MG, 1 IN	
6 HOUR(S), IV							48	HR
			Pepcid (Famotidine)	SS				
INTRAVENOUS							20 MG, 2 IN 1	
DAY(S), IV								
			Ventolin (Salbutamol)	C				
			Proventil (Salbutamol)	C				
			Ventolin (Salbutamol)	C				
			Atrovent					

			(Ipratropium Bromide)	C		
			Heparin (Heparin)	C		
			Solu-Medrol (Methylprednisolone Sodium Succinate)	C		
			Dextrose (Glucose)	C		

Date:12/03/99ISR Number: 3413408-8Report Type:Expedited (15-DaCompany Report #9912820
Age:35 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hepatic Enzyme Increased	Foreign	Abbott - Tranxene	PS	Abbott			
	Suicide Attempt	Health	Haloperidol	SS				
PO X1								
		Professional	Haloperidol	C				
		Other	Paroxetine	C				
			Paracetamol	C				

Date:12/08/99ISR Number: 3417802-0Report Type:Expedited (15-DaCompany Report #JRFBEL1999001977
Age:38 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Bipolar Disorder	Foreign	Haloperidol (Unspecified)					
	Depressed Mood	Literature						
	Mania	Health	(Haloperidol)	PS				
	Platelet Count Decreased	Professional	Flupenthixol Decanoate (Flupentixol Decanoate)	SS				
			Sulpiride (Sulpiride)	SS				
			Thioridazine (Thioridazine)	SS				
			Sedative Drugs (Hypnotics And Sedatives)	SS				

Date:12/08/99ISR Number: 3417803-2Report Type:Expedited (15-DaCompany Report #JRFBEL1999001953
Age:46 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Hospitalization - Initial or Prolonged	Acute Prerenal Failure Cardio-Respiratory Arrest Dyskinesia Muscle Rigidity Neuroleptic Malignant Syndrome Pulmonary Oedema Pyrexia	Foreign Health Professional	Haldol (Tablet) (Haloperidol) Chlorpromazine (Chlorpromazine) Thioridazine (Thioridazine)	PS C C		ORAL ORAL	MG, DAILY,	

Date:12/10/99ISR Number: 3418544-8Report Type:Expedited (15-DaCompany Report #PRIUSA1999006660
Age:53 YR Gender:Female I/FU:F

Outcome
Death
Required
Intervention to
Prevent Permanent

Impairment/Damage

	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Blood Ph Decreased	Literature	Haldol (Unspecified)					
	Bradycardia	Health	(Haloperidol)	PS		ORAL	ORAL	
	Coma	Professional	Carbamazepine					
	Conduction Disorder		(Cabamazepine)	SS		ORAL	ORAL	
	Convulsion		Nortriptyline					
	Hypotension		(Nortriptyline)	SS		ORAL	ORAL	
	Pco2 Decreased							
	Po2 Increased							

Date:12/10/99ISR Number: 3418548-5Report Type:Expedited (15-DaCompany Report #PRIUSA1999006658
Age:89 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Atrial Fibrillation	Literature	Haldol (Unspecified)					
Hospitalization -	Atrioventricular Block	Health	(Haloperidol)	PS		ORAL	ORAL	
Initial or Prolonged	Complete	Professional	Digoxin (Digoxin)	SS		ORAL	ORAL	
	Blood Creatine Increased		Carbidopa / Levodopa					
	Blood Pressure Decreased		(Sinemet)	SS		ORAL	ORAL	
	Blood Urea Increased							
	Bradycardia							
	Coma							
	Confusional State							
	Drug Level Above Therapeutic							
	Medication Error							
	Nausea							
	Oliguria							
	Renal Failure Chronic							
	Vomiting							

Date:12/10/99ISR Number: 3418554-0Report Type:Expedited (15-DaCompany Report #PRIUSA1999006657
Age:62 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Blood Alcohol Increased	Literature	Haldol (Unspecified)					
Hospitalization -	Blood Gases Abnormal	Health	(Haloperidol)	PS		ORAL		
Initial or Prolonged	Blood Ph Decreased	Professional	Nortriptyline					
Required	Cardio-Respiratory Arrest		(Nortriptyline)	SS				
Intervention to	Coma							
Prevent Permanent	Completed Suicide							
Impairment/Damage	Convulsion							
	Drug Level Above							
	Therapeutic							
	Electrocardiogram Qrs							
	Complex Prolonged							
	Hyperglycaemia							
	Hypotension							
	Intentional Misuse							
	Oliguria							
	Tachycardia							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/10/99ISR Number: 3418557-6Report Type:Expedited (15-DaCompany Report #PRIUSA1999006655
Age:57 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Abdominal Distension	Literature	Haldol (Unspecified)					
Hospitalization -	Blood Pressure Increased	Health	(Haloperidol)	PS		ORAL		
Initial or Prolonged	Cardiac Arrest	Professional	Eskalith (Lithium					
Required	Coma		Carbonate)	SS		ORAL	300 MG,	ORAL
Intervention to	Completed Suicide		Lopressor					
Prevent Permanent	Convulsion		(Metoprolol					
Impairment/Damage	Dialysis		Tartrate)	SS		ORAL		
	Drug Level Above		Kaolin (Kaolin)	SS		ORAL		
	Therapeutic		Klonopin					
	Electrocardiogram St		(Clonazepam)	SS		ORAL		
	Segment Elevation		Theochron					
	Electrocardiogram T Wave		(Theophylline)	SS		ORAL		
	Peaked		Synthroid					
	Extrapyramidal Disorder		(Levothyroxine					
	Hypoventilation		Sodium)	SS		ORAL		
	Ileus Paralytic		Sodium Fluoride					
	Injury		(Sodium Fluoride)	SS		ORAL		
	Overdose		Aspirin					
	Sinus Tachycardia		(Acetylsalicylic					
	Tachypnoea		Acid)	SS		ORAL		
	Therapeutic Agent		Tylenol					
	Toxicity		(Paracetamol)	SS		ORAL		
	Tremor		Naprosyn (Naproxen)	SS		ORAL		
	Ventricular Tachycardia		Cogentin					
			(Benzatropine					
			Mesilate)	SS		ORAL		
			Nitroglycerin					
			(Glyceril					
			Trinitrate)	SS		ORAL		

			Vitamin B Complex (B-Komplex "Leciva")	SS		ORAL	ORAL

Date:12/10/99ISR Number: 3418584-9Report Type:Expedited (15-DaCompany Report #PRIUSA1999006812
Age:22 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Death	Cardio-Respiratory Arrest	Literature	Haldol(Unspecified)				
Hospitalization -	Completed Suicide	Health	(Haloperidol)	PS		ORAL	ORAL 1 YR
Initial or Prolonged	Drug Level Above Therapeutic	Professional	Benztropine (Benztropine)	SS		ORAL	ORAL 1 YR
	Intentional Misuse						

Date:12/10/99ISR Number: 3418591-6Report Type:Expedited (15-DaCompany Report #PRIUSA1999006689
Age:70 YR Gender:Female I/FU:F

Outcome	PT
Death	Blood Creatinine Increased
Hospitalization - Initial or Prolonged	Blood Glucose Increased
Required Intervention to Prevent Permanent Impairment/Damage	Blood Potassium Decreased
	Bradycardia
	Cardiac Arrest
	Cardio-Respiratory Arrest
	Completed Suicide
	Depressed Level Of Consciousness

	Hypotension Intentional Misuse Lethargy	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Medication Residue White Blood Cell Count	Literature Health	Haldol(Unspecified) (Haloperidol)	PS		ORAL	ORAL
	Increased	Professional	Synthroid(Levothyrox ine Sodium)	SS		ORAL	ORAL
			Prinivil(Lisinopril)	SS		ORAL	ORAL
			Eskalith(Lithium Carbonate)	SS		ORAL	ORAL
			Dyazide(Dyazide)	SS		ORAL	ORAL

Date:12/10/99ISR Number: 3418597-7Report Type:Expedited (15-DaCompany Report #PRIUSA1999006688
Age:24 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Death Hospitalization -	Apnoea Bradycardia	Literature Health	Haldol(Unspecified) (Haloperidol)	PS		ORAL	120 MG, 1
Initial or Prolonged Required	Cardiac Arrest Cardio-Respiratory Arrest	Professional	Tylenol(Paracetamol)	SS		ORAL	TIME(S), ORAL 300 G,
Intervention to Prevent Permanent Impairment/Damage	Completed Suicide Depressed Level Of Consciousness Hypotension		Aleve(Naproxen Sodium)	SS		ORAL	1TIME(S), ORAL 22 G, 1
	Intentional Misuse Loss Of Consciousness Musculoskeletal Stiffness		Cogentin(Benzatropin e Mesilate)	SS		ORAL	TIME(S), ORAL 120 MG, 1
	Pulse Absent						TIME(S), ORAL

	Trismus		Trazodone(Trazodone)	SS		ORAL 1.5 G, 1
	Vomiting					TIME(S), ORAL
			Paxil(Paxetine Hydrochloride)	SS		ORAL 600 MG, 1 TIME(S), ORAL

Date:12/10/99ISR Number: 3418600-4Report Type:Expedited (15-DaCompany Report #PRIUSA1999006687
Age:51 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Death	Cardio-Respiratory Arrest	Literature	Haldol(Unspecified)			
Hospitalization -	Coma	Health	(Haloperidol)	PS		ORAL ORAL
Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Completed Suicide Mydriasis Overdose Pupil Fixed	Professional				

Date:12/10/99ISR Number: 3418602-8Report Type:Expedited (15-DaCompany Report #PRIUSA1999006685
Age:22 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Death	Cardiac Arrest	Literature	Haldol(Unspecified)			
Hospitalization -	Completed Suicide	Health	(Haloperidol)	PS		ORAL ORAL
Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage		Professional	Desipramine(Desipramine)	SS		ORAL ORAL

Date:12/10/99ISR Number: 3418605-3Report Type:Expedited (15-DaCompany Report #PRIUSA1999006684
Age:35 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Death	Agitation	Literature	Haldol(Tablet)				
Hospitalization -	Cardiac Arrest	Health	(Haloperidol)	PS		ORAL	1 TABLE, 30
Initial or Prolonged	Completed Suicide	Professional					IN 1 TIME(S),
Required	Convulsion						ORAL
Intervention to	Intentional Misuse		Aspirin(Acetylsalicy				
Prevent Permanent	Tachycardia		lic Acid)	SS		ORAL	1 TABLE, 500
Impairment/Damage	Toxicologic Test Abnormal						IN 1 TIME(S),
	Ventricular Fibrillation						ORAL
	Vomiting		Bupropion(Amfebutamo				
			ne)	SS		ORAL	100 MG, 30 IN
							1TIME(S),
							ORAL

Date:12/10/99ISR Number: 3418839-8Report Type:Expedited (15-DaCompany Report #PRIUSA1999006690
Age:42 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Death	Apallic Syndrome	Literature	Haldol (Injection)				
Hospitalization -	Coma	Health	(Haloperidol)	PS			
INTRAMUSCULAR	5 MG, 1 IN 4						
Initial or Prolonged	Dialysis	Professional					
HOUR (S), IM	2 DAY						
Required	Disseminated		Perphenazine				
Intervention to	Intravascular Coagulation		(Perphenazine)	SS			
PARENTERAL	8 MG, 1 IN 8						
Prevent Permanent	Haemodialysis						
HOUR (S),							
Impairment/Damage	Heart Rate Increased						
PARENT	2 DAY						
	Hypotension						

	Pyrexia					

Date:12/10/99ISR Number: 3418841-6Report Type:Expedited (15-DaCompany Report #PRIUSA1999006659
Age:76 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Blood Creatine	Literature	Haldol (Injection)					
Hospitalization -	Phosphokinase Increased	Health	(Haloperidol)	PS				
PARENTERAL							2 MG, 1 IN 6	
Initial or Prolonged	Cardio-Respiratory Arrest	Professional						
HOUR (S),								
Required	Convulsion							
PARENT								
Intervention to	Neuroleptic Malignant		Enalapril					
Prevent Permanent	Syndrome		(Enalapril)	C				
Impairment/Damage	Pneumonia Aspiration		Furosemide					
	Pyrexia		(Furosemide)	C				
			Oxazepam (Oxazepam)	C				
			Doxazosin					
			(Doxazosin)	C				
			Nitroglycerin					
			(Glyceryl					
			Trinitrate)	C				
			Fluoxetine					
			(Fluoxetine)	C				

Date:12/15/99ISR Number: 3422714-2Report Type:Expedited (15-DaCompany Report #JRFBEL1999001752
Age:48 YR Gender:Male I/FU:F

Outcome
Death
Hospitalization -
Initial or Prolonged

Required Intervention to Prevent Permanent Impairment/Damage	Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
			Blood Creatine Phosphokinase Increased	Foreign Health Professional	Haldol (Unspecified) (Haloperidol)	PS		
	10 MG, 2 IN 1	1 DAY(S), UNKNOWN	Bradyphrenia					
			Catatonia		Fluanxol (Flupentixol Dihydrochloride)	SS		
			Cold Sweat					
			Condition Aggravated					
			Delusion					
			Embolism		Zyprexa (Olanzapine)	SS		
			Hallucination, Auditory					
			Hypertension					
			Hypotension		Temesta (Lorazepam)	SS		
			Leukocytosis					
			Motor Dysfunction					
			Mutism					
			Neuroleptic Malignant Syndrome		Dalmadorm (Flurazepam Hydrochloride)	SS		
			Parkinson'S Disease					
			Pulmonary Embolism					
			Pulmonary Infarction					
			Pyrexia		Akineton (Biperiden Hydrochloride)	SS		
			Syncope					
			Tachycardia					
					Tenormin (Atenolol)	SS		

1 DAY(S),

UNKNOWN

Date:12/15/99ISR Number: 3422717-8Report Type:Expedited (15-DaCompany Report #JRFBEL1999002012
Age:31 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Blood Chloride Decreased	Literature	Haldol (Unspecified)					
Hospitalization -	Blood Phosphorus	Health	(Haloperidol)	PS				
TOTAL DOSE								
Initial or Prolonged	Increased	Professional						
1700 MG OVER								
Required	Blood Potassium Increased							
9 D.							9	DAY
Intervention to	Blood Sodium Decreased		Fentanyl					
Prevent Permanent	Cardiac Arrest		(Unspecified)					
Impairment/Damage	Electrocardiogram Qt		(Fentanyl)	C				
	Corrected Interval		Benzodiazepines					
	Prolonged		(Benzodiazepine					
	Po2 Increased		Derivatives)	C				
	Torsade De Pointes		Potassium					
			(Potassium)	C				
			Lovenox					
			(Heparin-Fraction,					
			Sodium Salt)	C				
			Famotidine					
			(Famotidine)	C				
			Fluconazole					
			(Fluconazole)	C				
			Metoclopramide					
			(Metoclopramide)	C				
			Bisacodyl					
			(Bisacodyl)	C				
			Docusate Sodium					
			(Docusate Sodium)	C				
			Casanthranol					

			(Casanthranol)	C		
			Piperacillin (Piperacillin)	C		
			Tazobactam (Tazobactam)	C		
			Gentamicin (Gentamicin)	C		
			Midazolam (Midazolam)	C		

Date:12/15/99ISR Number: 3422719-1Report Type:Expedited (15-DaCompany Report #JACFRA1999000400
Age:41 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hiccups Injection Site Inflammation Medication Error	Foreign Health Professional	Haldol Decanoas (50 Mg/Ml Injection) (Haloperidol Decanoate)	PS		INTRAVENOUS	MG, TOTAL, IV	
			Tegretol (Carbamazepine)	C				
			Mopral (Omeprazole)	C				
			Loxen (Nicardipine Hydrochloride)	C				
			Lovenox (Heparin-Fraction, Sodium Salt)	C				
			Motilium (Domperidone)	C				
			Augmentin Oral (Clavulin)	C				
			Speciafoldine (Folic Acid)	C				
			Nozinan (Levomepromazine)	C				
			Risperdal (Risperidone)	C				
			Rivotril (Clonazepam)	C				

Date:12/15/99ISR Number: 3422723-3Report Type:Expedited (15-DaCompany Report #JACGER1999000854
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Bradycardia Foetal	Foreign	Haldol (2 Mg/Ml					
	Caesarean Section	Health	Drops) (Haloperidol)	PS		ORAL	DROPS, DAILY,	
	Complications Of Maternal	Professional					ORAL/ UTERINE	
	Exposure To Therapeutic		Litium (Lithium					
	Drugs		Carbonate)	SS		ORAL	ORAL/UTERINE	

Date:12/17/99ISR Number: 3423853-2Report Type:Direct Company Report #
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Injection Site Induration	Health	Haldol Deconate					
	Injection Site Oedema	Professional	100mg Im	PS			INTRAMUSCULAR	100MG IM
	Injection Site Pain							

Date:12/17/99ISR Number: 3424733-9Report Type:Expedited (15-DaCompany Report #JRFBEL1999002031(0)
Age:23 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Extrapyramidal Disorder Impulsive Behaviour Parkinsonism	Literature Health Professional	Haloperidol (Unspecified)	PS			15 MG (DAILY)

Date:12/17/99ISR Number: 3424804-7Report Type:Expedited (15-DaCompany Report #PRIUSA1999008975
Age:30 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Death Hospitalization - Initial or Prolonged	Hyperpyrexia Neuroleptic Malignant Syndrome	Consumer	Haldol (Unspecified) (Haloperidol)	PS			5 MG, 1 IN 1 DAY(S),
			Sinemet (Sinemet)	C			
			Prozac (Fluoxetine Hydrochloride)	C			
			Ativan (Lorazepam)	C			

Date:12/20/99ISR Number: 3425697-4Report Type:Expedited (15-DaCompany Report #1999UW03396
Age:83 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Fall Hip Fracture	Study Health Professional	Haloperidol	PS		ORAL	25MG QD PO
			Metipranolol	C			
			Terazosin Hydrochloride	C			
			Lananoprost	C			
			Methazolamide	C			

Date:12/20/99ISR Number: 3425940-1Report Type:Expedited (15-DaCompany Report #JRFBEL1999001990
Age:67 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain Flatulence Ileus Paralytic Schizophrenia	Foreign Health Professional	Risperidone (Tablet) (Risperidone)	PS		ORAL	MG, DAILY, ORAL	
			Haldol (Unspecified) (Haloperidol)	SS		ORAL	MG, DAILY, ORAL	
			Chlorpromazine And Preparations (Chlorpromazine)	SS		ORAL	MG, DAILY, ORAL	
			Sulpiride (Sulpiride)	C				
			Mianserin Hydrochloride (Mianserin Hydrochloride)	C				
			Biperiden Hydrochloride (Biperiden Hydrochloride)	C				
			Promethazine Hydrochloride (Promethazine Hydrochloride)	C				

Phenobarbital (Phenobarbital)	C
Flunitrazepam (Flunitrazepam)	C
Alosenn (Alosenn)	C
Sennoside (Sennosides)	C
Protoporphyrin Disodium (Protoporphyrin Disodium)	C
Allopurinol (Allopurinol)	C
Etilefrine Hydrochloride (Etilefrine Hydrochloride)	C
Magnesium Oxide (Magnesium Oxide)	C
Cisapride (Unspecified) (Cisapride)	C
Inosine (Inosine)	C

Date:12/20/99ISR Number: 3426535-6Report Type:Expedited (15-DaCompany Report #JRFBEL1999000754
Age:46 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Amenorrhoea	Foreign	Haldol (1mg Tablet)					
	Dry Mouth	Health	(Haloperidol)	PS		ORAL	MG, DAILY	
	Fatigue	Professional						
	Headache		Seroxat (Paroxetine Hydrochloride)	C				
	Hyperacusis		Imovane (Zopiclone)	C				
	Joint Stiffness		Cipramil (Citalopram)	C				
	Lip Neoplasm Malignant Stage Unspecified							
	Nausea							
	Personality Disorder							
	Photosensitivity Reaction							
	Vision Blurred							

ORAL

Date:12/20/99ISR Number: 3426731-8Report Type:Expedited (15-DaCompany Report #D/98/03258/LEX
Age:27 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Jugular Vein Thrombosis	Foreign Health Professional	Leponex (Clozapine)	PS		ORAL	200 MG, THREE TIMES A DAY, ORAL	
			Dipiperon (Pipamperone)	SS		ORAL	80 MG, THREE TIMES A DAY, ORAL	
			Haloperidol (Haloperidol)	SS		ORAL	2 MG, TWICE A DAY, ORAL	

Date:12/21/99ISR Number: 3426905-6Report Type:Expedited (15-DaCompany Report #JACGER1999000863
Age:70 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Blood Creatine	Foreign	Haldol (Unspecified)					
Hospitalization -	Phosphokinase Increased	Health	(Haloperidol)	PS		ORAL		
MG, DAILY,								
Initial or Prolonged	Depressed Level Of	Professional						
ORAL								
	Consciousness		Valiquid (Diazepam)	C				
	Encephalitis Viral							
	Pyrexia							

Date:12/22/99ISR Number: 3428267-7Report Type:Expedited (15-DaCompany Report #PRIUSA1999009327
Age:46 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Bradycardia	Health	Haldol (Injection)					
	Hypotension	Professional	(Haloperidol)	PS				
INTRAMUSCULAR	5 MG, TIME							
(S), IM								
			Narcan (Naloxone Hydrochloride)	C				
			Insulin (Insulin)	C				

Date:12/22/99ISR Number: 3428268-9Report Type:Expedited (15-DaCompany Report #PRIUSA1999009294
Age:85 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Loss Of Consciousness	Consumer	Haldol (Injection)					
Initial or Prolonged	Sedation		(Haloperidol)	PS				
INTRAVENOUS	2 MG, 1 IN 4							
HOUR(S), IV								
			Librium (Chlordiazepoxide Hydrochloride)	C				
			Antibiotic (Antibiotics)	C				

				Sodium Chloride (Sodium Chloride)	C		
				Antihypertensives (Antihypertensives)	C		
				Packed Red Blood Cells (Blood Cells, Packed Human)	C		

Date:12/22/99ISR Number: 3428270-7Report Type:Expedited (15-DaCompany Report #PRIUSA1999009281
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Bradycardia Respiratory Arrest	Health Professional	Haldol (Injection) (Haloperidol)	PS		INTRAVENOUS	UNK, IV	

Date:12/22/99ISR Number: 3428272-0Report Type:Expedited (15-DaCompany Report #PRIUSA1999009266
Age:76 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent								

Impairment/Damage

PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Cough	Literature	Haldol (Unspecified)					
Dysphagia	Health	(Haloperidol)	PS			6 MG , DAILY,	
Dysphonia	Professional					UNKNOWN	
Hyporeflexia		Sertraline					
Nasopharyngeal Disorder		(Sertraline)	C				
Salivary Hypersecretion		Lithium (Lithium)	C				
Weight Decreased		Temazepam (Temazepam)	C				

Date:12/22/99ISR Number: 3428278-1Report Type:Expedited (15-DaCompany Report #JRFBEL1999001990
Age:67 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain	Foreign	Haldol (Unspecified)					
	Flatulence	Health	(Haloperidol)	PS		ORAL	MG, DAILY,	
	Ileus Paralytic	Professional					ORAL	
			Risperidone (Tablet) (Risperidone)	SS			MG, DAILY,	
							ORAL	
			Chlorpromazine And Preprations (Chlorpromazine)	SS		ORAL	MG, DAILY,	
							ORAL	
			Sulpiride	C				
			Mianserin Hydrochloride	C				
			Biperiden Hydrochloride	C				
			Promethazine Hydrochloride	C				
			Phenobarbital	C				
			Flunitrazepam	C				

Alosenn	C
Sennoside	C
Protoporphyrin Disodium	C
Allopurinol	C
Etilefrine Hydrochloride	C
Magnesium Oxide	C
Magnesium Oxide	C
Cisapride	C
Inosine	C

Date:12/29/99ISR Number: 3434312-5Report Type:Expedited (15-DaCompany Report #033-0073-990001
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardiac Arrest	Foreign	Dilantin (Phenytoin Sodium)	PS		INTRAVENOUS		
	Completed Suicide	Health						
	Status Epilepticus	Professional	Haldol (Haloperidol)	SS		INTRAVENOUS		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/30/99ISR Number: 3434349-6Report Type:Expedited (15-DaCompany Report #JACGER1999000949
Age:53 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Angiopathy Cataract Eye Disorder Gynaecomastia Hypertension Hyperthyroidism Vomiting Weight Increased	Foreign Consumer	Haldol Decanoat (50 Mg/Ml Injection) (Haloperidol Decanoate)	PS		INTRAMUSCULAR	150 MG, 1 IN 1 MONTH (S); 50 MG, 1 IN 1 MONTH (S), IM	
			Haldol (2 Mg/Ml Drops) (Haloperidol)	SS		ORAL	15 MG QD ORAL	
			Theralen Tablets	SS		ORAL	12 MG QD ORAL	
			Trilafon (Perphenazine) Tablets	PS		ORAL	8 MG QD ORAL	
			Haldol Tablets	SS		ORAL	1 MG QD ORAL	
			Nitrazepam	C				
			Cipramil	C				

OCCLUSIVE DRESSING

Date:12/30/99ISR Number: 3434994-8Report Type:Expedited (15-DaCompany Report #1999-12-0998
Age:75 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death Hospitalization - Initial or Prolonged	Blood Calcium Increased C-Reactive Protein Increased Malaise Neuroleptic Malignant Syndrome Pyrexia Sinus Tachycardia	Foreign Other	Trilafon (Perphenazine) Tablets	PS		ORAL	12 MG QD ORAL	
			Theralen Tablets	SS		ORAL	15 MG QD ORAL	
			Haldol Tablets	SS		ORAL	1 MG QD ORAL	
			Pargitan Mite	C				
			Behepan	C				
			Stesolid	C				
			Laxoberal	C				
			Morfin	C				
			Dolcontin	C				
			Nitrazepam	C				
			Cipramil	C				

			Norfloxacin	C			

Date:12/30/99ISR Number: 3435342-XReport Type:Expedited (15-DaCompany Report #JRFBEL1999002143
Age:75 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death Hospitalization - Initial or Prolonged	Blood Calcium Increased C-Reactive Protein Increased Malaise Neuroleptic Malignant Syndrome Pyrexia Sinus Tachycardia	Foreign Health Professional	Haldol (0.5 Mg Tablet) (Haloperidol) Trilafon (Perphenazine) Theralen (Alimemazine Tartrate) Pargitan Mite (Trihexyphenidyl Hydrochloride) Morfin Epidural (Morphine Hydrochloride) Nitrazepam "Nm Pharma" (Nitrazepam) Filtration Solution For Haemodialysis (Haemodialytics And Haemofiltrates) Lexinor	PS SS SS C C C C		ORAL ORAL ORAL	MG DAILY MG DAILY MG DAILY	

			(Norfloxacin)	C		
			Cipramil (Citalopram	C		
			Dolcontin (Morphine Sulfate)	C		
			Laxoberal (Sodium Picosulfate)	C		
			Behepan (Cyanocobalamin)	C		
			Stesolid (Diazepam)	C		

Date:12/30/99ISR Number: 3435343-1Report Type:Expedited (15-DaCompany Report #JRFBEL1999002168
Age:70 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blepharospasm	Foreign	Haldol (Unspecified)					
	Parkinsonism	Literature	(Haloperidol)	PS			3MG 3 IN 1	
	Tardive Dyskinesia	Health						DAY (S)
	Tremor	Professional	Lithium (Lithium)	SS				

Date:12/30/99ISR Number: 3435344-3Report Type:Expedited (15-DaCompany Report #JACGER1999000950
Age:85 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Amylase Increased	Foreign	Haldol (Tablet)					
	Lipase Increased	Health	(Haloperidol)	PS		ORAL	MG, DAILY	
	Pancreatitis	Professional						ORAL
			L-Thyroxin (Levothyroxine Sodium)	C				

Date:01/03/00ISR Number: 3435450-3Report Type:Expedited (15-DaCompany Report #1999CG01359
Age:88 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Abdominal Pain	Foreign	Avlocardyl	PS				

Life-Threatening	Abdominal Pain Upper	Health	Zestril	SS			
Hospitalization -	Agitation	Professional	Equanil	SS			
Initial or Prolonged	Back Pain	Other	Lasilix	SS			
	Blood Amylase Increased		Corvasal	SS			
	Hypotension		Soluspan	SS			
	Intestinal Infarction		Haldol	SS			
	Intestinal Ischaemia						
	Nausea						
	Pancreatitis Acute						
	Vomiting						

Date:01/04/00ISR Number: 3436522-XReport Type:Expedited (15-DaCompany Report #JRFBEL1999002166
Age:44 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Dyskinesia	Foreign	Haldol Decanoate					
Initial or Prolonged	Dystonia	Literature	(Injection)					
	Grand Mal Convulsion	Health	(Haloperidol					
	Oral Intake Reduced	Professional	Decanoate)	PS			150 MG, 1 IN	2 WEEK (S)
	Rib Fracture							
	Scapula Fracture		Clozapine					
	Speech Disorder		(Clozapine)	SS			MG, DAILY	
	Tardive Dyskinesia							

Date:01/04/00ISR Number: 3436619-4Report Type:Expedited (15-DaCompany Report #JRFBEL1999000121
Age:20 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Hospitalization - Initial or Prolonged Required	Attention Deficit/Hyperactivity Disorder Blood Creatine Phosphokinase Increased Choreoathetosis Extensor Plantar Response Febrile Convulsion Hallucination Hyperreflexia Hypertension Insomnia Leukocytosis Logorrhoea Loss Of Consciousness Multiple Sclerosis Muscle Rigidity Neuroleptic Malignant Syndrome Obsessive Thoughts Opisthotonus Prostration Pyrexia Speech Disorder	Foreign Literature Health Professional	Haldoperidol (5 Mg Tablet) (Haloperidol) Clonazepam (Clonazepam) Promethazine (Promethazine) Chlorpromazine (Chlorpromazine) Trifluoperazine (Trifluoperazine) Benzodiapine (Chlordiazepoxide) Baclofen (Baclofen) Antihypertensive (Antihypertensives) Curare (Tubocurarine)	PS C C C C C C		ORAL	MG, DAILY, ORAL	
Intervention to Prevent Permanent Impairment/Damage								

Date:01/12/00ISR Number: 3443448-4Report Type:Expedited (15-DaCompany Report #219977
Age:76 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Confusional State Faecal Incontinence Fall Parkinson'S Disease Syncope	Foreign Other	Valium (Diazepam) Haloperidol (Haloperidol) Largactil (Chlorpromazine)	PS SS SS		ORAL	7.5 MG DAILY 1.5 MG DAILY 25 MG DAILY	

	Urinary Incontinence					
ORAL						
			Aldomet (Methyldopa)	SS		
1.5 GRAM						
DAILY						
			Digoxin	C		
			Folic Acid	C		

Date:01/12/00ISR Number: 3443901-3Report Type:Expedited (15-DaCompany Report #JRFUSA2000000095
Age:52 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Asthenia	Consumer	Risperdal (Tablet)				
Initial or Prolonged	Cardiac Arrest		Risperidone)	PS		ORAL	3 MG, 2 IN 1
Required	Chest Pain						DAY(S), ORAL
Intervention to	Headache		Haloperidol				
Prevent Permanent	Parkinsonism		(Haloperidol)	SS		ORAL	2 MG, 4 IN 1
Impairment/Damage	Tachycardia						DAY(S), ORAL
	Tremor		Risperdal (Tablet)				
			(Risperidone)	SS		ORAL	1.5 MG, 4 IN
							1 DAY(S),
							ORAL
			Risperdal (Tablet)				
			Risperidone)	SS		ORAL	7.5 MG, 1 IN

1 DAY(S),

ORAL

			Risperdal (Tablet) (Risperidone)	SS	ORAL

8.5 MG, 1 IN

1 DAY(S),

ORAL

			Ativan (Lorazepam)	C	
			Olanzapine (Olanzapine)	C	

Date:01/13/00ISR Number: 3443601-XReport Type:Expedited (15-DaCompany Report #JRFUSA2000000095
Age:52 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Asthenia Cardiac Arrest	Consumer	Haloperidol (Haloperidol)	PS		ORAL	2 MG, 4 IN 1	
Required Intervention to Prevent Permanent Impairment/Damage	Chest Pain Feeling Cold Headache Parkinsonism Pulse Absent Tachycardia Tremor		Risperdal (Tablet) (Risperidone)	SS		ORAL	3MG, 2 IN 1 1.5MG, 4IN1, 7.5MG, 1IN1, 8.5MG, 1IN1DAY(S),	DAY(S), ORAL
			Ativan (Lorazepam)	C				
			Olanzapine (Olanzapine)	C				

Date:01/13/00ISR Number: 3443607-0Report Type:Expedited (15-DaCompany Report #JRFBEL2000000043
Age:16 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Disability	Abnormal Behaviour Amnesia Blood Creatine Phosphokinase Increased Clonic Convulsion Cognitive Disorder Dystonia Extensor Plantar Response Hyperhidrosis Hyperreflexia Hypertonia Irritability Liver Function Test Abnormal Muscle Rigidity Neuroleptic Malignant Syndrome Petechiae Posturing Pyrexia Staphylococcal Infection Tachycardia White Blood Cell Count Increased	Literature Health Professional	Haldol (Unspecified) (Haloperidol) Vancomycin (Vancomycin)	PS SS		INTRAVENOUS	IV

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/13/00ISR Number: 3443608-2Report Type:Expedited (15-DaCompany Report #JACGBR2000000006
Age:22 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Bradycardia Catatonia Cold Sweat Convulsion Depressed Level Of Consciousness Extrapyramidal Disorder Hyperhidrosis Neuroleptic Malignant Syndrome Pallor Sinus Arrest Stupor	Foreign Health Professional	Haldol (10 Mg Tablet) (Haloperidol) Chlorpromazine (Chlorpromazine) Zuclopenthixol (Zuclopenthixol) Antiparkinsonian Medication (Antiparkinsonian)	PS SS SS C		ORAL INTRAMUSCULAR	10 MG 4 IN 1 100 MG 1 IN 150 MG 4 IN 1 UNKNOWN MG DAILY IM	DAY(S) ORAL 24 HOUR(S) : DAY(S) 60 HR

Date:01/18/00ISR Number: 3444768-XReport Type:Direct Company Report #
Age:52 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Disturbance In Attention Mental Impairment Tremor		Haldol	PS		IN STOMACH	1 MO INJECTED	1 MON

Date:01/18/00ISR Number: 3445768-6Report Type:Expedited (15-DaCompany Report #PRIUSA1999009266
Age:76 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Barium Swallow Abnormal Cough Dysphagia Dysphonia Dyspnoea Hyporeflexia Nasopharyngeal Disorder Weight Decreased	Literature Health Professional	Haldol (Unspecified) (Haloperidol) Sertraline (Sertraline) Lithium (Lithium) Temazepam (Temazepan)	PS C C C			6 MG, DAILY	6 WK

Date:01/20/00ISR Number: 3446333-7Report Type:Expedited (15-DaCompany Report #DEU002517
Age:8 DY Gender:Male I/FU:I

Outcome	PT
Life-Threatening Hospitalization - Initial or Prolonged	Apgar Score Low Attention Deficit/Hyperactivity Disorder Benign Congenital Hypotonia Complications Of Maternal Exposure To Therapeutic Drugs Cyst Decreased Activity Excitability Irritability Opisthotonus

		Premature Baby Thrombocythaemia Tremor Neonatal	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
			Foreign	Akineton	PS		ORAL
5 MG DAILY	PO						
			Literature	Serenace	SS		ORAL
10 MG DAILY	PO		Health				
			Professional	Promethazine	SS		
			Other	Nitrazepam	SS		
				Chlorpromazine	SS		

Date:01/21/00ISR Number: 3446752-9Report Type:Expedited (15-DaCompany Report #JACGER2000000068
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization - Initial or Prolonged	Medication Error	Foreign Health Professional	Haldol Decanoat(50 Mg/Ml Injection) (Haloperidol Decanoate)	PS		
INTRAMUSCULAR	150 MG, 1 IN 1 TIME (S), IM					

Date:01/24/00ISR Number: 3447052-3Report Type:Expedited (15-DaCompany Report #JACGBR200000021
Age:76 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization - Initial or Prolonged	Drug Interaction Dystonia	Foreign Health	Haldol (Unspecified) (Haloperidol)	PS		ORAL
1 MG, 2 IN 1 DAY(S), ORAL						
	Grand Mal Convulsion Inappropriate Antidiuretic Hormone	Professional	Fluoxetine (Fluoxetine)	SS		ORAL
20 MG, 1 IN 1						

	Secretion						
DAY(S), ORAL							
				Bendrofluazide (Bendroflumethiazide)	C		
				Atenolol (Atenolol)	C		
				Ranitidine (Ranitidine)	C		

Date:01/24/00ISR Number: 3447739-2Report Type:Expedited (15-DaCompany Report #JACFRA2000000037
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Aggression	Foreign	Haldol Decanoas (50			
	Murder	Health Professional Company	Mg/Ml Injection (Haloperidol Decanoate)	PS		
INTRAMUSCULAR 35 MG, 1 IN 3						
		Representative				
WEEK(S), IM						
			Clopixol (Zuclophenthixol Decanoate)	SS		
INJECT						

Date:01/27/00ISR Number: 3447251-0Report Type:Expedited (15-DaCompany Report #A001108
Age:76 YR Gender:Male I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Barium Swallow Abnormal
	Cough

		Dysphagia Dysphonia Hyporeflexia	Report Source	Product	Role	Manufacturer	Route	Dose Duration
		Neuroleptic Malignant Syndrome	Foreign Literature	Zoloft Tablets	PS		ORAL	200.00 MG TOTAL:ORAL 6 WK
		Parkinsonism Weight Decreased	Health Professional	Haloperidol	SS		ORAL	6.00 MG TOTAL:ORAL 6 WK
				Lithium	SS		ORAL	ORAL 6 WK
				Temazepam	SS			6 WK

Date:01/27/00ISR Number: 3447532-0Report Type:Expedited (15-DaCompany Report #JACGER1999000863
Age:71 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Death Life-Threatening Hospitalization - Initial or Prolonged	Blood Creatine Phosphokinase Increased Depressed Level Of Consciousness Encephalitis Viral Myotonia Pyrexia	Foreign Health Professional	Haldol (Unspecified) (Haloperidol) Valiquid (Diazepam) Atosil (Isopromethazine Hydrochloride)	PS C C		ORAL	MG, DAILY, ORAL

Date:01/27/00ISR Number: 3447539-3Report Type:Expedited (15-DaCompany Report #JRFBEL2000000145
Age:42 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Drug Interaction Electrocardiogram Abnormal Loss Of Consciousness Sedation Supraventricular	Literature Health Professional	Haloperidol (Unspecified) (Haloperidol) Paroxetine (Paroxetine) Ethanol (Ethanol)	PS SS SS			

	Extrasystoles		Cocaine (Cocaine)	SS			
	Ventricular Tachycardia		Methadone (Methadone)	SS			

Date:01/28/00ISR Number: 3447971-8Report Type:Expedited (15-DaCompany Report #HQ0645220JAN2000
Age:22 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Aggression	Literature	Artane Tablet	PS			10 MG DAILY, 2 MG, 15 MG DAILY	
	Akathisia							
	Condition Aggravated							
	Drug Withdrawal Syndrome		Clozapine	SS			SEE IMAGE	
	Dystonia		Haloperidol	SS			20 MG DAILY, 10 MG DAILY	
	Medication Error							
	Overdose		Perphenazine	SS			16 MG DAILY, 4MG DISCONTINUATION	
	Parkinsonism							
	Psychotic Disorder							
	Suicide Attempt							
			Procyclidine	SS			INTRAMUSCULAR	10 MG, INTRAMUSCULAR

Date:01/28/00ISR Number: 3448267-0Report Type:Expedited (15-DaCompany Report #001-0073-M0000013
Age:78 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged Other	Aggression Arthritis Drug Interaction Drug Level Above Therapeutic Parkinson'S Disease Renal Failure Urinary Tract Infection	Consumer	Dilantin Kapseals 100 Mg (Phenytoin Sodium) Procardia (Nifedipine) Lasix (Furosemide) Sinemet (Levodopa, Carbidopa) Celebrex (Celecoxib) Keflex (Cefalexin Monohydrate) Haldol (Haloperidol) Unspecified Renal Drug	PS SS SS SS SS SS SS SS		ORAL	100 MG (DAILY), PER ORAL

Date:02/01/00ISR Number: 3449652-3Report Type:Expedited (15-DaCompany Report #JACGER2000000104
Age:30 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Death	Cardiomegaly	Foreign Health Professional	Haldol (Tablet) (Haloperidol) Neurocil (Levomepromazine Maleate) Hypnorex (Lithium	PS SS		ORAL ORAL	MG, DAILY, ORAL MG, DAILY, ORAL (SEE IMAGE)

			Carbonate)	SS		ORAL
MG, DAILY,						
ORAL						
			Diazepam (Diazepam)	SS		ORAL
MG, DAILY,						
ORAL						

Date:02/01/00ISR Number: 3449655-9Report Type:Expedited (15-DaCompany Report #JACGER2000000102
Age:41 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Circulatory Collapse	Foreign	Haldol (Tablet)			
	Pulmonary Embolism	Health	(Haloperidol)	PS		ORAL
MG, DAILY,						
		Professional				
ORAL						
			Valium (Diazepam)	SS		ORAL
MG, DAILY,						
ORAL						
			Fraxiparin (Heparin-Fraction, Calcium Salt)	C		

Date:02/01/00ISR Number: 3449658-4Report Type:Expedited (15-DaCompany Report #JACGBR2000000028
Age:43 YR Gender:Female I/FU:I

Outcome	PT
Other	Depressed Level Of Consciousness
	Faecal Incontinence

		Hypotonia Neurotoxicity Tremor	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
			Foreign Health Professional	Haldol (Unspecified) (Haloperidol)	PS		ORAL
MG, DAILY,							
ORAL							
				Lithium Carbonate (Lithium Carbonate)	SS		ORAL
MG, DAILY,							
ORAL							
				Carbamazepine (Carbamazepine)	C		
				Propantheline (Propantheline)	C		
				Procyclidine (Procyclidine)	C		
				Entera (Other Combinations Of Nutrients)	C		

Date:02/01/00ISR Number: 3449833-9Report Type:Expedited (15-DaCompany Report #JRFUSA2000000315
Age:49 YR Gender:Male I/FU:I

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Death		Emphysema Headache	Health Professional	Haldol (Injection) (Haloperidol)	PS		ORAL
150 MG, 1 IN							
		Sudden Death					
1 MONTH(S),							
ORAL							
				Risperdal (4 Mg Tablet) (Risperidone)	SS		ORAL
4 MG, 1 IN 1							
DAY(S), ORAL							

Date:02/02/00ISR Number: 3449798-XReport Type:Expedited (15-DaCompany Report #PRIUSA1999009327
Age:46 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Bradycardia Hypotension	Health Professional	Haldol (Injection) (Haloperidol)	PS		INTRAMUSCULAR	5 MG, 1 TIME	(S) IM
			Narcan (Naloxone Hydrochloride)	C				

Date:02/02/00ISR Number: 3449815-7Report Type:Expedited (15-DaCompany Report #HQ653020JAN2000
Age:39 YR Gender:Male I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Blood Creatinine Increased
Other	Blood Urea Increased
	Depressed Level Of Consciousness
	Disseminated Intravascular Coagulation
	Haemodialysis
	Hypotension
	Muscle Rigidity
	Myoglobin Blood Increased
	Neuroleptic Malignant

	Syndrome						
	Pyrexia						
	Renal Failure Acute						
	Respiratory Rate	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Increased	Literature	Artane Tablet				
	Rhabdomyolysis		(Trihexphenidyl)	PS		ORAL	2 MG 3X PER 1
	Stupor						DAY 19 DAY
	Tachycardia		Haloperidol				
	Thrombocytopenia		(Haloperidol)	SS		ORAL	4 MG 3X PER 1
	Tremor						DAY 19 DAY

Date:02/02/00ISR Number: 3450155-0Report Type:Direct Company Report #
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Agitation		Amantadine	PS		ORAL	100MG PO QD
Initial or Prolonged	Flushing						12H
Other	Muscle Rigidity		Haldol	SS			INTRAVENOUS 1MG IV/IM X 1
	Neuroleptic Malignant						
	Syndrome						
	Pyrexia						
	Tremor						

Date:02/02/00ISR Number: 3450553-5Report Type:Expedited (15-DaCompany Report #FLUV00300000423
Age:68 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Agitation	Foreign	Fluvoxamine	PS		ORAL	50 MG DAILY
Initial or Prolonged	Akathisia	Literature					PO
	Drug Level Above	Other	Flupenthixol				
	Therapeutic		Decanoate	SS			DAILY

	Poisoning Deliberate		Haloperidol	SS		ORAL
5 MG DAILY PO						
	Restless Legs Syndrome		Lithium	SS		ORAL
400 MG BID						
	Restlessness					
PO; 400 MG						
	Suicidal Ideation					
DAILY						
	Suicide Attempt		Trihexyphenidyl	SS		ORAL
2 MG PO						

Date:02/07/00ISR Number: 3454161-1Report Type:Expedited (15-DaCompany Report #LITH00200000551
Age:68 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Agitation	Foreign	Lithium	PS		ORAL
400 MG BID						
Initial or Prolonged	Akathisia	Literature				
PO, 400 MG						
	Condition Aggravated	Other				
DAILY UNK						
	Depressed Mood		Fluvoxamine	SS		ORAL
50 MG DAILY						
	Drug Interaction					
PO						
	Drug Level Above		Navane	SS		
DAILY						
	Therapeutic		Haloperidol	SS		ORAL
5 MG DAILY PO						
	Poisoning Deliberate		Trihexyphenidyl	SS		ORAL
2 MG PO						
	Restlessness					
	Suicidal Ideation					
	Tremor					

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/07/00ISR Number: 3454179-9Report Type:Expedited (15-DaCompany Report #JACGER2000000109
Age:37 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anxiety Suicidal Ideation	Foreign Study Health Professional	Haldol (Tablet) (Haloperidol)	PS		ORAL	2 MG, 2 IN 1	DAY(S), ORAL
			Risperdal (2 Mg Tablet) (Risperidone)	SS		ORAL	1 MG, 2 IN 1	DAY(S), ORAL
			Valverde (Valerian Extract)	C				

Date:02/08/00ISR Number: 3454263-XReport Type:Expedited (15-DaCompany Report #JACGER2000000103
Age:55 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death Life-Threatening Hospitalization - Initial or Prolonged	Condition Aggravated Pulmonary Embolism Right Ventricular Failure	Foreign Health Professional	Haldol (Tablet) (Haloperidol)	PS		ORAL	MG, DAILY,	
			Glianimon (Benperidol)	SS		INTRAVENOUS	8 MG, DAILY,	IV
			Tofranil (Imipramine Hydrochloride)	C				
			Fraxiparin (Heparin-Fraction, Calcium Salt)	C				

Date:02/08/00ISR Number: 3454682-1Report Type:Expedited (15-DaCompany Report #JACFRA2000000064
Age:88 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Thyroid Stimulating Hormone Decreased	Foreign Health	Haldol (Solution) (Haloperidol)	PS		ORAL	DROP, DAILY,	
	Dyskinesia	Professional					ORAL	
	Hyperthyroidism		Digoxine Nativelle (Digoxin)	C				
	Thyroxine Increased		Tanakan (Ginkgo Tree Leaves Extract)	C				
	Urine Abnormality		Trivastal (Piribedil)	C				
			Aldactazine (Aldactazine)	C				
			Moxonidine (Moxonidine)	C				

Date:02/11/00ISR Number: 3457032-XReport Type:Expedited (15-DaCompany Report #A044-002-002068
Age:76 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agitation	Foreign	Aricept (Donepezil)	PS		ORAL	10 MG, 1 IN 1	
	Narcolepsy	Health					D, PER ORAL	
	Sedation	Professional	Haldol (2 Mg/Ml)					
	Upper Respiratory Tract		(Haloperidol)	SS				
INTRAVENOUS	INTRAENOUS							
	Infection		Monicor Lp (Isosorbide Mononitrate)	C				

			Tildiem (Diltiazem Hydrochloride)	C			
			Bricanyl (Terbutaline Sulfate)	C			
			Pulmicort (Budesonide)	C			

Date:02/14/00ISR Number: 3457548-6Report Type:Expedited (15-DaCompany Report #A003284
Age:68 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agitation	Foreign	Lithane Tablets	PS		ORAL	50.00 MG	
	Akathisia	Literature	Fluvoxamine	SS		ORAL		
	Condition Aggravated	Health						
	Depressed Mood	Professional	Haloperidol	SS		ORAL		
	Difficulty In Walking		Chlorpromazine	C				
	Emotional Distress		Thioridazine	C				
	Movement Disorder		Mianscrin	C				
	Poisoning Deliberate		Amitriptyline	C				
	Restlessness							
	Suicidal Ideation							
	Tremor							

Date:02/14/00ISR Number: 3457853-3Report Type:Expedited (15-DaCompany Report #CH98030121A
Age:47 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Foreign	Zyprexa (Olanzapine)	PS				
Life-Threatening	Diabetes Mellitus	Study	Haloperidol	SS				
Hospitalization - Initial or Prolonged	Diarrhoea	Health Professional	Chloraldurat (Chloral Hydrate)	C				
	Electrolyte Imbalance		Lorazepam	C				
	Gastrointestinal Infection		Pipamperone	C				
	Polydipsia		Oxazepam	C				
	Vomiting		Antra	C				
	Water Intoxication							

Date:02/14/00ISR Number: 3459091-7Report Type:Periodic Company Report #001-0945-990411
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Confusional State Depression Drug Interaction Hallucination Mood Swings	Health Professional	Neurontin (Gabapentin) Haldol (Haloperidol)	PS SS			1500 MG (DAILY) , 5 MG ((DAILY)	/ MONTHS AGO

Date:02/16/00ISR Number: 3458016-8Report Type:Direct Company Report #
Age: Gender:Female I/FU:I

Outcome	PT
Death	Agitation
	Brain Damage
	Coagulopathy
	Coma
	Convulsion

	Deep Vein Thrombosis						
	Diabetes Mellitus						
	Hallucination, Visual	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Hyperglycaemia		Haldol	PS			
INTRAMUSCULAR	5 MG IM						
	Hyperpyrexia						
	Hypotension						
	Hypothalamo-Pituitary						
	Disorders						
	Hypoxia						
	Hypoxic Encephalopathy						
	Metabolic Acidosis						
	Psychotic Disorder						
	Pulmonary Embolism						
	Pulse Absent						
	Pupil Fixed						
	Respiratory Arrest						
	Respiratory Depression						
	Restlessness						
	Skin Warm						
	Soliloquy						
	Speech Disorder						
	Supraventricular						
	Tachycardia						
	Tachycardia						
	Thrombocytopenia						
	Urinary Incontinence						

Date:02/16/00ISR Number: 3458750-XReport Type:Expedited (15-DaCompany Report #JRFBEL2000000274
Age:68 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Agitation	Foreign	Haldol (Unspecified)				
	Akathisia	Literature	(Haloperidol)	PS			
	Chemical Poisoning	Health	Chlorpromazine				
	Condition Aggravated	Professional	(Cloropromazine)	SS			
	Depressed Mood		Thioridazine				
	Drug Interaction		(Thioridazine)	SS			
	Restlessness		Amitriptyline				
	Suicidal Ideation		(Amitriptyline)	SS			
	Suicide Attempt		Mianserin				
	Tremor		(Mianserin)	SS			
			Lithium (Lithium)	SS			

	Flupenthixol Decanoate (Flupentixol Decanoate)	SS	
MG, 1 IN 1 MONTH(S)			
	Trihexyphenidyl (Trihexyphenidyl)	SS	ORAL
2 MG, 2 IN 1 DAY(S), ORAL			
	Fluvoxamine (Fluvoxamine)	SS	
MG, DAILY			

Date:02/17/00ISR Number: 3459312-0Report Type:Expedited (15-DaCompany Report #JRFBEL2000000295
Age:38 YR Gender:Male I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Blood Creatine Phosphokinase Increased

		Myalgia Rhabdomyolysis					
			Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
			Foreign Health Professional	Haldol (Concentrate) (Haloperidol) Haldol Decanoate (Unspecified) Haloperidol Decanoate) Trittico (Trazodone Hydrochloride) Prozac (Fluoxetine Hydrochloride) Hmg Coa Reductase Inhibitors (Proteinase Inhibitors)	PS SS C C C		ORAL
ORAL							

Date:02/17/00ISR Number: 3459313-2Report Type:Expedited (15-DaCompany Report #PRIUSA2000001429
Age:75 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Death	Abnormal Behaviour Convulsion Extrapyramidal Disorder Medication Error Muscle Rigidity Tardive Dyskinesia Tremor Weight Decreased	Consumer	Haldol (Tablet) (Haloperidol)	PS		ORAL
10 MG, PRN,						
ORAL						

Date:02/17/00ISR Number: 3459314-4Report Type:Expedited (15-DaCompany Report #JRFBEL1999002000
Age:55 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Other	Blood Creatine	Foreign	Haloperidol			

Required	Phosphokinase Increased	Health	(Haloperidol)	PS	ORAL
MG, DAILY,					
Intervention to	Hypokalaemia	Professional			
ORAL					
Prevent Permanent	Hyponatraemia		Risperidone (Tablet)		
Impairment/Damage	Inappropriate		(Risperidone)	SS	ORAL
MG, DAILY,					
	Antidiuretic Hormone				
ORAL					
	Secretion		Risperidone (Tablet)		
	Muscle Rigidity		(Risperidone)	SS	ORAL
MG, DAILY,					
	Neuroleptic Malignant				
ORAL					
	Syndrome		Levomepromazine		
	Polydipsia		Maleate		
	Polyuria		(Levomepromazine		
	Pyrexia		Maleate)	C	
	Tremor				
	Water Intoxication				

Date:02/18/00ISR Number: 3459243-6Report Type:Direct Company Report #
Age:37 YR Gender:Male I/FU:I

Outcome
Life-Threatening
Hospitalization -
Initial or Prolonged

Required Intervention to Prevent Permanent Impairment/Damage	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Neuroleptic Malignant Syndrome		Haloperidol Decanoate 300mg Q Month	PS			300 MG Q	MONTH
								CHRONICALLY

Date:02/22/00ISR Number: 3462021-5Report Type:Expedited (15-DaCompany Report #2000CG00102
Age:78 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Alanine Aminotransferase Increased Aspartate Aminotransferase Increased Blood Creatine Phosphokinase Increased Blood Creatinine Increased Renal Failure Rhabdomyolysis	Foreign Health Professional Other	Tenormine Aricept Haldol	PS SS SS				

Date:02/22/00ISR Number: 3462027-6Report Type:Expedited (15-DaCompany Report #JACFRA2000000125
Age:35 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Leukocytosis Pyrexia	Foreign Health Professional	Haldol (20 Mg Tablet) (Haloperidol) Tercian	PS		ORAL	20 MG, 3 IN 1	DAY (S), ORAL

			(Cyamemazine0	SS		ORAL
ORAL						
			Teralithe Sodium (Lithium Carbonate)	SS		ORAL
MG, DAILY,						
ORAL						
			Clopixol (Zuclopenthixol Decanoate)	SS		
INTRAMUSCULAR	IM					

Date:02/22/00ISR Number: 3462030-6Report Type:Expedited (15-DaCompany Report #JACFRA2000000119
Age:78 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Creatine Phosphokinase Increased	Foreign Health	Haldol (Unspecified) (Haloperidol)	PS		ORAL	MG, DAILY,	
Required	Blood Creatinine	Professional				ORAL		
Intervention to	Increased		Tenormine (Atenolol)	SS		ORAL	MG, DAILY,	
Prevent Permanent	Blood Urea Increased					ORAL		
Impairment/Damage	Hepatic Enzyme Increased		Aricept (Donepezil Hydrochloride)	SS		ORAL	TABLE, DAILY,	
	Renal Failure							
	Rhabdomyolysis							
ORAL								

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/23/00ISR Number: 3461298-XReport Type:Expedited (15-DaCompany Report #JRFBEL2000000302
Age:29 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Abdominal Distension Abdominal Pain Anion Gap Increased Ascites Blood Bicarbonate Decreased Blood Bilirubin Increased Blood Creatine Increased Blood Creatine Phosphokinase Increased Bradycardia Bradypnoea Circulatory Collapse Colonic Obstruction Coma Convulsion Escherichia Infection Gastrointestinal Necrosis Hepatic Enzyme Increased Hepatocellular Damage Hypoglycaemia Hyponatraemia Hypotension Kaolin Cephalin Clotting Time Prolonged Lactic Acidosis Metabolic Acidosis Pallor Pco2 Decreased Peritonitis	Foreign Literature Health Professional	Haldol (Unspecified)(Haloperidol) Nozinan (Levomepromazine) Parkinane (Trihexyphenidyl Hydrochloride) Heptaminol (Heptaminol) Tegretol (Carbamazepine)	PS SS SS SS SS		ORAL ORAL ORAL ORAL ORAL	MG, DAILY, ORAL 5 MG, 2 IN 1 DAY(S), ORAL 190 MG, 3 IN 1 DAY(S), ORAL 400 MG, 2 IN 1 DAY(S), ORAL	

Prothrombin Time
Prolonged
Pyrexia
Renal Impairment
Respiratory Distress
Sepsis
Vomiting

Date:02/23/00ISR Number: 3463767-5Report Type:Periodic Company Report #JRFUSA1999002438
Age:77 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Condition Aggravated	Health Professional	Risperdal (2 Mg Tablet) (Risperidone)	PS		ORAL	2 MG, PRN,	ORAL
			Haldol (Injection) (Haloperidol)	SS		INTRAMUSCULAR	PRN, IM	

Date:02/23/00ISR Number: 3463775-4Report Type:Periodic Company Report #JRFUSA1999002656
Age:25 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Neuroleptic Malignant Syndrome Tachycardia	Health Professional	Risperdal (3 Mg Tablet) (Risperidone)	PS		ORAL	3 MG, 1 IN 1	

DAY(S), ORAL

(SEE IMAGE)

				Haldol Decanoate (Injection) (Haloperidol Decanoate)	SS		

INTRAMUSCULAR 1 IN 1

MONTH(S), IM

Date:02/23/00ISR Number: 3463789-4Report Type:Periodic Company Report #JRFUSA1999002833
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Condition Aggravated	Health Professional	Risperdal (1 Mg Tablet) (Risperidone)	PS		ORAL	1 MG, 2 IN 1 DAY(S), ORAL
			Haldol (Tablet) (Haloperidol)	SS		ORAL	10 MG, DAILY, ORAL

Date:02/23/00ISR Number: 3467094-1Report Type:Periodic Company Report #JRFUSA1999000190
Age:28 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Aggression Alopecia Anxiety	Consumer	Risperdal (Tablet)(Risperidone)	PS		ORAL	SEE IMAGE , ORAL
	Condition Aggravated Coordination Abnormal Dermatitis		Haldol (Tablet)(Halopeidol)	SS		ORAL	ORAL
	Dystonia		Zinc (Zinc)	C			

Gastrointestinal Disorder
Headache
Hepatocellular Damage
Herpes Zoster
Hypersensitivity
Hypertension
Injury
Insomnia
Muscular Weakness
Sedation
Tachycardia
Thinking Abnormal

Date:02/23/00ISR Number: 3468251-0Report Type:Periodic Company Report #JAUSA35395
Age:78 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Delirium Extrapyramidal Disorder Hypokinesia Sedation	Health Professional	Risperdal (Risperidone)	PS			(.5 MG 1 DAILY	29-NOV-98):
			Haldol (Haloperidol)	SS			HS INTRAVENOUS	15 MG, 1 IN 1 TIME (S), IV

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/23/00ISR Number: 3468311-4Report Type:Periodic Company Report #JAUSA35899
Age:43 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged (30-JUN-97):	Agitation Dermatitis Bullous Insomnia	Consumer	Risperdal (Tablet) (Risperidone)	PS				ESTIMATED DATES
			Haldol Decanoas (Haloperidol Decanoate)	SS				(01-JUL-97): ESTIMATED DATES
			Benzodiazepines	C				

Date:02/23/00ISR Number: 3468793-8Report Type:Periodic Company Report #JAUSA36953
Age:30 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged (2 MG 2 DAILY 15-APR-98):	Aggression Condition Aggravated	Consumer Health Professional	Risperdal (Tablet 2 Mg) (Risperidone)	PS				
			Haldol Decanoas (Solution 100 Mg/Ml) (Haloperidol Decanoate)	SS		INTRAMUSCULAR	100 MG, 1 IN	1 MONTH(S), IM
			Tegretol (Tablet) (Carbamepine)	C				
			Cogentin (Tablet) Benzatropine					

				Mesilate	C	
				Prozac (Capsules) (Fluoxetine)	C	

Date:02/24/00ISR Number: 3461958-0Report Type:Direct Company Report #
Age:85 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Life-Threatening	Blood Culture Positive	Health	Haldol 1mg Im X1	PS		
INTRAMUSCULAR 1MG IM X 1						
	Blood Pressure Increased	Professional	Haldol 2mg Im X 1	SS		
INTRAMUSCULAR 2MG IM X 1						
	Body Temperature Increased					
	Chills					
	Mental Impairment					
	Oxygen Saturation Decreased					
	White Blood Cell Count Increased					

Date:02/24/00ISR Number: 3462691-1Report Type:Expedited (15-DaCompany Report #JAOCAN200000015
Age: Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Hepatic Cirrhosis	Foreign Health Professional	Haloperidol Decanoate (Haloperidol Decanoate)	PS		
INTRAMUSCULAR 240 MG, 1 IN						

2 WEEK(S), IM

Date:02/28/00ISR Number: 3464456-3Report Type:Expedited (15-DaCompany Report #US_000235857
Age:48 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Catatonia	Study	Haloperidol	PS			10 MG DAY	
	Condition Aggravated	Health Professional	Benztropine (Benzatropine)	SS			3 MG DAY	
	Neuroleptic Malignant Syndrome		Ativan (Lorazepam)	C				
	Refusal Of Treatment By Relative		Felodipine	C				
	Tremor							

Date:02/28/00ISR Number: 3464476-9Report Type:Expedited (15-DaCompany Report #JACGER2000000222
Age:18 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Neutropenia	Foreign Health Professional	Risperdal (Tablet) (Risperidone)	PS		ORAL	SEE IMAGE	
			Haldol (Tablet) (Haloperidol)	SS		ORAL	SEE IMAGE	
			Leponex (Clozapine)	SS		ORAL	SEE IMAGE	
			Ciatyl-Z (Zuclopenthixol Hydrochloride)	SS		ORAL	MG, ORAL	
			Taxilan (Perazine)	SS			MG, DAILY;	
			Tavor (Lorazepam)	SS			MG, DAILY	
			Sulp (Sulpiride)	SS		ORAL	SEE IMAGE	
			Akineton (Biperiden				SEE IMAGE	

			Hydrochloride)	C			

Date:02/28/00ISR Number: 3465088-3Report Type:Expedited (15-DaCompany Report #DEU002667
Age:45 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Abnormal Behaviour	Foreign	Akineton	PS				
INTRAMUSCULAR							5 MG DAILY	IM
Initial or Prolonged	Condition Aggravated	Health	Serenace	SS				
INTRAMUSCULAR							5 MG DAILY	IM
	Depressed Level Of	Professional	Serenace	SS		OTHER		
15 MG DAILY								
	Consciousness	Other						
OTHER								
	Faecal Incontinence		Serenace	SS				
	Hyperhidrosis		Horizon	C				
	Leukocytosis		Kn Sol. 3b	C				
	Muscle Rigidity		Bisulase	C				
	Neuroleptic Malignant		Plas-Amino	C				
	Syndrome		Adalat	C				
	Pneumonia							
	Productive Cough							
	Pyrexia							
	Respiratory Depression							
	Speech Disorder							
	Urinary Incontinence							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/29/00ISR Number: 3465452-2Report Type:Expedited (15-DaCompany Report #PRIUSA2000001807
Age:29 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Arrhythmia Dehydration Status Epilepticus	Consumer	Haldol Decanoate (Injection) (Haloperidol Decanoate)	PS		INTRAMUSCULAR	100 MG, IM	
			Unspecified Oral Supplementation	C				

Date:02/29/00ISR Number: 3465454-6Report Type:Expedited (15-DaCompany Report #JACGER2000000214
Age:66 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death Life-Threatening Required Intervention to Prevent Permanent Impairment/Damage	Cyanosis Enuresis Pneumatic Compression Therapy Pulmonary Embolism	Foreign Health Professional	Haldol Decanoat (50 Mg/Ml Injection) (Haloperidol Decanoate)	PS		INTRAMUSCULAR	100 MG, 1 IN 1 TIME(S) IM	
			Ciatyl-Z-Acuphase (Zuclopenthixol Acetate)	SS		INTRAMUSCULAR	100 MG, 1 IN 1 DAYS (S), IM	
			Ciatyl-Z Depot (Zuclopenthioxol Decanoate)	SS		INTRAMUSCULAR	400 MG, 1 IN 1 DAY (S), IM	

Date:02/29/00ISR Number: 3465591-6Report Type:Expedited (15-DaCompany Report #JACGER2000000220
Age:54 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blister Cyanosis Erythema Hypersensitivity Oxygen Saturation Decreased Pyrexia Respiratory Failure	Foreign Health Professional	Haldol Haloperidol Decanoate Ciatyl (Clopenthixol Hydrochloride) Ciatyl-Z (Zuclopenthixol Hydrochloride) Lyogen (Fluphenazine) Ramipril Clexane (Heparin-Fraction, Sodium Salt) Bronchoretard (Theophylline)	PS SS SS SS SS C C C		INTRAVENOUS INTRAMUSCULAR INTRAVENOUS ORAL ORAL	MG, DAILY, IV 50 MG, 1 IN 4 WEEK(S), IM MG, DAILY, IV MG, DAILY, MG, DAILY,

(SEE IMAGE)

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/29/00ISR Number: 3465869-6Report Type:Expedited (15-DaCompany Report #HQ1152922FEB2000
Age:18 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Neutropenia	Study Health Professional	Tavor (Lorazepam)	PS		ORAL	"2 MG, 8 MG, 0.5 MG" ORAL	62 DAY
Other			Ciatyl (Clopenthixol Hydrochloride)	SS			600 MG 1X PER 1 DAY	1 DAY
			Clozapine (Clozapine0	SS			100 MG-250 MG DAILY	15 DAY
			Haldol (Haloperidol)	SS			5 MG - 50 MG DAILY	26 DAY
			Risperdal (Risperidone)	SS			2MG - 4 MG DAILY	5 DAY
			Sulpiride (Sulpiride)	SS			100 MG - 200 MG DAILY	5 DAY
			Taxilan (Perazine)	C			100 MG - 200 MG DAILY	
			Akineton	C				

Date:02/29/00ISR Number: 3465891-XReport Type:Expedited (15-DaCompany Report #JRFBEL2000000172
Age:34 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Amenorrhoea	Foreign	Haldol (Tablet)					

Initial or Prolonged	Hyperprolactinaemia	Health	(Haloperidol)	PS	ORAL MG, DAILY,
	Pituitary Tumour	Professional			ORAL
			Risperidone (Tablet) (Risperidone)	SS	ORAL MG, DAILY, ORAL
			Flunitrazepam (Flunitrazepam)	C	
			Mianserin Hydrochloride (Mianserin Hydrochloride)	C	
			Chlordiazepoxide (Chlordiazepoxide)	C	
			Trihexyphenidyl Hydrochloride (Trihexyphenidyl Hydrochloride)	C	
			Biperiden Hydrochloride (Biperiden Hydrochloride)	C	

Date:02/29/00ISR Number: 3465893-3Report Type:Expedited (15-DaCompany Report #PRIUSA2000001700
Age:79 YR Gender:Female I/FU:I

Outcome	PT
Death	Balance Disorder
Hospitalization - Initial or Prolonged	Cardiac Failure
	Constipation
	Difficulty In Walking
	Dizziness

		Dysphagia					
		Faecal Incontinence					
		Fatigue	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
		Feeling Hot	Consumer	Haldol (Unspecified)			
		Hallucination		(Haloperidol)	PS		
		Mood Altered					
		Pallor					
		Restlessness					
		Speech Disorder					
		Tremor					
		Urinary Incontinence					
		Vision Blurred					

Date:02/29/00ISR Number: 3465895-7Report Type:Expedited (15-DaCompany Report #JACGER2000000227
Age:72 YR Gender:Female I/FU:I

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Hospitalization -		Bronchospasm	Foreign	Haldol (Tablet)			
Initial or Prolonged		Dysphagia	Health	(Haloperidol)	PS		ORAL
SEE IMAGE							
		Dyspnoea	Professional	Cipramil			
		Goitre		(Citalopram)	SS		ORAL
SEE IMAGE							
		Mastication Disorder					
		Tracheal Obstruction					

Date:02/29/00ISR Number: 3465897-0Report Type:Expedited (15-DaCompany Report #JACGER2000000222
Age:18 YR Gender:Male I/FU:I

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Hospitalization -		Neutropenia	Foreign	Haldol (Tablet)			
Initial or Prolonged			Health	(Haloperidol)	PS		ORAL
SEE IMAGE							
			Professional	Leponex (Clozapine)	SS		ORAL
SEE IMAGE							
				Ciatyl-Z			
				(Zuclopenthixol			
				Hydrochloride)	SS		
MG, DAILY							

	Taxilan (Perazine)	SS	ORAL
SEE IMAGE			
	Tavor (Lorazepam)	SS	
SEE IMAGE			
	Sulp (Sulpiride)	SS	ORAL
SEE IMAGE			
	Risperidal (Tablet) (Risperidone)	SS	ORAL
SEE IMAGE			
	Akineton (Biperiden Hydrochloride)	C	

Date:02/29/00ISR Number: 3465899-4Report Type:Expedited (15-DaCompany Report #JACFRA2000000139
Age:60 YR Gender:Male I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Bladder Disorder
	Blood Creatine Phosphokinase Increased
	Blood Creatine Phosphokinase Mb Increased
	Blood Creatinine Increased
	Klebsiella Infection
	Myoglobinuria
	Pyrexia
	Renal Failure Acute

		Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Rhabdomyolysis Urinary Tract Infection							
		Foreign Health Professional	Haldol (Unspecified) (Haloperidol)	PS		ORAL	MG, DAILY,	ORAL
			Doliprane (Paracetamol)	SS		ORAL	8 IN 1	DAY(S), ORAL
			Largactil (Chlorpromazine Hydrochloride)	SS		ORAL	MG,	DAILY,ORAL
			Augmentin (Clavulin)	SS		ORAL	ORAL	
			Surmontil (Trimipramine)	SS		ORAL	MG, DAILY,	ORAL
			Seresta (Oxazepam)	SS		ORAL	50 MG, 4 IN 1	DAY(S), ORAL
			Akineton (Biperiden Hydrochloride)	C				
			Sulfarlem (Anethole Trithione)	C				
			Hept-A-Myl (Heptaminol Hydrochloride)	C				

Date:02/29/00ISR Number: 3465902-1Report Type:Expedited (15-DaCompany Report #JACFRA2000000136
Age:20 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Attention	Foreign	Haldol (Unspecified)					

Hospitalization - Initial or Prolonged	Deficit/Hyperactivity Disorder Cardiac Arrest Coma Infection Labile Blood Pressure Pyrexia	Health Professional Company Representative	(Haloperidol) Risperdal (1 Mg Tablet) (Risperidone) Tranxene (Clorazepate Dipotassium) Tiapridal (Tiapride)	PS SS SS SS		ORAL ORAL SEE IMAGE ORAL ORAL

Date:02/29/00ISR Number: 3466515-8Report Type:Direct Company Report #
Age:37 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Akathisia		Haldol	PS		INTRAVENOUS DRIP	5 MG IV	
	Anxiety							
	Feeling Abnormal		Vitamin B Complex	C				
	Screaming							

Date:03/02/00ISR Number: 3466881-3Report Type:Expedited (15-DaCompany Report #A044-002-002068
Age:74 YR Gender:Male I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Agitation
	Aspiration
	Drug Interaction
	Feeding Disorder

	Lower Respiratory Tract Infection Narcolepsy	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
	Sedation	Foreign	Aricept (Donepezil)	PS		ORAL
10 MG, 1 IN 1						
		Health				
D, PER ORAL						
		Professional	Haldol (2mg/Ml) (Haloperidol)	SS		
10 DROPS PER						
NIGHT, 10						
DROPS						
			Monicor Lp (Isorsorbide Mononitrate)	C		
			Tildiem (Diltiazem Hydrochloride)	C		
			Bricanyl (Terbutaline Sulfate)	C		
			Pulmicort (Budesondie)	C		

Date:03/02/00ISR Number: 3468284-4Report Type:Expedited (15-DaCompany Report #JACGER2000000226
Age:42 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Angina Pectoris	Foreign	Haldol	PS		
INTRAVENOUS DAILY, IV						
Initial or Prolonged	Dyspnoea	Health	Glianimon			
	Hypokalaemia	Professional	(Benperidol)	SS		
DAILY						
			Hypnorex (Lithium Carbonate)	SS		
DAILY, ORAL						
			Ciatyl-Z Akuphase (Zuclopenthixol Acetate)	SS		
INTRAMUSCULAR DAILY, IM						
			Ciatyl (Clopenthixol			

			Hydrochloride)	C		
INTRAVENOUS DAILY, IV						
			Diazepam	C		
			Tavor	C		
			Clexane	C		

Date:03/06/00ISR Number: 3470543-6Report Type:Expedited (15-DaCompany Report #US_980910156
Age:79 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Agitation	Study	Haldol (Haloperidol)	PS			0.5 MG/BID	
Initial or Prolonged	Cellulitis	Health						DAY
	Confusional State	Professional	Trazodone	C				
	Fall		Aricept (Donepezil					
	Gait Disturbance		Hydrochloride)	C				
	Oedema Peripheral		Vitamin E	C				
	Orthostatic Hypotension							
	Pain							
	Rash Erythematous							
	Skin Warm							

Date:03/07/00ISR Number: 3471284-1Report Type:Expedited (15-DaCompany Report #DEU002690
Age:60 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Anuria	Foreign	Akineton	PS				
INTRAVENOUS							2.5 MG	DAILY
Initial or Prolonged	Blood Creatine	Literature						
IV							1	DAY
	Phosphokinase Increased	Health	Serenance					
	Blood Creatinine	Professional	(Haloperidol)	SS				
INTRAVENOUS							2.5 MG	DAILY
	Increased	Other						
IV							1	DAY
	Blood Urea Increased		Akineton	C				
	Dialysis		Serenance	C				
	Hyperhidrosis		Contomin	C				
	Myoglobin Blood Increased		Levotomin	C				
	Myoglobinuria		Rohypnol	C				
	Peripheral Coldness		Alosenn	C				
	Pyrexia		Euglucon	C				
	Tachycardia		Contomin	C				
	Tachypnoea		Acenalin	C				
	Tremor		Senevacul	C				

Date:03/07/00ISR Number: 3471604-8Report Type:Expedited (15-DaCompany Report #JRFBEL2000000464
Age:23 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Autonomic Neuropathy	Foreign	Haldol (Unspecified)					
	Blood Creatine	Study	(Haloperidol)	PS		ORAL		
ORAL								
	Phosphokinase Increased	Literature	Chlorpromazine					
	Extrapyramidal Disorder	Health	(Chlorpromazine)	SS				
	Neuroleptic Malignant Syndrome	Professional						
	Pulmonary Embolism							
	Pyrexia							

Date:03/07/00ISR Number: 3471607-3Report Type:Expedited (15-DaCompany Report #JRFBEL2000000463
Age:35 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Autonomic Nervous System Imbalance	Foreign Study	Haldol (Unspecified) (Haloperidol)	PS			LOADING RATE (CPZ DOSE EQ/D)=0.63	
	Blood Creatine Phosphokinase Increased	Literature Health Professional						
	Extrapyramidal Disorder							
	Neuroleptic Malignant Syndrome							
	Pulmonary Embolism							
	Pyrexia							

Date:03/07/00ISR Number: 3471611-5Report Type:Expedited (15-DaCompany Report #PRIUSA2000001847
Age:79 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Bladder Disorder	Consumer	Haldol (Tablet)					
	Dementia Alzheimer'S Type		(Haloperidol)	PS		ORAL	2 MG, ORAL	
	Embolism		Unspecified Heart					
	Nervous System Disorder		Medication	C				
	Parkinson'S Disease							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/07/00ISR Number: 3471645-0Report Type:Expedited (15-DaCompany Report #A044-002-002068
Age:74 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Agitation Anorexia Drug Interaction Hypersensitivity Lower Respiratory Tract Infection Narcolepsy Prostration Pyrexia Sedation	Foreign Health Professional	Aricept (Donepezil) Haldol (2mg/Ml) (Haloperidol) Monicor Lp (Isosorbide Mononitrate) Tildiem (Diltiazem Hydrochloride) Bricanyl (Terbutaline Sulfate) Pulmicort (Budesonide)	PS SS C C C		ORAL	10 MG, 1 IN 1 D, PER ORAL 10 DROPS PER NIGHT, 10 DROPS

Date:03/07/00ISR Number: 3471678-4Report Type:Expedited (15-DaCompany Report #HQ1357503MAR2000
Age:44 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Life-Threatening Hospitalization - Initial or Prolonged Other	Coma Convulsion Drug Interaction Loss Of Consciousness Psychotic Disorder Respiratory Distress Syncope White Blood Cell Count Decreased	Health Professional	Ativan Injection Clozaril Haldol	PS SS SS		ORAL	INTRAMUSCULAR 1 MG, INTRAMUSCULAR 500 MG, ORAL

Date:03/08/00ISR Number: 3472197-1Report Type:Expedited (15-DaCompany Report #US_000235857
Age:48 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Catatonia	Study	Haloperidol	PS			10 MG DAY	
	Echopraxia	Health Professional	Benztropine (Benzatropine)	SS			3 MG DAY	
	Extrapyramidal Disorder							
	Liver Function Test Abnormal		Ativan (Lorazepam)	C				
	Parkinsonism		Felodipine	C				
	Waxy Flexibility							

Date:03/09/00ISR Number: 3472442-2Report Type:Expedited (15-DaCompany Report #JACFRA2000000170
Age:3 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Accidental Exposure	Foreign Health Professional	Haldol Decanoas (50 Mg/Ml Injection) (Haloperidol Decanoate)	PS		ORAL	0.5 VIAL,	TOTAL, ORAL
	Sedation							
	Strabismus							

Date:03/09/00ISR Number: 3473541-1Report Type:Expedited (15-DaCompany Report #JRFUSA2000000095
Age:52 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Aggression Arthralgia	Consumer	Risperdal (Tablet) (Risperidone)	PS		ORAL	3 MG, 2 IN 1
Required	Asthenia						DAY (S), ORAL
Intervention to Prevent Permanent Impairment/Damage	Cardiac Arrest Chest Pain Condition Aggravated		Risperdal (Tablet) (Risperidone)	SS		ORAL	7 MG, DAILY,ORAL
	Difficulty In Walking Drug Withdrawal Syndrome		Risperdal (Tablet) (Risperidone)	SS		ORAL	6 MG, DAILY, ORAL
	Headache						
	Joint Stiffness Memory Impairment		Risperdal (Tablet) (Risperidone)	SS		ORAL	7.5 MG, DAILY, ORAL
	Overdose						
	Parkinsonism Psychiatric Symptom		Risperdal (Tablet) (Risperidone)	SS		ORAL	8.5 MG, DAILY,ORAL
	Pulse Absent						
	Restlessness Sleep Disorder		Haloperidol (Haloperidol)	SS		ORAL	2 MG, 4 IN 1
	Tachycardia						DAY (S), ORAL
	Tremor		Ativan (Lorazepam)	SS		ORAL	2 MG, 4 IN 1
	Weight Decreased						DAY(S), ORAL
			Olanzapine (Olanzapine)	C			

Date:03/13/00ISR Number: 3477431-XReport Type:Periodic Company Report #JRFUSA1999002656
Age:25 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Neuroleptic Malignant Syndrome Tachycardia	Health Professional	Haldol Decanoate (Injection) (Haloperidol Decanoate)	PS		INTRAMUSCULAR	1 IN 1 MONTH	(S) IM
			Risperdal (3 Mg Tablet) (Risperidone)	SS		ORAL	3 MG, 1 IN 1	DAY (S), ORAL

Date:03/14/00ISR Number: 3475524-4Report Type:Expedited (15-DaCompany Report #228962
Age:42 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anuria Drug Interaction Drug Level Below Therapeutic Haemodialysis Pyelonephritis Restlessness Vesicoureteric Reflux	Foreign Literature Health Professional	Cercine (Diazepam)	PS		ORAL	2 MG DAILY	
			Rohypnol (Flunitrazepam)	SS		INTRAVENOUS	2 MG DAILY	INTRAVENOUS
			Silece (Flunitrazepam)	SS		ORAL	2 MG DAILY	ORAL
			Predonine (Prednisolone Or Prednisolone Acetate Or Prednisolone Sodium Succinate	SS		ORAL	80 MG DAILY	ORAL
			Ciclosporin					

			(Cyclosporine)	SS		ORAL
400 MG DAILY						
ORAL						
			Azathioprine (Azathioprine)	SS		ORAL
200 MG DAILY						
ORAL						
			Lasix (Furosemide)	SS		ORAL
80 MG DAILY						
ORAL						
			Levotomin (Methotrimeprazine)	SS		ORAL
75 MG DAILY						
ORAL						
			Tolopelon (Timiperone)	SS		ORAL
9 MG DAILY						
ORAL						
			Serenace (Haloperidol)	SS		ORAL
5 MG DAILY						
ORAL						

Date:03/14/00ISR Number: 3475542-6Report Type:Expedited (15-DaCompany Report #HQ1439508MAR2000
Age:69 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Fall	Health Professional	Parkinane Capsule, Sustained Release			
Other	Hallucinations, Mixed		(Trihexyphenidyl)	PS		ORAL
ORAL	Malaise	Other				
			Cibadrex (Benazepril Hydrochloride, Hydrochlorothiazide)	SS		
			Haldol (Haloperidol)	SS		
			Ivadal (Zolpidem Tartrate)	SS		
			Nuctalon (Estazolam)	SS		

			Zyrtec (Cetirizine Hydrochloride)	SS		

Date:03/14/00ISR Number: 3475640-7Report Type:Expedited (15-DaCompany Report #JACFRA2000000170
Age:3 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Toxicity Medication Error Sedation Strabismus Vomiting	Foreign Health Professional	Haldol Decanoas (50 Mg/Ml Injection) (Haloperidol Decanoate)	PS		ORAL	50 MG, TOTAL, ORAL	

Date:03/14/00ISR Number: 3475768-1Report Type:Expedited (15-DaCompany Report #JRFBEL2000000351
Age:35 YR Gender:Male I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged Other	Blood Magnesium Decreased Condition Aggravated Convulsion Drug Toxicity Electrocardiogram Qt Corrected Interval Prolonged Hypokalaemia Restlessness Sinus Tachycardia

		Torsade De Pointes Ventricular Tachycardia					
			Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
			Foreign Literature	Haldol (Injection) (Haloperidol)	PS		
INTRAVENOUS	IV	3 DAY					
			Health Professional	Haldol (Unspecified) (Haloperidol)	SS		
SUBCUTANEOUS	MG, DAILY,						
SUBCU	1 DAY						

Date:03/14/00ISR Number: 3475773-5Report Type:Expedited (15-DaCompany Report #JRFBEL2000000396
Age:82 YR Gender:Female I/FU:I

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Other		Blood Magnesium Decreased Electrocardiogram Abnormal	Foreign Literature Health	Haloperidol (Injection) (Haloperidol)	PS		
INTRAVENOUS	10 MG, 1 IN 1	Hypocalcaemia	Professional				
TIME(S), IV		Hypokalaemia Loss Of Consciousness Torsade De Pointes					

Date:03/14/00ISR Number: 3475795-4Report Type:Expedited (15-DaCompany Report #JRFUSA2000000095
Age:52 YR Gender:Male I/FU:F

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Hospitalization -		Aggression	Consumer	Haloperidol			
Initial or Prolonged		Arthralgia		(Haloperidol)	PS		ORAL
2 MG, 4 IN 1							
Required		Asthenia					
DAY(S), ORAL							
Intervention to		Cardiac Arrest		Risperdal (Tablet)			
Prevent Permanent		Chest Pain		(Risperidone)	SS		ORAL
SEE IMAGE							
Impairment/Damage		Difficulty In Walking		Ativan (Lorazepam)	SS		ORAL
2 MG, 4 IN 1							

	Drug Effect Decreased					
DAY(S), ORAL						
	Drug Withdrawal Syndrome		Olanzapine			
	Headache		(Olanzapine)	C		
	Heart Rate Increased					
	Ill-Defined Disorder					
	Joint Stiffness					
	Memory Impairment					
	Overdose					
	Parkinson'S Disease					
	Peripheral Coldness					
	Pulse Absent					
	Restlessness					
	Sleep Disorder					
	Tachycardia					
	Tremor					
	Weight Decreased					

Date:03/14/00ISR Number: 3475800-5Report Type:Expedited (15-DaCompany Report #JRFUSA2000001497
Age:48 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Required Intervention to Prevent Permanent Impairment/Damage	Pituitary Tumour Benign	Health Professional	Haldol (Tablet) (Haloperidol)	PS		ORAL	5 MG, DAILY,ORAL
			Risperdal (Tablet) (Risperidone)	SS		ORAL	

Date:03/20/00ISR Number: 3477933-6Report Type:Expedited (15-DaCompany Report #US_980910156
Age:79 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agitation	Study	Haldol (Haloperidol)	PS			0.5 MG/BID	DAY
	Cellulitis	Health						
	Confusional State	Professional	Trazodone	C				
	Fall		Aricept (Donepezil Hydrochloride)	C				
	Gait Disturbance		Vitamin E	C				
	Oedema Peripheral							
	Pain							
	Rash Erythematous							
	Skin Warm							

Date:03/20/00ISR Number: 3478005-7Report Type:Expedited (15-DaCompany Report #USA012981
Age:1 DY Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Abdominal Distension	Foreign	Akineton	PS				
	Atrioventricular Block	Literature	Chlorpromazine	SS				
	Atrioventricular Block	Health	Haloperidol	SS				
	Second Degree	Professional	Electroconvulsive Therapy	SS				
	Bradycardia Foetal	Other						
	Complications Of Maternal Exposure To Therapeutic Drugs							
	Electrocardiogram Qt Prolonged							
	Foetal Disorder							
	Heart Block Congenital							
	Premature Labour							
	Respiratory Disorder Neonatal							

Date:03/22/00ISR Number: 3478570-XReport Type:Expedited (15-DaCompany Report #JACFRA2000000184
Age:69 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Hospitalization - Initial or Prolonged	Hallucination, Auditory Hallucination, Visual	Foreign Health	Haldol (Unspecified) (Haloperidol)	PS		ORAL
ORAL						
	Malaise	Professional	Zyrtec (Cetirizine Hydrochloride)	SS		ORAL
ORAL						
			Parkinane (Trihexyphenidyl Hydrochloride)	SS		ORAL
ORAL						
			Nuctalon (Estazolam)	SS		ORAL
ORAL						
			Ivadal (Zolpidem Tartrate)	SS		ORAL
ORAL						
			Cibadrex (Cibadrex)	SS		ORAL
ORAL						

Date:03/22/00ISR Number: 3478784-9Report Type:Expedited (15-DaCompany Report #JACFRA2000000190
Age:78 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agranulocytosis	Foreign Health Professional	Haldol (20mg/Ml Solution) (Haloperidol)	PS		ORAL		
ORAL								
			Nitriderm Tts (Glyceryl					

			Trinitrate)	C		
			Vitamines B1 - B6 Roche (Vitamins B1-B6 (R))	C		

Date:03/22/00ISR Number: 3478993-9Report Type:Expedited (15-DaCompany Report #PRIUSA2000002538
Age:44 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardiac Arrest	Health	Haldol (Injection)					
Hospitalization -	Tardive Dyskinesia	Professional	(Haloperidol)	PS		INTRAVENOUS	10 MG, 1 TIME	
Initial or Prolonged								
(S), IV								
			Thorazine (Chlorpromazine Hydrochloride)	C				
			Depakote (Valproate Semisodium)	C				
			Cogentin (Benzatropine Mesilate)	C				
			Zyprexa (Olanzapine)	C				
			Klonopin (Clonazepam)	C				

Date:03/22/00ISR Number: 3478994-0Report Type:Expedited (15-DaCompany Report #JACFRA2000000136
Age:20 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Attention	Foreign	Haldol (5 Mg/Ml					
Hospitalization -	Deficit/Hyperactivity	Health	Injection)					
Initial or Prolonged	Disorder	Professional	(Haloperidol)	PS		INTRAMUSCULAR	INJECT	
	Blood Creatine Phosphokinase Increased	Company Representative	Haldol Faible (0.5 Mg/Ml Solution)					
	Cardiac Arrest		(Haloperidol)	SS		ORAL	15 DROP, 2 IN	
	Coma						1 DAY(S),	
	Electrolyte Imbalance						ORAL	

	Enzyme Abnormality		Risperdal (1 Mg			
	Gastrointestinal		Tablet)			
	Haemorrhage		(Risperidone)	SS		ORAL
1 MG, 1 IN 1						
	Haemoglobin Decreased					
DAY(S), ORAL						
	Hypoxia		Tiapridal (Tiapride)	SS		ORAL
ORAL						
	Infection		Tranxene			
	Labile Blood Pressure		(Clorazepate			
	Pyrexia		Dipotassium)	C		
	Staphylococcal Infection		Depakine (Valproate			
	Thrombocytopenia		Sodium)	C		

Date:03/22/00ISR Number: 3479156-3Report Type:Expedited (15-DaCompany Report #JRFBEL2000000721
Age:60 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Coma	Foreign	Haldol (Unspecified)			
Initial or Prolonged	Computerised Tomogram	Literature	(Haloperidol)	PS		
Required	Abnormal	Health	Dantrolene Sodium			
Intervention to	Muscle Rigidity	Professional	(Dantrolene Sodium)	SS		
Prevent Permanent	Nuclear Magnetic					
Impairment/Damage	Resonance Imaging					
	Abnormal					
	Quadriplegia					

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/22/00ISR Number: 3479187-3Report Type:Expedited (15-DaCompany Report #JRFBEL2000000635
Age:64 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Blood Magnesium Decreased	Foreign	Haldol (Unspecified)					
	Electrocardiogram	Literature	(Haloperidol)	PS				
							INTRAVENOUS	MG. TOTAL, IV
	Abnormal	Health	Nifedipine					
	Electrocardiogram Qt	Professional	(Nifedipine)	C				
	Prolonged		Enalapril(Enalapril)	C				
	Torsade De Pointes		Sucralfate					
	Ventricular Extrasystoles		(Sucralfate)	C				
	Ventricular Tachycardia		Furosemide					
			(Furosemide)	C				
			Lorazepam					
			(Lorazepam)	C				
			Metoclopramide					
			(Metoclopramide)	C				
			Salbutamol					
			(Salbutamol)	C				

Date:03/23/00ISR Number: 3479114-9Report Type:Direct Company Report #USP 52929
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Medication Error		Haldol 2mg	PS	Mylan			
			Haldol 5mg	SS	Mylan			

Date:03/23/00ISR Number: 3479379-3Report Type:Expedited (15-DaCompany Report #JACFRA2000000136
Age:20 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Attention	Foreign	Risperdal (1 Mg					
Hospitalization -	Deficit/Hyperactivity	Health	Tablet)					
Initial or Prolonged	Disorder	Professional	(Risperidone)	PS		ORAL	1 MG, 1 IN 1	
	Blood Creatine	Company					DAY (S), ORAL	
	Phosphokinase Increased	Representative	Haldol (5 Mg/Ml					
	Blood Electrolytes		Injection)					

	Abnormal		(Haloperidol)	SS		
INJECT						
	Cardiac Arrest		Haldol Faible (0.5			
	Coma		Mg/Ml Solution)			
	Enzyme Abnormality		(Haloperidol)	SS		ORAL
15 DROPS, 2						
	Extrapyramidal Disorder					
IN 1 DAY (S),						
	Gastrointestinal					
ORAL						
	Haemorrhage		Tiapridal (Tiapride)	SS		ORAL
ORAL						
	Hypoxia		Tranxene			
	Infection		(Clorazepate			
	Labile Blood Pressure		Dipotassium)	C		
	Pyrexia		Depakine (Valproate			
	Staphylococcal Infection		Sodium)	C		
	Thrombocytopenia					

Date:03/23/00ISR Number: 3479446-4Report Type:Expedited (15-DaCompany Report #231189
Age:29 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Hepatitis	Foreign	Rivotril			
Initial or Prolonged		Other	(Clonazepam)	PS		ORAL
20 DOSE FORM						
1 PER DAY						
ORAL						

			Haldol (Haloperidol)	SS		ORAL
20 MG 2 PER DAY ORAL						
			Risperdal (Risperidone)	C		

Date:03/24/00ISR Number: 3479734-1Report Type:Expedited (15-DaCompany Report #A008863
Age:69 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Fall	Foreign	Zyrtec Tablets	PS		ORAL	ORAL
	Hallucinations, Mixed	Health Professional	Haloperidol	SS		ORAL	ORAL
			Trihexyphenidyl	SS		ORAL	ORAL
			Estazolam	SS		ORAL	ORAL
			Zolpidem	C			
			Cibadrex	C			
			Unspecified Medications	C			

Date:03/24/00ISR Number: 3479752-3Report Type:Expedited (15-DaCompany Report #A008820
Age:51 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Abnormal Behaviour	Literature	Lithane Tablets	PS		ORAL	ORAL
	Depression	Health Professional	Haloperidol	SS		ORAL	ORAL
	Feeling Abnormal		St. John'S Wort	SS		ORAL	900.00 MG TOTAL:TID:ORAL
	Hallucination						
	Inappropriate Affect						
	Libido Increased						
	Mania						
	Psychomotor Hyperactivity						

Speech Disorder
Stress

Date:03/27/00ISR Number: 3480372-5Report Type:Expedited (15-DaCompany Report #JACFRA2000000195
Age:29 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hepatitis	Foreign Health Professional	Haldol (20 Mg Tablet) (Haloperidol)	PS		ORAL	20 MG, 1 IN 1	DAY(S), ORAL
			Rivotril (Clonazepam)	SS		ORAL	ORAL	
			Tercian (Cyamemazine)	SS		ORAL	20 MG, DAILY,	ORAL
			Risperdal (Unspecified) (Risperidone)	C				

Date:03/28/00ISR Number: 3481233-8Report Type:Expedited (15-DaCompany Report #00F--10241
Age:69 YR Gender:Female I/FU:I

Outcome	PT	Report Source
Hospitalization - Initial or Prolonged	Hallucinations, Mixed	Foreign Health Professional
	Malaise	

Other

Product	Role	Manufacturer	Route	Dose	Duration
Cibadrex Tablet (Benazepril Hcl + Hydrochlorothiazide)	PS		ORAL	UNK, DAILY,	ORAL
Haldol Tablet (Haloperidol)	SS		ORAL	UNK, UNK,	ORAL
Nuctalon Tablet (Estazolam)	SS		ORAL	UNK, UNK,	ORAL
Zyrtec Tablet (Cetirizine)	SS		ORAL	UNK, UNK,	ORAL
Ivadal Tablet (Zolpidem Tartrate)	SS		ORAL	UNK, UNK,	ORAL
Parkinane Lp Slow Release Capsules (Trihexyphenidyl Hydrochloride)	SS		ORAL	UNK, UNK,	ORAL
Avlocardyl L.P. Slow Release Table	C				
Xanax Tablet	C				

Date:03/29/00ISR Number: 3481438-6Report Type:Direct Company Report #
Age:45 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Neuroleptic Malignant Syndrome		Haloperidol	PS				
			Lorazepam	C				
			Diphenhydramine	C				
			Benztropine	C				
			Diltiazem	C				
			Maxzide	C				
			Fosinopril	C				
			Lithium Carbonate	C				

Date:03/31/00ISR Number: 3482508-9Report Type:Expedited (15-DaCompany Report #JACFRA2000000136
Age:20 YR Gender:Male I/FU:F

Outcome	PT
Life-Threatening Hospitalization - Initial or Prolonged	Attention Deficit/Hyperactivity Disorder
	Bacterial Infection
	Blood Creatine Phosphokinase Increased
	Blood Electrolytes Abnormal
	Cardiac Arrest
	Coma
	Enzyme Abnormality
	Extrapyramidal Disorder
	Gastrointestinal Haemorrhage

Hypoxia Labile Blood Pressure Liver Function Test	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Abnormal Lung Disorder	Foreign Health	Risperdal (Risperidone)	PS		ORAL	1 MG, 1 IN 1
Muscle Disorder	Professional					DAY(S), ORAL
Pyrexia Skin Infection	Company Representative	Haldol (Haloperidol)	SS		INJECT	
Staphylococcal Infection Thrombocytopenia		Haldol Faible (Haloperidol)	SS		ORAL	15 DROP, 2 IN 1 DAY(S), ORAL
		Tiapridal (Tiapride)	SS		ORAL	ORAL
		Tranxene (Clorazepate Dipotassium)	C			
		Depakine (Valproate Sodium)	C			

Date:04/03/00ISR Number: 3483603-0Report Type:Direct Company Report #
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Dystonia		Haloperidol	PS		INTRAVENOUS	IV 3 DOSES
Initial or Prolonged	Hyperhidrosis Muscle Rigidity Neuroleptic Malignant Syndrome Tachycardia Tremor						

Date:04/03/00ISR Number: 3483734-5Report Type:Expedited (15-DaCompany Report #D/99/01660/LEX
Age:46 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Left Ventricular Failure	Foreign	Leponex (Clozapine)	PS		ORAL	600 MG, ORAL	
	Megacolon Pulmonary Oedema Sepsis	Health Professional	Neurocil (Levomepromazine Maleate)	SS		ORAL	150 MG, ORAL	
	Shock		Haldol Decanoate (Haloperidol Decanoate)	SS			50 MG, EVERY	THREE WEEKS,
			Sostril (Ranitidine Hydrochloride) - Chronic Gastritis	C			UNKNOWN	
			Akineton Retard (Biperiden Hydrochloride)- Epms	C				
			Bifetiral (Lactulose)- Obstipation	C				
			Ferro "Sanol" (Ferro "Sanol") - Hypoferric Anaemia	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/04/00ISR Number: 3483869-7Report Type:Direct Company Report #
Age:18 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required	Electrocardiogram Qt		Haldol Iv	PS				
INTRAVENOUS							40MG PER HOUR	
Intervention to	Prolonged							
IV DRIP							5	HR
Prevent Permanent	Torsade De Pointes							
Impairment/Damage	Ventricular Extrasystoles							

Date:04/04/00ISR Number: 3484185-XReport Type:Expedited (15-DaCompany Report #FLUV00300001630
Age:28 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Atrioventricular Block	Foreign	Fluvoxamine					
Initial or Prolonged	First Degree	Literature	(Fluvoxamine)	PS				
100 DAILY								
	Bundle Branch Block	Other						
UNK, 150 MG								
	Bilateral							
DAILY UNK, 50								
	Constipation							
MG DAILY UNK								
	Dizziness		Haloperidol					
	Drug Interaction		(Haloperidol)	SS				
UNK DAILY UNK								
	Extrapyramidal Disorder		Risperidone					
	Fatigue		(Risperidone)	SS		ORAL		
2 MG DAILY								
	Intentional Misuse							
UNK, 4 MG								
	Joint Stiffness							
DAILY UNK, 2								
	Nausea							
MG DAILY UNK,								
	Orthostatic Hypotension							
24 MG DAILY								
	Paranoia							
	Sinus Tachycardia							
	Suicide Attempt							
	Syncope							
	Thinking Abnormal							

Date:04/04/00ISR Number: 3484197-6Report Type:Expedited (15-DaCompany Report #200010806RHF
Age:60 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cholestasis	Foreign	Furosemide (Lasilix)	PS		ORAL	40 MG/DAY PO	1 DAY
Hospitalization -	Confusional State	Other	Haloperidol (Haldol)	SS		ORAL	1 MG/DAY PO	1 DAY
Initial or Prolonged	Hepatocellular Damage Oesophageal Carcinoma		Ketamine Hydrochooride (Ketalar)	SS		ORAL	500 MG /DAY PO	6 DAY
			Ceftriaxone Sodium (Rocephine)	SS			INTRAVENOUS	1 G/DAY IV 5 DAY
			Omeprazole (Mopral)	SS		ORAL	20 MG/DAY PO	1 DAY
			Heparin-Fraction, Sodium Salt (Clivarine)	SS			SUBCUTANEOUS	QD SC 1 DAY

Date:04/04/00ISR Number: 3484216-7Report Type:Expedited (15-DaCompany Report #JRFBEL2000000646
Age:31 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Anxiety Completed Suicide Condition Aggravated	Foreign Health Professional	Haloperidol (Unspecified) (Haloperidol)	PS		ORAL	MG, DAILY,	
	Hallucination						ORAL	
	Overdose Persecutory Delusion		Risperidone (Tablet) (Risperidone)	SS		ORAL	MG, DAILY,	

ORAL							
			Perphenazine Fendizoate (Perphenazine)	SS			ORAL
MG, DAILY,							
ORAL							
			Fluphenazine Maleate (Fluphenazine Maleste)	C			
			Clonazepam (Clonazepam)	C			
			Trihexyphenidyl Hydrcholoride (Trihexyphenidyl Hydrochloride)	C			
			Biperiden Hydrochloride (Biperiden Hydrochloride)	C			
			Flunitrazepam (Flunitrazepam)	C			
			Zopiclone (Zopiclone)	C			
			Vegetamin A (Vegetamin A)	C			

Date:04/04/00ISR Number: 3484217-9Report Type:Expedited (15-DaCompany Report #JACFRA2000000227
Age:60 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cholestasis	Foreign	Haldol (Unspecified)					
Hospitalization -	Confusional State	Health	(Haloperidol)	PS		ORAL	MG, DAILY,	
Initial or Prolonged	Liver Function Test	Professional						
ORAL								
	Abnormal		Ketalar (Ketamine Hydrochloride)	SS		ORAL		
ORAL								

Date:04/05/00ISR Number: 3484544-5Report Type:Expedited (15-DaCompany Report #JAOCAN2000000230
Age:35 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Glaucoma	Foreign Health Professional	Haloperidol Decanoate (Haloperidol Decanoate)	PS				

Date:04/06/00ISR Number: 3484841-3Report Type:Expedited (15-DaCompany Report #JRFUSA2000000344
Age:51 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Polycythaemia Vera	Study Health Professional	Risperdal (Risperidone)	PS		ORAL	8 MG, DAILY,	ORAL
			Haldol (Unspecified) (Haloperidol)	SS		ORAL	14 MG, DAILY,	ORAL
			Olanzapine (Olanzapine)	SS		ORAL	17.5 MG,	DAILY, ORAL
			Atenolol (Atenolol)	C				
			Clonazepam					

(Clonazepam)	C	
Cogentin (Benzatropine Mesilate)	C	
Atenolol (Atenolol)	C	
Clonazepam (Clonazepam)	C	
Cogentin (Benzatropine Mesilate)	C	

Date:04/06/00ISR Number: 3484875-9Report Type:Expedited (15-DaCompany Report #J081-002-000345
Age:60 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blood Creatine Phosphokinase Increased	Foreign Health	Aricept (Donepezil)	PS		ORAL	5 MG, 1 IN 1 D, PER ORAL	
	Drug Interaction Muscle Rigidity Myoglobin Blood Increased Myoglobin Urine Neuroleptic Malignant Syndrome Pyrexia Speech Disorder Developmental	Professional	Artane (Trihexyphenidyl Hydrochloride)	SS		ORAL	6 MG, PER ORAL	
			Barnetil (Sultopride)	SS		ORAL	1200 MG, 6 IN 1 D, PER ORAL	
			Serenace (Haloperidol)	SS		ORAL	18 MG, 6 IN 1 D, PER ORAL	
			Levotomin (Levomepromazine Maleate)	SS		ORAL	75 MG, 3 IN 1 D, PER ORAL	
			Vegetamin A (Vegetamin A)	SS		ORAL	2 TABLETS, 2	

IN 1 D, PER

ORAL

Barnetil (Sultopride)	SS		ORAL

300 MG, 3 IN

1 D, PER ORAL

Levotomin (Levomepromazine Maleate)	SS		ORAL

50 MG, 1 IN 1

D, PER ORAL

Acenalin (Cisapride)	C		

Date:04/07/00ISR Number: 3485228-XReport Type:Expedited (15-DaCompany Report #10338283
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Sudden Death	Foreign	Cefepime Hcl	PS		
INTRAVENOUS 2 GRAM, 1/1						
		Study				
DAY IV						
		Health	Cimetidine	SS		
		Professional	Haloperidol	SS		
		Other				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/07/00ISR Number: 3485920-7Report Type:Expedited (15-DaCompany Report #232584
Age:60 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cholestasis	Foreign	Rocephine					
	Confusional State	Other	(Ceftriaxone Sodium)	PS				
INTRAVENOUS							1 GRAM	DAILY
	Hepatocellular Damage							
INTRAVENOUS								
	Liver Function Test		Haldol (Haloperidol)	SS		ORAL		
1 MG DAILY								
	Abnormal							
ORAL								
			Ketalar (Ketamine Hydrochloride) 500 Mg	SS		ORAL		
ORAL								
			Mopral (Omeprazole)	SS		ORAL		
20 MG DAILY								
ORAL								
			Lasilix (Furosemide)	SS		ORAL		
40 MG DAILY								
ORAL								
			Clivarine (Reviparin Sodium)	C				

Date:04/10/00ISR Number: 3486175-XReport Type:Expedited (15-DaCompany Report #JRFBEL2000000721
Age:60 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Binocular Eye Movement	Foreign	Haldol (Unspecified)					
Initial or Prolonged	Disorder	Literature	(Haloperidol)	PS				
MG, DAILY								
Required	Blood Creatine	Health						
(SEE IMAGE)								
Intervention to	Phosphokinase Increased	Professional	Dantrolene Sodium					
Prevent Permanent	Body Temperature		(Dantrolene Sodium)	SS				
INTRAVENOUS							MG, DAILY, IV	2 DAY
Impairment/Damage	Increased							
	Brain Scan Abnormal							
	Circulatory Collapse							

	Coma					
	Csf Pressure Increased					
	Csf Protein Increased					
	Depressed Level Of Consciousness					
	Disorientation					
	Hyperhidrosis					
	Hyperreflexia					
	Hypoglycaemia					
	Leukocytosis					
	Muscle Rigidity					
	Neuroleptic Malignant Syndrome					
	Paralysis Flaccid					
	Quadriplegia					

Date:04/10/00ISR Number: 3486176-1Report Type:Expedited (15-DaCompany Report #JRFBEL2000000914
Age:60 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Death	Agranulocytosis	Foreign	Haldol (Unspecified)				
Hospitalization -	Bone Marrow Depression	Health	(Haloperidol)	PS		ORAL	
ORAL							
Initial or Prolonged	Drug Effect Decreased	Professional	Tamoxifen Nm Pharma				
	Drug Toxicity		(Tamoxifen Citrate)	SS			
	Leukopenia		Lamictal				
	Pyrexia		(Lamotrigine)	SS			
	Sepsis		Levaxin (Levothyroxine Sodium)	C			

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/11/00ISR Number: 3486823-4Report Type:Expedited (15-DaCompany Report #JRFBEL2000000880
Age:36 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Disability	Cerebellar Syndrome	Foreign Health Professional	Haldol (Unspecified) (Haloperidol)	PS				
	Decreased Appetite		Largactil	C				
	Difficulty In Walking		Cisordinol	C				
	Hallucination, Auditory		Leponex	C				
	Hypoaesthesia		Glucophage	C				
	Hyporeflexia		Tegretol Slow Retard	C				
	Movement Disorder		Efexor	C				
	Night Sweats		Akineton	C				
	Paresis		Amaryl	C				
	Polyneuropathy		Flunipam	C				
	Psychotic Disorder		Sobril	C				
	Schizophrenia		Rivotril	C				
	Urinary Incontinence		Flux	C				
	Vitamin B12 Decreased		Vitamin B12	C				
			Cosylan	C				
			Paracet	C				

Date:04/12/00ISR Number: 3487557-2Report Type:Expedited (15-DaCompany Report #JRFBEL1999002000
Age:55 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other Required Intervention to Prevent Permanent Impairment/Damage	Blood Creatine Phosphokinase Increased	Foreign Health Professional	Risperidone (Tablet) (Risperidone)	PS		ORAL	MG, TABLET, ORAL	
	Hypokalaemia							
	Hyponatraemia		Haloperidol (Tablet) (Haloperidol)	SS		ORAL	MG, DAILY, ORAL	
	Inappropriate Antidiuretic Hormone Secretion							
	Muscle Rigidity		Levomepromazine Maleate (Levomepromazine Maleate)	C				
	Neuroleptic Malignant Syndrome							
	Polydipsia							
	Polyuria							
	Pyrexia							

Tremor
Water Intoxication

Date:04/13/00ISR Number: 3488132-6Report Type:Expedited (15-DaCompany Report #200010901RHF
Age:52 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Agranulocytosis	Foreign	Furosemide (Lasilix)					
Life-Threatening	Leukopenia	Other	Tablets	PS		ORAL	80 MG/DAY PO	16 DAY
Hospitalization -	Lymphocyte Percentage		Haloperidol (Haldol)	SS		ORAL	3 U/DAY PO	16 DAY
Initial or Prolonged	Increased Neutrophil Percentage Decreased		Heparin-Fraction, Sodium Salt (Innohep)	SS		SUBCUTANEOUS	SC	16 DAY
	Red Blood Cell Count Decreased		Lisinopril (Zestril) Tablets	SS		ORAL	2.5 MG/DAY PO	16 DAY
			Midazolam Hydrochloride (Hypnovel) Solution For Injection	SS		INTRAVENOUS	IV	
			Clorazepate Dipotassium					

			(Tranxene) Tablets	SS		ORAL
150 MG/DAY PO	16 DAY					

Date:04/17/00ISR Number: 3489382-5Report Type:Expedited (15-DaCompany Report #JACFRA2000000242
Age:61 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization - Initial or Prolonged	Pulmonary Embolism Thrombocytopenia	Foreign Health Professional	Haldol (2 Mg/Ml Solution) (Haloperidol)	PS		ORAL
DROP, DAILY,						
ORAL						
			Nozinan (Levomepromazine)	SS		
			Heparin Sodique "Choay" (Heparin)	SS		
INTRAVENOUS	U, DAILY, IV					
			Pro-Dafalgan	C		
			Mopral	C		
			Geluprane	C		
			Norset	C		
			Bi-Tildiem	C		
			Skenan	C		
			Forlax	C		

Date:04/17/00ISR Number: 3489435-1Report Type:Expedited (15-DaCompany Report #JACGER2000000214
Age:66 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Death Life-Threatening Required Intervention to Prevent Permanent Impairment/Damage	Cardiomegaly Coronary Artery Disease Cyanosis Enuresis Left Ventricular Failure Pneumatic Compression Therapy Pulmonary Haemorrhage	Foreign Health Professional	Haldol Decanoat (50 Mg/Ml Injection) (Haloperidol Decanoate)	PS		
INTRAMUSCULAR	100 MG, 1 IN					
1 TIME(S), IM						
			Ciatyl-Z-Acuphase (Zuclopenthixol Acetate)	SS		
INTRAMUSCULAR	100 MG, 1 IN					

		Pulmonary Oedema					
1 DAY(S), IM							
				Ciatyl-Z Depot (Zuclopenthixol Decanoate)	SS		
INTRAMUSCULAR	400 MG, 1 IN						
1 DAY(S), IM							

Date:04/18/00ISR Number: 3489134-6Report Type:Direct Company Report #
Age:35 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Life-Threatening	Drug Level Above	Health	Haloperidol	PS		
INTRAVENOUS 2-4 MG	IV Q					
Hospitalization - 2-4 PRN	Therapeutic	Professional				
Initial or Prolonged	Drug Toxicity		Ativan	C		
	Muscle Rigidity		Ceftriaxone	C		
	Neuroleptic Malignant Syndrome		Lamotrigine	C		
	Opisthotonus					
	Pyrexia					

Date:04/18/00ISR Number: 3489703-3Report Type:Expedited (15-DaCompany Report #JACFRA2000000250
Age:52 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Agranulocytosis	Foreign	Haldol (Unspecified)					
Life-Threatening	Leukopenia	Health	(Haloperidol)	PS		ORAL		
ORAL								
		Professional	Innohep (Heparin-Fraction, Sodium Salt)	SS				
SUBCUTANEOUS	SUBCUTANEOUS							
			Zestril (Lisinopril)	SS		ORAL		
MG, DAILY,								
ORAL								
			Hyponevel (Midazolam Hydrochloride)	SS				
INTRAVENOUS	IV							
			Tranxene (Clorazepate Dipotassium)	SS		ORAL		
MG, DAILY,								
ORAL								
			Lasilix (Furosemide)	SS		ORAL		
MG, DAILY,								
ORAL								

Date:04/18/00ISR Number: 3490115-7Report Type:Expedited (15-DaCompany Report #C2000-0258.01
Age:65 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dehydration	Consumer	Haloperidol Tablets 5 Mg Mylan	PS	Mylan	ORAL		
	Dysphagia							
5 MG BID,								
Other	Medication Error							
ORAL								

Date:04/18/00ISR Number: 3490849-4Report Type:Periodic Company Report #9-181-0772
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Injection Site Oedema	Health Professional	Haloperidol 500 Mg	PS		INTRAMUSCULAR	75 MG IMX 14	DAYS

Date:04/18/00ISR Number: 3490853-6Report Type:Periodic Company Report #9-186-0772
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Injection Site Oedema	Health Professional	Haloperidol 500 Mg	PS		INTRAMUSCULAR	150 MG IM X	28 DAYS

Date:04/18/00ISR Number: 3490860-3Report Type:Periodic Company Report #9-187-0772
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Injection Site Oedema	Health Professional	Haloperidol 500 Mg	PS			100 MG X 2	WKS

Date:04/19/00ISR Number: 3490407-1Report Type:Expedited (15-DaCompany Report #233564
Age:52 YR Gender:Female I/FU:I

Outcome	PT
Death	Agranulocytosis
Life-Threatening	Anaemia
	Leukopenia
	Lymphocytosis

		Neutropenia White Blood Cell Count Decreased	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
			Foreign Other	Hypnovel (Inj) (Midazolam Hydrochloride) 5 Mg	PS		
INTRAVENOUS	INTRAVENOUS						
				Haldol (Haloperidol)	SS		ORAL
2 DOSE FORM							
DAILY ORAL							
				Innohep (Tinzaparin Sodium)	SS		
SUBCUTANEOUS	SUBCUTANEOUS						
				Zestril (Lisinopril) 5 Mg	SS		ORAL
2.5 MG DAILY							
ORAL							
				Tranxene (Clorazepate Dipotassium) 50 Mg	SS		ORAL
150 MG DAILY							
ORAL							
				Lasilix (Furosemide) 80 Mg	SS		ORAL
80 MG DAILY							
ORAL							

Date:04/19/00ISR Number: 3490431-9Report Type:Expedited (15-DaCompany Report #JRFBEL2000001062
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization - Initial or Prolonged	Abdominal Distension Atrioventricular Block	Foreign Literature	Haldol (Unspecified) (Haloperidol)	PS		
INTRA-UTERINE	UTERINE 5 WK					
Required Intervention to Prevent Permanent	Second Degree Bradycardia Bradycardia Foetal	Health Professional	Akineton (Biperiden Hydrochloride) Chlorpromazine	SS		
INTRA-UTERINE	UTERINE 5 WK					

Impairment/Damage		Caesarean Section		(Chlorpromazine)	SS		
INTRA-UTERINE	UTERINE	5 WK					
		Complications Of Maternal Exposure To Therapeutic Drugs		Electroconvulsive Therapy (Unspecified)	SS		
INTRA-UTERINE	UTERINE						
		Electrocardiogram Qt Corrected Interval Prolonged					
		Heart Rate Decreased					
		Neonatal Disorder					
		Respiratory Disorder Neonatal					
		Tachycardia					

Date:04/20/00ISR Number: 3490771-3Report Type:Expedited (15-DaCompany Report #JACGER2000000220
Age:54 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Blister	Foreign	Haldol	PS				
INTRAVENOUS	MG, DAILY, IV							
Initial or Prolonged	Cyanosis	Health Professional	Haldol Decanoat (50 Mg/Ml Injection) (Haloperidol Decanoate)	SS				
	Drug Toxicity							
	Erythema							
	Hypersensitivity							
INTRAMUSCULAR	50 MG, 1 IN 4							
	Oxygen Saturation							
WEEK(S), IM								
	Decreased		Ciatyl (Clopenthixol Hydrochloride)	SS				
	Pyrexia							
INTRAVENOUS	MG, DAILY, IV							
	Respiratory Failure		Ciatyl-Z (Zuclopenthixol Hydrochloride)	SS		ORAL		
MG, DAILY								
ORAL								

				Lyogen (Fluphenazine)	SS		ORAL
MG, DAILY,							
ORAL							
				Delix (Ramipril)	C		
				Clexane (Heparin-F-Raction, Sodium Salt)	C		
				Bronchoretard (Theophylline)	C		

Date:04/26/00ISR Number: 3493090-4Report Type:Expedited (15-DaCompany Report #PRIUSA2000004255
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Cardiac Arrest Drug Interaction	Health Professional	Haldol (Injection) (Haloperidol)	PS		INTRAVENOUS	10 MG, 1 TIME	
(S), IV								
			Epinephrine (Epinephrine)	SS				

Date:04/26/00ISR Number: 3493501-4Report Type:Expedited (15-DaCompany Report #JACGER2000000478
Age:70 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Medication Error Sedation	Foreign Health Professional	Haldol Decanoat(50 Mg/Ml Injection) (Haloperidol Decanoate)	PS		INTRAVENOUS	100 MG, 1 IN	
1 TIME(S), IV								

Date:04/26/00ISR Number: 3493502-6Report Type:Expedited (15-DaCompany Report #JACGER2000000497
Age:71 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
	Arrhythmia	Foreign Health Professional	Haldol Decanoat(50 Mg/Ml Injection)(Haloperidol Decanoate)	PS		
INTRAMUSCULAR 50 MG, 1 IN 4 WEEK(S), IM						

Date:04/26/00ISR Number: 3493503-8Report Type:Expedited (15-DaCompany Report #PRIUSA2000004311
Age:43 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Face Oedema Oedema Peripheral Pruritus	Health Professional	Haldol Decanoate (Injection) (Haloperidol Decanoate)	PS		
INTRAMUSCULAR 200 MG, 1 IN 1 MONTH(S), IM						
			Zoloft (Sertraline Hydrochloride)	C		
			Zyprexa (Olanzapine)	C		
			Cogentin (Benzatropine Mesilate)	C		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/27/00ISR Number: 3493488-4Report Type:Direct Company Report #
Age:9 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Depressed Level Of Consciousness Dyspnoea Extrapyramidal Disorder Hyperventilation Muscle Rigidity		Haloperidol Paroxetine	PS SS		INTRAMUSCULAR	3 MG IM X1 10MG QD	

Date:04/27/00ISR Number: 3493845-6Report Type:Expedited (15-DaCompany Report #JRFBEL2000001092
Age:64 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death Other Required Intervention to Prevent Permanent Impairment/Damage	Muscle Rigidity Mutism Neuroleptic Malignant Syndrome Pneumonia Pyrexia Stupor Waxy Flexibility	Literature Health Professional	Haloperidol (Haloperidol)	PS				

Date:04/27/00ISR Number: 3493877-8Report Type:Expedited (15-DaCompany Report #J081-002-000345
Age:60 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blood Creatine Phosphokinase Increased Condition Aggravated Dehydration Depressed Level Of Consciousness	Foreign Health Professional	Aricept (Donepezil) Artane (Trihexyphenidyl Hydrochloride)	PS SS		ORAL ORAL	3 MG, 1 IN 1 D, PER ORAL 6 MG, PER ORAL	

	Drug Interaction Muscle Rigidity	Barnetil (Sultopride)	SS	ORAL
1200 MG, 3 IN 1 D, PER ORAL	Myoglobin Blood Increased Myoglobinuria Neuroleptic Malignant Syndrome Pyrexia Speech Disorder	Serenace (Haloperidol)	SS	ORAL
18 MG, 6 IN 1 D, PER ORAL		Levotomin (Levomepromazine Maleate)	SS	ORAL
75 MG, 3 IN 1 D, PER ORAL, 50 MG		Vegetamin A (Vegetamin A)	SS	ORAL
2 TABLETS, 2 IN 1 D, PER ORAL		Acenalin (Cisapride)	SS	ORAL
7.5 MG, 3 IN 1 D, PER ORAL				

Date:04/28/00ISR Number: 3493985-1Report Type:Direct Company Report #
Age:55 YR Gender:Female I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Constipation Faecaloma Intestinal Obstruction

	Vomiting						
		Report Source	Product	Role	Manufacturer		Route
Dose	Duration						
			Haloperidol	PS			
			Benztropine	SS			

Date:05/01/00ISR Number: 3494648-9Report Type:Direct Company Report #
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Other	Pollakiuria		Haloperidol 10 Mg			
	Urinary Incontinence		Tabs. (Roxane)	PS	(Roxane)	ORAL
10MG PO AM						
AND HS						

Date:05/01/00ISR Number: 3495052-XReport Type:Expedited (15-DaCompany Report #JRFBEL2000001142
Age:27 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization -	Cerebellar Atrophy	Literature	Haldol (Unspecified)			
Initial or Prolonged	Computerised Tomogram	Health	(Haloperidol)	PS		
Disability	Abnormal	Professional	Lithium Carbonate			
Required	Convulsion		(Lithium Carbonate)	SS		
Intervention to	Coordination Abnormal		Diazepam (Diazepam)	SS		
Prevent Permanent	Depressed Level Of					
Impairment/Damage	Consciousness					
	Drug Interaction					
	Electroencephalogram					
	Abnormal					
	Extensor Plantar Response					
	Gait Disturbance					
	Muscle Rigidity					
	Nystagmus					
	Speech Disorder					

Date:05/02/00ISR Number: 3495192-5Report Type:Direct Company Report #
Age:44 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hallucination Joint Stiffness Parkinsonian Gait Tremor		Haloperidol Haldol-D	PS SS			10MG Q HS	

Date:05/02/00ISR Number: 3495470-XReport Type:Expedited (15-DaCompany Report #JACGER2000000507
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Foreign Health Professional	Haldol (2mg/Ml Drops) (Haloperidol)	PS		ORAL	1 MG, 1 IN 1 TIME(S),	ORAL

Date:05/03/00ISR Number: 3496475-5Report Type:Expedited (15-DaCompany Report #JRFBEL2000001143
Age:32 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Aggression Apathy	Foreign Literature	Haloperidol (Tablet) (Haloperidol)	PS			MG, DAILY	
	Brain Neoplasm Cerebellar Syndrome	Health Professional	Lithium Carbonate (Lithium Carbonate)	SS			MG, DAILY	3 YR
	Coordination Abnormal Cough Diarrhoea Difficulty In Walking Drug Toxicity Dysarthria Intention Tremor Irritability Memory Impairment Osteosarcoma Localised Pyrexia Q Fever Speech Disorder Stupor		Levomepromazin (Levomepromazine)	C				

Date:05/03/00ISR Number: 3496477-9Report Type:Expedited (15-DaCompany Report #JACGER2000000524
Age:73 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Malignant Hypertension	Foreign Health Professional	Haldol Decanoat (50 Mg/Ml Injection) (Haloperidol Decanoate)	PS		INTRAMUSCULAR	100 MG, 1 IN 4 WEEK (S),	IM

Date:05/03/00ISR Number: 3496684-5Report Type:Expedited (15-DaCompany Report #JRFBEL2000001178
Age:31 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Disability	Aggression Agitation Belligerence Emotional Disorder Extrapyramidal Disorder Irritability Mood Swings Persecutory Delusion Suicidal Ideation Tremor	Literature Health Professional	Haloperidol (Unspecified) (Haloperidol) Lorazepam (Lorazepam) Narcotica (Unspecified) Oxandrolone (Oxandrolone) Antibiotics (Antibiotics)	PS C C C C				

Date:05/03/00ISR Number: 3496743-7Report Type:Expedited (15-DaCompany Report #JRFBEL2000000646
Age:31 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Anxiety Completed Suicide Dystonia	Foreign Health Professional	Haloperidol (Unspecified) (Haloperidol) Risperidone (Tablet)	PS		ORAL	MG, DAILY, ORAL	

			(Risperidone)	SS			ORAL
MG, DAILY,							
ORAL							
			Perphenazine Fendizoate (Perphenazine)	SS			ORAL
MG, DAILY,							
ORAL							
			Fluphenazine Maleate (Fluphenazine Maleate)	C			
			Clonazepam (Clonazepam)	C			
			Trihexyphenidyl Hydrochloride (Trihexyphenidyl Hydrochloride)	C			
			Biperiden Hydrochloride (Biperiden Hydrochloride)	C			
			Flunitrazepam (Flunitrazepam)	C			
			Zopiclone (Zopiclone)	C			
			Vegetamin A (Vegetamin A)	C			

Date:05/05/00ISR Number: 3496637-7Report Type:Expedited (15-DaCompany Report #C2000-0258.01
Age:64 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dehydration	Consumer	Haloperidol Tablets 5 Mg Mylan	PS		ORAL	5MG BID, ORAL	
	Dysphagia							
Other	Medication Error		Verelan	C				
			Synthroid	C				
			Prilosec	C				
			Diovan	C				
			Albuterol	C				
			Cardura	C				

Date:05/08/00ISR Number: 3497164-3Report Type:Direct Company Report #
Age:21 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drooling		Risperidone	PS		ORAL	3 MG PO	
	Feeling Jittery		Haldol	SS			PRN AT MHC	
Other	Muscle Rigidity		Benadryl	SS		ORAL	25 MG PO	
	Neuroleptic Malignant Syndrome							
	Pyrexia							
	Speech Disorder							
	Tachycardia							
	Tremor							

Date:05/08/00ISR Number: 3497807-4Report Type:Expedited (15-DaCompany Report #JRFBEL2000001143
Age:32 YR Gender:Male I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Abnormal Behaviour
	Aggression

		Apathy Cerebellar Syndrome Coordination Abnormal	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
		Cough Depression Diarrhoea Difficulty In Walking	Foreign Literature Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute Div Ortho Pharm	
MG, DAILY							
		Drug Level Above Therapeutic		Lithium Carbonate (Lithium Carbonate)	SS		
MG, DAILY	3 YR						
		Drug Toxicity Dysarthria Intention Tremor Irritability Mental Disorder Due To A General Medical Condition Pyrexia Q Fever Stupor		Levomepromazin (Levomepromazine)	C		

Date:05/09/00ISR Number: 3498062-1Report Type:Direct Company Report #
Age:80 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - 2 DOSES	Hypertension		Haloperidol 2.5mg Im	PS		
Initial or Prolonged	Joint Stiffness Muscle Contractions Involuntary Neuroleptic Malignant Syndrome Pyrexia Tremor					

Date:05/10/00ISR Number: 3499079-3Report Type:Expedited (15-DaCompany Report #F/00/01077/EXELON
Age:77 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Mouth Haemorrhage	Foreign	Exelon	PS	Novartis	

Initial or Prolonged	Mucosal Haemorrhage	Health		Pharmaceuticals Corp	ORAL
1.5 MG, TWICE					
Required	Stevens-Johnson Syndrome	Professional			
A DAY, ORAL;					
Intervention to	Thrombocytopenia		Haldol (Haloperidol)	SS	
UNSPECIFIED,					
Prevent Permanent			Solupred		
Impairment/Damage			(Prednisolone Sodium		
			Sulfobenzoate)	C	
UNSPECIFIED,					
			Zyloric		
			(Allopurinol)	C	

Date:05/10/00ISR Number: 3499999-XReport Type:Expedited (15-DaCompany Report #PRIUSA2000001325
Age:86 YR Gender:Male I/FU:F

Outcome	PT
Death	Acute Prerenal Failure
	Acute Respiratory
	Distress Syndrome
	Anxiety
	Asthenia
	Blood Creatine
	Phosphokinase Increased
	Cardiac Failure

	Congestive Cardiomyopathy Cerebral Atrophy Coma Computerised Tomogram Abnormal Confusional State Delirium Dyskinesia Echocardiogram Abnormal Hypoxia Lethargy Mental Impairment Peripheral Ischaemia Pleural Effusion Pleural Infection Respiratory Failure Spleen Disorder Thrombocytopenia Ventricular Hypertrophy	Report Source Study Health Professional	Product Levaquin Levaquin (Injection) (Levofloxacin) Haldol Dobutamine (Dobutamine) Dopamine (Dopamine) Milrinone (Milrinone) Digoxin (Digoxin)	Role PS SS SS C C C C	Manufacturer Rw Johnson Pharmaceutical Research Institute Div Ortho Pharm	Route ORAL INTRAVENOUS INTRAVENOUS	Dose 250 MG, DAILY, ORAL 250 MG, DAILY, IV 1 IN 1 TIME(S), IV	Duration

Date:05/11/00ISR Number: 3498909-9Report Type:Direct Company Report #
Age:69 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Neuroleptic Malignant Syndrome Pyrexia Tremor	Health Professional	Haldol 1 Mg + 2 Mg Glucotrol Xl Norvasc Asa	PS C C C		ORAL	1-2 MG PO/IM Q4-6H PRN	

Date:05/12/00ISR Number: 3499873-9Report Type:Expedited (15-DaCompany Report #A0061345A
Age:22 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Aggression Choking Sensation Convulsion Drug Effect Decreased Drug Ineffective Loss Of Consciousness Neck Pain Pain In Extremity Vomiting	Consumer	Lamictal Tablet (Lamotrigine) Haloperidol Risperidone	PS SS C	Glaxo Wellcome Inc	ORAL	100 MG/TWICE PER DAY/ORAL	

Date:05/15/00ISR Number: 3499992-7Report Type:Direct Company Report #
Age:43 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardio-Respiratory Arrest Hypotension Neuroleptic Malignant Syndrome Pain Pyrexia Sepsis Tachycardia		Clozapine 100mg (Novartis) Haloperidol 10mg (Geneva) Olanzapine Divalproex Benztropine Asa (Ec) Lorazepam Docusate	PS SS C C C C C C	Novartis Geneva	ORAL ORAL	100MG BID PO 10MG BID PO	

Date:05/15/00ISR Number: 3500828-6Report Type:Expedited (15-DaCompany Report #PRIUSA2000004824
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Hospitalization - Initial or Prolonged	Agitation Confusional State	Consumer	Haldol	PS	Rw Johnson Pharmaceutical Research Institute	INTRAVENOUS	1 MG, 1 TIME, IV	
			Haldol (Injection) (Haloperidol)	SS		INTRAVENOUS		

Date:05/15/00ISR Number: 3500829-8Report Type:Expedited (15-DaCompany Report #GBR001222
Age:56 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Chromaturia Faeces Discoloured Hepatitis Cholestatic Jaundice Nausea	Foreign Health Professional Other	Meridia	PS	Knoll Pharmaceutical Co Sub Basf Corp	ORAL	10 MG DAILY, PO	
			Haldol (Injection) (Haloperidol)	SS		INTRAVENOUS	2 MG, 1 TIME; 5 MG 1 TIME; 10 MG, 1 TIME, IV	
			Logimax	C				

Date:05/15/00ISR Number: 3501209-1Report Type:Expedited (15-DaCompany Report #00P-056-0089614-00 (0)
Age:52 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death Life-Threatening	Agranulocytosis	Foreign Health	Tranxene	PS	Abbott Laboratories Pharmaceutical			

			Professional			Products Div	ORAL
150 MG, 1 IN 1 D, PER ORAL							
				Haloperidol (Haloperidol)	SS		ORAL
3 UNIT, 1 IN 1 D, PER ORAL							
				Heparin-Fraction, Sodium Salt (Heparin-Fraction, Sodium Salt)	SS		
SUBCUTANEOUS	SUBCUTANEOUS						
				Lisinopril (Lisinopril)	SS		ORAL
2.5 MG, 1 IN 1 D, PER ORAL							
				Midazolam Hydrochloride (Midazolam Hydrochloride)	SS		
INTRAVENOUS	INTRAVENOUS						
				Furosemide (Furosemide)	SS		ORAL
80 MG, 1 IN 1 D, PER ORAL							

Date:05/15/00ISR Number: 3501269-8Report Type:Expedited (15-DaCompany Report #JACFRA2000000222
Age:29 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Agitation Eosinophilia Neutropenia Staphylococcal Infection	Foreign Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute Div Ortho Pharm	ORAL	4 MG 1 IN 1	

DAY(S) ORAL

			Gardenal (Phenobarbital)	SS		ORAL

100 MG 1 IN 1

DAY(S) ORAL

			Tranxene (Clorazepate Dipotassium)	C		
			Haldol (5 Mg/Ml Injection) (Haloperidol)	C		

Date:05/16/00ISR Number: 3500993-0Report Type:Expedited (15-DaCompany Report #232584
Age:60 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Cholestasis	Foreign	Rocephine			
	Confusional State	Other	(Ceftriaxone Sodium)	PS	Hlr Technology	
INTRAVENOUS 1 GRAM	DAILY					
	Hepatic Function Abnormal					
INTRAVENOUS						
	Hepatocellular Damage		Haldol (Haloperidol)	SS		ORAL
1 MG DAILY						
ORAL						
			Ketalar (Ketamine Hydrochloride) 500 Mg	SS		ORAL
ORAL						
			Lasilix (Furosemide)	SS		ORAL
40 MG DAILY						
ORAL						
			Mopral (Omeprazole)	SS		ORAL
20 MG DAILY						
ORAL						
			Clivarine (Reviparin Sodium)	C		

Date:05/16/00ISR Number: 3501191-7Report Type:Expedited (15-DaCompany Report #200010806RHF
Age:60 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cholestasis	Foreign	Lasix	PS	Aventis Pharmaceuticals Inc	ORAL	40 MG/DAY PO	8 DAY
Hospitalization - Initial or Prolonged	Confusional State	Other	Haloperidol (Haldol)	SS		ORAL	1 MG/DAY PO	8 DAY
	Hepatocellular Damage		Ketamine Hydrochloride (Ketalar)	SS		ORAL	500 MG/DAY PO	6 DAY
	Liver Function Test Abnormal		Ceftriaxone Sodium (Rocephine)	SS		INTRAVENOUS	1 G/DAY IV	12 DAY
			Omeprazole (Mopral)	SS		ORAL	20 MG/DAY PO	8 DAY
			Heparin-Fraction, Sodium Salt (Clivarine)	SS		SUBCUTANEOUS	QD SC	8 DAY

Date:05/18/00ISR Number: 3501779-3Report Type:Expedited (15-DaCompany Report #PRIUSA2000004995
Age:73 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Asthenia	Consumer	Haldol	PS	Rw Johnson Pharmaceutical Research Institute	INTRAMUSCULAR	2.5 MG, 1 IN 1 TIME(S),	
Disability	Difficulty In Walking							
	Loss Of Consciousness							
	Movement Disorder						IM; 5 MG, 4 TIME(S),	IM
			Lithium (Lithium)	C				
			Lorazepam					

			(Lorazepam)	C		
			Mellaril (Thioridazine Hydrochloride)	C		

Date:05/18/00ISR Number: 3502240-2Report Type:Expedited (15-DaCompany Report #JACFRA2000000315
Age:19 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Bradycardia Coma Hypotension Hypotonia	Foreign Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute Div Ortho Pharm	ORAL	150 MG,	
	Loss Of Consciousness						TOTAL, ORAL	
	Suicide Attempt		Havlane (Loprazolam Mesilated)	SS		ORAL	10 MG, TOTAL,	
							ORAL	

Date:05/22/00ISR Number: 3503482-2Report Type:Direct Company Report #
Age:65 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Hospitalization - Initial or Prolonged	Cardiovascular Disorder Chills Depressed Level Of Consciousness	Health Professional	Haloperidol Concentrate, Mfr. Pharm. Assoc. Inc.	PS	Mfr: Pharm. Assoc. Inc		Required 5 MG BID	
Intervention to Prevent Permanent Impairment/Damage	Dysphagia Extrapyramidal Disorder Hyperhidrosis Leukocytosis Muscle Rigidity Neuroleptic Malignant Syndrome Restlessness Tachycardia Tremor		Haloperidol Tablets, Mfr Geneva Inh Benztropine Enteric Coated Aspirin Vistaril Vitamin B6	SS C C C C C	Mfr Geneva		1 MG BID	

Urinary Incontinence

Date:05/23/00ISR Number: 3503592-XReport Type:Expedited (15-DaCompany Report #JACGER2000000598
Age:43 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Hospitalization - Initial or Prolonged	Brain Hypoxia Cardiac Arrest Drug Interaction Hypertension Loss Of Consciousness	Foreign Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute Div Ortho Pharm	ORAL	10 MG, 3 IN 1	DAY(S), ORAL
			Haemiton (Clonidine Hydrochloride)	SS		ORAL	PRN, ORAL	
			Laubeel (Lorazepam)	SS		ORAL	1 MG, 4 IN 1	DAY(S), ORAL
			Lyogen (Fluphenazine)	SS		ORAL	4 MG, 2 IN 1	DAY(S), ORAL
			Neurocil (Levomepromazine Maleate)	SS		ORAL	80 MG, 4 IN 1	DAY(S), ORAL
			Nifedipin	SS		ORAL	10 MG, PRN,	

ORAL						
			Ximovan (Zopiclone)	SS		ORAL
7.5 MG, 1 IN						
1 DAY(S),						
ORAL						

Date:05/24/00ISR Number: 3503394-4Report Type:Expedited (15-DaCompany Report #M2000.0325
Age:65 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Aphasia Hyperhidrosis	Health Professional	Haloperidol	PS	Geneva Pharmaceuticals Inc	ORAL
2 MG , BID,						
	Leukocytosis					
PO						
	Mental Impairment		Isoniazid	C		
	Muscle Rigidity		Cogentin	C		
	Pyrexia		Asa	C		
	Tachycardia		Vistral	C		

Date:05/24/00ISR Number: 3504074-1Report Type:Expedited (15-DaCompany Report #JACFRA2000000329
Age:73 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Cerebellar Syndrome Constipation Disorientation Flatulence	Foreign Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute Div Ortho Pharm	ORAL
5 MG, 1 IN 1						
	Hypokinesia					
DAY(S), ORAL						
	Parkinson'S Disease		Theralene (Alimemazine Tartrate)	SS		ORAL
35 MG, 1 IN 1						
DAY(S), ORAL						
			Spasfon (Spasfon)	C		
			Dafalgan			

			(Paracetamol)	C		

Date:05/24/00ISR Number: 3504075-3Report Type:Expedited (15-DaCompany Report #JRFBEL2000001303
Age:86 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Coordination Abnormal Sedation	Foreign Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute Div Ortho Pharm	ORAL	MG, DAILY,	
			Risperdal (Tablet) (Risperidone)	SS		ORAL	MG, DAILY,	
			Disipal (Orphenadrine Hydrochloride)	C				
			Oxabenz (Oxazepam)	C				

Date:05/26/00ISR Number: 3505278-4Report Type:Expedited (15-DaCompany Report #JRFBEL2000001390
Age:31 YR Gender:Male I/FU:I

Outcome
Hospitalization - Initial or Prolonged Required

Intervention to Prevent Permanent Impairment/Damage

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Agitation	Literature	Haldol	PS	Rw Johnson Pharmaceutical Research Institute Div Ortho Pharm		10 MG, 2 IN 1	
	Blood Creatine Phosphokinase Increased	Health Professional						
	Blood Creatinine Increased							DAY(S)
	Bradypnoea		Haloperidol Decanoate (Injection) (Haloperidol Decanoate)	SS		INTRAMUSCULAR	100 MG, IM	
	Coma							
	Dry Skin							
	Epistaxis							
	Hyperpyrexia							
	Hypertension		Propranolol (Propranolol)	C				
	Hyponatraemia							
	Muscle Rigidity		Valproic Acid (Valproic Acid)	C				
	Neuroleptic Malignant Syndrome							
	Oxygen Saturation Decreased		Benztropine (Benztropine)	C				
	Platelet Count Decreased							
	Prothrombin Time Prolonged							
	Respiratory Rate Increased							
	Tachycardia							

Date:05/26/00ISR Number: 3505919-1Report Type:Periodic Company Report #71131-001
Age:7 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Anxiety	Consumer	Haloperidol	PS	Roxane Laboratories Inc		5 MG DAY ONE, 2.5 MG DAY TWO	
	Medication Error							
	Sedation							
	Tremor							

Date:05/30/00ISR Number: 3506143-9Report Type:Expedited (15-DaCompany Report #JACGER2000000599
Age:29 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Abortion Spontaneous	Foreign Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute	INTRAMUSCULAR	50 MG, 1 IN 1	MONTH (S), IM

Date:05/31/00ISR Number: 3505838-0Report Type:Direct Company Report #
Age:28 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Bradycardia		Lorazepam 2mg/Ml	PS		INTRAVENOUS		
	Cardio-Respiratory Arrest					BOLUS	2MG ONCE	
	Coma					INTRAVENOUS		
						BOLUS		
			Haloperidol 5mg/Ml	SS		INTRAVENOUS		
						BOLUS	2MG ONCE	
						INTRAVENOUS		
						BOLUS		
			Vasotec	C				

			Amiodarone	C		

Date:06/02/00ISR Number: 3508018-8Report Type:Expedited (15-DaCompany Report #JACGER2000000720
Age:37 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Life-Threatening Hospitalization - Initial or Prolonged Required	Coma Quadriplegia Respiratory Depression Rhabdomyolysis	Foreign Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute Div Ortho Pharm	ORAL
90 MG, 1 IN 1 TIME (S) , ORAL						
Intervention to Prevent Permanent Impairment/Damage	Suicide Attempt		Wodka (Ethanol)	SS		ORAL
350 ML, 1 IN 1 TIME (S) , ORAL						
			Saroten (Amitriptyline Hydrochloride)	SS		ORAL
100 MG, 1 IN 1 TIME (S) , ORAL						
			Diclofenac (Diclofenac)	SS		ORAL
250 MG, 1 IN 1 TIME (S) , ORAL						
			Mogadan Roche (Nitrazpam)	SS		ORAL
70 MG, 1 IN 1 TIME (S) , ORAL						

			Betadorm (Betadorm)	SS		ORAL
310 MG 1 IN 1 TIME (S) , ORAL						
			Diazepam (Diazepam)	SS		ORAL
10 TABLE, 1 IN 1 TIME (S), ORAL						
			Atosil (Isopromethazine Hydrochloride)	SS		ORAL
1000 MG, 1 IN 1 TIME (S) , ORAL						

Date:06/02/00ISR Number: 3508019-XReport Type:Expedited (15-DaCompany Report #JRFBEL2000001411
Age:21 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Completed Suicide	Foreign	Haldol	PS	Rw Johnson	
Other	Intentional Misuse	Health			Pharmaceutical	
	Suicide Attempt	Professional			Research Institute	
					Div Ortho Pharm	ORAL
DAILY, ORAL						
			Risperidone (Unspecified) (			
			Risperidone)	SS		ORAL
DAILY, ORAL						
			Promethazine Hcl	C		
			Biperiden	C		
			Brotizolam	C		
			Flunitrazepam	C		
			Levomepromazine	C		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/02/00ISR Number: 3508083-8Report Type:Expedited (15-DaCompany Report #JACGER2000000746
Age:67 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Extrapyramidal Disorder Medication Error Psychotic Disorder	Foreign Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute	INTRAVENOUS	15 MG, IV	
	Sedation		Atosil (Isopromethazine Hydrochloride)	SS		INTRAVENOUS	200 MG, IV	
			Tasmar (Tolcapone)	SS		ORAL		
			Dopergin (Lisuride Maleate)	SS		ORAL		
			Amantadin (Amantadine Hydrochloride)	SS		ORAL		
			Striaton (Sinemet)	SS		ORAL		

Date:06/02/00ISR Number: 3508085-1Report Type:Expedited (15-DaCompany Report #JACGER2000000713
Age:62 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Medication Error Pneumonia Respiratory Depression	Foreign Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute	INTRAVENOUS	5 MG, 1 IN 1	TIME(S), IV
			Tavor (Lorazepam)	SS		ORAL	2.5 MG, 1 IN	1 TIME(S),

Date:06/02/00ISR Number: 3508087-5Report Type:Expedited (15-DaCompany Report #JACGER2000000690
Age:20 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hepatic Enzyme Increased Hypertonia Sedation	Foreign Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute			
	Tachycardia					INTRAVENOUS	240 MG,	DAILY, IV

Date:06/02/00ISR Number: 3508089-9Report Type:Expedited (15-DaCompany Report #JACGER2000000686
Age:62 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hypothermia Medication Error	Foreign Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute			
						INTRAVENOUS	IV	

Date:06/02/00ISR Number: 3508091-7Report Type:Expedited (15-DaCompany Report #JACFRA2000000190
Age:78 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agranulocytosis	Foreign Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute	ORAL	MG, DAILY,	
			Haldol Faible (0.5 Mg/Ml Solution) (Haloperidol)	SS		ORAL	DROPS, DAILY,	

ORAL

			Rocephine (Ceftriaxone Sodium)	SS	
SUBCUTANEOUS	G, DAILY,				

SUBCU

			Nitriderm Tts (Glyceryl Trinitrate)	C	
			Vitamines B1-B6 Roche (Vitamins B1-B6 (R))	C	Roche
			Fragmine (Heparin-Fraction, Sodium Salt)	C	

Date:06/02/00ISR Number: 3508093-0Report Type:Expedited (15-DaCompany Report #JACGER2000000755
Age:55 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
	Agitation	Foreign Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute	ORAL
200 MG, PRN,						

ORAL

			L-Thyroxin (Levothyroxine Sodium)	SS	ORAL
1250 MG, PRN,					

ORAL

Date:06/02/00ISR Number: 3508095-4Report Type:Expedited (15-DaCompany Report #JACGER2000000763
Age:52 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
	Dry Mouth Fatigue Hyperhidrosis	Foreign Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute	ORAL
50 MG, 1 IN 1						

	Restlessness					
TIME(S), ORAL						
	Suicide Attempt		Tilidalor (Tilidine)	SS		ORAL
1737.5 MG, 1						
IN 1 TIME(S),						
ORAL						
			Wodka	SS		ORAL
350 ML, 1 IN						
1 TIME(S),						
ORAL						

Date:06/02/00ISR Number: 3508097-8Report Type:Expedited (15-DaCompany Report #JACGER2000000725
Age:34 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
	Sedation Suicide Attempt	Foreign Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute	ORAL
7 MG, 1 IN 1						
TIME(S), ORAL						
			Taxilan (Perazine)	SS		ORAL
300 MG, 1 IN						
1 TIME(S),						
ORAL						
			Atosil (Isopromethazine Hydrochloride)	SS		ORAL
200 MG, 1 IN						
1 TIME(S),						
ORAL						
			Tavor (Lorazepam)	SS		ORAL
200 MG, 1 IN						

1 TIME(S),

ORAL

			Diazepam (Diazepam)	SS		ORAL

20 MG, 1 IN 1

TIME(S), ORAL

Date:06/06/00ISR Number: 3508800-7Report Type:Direct Company Report #
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Life-Threatening	Chills		Haloperidol			
Hospitalization -	Depressed Level Of		Concentrate Mfr.			
Initial or Prolonged	Consciousness		Pharm. Assoc. Inc.	PS	Mfr. Pharm. Assoc.	
Required	Dysphagia				Inc.	
5MG BID						
Intervention to	Extrapyramidal Disorder		Haloperidol Tablets,			
Prevent Permanent	Hyperhidrosis		Mfr: Geneva	SS	Geneva	
1 MG BID						
Impairment/Damage	Leukocytosis		Inh	C		
	Muscle Rigidity		Benztropine	C		
	Neuroleptic Malignant		Enteric Coated			
	Syndrome		Aspirin	C		
	Restlessness		Vistaril	C		
	Tachycardia		Vitamin B6	C		
	Tremor					
	Urinary Incontinence					

Date:06/06/00ISR Number: 3509508-4Report Type:Expedited (15-DaCompany Report #200010806RHF
Age:60 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Blood Bilirubin Increased	Foreign	Lasix	PS	Aventis	
Hospitalization -	Cholestasis	Other			Pharmaceuticals Inc	ORAL
40 MG/DAY PO 8 DAY						
Initial or Prolonged	Confusional State		Haloperidol (Haldol)	SS		ORAL
1 MG/DAY PO 8 DAY						
	Hepatic Steatosis		Ketamine			
	Hepatocellular Damage		Hydrochloride			

	Hyponatraemia		(Ketalar)	SS		ORAL
500 MG/DAY PO 6 DAY						
	Liver Function Test Abnormal		Ceftriaxone Sodium (Rocephine)	SS		
INTRAVENOUS 1 G/DAY IV 12 DAY						
			Omeprazole (Mopral)	SS		ORAL
20 MG/DAY PO 8 DAY						
			Heparin-Fraction, Sodium Salt (Clivarine)	SS		
SUBCUTANEOUS QD SC 8 DAY						
			Morphine	C		

Date:06/06/00ISR Number: 3509515-1Report Type:Expedited (15-DaCompany Report #S00-GER-00732-01
Age:72 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Drug Interaction	Foreign	Citalopram	PS	Forest Laboratories	
20 MG QD PO	Dysphagia	Health			Inc	ORAL
	Mastication Disorder	Professional Other	Cipramil (Citalopram Hydrobromide)	SS		ORAL
40 MG QD PO						
			Cipramil (Citalopram Hydrobromide)	SS		ORAL
20 MG QD PO						
			Haldol (Haloperidol)	SS		ORAL
5 MG QD PO						
			Haldol (Haloperidol)	SS		ORAL
7 MG QD PO						
			Haldol (Haloperidol)	SS		ORAL
3 MG QD PO						

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/07/00ISR Number: 3509629-6Report Type:Expedited (15-DaCompany Report #2000-DE-Y0084
Age:73 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Drug Interaction	Foreign	Flomax	PS	Boehringer Ingelheim			
	Sudden Death	Other			Pharmaceuticals Inc	ORAL	UNK, SEE	
							B.5/PO	5 DAY
			Haloperidol Estave	SS		ORAL	15 ANZ/PO	

Date:06/07/00ISR Number: 3509775-7Report Type:Expedited (15-DaCompany Report #HQ6788402JUN2000
Age:29 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Bronchospasm	Health	Inderal	PS	Wyeth Ayerst			
	Drug Interaction	Professional			Laboratories Inc	ORAL	40 MG 2X PER	
	Dry Mouth						1 DAY, ORAL	
	Headache		Haloperidol	SS		ORAL	ORAL	
	Hypertension		Inderal Tablet	SS		ORAL	20 MG 1X PER	
	Visual Disturbance						1 DAY, ORAL	
			Albuterol	C				
			Diltiazem	C				
			Diphenhydramine	C				
			Doxepin	C				
			Lorazepam	C				
			Potassium Chloride	C				

Date:06/07/00ISR Number: 3509856-8Report Type:Direct Company Report #
Age:18 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dystonia		Haldol	PS			PRIOR TO	

	Muscle Spasms					

ADMISSION

Date:06/08/00ISR Number: 3510641-1Report Type:Expedited (15-DaCompany Report #JAFRA42295
Age:89 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Hypoglycaemia	Foreign	Haldol	PS	Rw Johnson			
Hospitalization - Initial or Prolonged	Hypothermia	Health Professional			Pharmaceutical Research Institute	ORAL		
			Fonxylane (Buflomedil Hydrochloride)	SS		ORAL	3 IN 1	DAY(S), ORAL
			Mopral (Omeprazole)	C				
			Tardyferon (Ferrous Sulfate)	C				
			Ciflox (Ciprofloxacin)	C				
			Bactrim (Bactrim)	C				

Date:06/09/00ISR Number: 3510907-5Report Type:Expedited (15-DaCompany Report #JRFBEL2000001275
Age:17 YR Gender:Female I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Attention Deficit/Hyperactivity Disorder

		Condition Aggravated Confusional State Electroencephalogram	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
		Abnormal Emotional Disorder Excitability	Foreign Health Professional	Risperdal	PS	Janssen Research Fdn Div Johnson And Johnson	ORAL
MG, DAILY,							
		Psychotic Disorder					
ORAL							
				Risperidone (Tablet) (Risperidone)	SS		ORAL
MG, DAILY,							
ORAL							
				Haldol (Unspecified) (Haloperidol)	SS		ORAL
MG, DAILY,							
ORAL							
				Haldol (Tablet) (Haloperidol)	SS		ORAL
MG, DAILY,							
ORAL							
				Levomepromazine Maleate (Levomepromazine Maleate)	SS		ORAL
MG, DAILY,							
ORAL							
				Vegetamin A (Vegetamin A)	SS		ORAL
TABLE, DAILY,							
ORAL							
				Vegetamin B (Vegetamin B (R))	SS		ORAL
TABLET,							
DAILY, ORAL							
				Chlorpromazine Hydrochloride (Chlorpromazine Hydrochloride)	SS		ORAL
MG, DAILY,							

ORAL

			Valproate Sodium (Valproate Sodium)	C		
			Carbamazeepine (Carbamazepine)	C		
			Fluoxetine (Fluoxetine)	C		
			Biperiden Hydrochloride (Biperiden Hydrochoride)	C		
			Flunitrazepam (Flunitrazepam)	C		
			Phenobarbital (Phenobarbital)	C		

Date:06/09/00ISR Number: 3511109-9Report Type:Expedited (15-DaCompany Report #JACFRA2000000227
Age:60 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Death	Blood Bilirubin Increased	Foreign	Haldol	PS	Rw Johnson		
Hospitalization -	Cholestasis	Health			Pharmaceutical		
Initial or Prolonged	Condition Aggravated	Professional			Research Institute		
	Confusional State				Div Ortho Pharm	ORAL	MG, DAILY,
	Hepatic Function Abnormal						ORAL
	Hyponatraemia		Ketalar (Ketamine Hydrochloride)	SS		ORAL	ORAL
			Lasilix (Furosemide)	SS		ORAL	MG, DAILY,

ORAL

				Rocephine (Ceftriaxone Sodium)	SS		
INTRAVENOUS	G, DAILY, IV						
				Mopral (Omeprazole)	SS		ORAL
20 MG, 1 IN 1 DAY(S), ORAL							
				Clivarine (Heparin-Fraction, Sodium Salt)	SS		
SUBCUTANEOUS							
				Morphine (Morphine)	C		

Date:06/12/00ISR Number: 3512150-2Report Type:Expedited (15-DaCompany Report #JRFBEL1999000060
Age:48 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Blood Creatine Phosphokinase Increased Chills Constipation Haematuria Haemorrhage Infection Laryngitis Leukocytosis Nephrolithiasis Neuroleptic Malignant Syndrome Pyrexia	Foreign Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute			
					Div Ortho Pharm	ORAL	MG, DAILY,	ORAL
			Risperidone	SS		ORAL	MG, DAILY,	ORAL
			Levomepromazine Maleate (Levomepromazine Maleate)	SS		ORAL	MG, DAILY,	ORAL
			Halosten	C				
			Biperiden Hydrochloride	C				
			Flunitrazepam	C				

Date:06/13/00ISR Number: 3512579-2Report Type:Expedited (15-DaCompany Report #232584
Age:60 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Blood Bilirubin Increased	Foreign	Rocephin	PS	Hlr Technology	INTRAVENOUS	1 GRAM	DAILY
	Cholestasis	Other				INTRAVENOUS		
	Confusional State		Haldol	SS		ORAL	1 MG	DAILY
	Hepatic Steatosis					ORAL		
	Hepatocellular Damage		Ketalar	SS		ORAL	ORAL	
	Hyponatraemia		Lasilix	SS		ORAL	40 MG	DAILY
	Liver Function Test					ORAL		
	Abnormal		Mopral	SS		ORAL	20 MG	DAILY
						ORAL		
			Clivarine	SS		SUBCUTANEOUS	SUBCUTANEOUS	

Date:06/13/00ISR Number: 3512903-0Report Type:Expedited (15-DaCompany Report #PRIUSA2000006032
Age:33 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardiac Arrest	Health	Haldol	PS	Rw Johnson			
	Sinus Bradycardia	Professional			Pharmaceutical			
					Research Institute	INTRAMUSCULAR	4 MG, 1 TIME	
						(S), IM		
			Biaxin (Clarithromycin)	C				
			Crixivan (Indinavir Sulfate)	C				
			Declomycin					

(Demeclocycline Hydrochloride)	C
Diflucan (Fluconazole)	C
Diltiazem (Diltiazem)	C
Docusate (Docusate)	C
Epivir (Lamivudine)	C
Tussinoex (Tussionex)	C
Humabid (Guaifenesin)	C
Megace (Megestrol Acetate)	C
Pepcid (Famotidine)	C
Promethazine (Promethazine)	C
Sustiva (Efavirenz)	C
Retrovir (Zidovudine)	C
Septra Ds (Bactrim)	C
Effexor Xl (Venlafaxine Hydrochloride)	C
Benadryl (Diphenhydramine Hydrochloride)	C
Cefepime (Cefepime)	C

Date:06/14/00ISR Number: 3516315-5Report Type:Periodic Company Report #JRFUSA1999000190
Age:28 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Aggression Alopecia Anxiety Condition Aggravated	Consumer	Haldol	PS	Rw Johnson Pharmaceutical Research Institute Div Ortho Pharm	ORAL	ORAL	
	Convulsion Coordination Abnormal Dermatitis		Risperdal (Tablet)(Risperidone)	SS		ORAL	SEE IMAGE	
	Dystonia Gastrointestinal Disorder Headache		Zinc (Zinc)	C				

Hepatocellular Damage
Herpes Zoster
Hypersensitivity
Hypertension
Injury
Insomnia
Muscular Weakness
Sedation
Tachycardia
Thinking Abnormal

Date:06/14/00ISR Number: 3516316-7Report Type:Periodic Company Report #JRFUSA1999001216
Age: Gender:Male I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Condition Aggravated
	Dizziness

Malaise

		Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
		Consumer	Haldol	PS	Rw Johnson Pharmaceutical Research Institute Div Ortho Pharm	ORAL
ORAL						
			Risperdal (Tablet)(Risperidone)	SS		ORAL
ORAL						

Date:06/14/00ISR Number: 3516320-9Report Type:Periodic Company Report #JRFUSA1999001309
Age:34 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Life-Threatening	Electrocardiogram Qt Prolonged	Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute	
INTRAVENOUS	5, PRN, IV					
			Propulsid (Unspecified)(Cisapr ide)	SS		ORAL
10 MG, 4 IN 1						
DAY(S), ORAL						

Date:06/14/00ISR Number: 3516323-4Report Type:Periodic Company Report #JRFUSA1999002438
Age:77 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization - Initial or Prolonged	Condition Aggravated	Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute	
INTRAMUSCULAR	PRN, IM					
			Risperdal (2 Mg Tablet) (Risperidone)	SS		ORAL
2 MG, PRN,						

ORAL

Date:06/14/00ISR Number: 3516326-XReport Type:Periodic Company Report #JRFUSA1999002833
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Condition Aggravated	Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute Div Ortho Pharm	ORAL	10 MG, DAILY,	
			Risperdal (1 Mg Tablet) (Risperidone)	SS		ORAL	1 MG, 2 IN 1	DAY(S),

Date:06/14/00ISR Number: 3516330-1Report Type:Periodic Company Report #JRFUSA2000000014
Age:20 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Condition Aggravated	Consumer	Haldol	PS	Rw Johnson Pharmaceutical Research Institute Div Ortho Pharm	ORAL		

ORAL

			Risperdal (Tablet)(Risperidone)	SS		ORAL
SEE IMAGE						
			Cogentin (Benzatropine Mesilate)	C		
			Ativan (Lorazepam)	C		

Date:06/14/00ISR Number: 3516335-0Report Type:Periodic Company Report #JRFUSA2000000064
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Hypotension Neuroleptic Malignant Syndrome	Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute	
Required Intervention to Prevent Permanent Impairment/Damage					Div Ortho Pharm	ORAL
ORAL			Haldol Decanoate (100 Mg/Ml Injection)(Haloperidol Decanoate)	SS		
INTRAMUSCULAR 100 MG, 1 IN 1 MONTH(S), IM						
			Risperdal (Tablet)(Risperidone)	SS		ORAL
2 MG, 1 IN 1 DAY(S), ORAL						
			Klonopin (Clonazepam)	C		
			Depakote (Valproate Semisodium)	C		

Date:06/14/00ISR Number: 3516338-6Report Type:Periodic Company Report #PRIUSA1999000936
Age:15 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Required	Extrapyramidal Disorder	Consumer Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute	INTRAVENOUS	20 MG, 1 Intervention to TIME(S), IV	
Prevent Permanent Impairment/Damage			Ritalin (Methylphenidate Hydrochloride)	C				
			Prozac (Fluoxetine Hydrochloride)	C				
			Valium (Diazepam)	C				
			Promethazine Hydrochloride (Promethazine Hydrochloride)	C				
			Flumazenil (Flumazenil)	C				
			Cefotaxime (Cefotaxime)	C				
			Tobramycin (Ttobramycin)	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/14/00ISR Number: 3516342-8Report Type:Periodic Company Report #PRIUSA1999001063
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Torsade De Pointes	Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute	INTRAVENOUS	IV	

Date:06/14/00ISR Number: 3516355-6Report Type:Periodic Company Report #PRIUSA1999006091
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Neuroleptic Malignant Syndrome	Consumer	Haldol	PS	Rw Johnson Pharmaceutical Research Institute Div Ortho Pharm		0.5 MG, 3	TIME(S)

Date:06/14/00ISR Number: 3516358-1Report Type:Periodic Company Report #PRIUSA1999006275
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Tardive Dyskinesia	Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute Div Ortho Pharm	ORAL	ORAL	
			Levoxyl (Levothyroxine Sodium)	C				
			Lasix (Furosemide)	C				
			Dapsone (Dapsone)	C				
			Lopressor (Metoprolol Tartrate)	C				
			Vistaril (Hydroxyzine					

			Embonate)	C		
			Paxil (Paroxetine Hydrochloride)	C		

Date:06/14/00ISR Number: 3516359-3Report Type:Periodic Company Report #PRIUSA1999008456
Age:57 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Excoriation	Health	Haldol	PS	Rw Johnson	
	Extrapyramidal Disorder	Professional			Pharmaceutical	
	Fall				Research Institute	
	Neuroleptic Malignant				Div Ortho Pharm	
0.5 MG, 1 IN						
	Syndrome					
1 DAY(S)						
			Depakote (Valproate Semisodium)	SS		ORAL
1500 MG, 1 IN						
1 DAY(S),						
ORAL						

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/14/00ISR Number: 3516361-1Report Type:Periodic Company Report #PRIUSA2000000066
Age:69 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Neuroleptic Malignant Syndrome	Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute		1 MG, 1 IN 6	HOUR(S)
			Heparin (Heparin)	C				
			Pepcid (Famotidine)	C				
			Proventil (Salbutamol)	C				
			Cardizem (Diltiazem Hydrochloride)	C				
			Capoten (Captopril)	C				

Date:06/14/00ISR Number: 3516362-3Report Type:Periodic Company Report #PRIUSA2000002494
Age:71 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Condition Aggravated Sedation	Consumer	Haldol	PS	Rw Johnson Pharmaceutical Research Institute	INTRAMUSCULAR	5 MG, 1 IN 1	TIME(S), IM
			Sinement (Sinemet)	C				
			Ativan (Lorazepam)	C				
			Paxil (Paroxetine Hydrochloride)	C				

Date:06/14/00ISR Number: 3516363-5Report Type:Periodic Company Report #PRIUSA2000002510
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Tardive Dyskinesia	Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute			

Div Ortho Pharm

Date:06/14/00ISR Number: 3538069-9Report Type:Periodic Company Report #PRIUSA1999005117
Age: Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Laboratory Test Abnormal	Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute Div Ortho Pharm	ORAL		

SEE IMAGE

Date:06/14/00ISR Number: 3538081-XReport Type:Periodic Company Report #PRIUSA1999005538
Age:41 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Mood Swings Therapeutic Response Unexpected	Consumer	Haldol	PS	Rw Johnson Pharmaceutical Research Institute Div Ortho Pharm	ORAL		

PO

Date:06/14/00ISR Number: 3538084-5Report Type:Periodic Company Report #PRIUSA1999006095
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Urine Abnormality	Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute Div Ortho Pharm			

Date:06/14/00ISR Number: 3538086-9Report Type:Periodic Company Report #PRIUSA1999007265
Age:46 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Pruritus	Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute	INTRAMUSCULAR	IM	

Date:06/14/00ISR Number: 3538088-2Report Type:Periodic Company Report #PRIUSA1999007310
Age:50 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Angioneurotic Oedema	Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute	INTRAMUSCULAR	IM	

Date:06/14/00ISR Number: 3538089-4Report Type:Periodic Company Report #PRIUSA1999003679
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Cellulitis Dermatitis Dysphagia Hyperhidrosis Paraesthesia	Consumer	Haldol	PS	Rw Johnson Pharmaceutical Research Institute Div Ortho Pharm			
			Risperdal (Risperidone)	SS				

				Erythromycin (Erythromycin)	SS		

Date:06/14/00ISR Number: 3538090-0Report Type:Periodic Company Report #PRIUSA1999001240
Age:47 YR Gender:Female I/FU:I

Outcome	Duration	PT	Report Source	Product	Role	Manufacturer	Route
		Attention Deficit/Hyperactivity Disorder	Consumer	Haldol	PS	Rw Johnson Pharmaceutical Research Institute	
		Dystonia				Div Ortho Pharm	ORAL
PO							
		Hypertonia		Haldol (Injection)			
		Hypotonia		(Haloperidol)	SS		
INTRAMUSCULAR	IM						
		Insomnia					
		Oedema Mouth					
		Syncope					

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/14/00ISR Number: 3538091-2Report Type:Periodic Company Report #PRIUSA1999007250
Age:88 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Gait Disturbance	Consumer	Haldol	PS	Rw Johnson Pharmaceutical Research Institute Div Ortho Pharm	ORAL	SEE IMAGE	
	Speech Disorder							
	Urinary Incontinence							
			Synthroid	C				

Date:06/14/00ISR Number: 3538092-4Report Type:Periodic Company Report #PRIUSA1999008053
Age:13 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Flushing	Consumer Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute Div Ortho Pharm	ORAL	SEE IMAGE	
			Zoloft	C				
			Tenex	C				
			Adderall	C				

Date:06/14/00ISR Number: 3538093-6Report Type:Periodic Company Report #PRIUSA1999009651
Age: Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Blood Creatine Phosphokinase Increased	Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute			
	Confusional State							
	Hypertonia							
	Liver Function Test Abnormal							
	Pyrexia							

Date:06/14/00ISR Number: 3538164-4Report Type:Periodic Company Report #PRIUSA1999008442
Age:67 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Hypercalcaemia	Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute			
			Tegretol	C				
			Clonidine	C				
			Thorazine	C				
			Cardizem	C				
			Vasotec	C				
			Imodium	C				
			Pepcid	C				
			Epogen	C				
			Iron	C				
			Insulin	C				
			Atrovent	C				
			Synthroid	C				
			Amphotericin	C				
			Lopressor	C				
			Potassium Chloride	C				
			Cipro	C				
			Maxipime	C				
INTRAVENOUS							2 MG, 1 IN 6	HOUR (S), IV

				Sodium Chloride	C		

Date:06/14/00ISR Number: 3538165-6Report Type:Periodic Company Report #PRIUSA2000001548
Age:20 YR Gender:Male I/FU:I

Outcome	Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
			Apathy	Consumer	Haldol	PS	Rw Johnson Pharmaceutical Research Institute	
			Dry Mouth					
			Eye Disorder					
INTRAMUSCULAR	IM	15 YR						
			Myopathy					
			Skin Discolouration					

Date:06/14/00ISR Number: 3538166-8Report Type:Periodic Company Report #PRIUSA2000001999
Age:47 YR Gender:Male I/FU:I

Outcome	Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
			Bone Pain	Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute	
			Dystonia					
			Toothache					
INTRAVENOUS	75 MG, 1 IN 1 TIME (S), IV							
					Tiazac	C		
					Avapro	C		
					Ativan	C		

Date:06/14/00ISR Number: 3538167-XReport Type:Periodic Company Report #PRIUSA2000003166
Age:47 YR Gender:Female I/FU:I

Outcome	Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
			Constipation	Consumer	Haldol	PS	Rw Johnson Pharmaceutical Research Institute	
			Dry Mouth					
			Fatigue					
			Hypertonia				Div Ortho Pharm	ORAL
	2 MG, ORAL	20 YR						
			Pollakiuria		Prempro	C		
			Pulmonary Congestion					

	Renal Cyst					
	Tardive Dyskinesia					
	Weight Increased					

Date:06/14/00ISR Number: 3538168-1Report Type:Periodic Company Report #PRIUSA2000003285
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Medication Error	Health	Haldol	PS	Rw Johnson			
	Muscle Spasms	Professional			Pharmaceutical			
	Oedema Peripheral				Research Institute			
INTRAMUSCULAR							2 MG, 1 IN 1	
	Sedation							
DAY (S), IM								
			Estrogen	C				

Date:06/14/00ISR Number: 3538169-3Report Type:Periodic Company Report #JRFUSA1999001663
Age:86 YR Gender:Female I/FU:I

Outcome	PT
	Aggression
	Confusional State
	Dry Mouth
	Gait Disturbance

	Sedation						
		Report Source	Product	Role	Manufacturer	Route	Dose Duration
		Consumer	Haldol	PS	Rw Johnson Pharmaceutical Research Institute Div Ortho Pharm	ORAL	SEE IMAGE
			Risperdal (1 Mg Tablet) (Risperidone)	SS		ORAL	SEE IMAGE
			Paxil	C			
			Effexor	C			
			Aricept	C			

Date:06/14/00ISR Number: 3538170-XReport Type:Periodic Company Report #JRFUSA2000001377
Age:26 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Amenorrhoea Fatigue	Consumer	Haldol	PS	Rw Johnson Pharmaceutical Research Institute Div Ortho Pharm	ORAL	ORAL
			Haldol (Injection) (Haloperidol)	SS			INTRAMUSCULAR IM
			Risperdal (Tablet) (Risperidone)	SS		ORAL	5 MG, DAILY, PO

Date:06/14/00ISR Number: 3538171-1Report Type:Periodic Company Report #JRFUSA1999001854
Age:23 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Attention Deficit/Hyperactivity	Health Professional	Haldol	PS	Rw Johnson Pharmaceutical		

	Disorder					Research Institute	
INTRAMUSCULAR IM							
	Malaise		Risperdal (Tablet) (Risperidone)	SS			ORAL
SEE IMAGE							
			Ativan	C			
			Oxycontin	C			

Date:06/14/00ISR Number: 3538172-3Report Type:Periodic Company Report #JRFUSA2000000250
Age:39 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
	Hypotension	Health	Haldol	PS	Rw Johnson	
	Syncope	Professional			Pharmaceutical Research Institute	ORAL
17.5 MG,						
DAILY, ORAL						
			Risperdal (3 Mg Tablet) (Risperidone)	SS		ORAL
3 MG, 2 IN 1						
DAY (S) ,						
ORAL						

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/16/00ISR Number: 3514620-XReport Type:Direct Company Report #
Age:80 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dyspnoea		Duragesic 25 Mcg	PS		TOPICAL	25 MCG	TOP.
	Sedation		Haldol 1 Mg Iv	SS		INTRAVENOUS		
	Tachypnoea		Morphine So4 2 Mg	SS	Iv 2 Mg	INTRAVENOUS		

Date:06/19/00ISR Number: 3515071-4Report Type:Direct Company Report #
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Neuroleptic Malignant Syndrome		Haloperidol Oral Solution Usp Concentrate 2 Mg/Ml	PS		ORAL	ORAL 5MG	TWICE A DAY
			Cogentin	C				
			Aspirin	C				
			Isoniazid	C				

Date:06/20/00ISR Number: 3515912-0Report Type:Direct Company Report #
Age:43 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Face Oedema	Health	Haldol	PS			PILLS 4MG	
Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Jaw Disorder	Professional						
	Loss Of Consciousness							
	Obstructive Airways Disorder							
	Pharyngeal Oedema							
	Tongue Oedema							

Date:06/20/00ISR Number: 3515920-XReport Type:Direct Company Report #
Age:43 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Dyspnoea	Consumer	Haldol 4mg Begun					
	Face Oedema		4/27/2000	PS				
							4MG HALDOL	
	Hypersensitivity							
							PILL FORM	
	Loss Of Consciousness							
	Pain							
	Pharyngeal Oedema							
	Tongue Oedema							
	Trismus							

Date:06/20/00ISR Number: 3516502-6Report Type:Periodic Company Report #
Age:65 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Neuroleptic Malignant Syndrome	Health Professional User Facility	Haloperidol	PS	Pharmaceutical Assoc Inc Div Beach Products		ORAL 5 MG TWICE A DAY	
Required							Intervention to Prevent Permanent Impairment/Damage	
			Cogentin	C				
			Aspirin	C				
			B6	C				
			Isonaizid	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/20/00ISR Number: 3516586-5Report Type:Expedited (15-DaCompany Report #JACGER2000000950
Age:40 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Fatigue Suicide Attempt	Foreign Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute Div Ortho Pharm	ORAL	5 MG, 1 IN 1	TIME (S), ORAL
			Dipiperon (40 Mg Tablet) (Pipamperone)	SS		ORAL	400 MG, 1 IN	1 TIME (S) , ORAL
			Saroten (Amitriptyline Hydrochloride)	SS		ORAL	220 MG, 1 IN	1 TIME (S), ORAL
			Tranxilium (Clorazepate Dipotassium)	SS		ORAL	20 MG, 1 IN 1	TIME (S) , ORAL
			Tramal (Tramadol Hydrochloride)	SS		ORAL	2 TABLE, 1 IN	1 TIME (S), ORAL

Date:06/20/00ISR Number: 3516757-8Report Type:Expedited (15-DaCompany Report #JACGER2000000936
Age:53 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Gait Disturbance	Foreign	Haldol	PS	Rw Johnson Pharmaceutical			
	Suicide Attempt	Health Professional			Research Institute	ORAL	100 MG, 1 IN	1 TIME(S)
						ORAL		
			Alcohol (Ethanol)	SS		ORAL	1 IN 1	TIME(S)

Date:06/21/00ISR Number: 3517091-2Report Type:Expedited (15-DaCompany Report #A019580
Age:67 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Medication Error	Foreign	Atarax	PS	Roerig Div Pfizer			
Hospitalization -	Respiratory Failure	Consumer			Inc	ORAL		
Initial or Prolonged			Haloperidol	SS		ORAL		
Required			Prazepam	SS		ORAL		
Intervention to			Zopiclone	SS		ORAL		
Prevent Permanent Impairment/Damage								

Date:06/21/00ISR Number: 3517314-XReport Type:Expedited (15-DaCompany Report #JRFUSA2000000095
Age:52 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Required	Aggression Akathisia Arthralgia	Consumer	Risperdal	PS	Janssen Research Fdn Div Johnson And Johnson	ORAL	SEE IMAGE	
Intervention to Prevent Permanent Impairment/Damage	Asthenia Bradykinesia Cardiac Arrest		Haloperidol (Haloperidol)	SS		ORAL	2 MG, 4 IN 1	DAY (S), ORAL
	Chest Pain		Ativan (Lorazepam)	SS		ORAL	2 MG, 4 IN 1	DAY (S), ORAL
	Difficulty In Walking Drug Withdrawal Syndrome Memory Impairment Muscle Rigidity Overdose Parkinson'S Disease Peripheral Coldness Pulse Absent Red Blood Cell Count Decreased Restlessness Sleep Disorder Tachycardia Tardive Dyskinesia Tremor Weight Decreased White Blood Cell Count Decreased		Olanzapine (Olanzapine)	C				

Date:06/23/00ISR Number: 3518570-4Report Type:Expedited (15-DaCompany Report #A019617
Age:64 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Aggression Angina Pectoris	Foreign Literature	Procardia Haloperidol	PS SS	Pfizer Inc	ORAL	ORAL INTRAVENOUS	174.00 MG

	Atelectasis	Health			
TOTAL: DAILY:					
	Cardiac Disorder	Professional			
INTRAVENOUS 14 HR					
	Coronary Artery Disease		Enalapril	C	
	Delirium		Sucralfate	C	
	Hypoxia		Furosemide	C	
	Paranoia		Lorazepam	C	
	Post Procedural		Meotclopramide	C	
	Complication		Salbutamol	C	
	Restlessness				
	Torsade De Pointes				
	Ventricular Tachycardia				

Date:06/23/00ISR Number: 3518711-9Report Type:Expedited (15-DaCompany Report #A0061345A
Age:22 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Choking Sensation	Consumer	Lamictal	PS	Glaxo Wellcome Inc	ORAL	100 MG/TWICE
Initial or Prolonged	Convulsion						PER RAY/ORAL
	Drug Ineffective		Haloperidol	SS			
	Loss Of Consciousness		Risperidone	C			
	Neck Pain						
	Pain In Extremity						
	Paralysis						
	Vomiting						

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/23/00ISR Number: 3518756-9Report Type:Expedited (15-DaCompany Report #238490
Age:35 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain Abdominal Pain Upper	Foreign Other	Valium	PS	Hoffmann La Roche Inc	INTRAMUSCULAR	60 MG DAILY;	
	Blood Bilirubin Increased					INTRAMUSCULAR		
	C-Reactive Protein Increased		Mepronizine (Aceprometazine/Meprobamate)	SS		ORAL		
	Hepatitis					ORAL		
	Liver Function Test Abnormal		Nozinan (Methotrimeprazine)	SS		ORAL		
	Pyrexia		Loxapac (Loxapine)	SS		INTRAMUSCULAR	450 MG DAILY	
						INTRAMUSCULAR		
			Haldol (Haloperidol) 5 Mg/Ml	SS		INTRAMUSCULAR	30 MG DAILY	
						INTRAMUSCULAR		

Date:06/27/00ISR Number: 3519537-2Report Type:Direct Company Report #USP 53154
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Medication Error		Haldol	PS	Geneva			
			Prednisone	SS				
			Dexamethasone	SS				

Date:06/27/00ISR Number: 3519953-9Report Type:Direct Company Report #
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Dyspnoea		Haloperidol	PS		INTRAVENOUS	8MG IV Q6	

Hospitalization - Initial or Prolonged	Oxygen Saturation Decreased Tachypnoea Ventricular Tachycardia					

Date:06/27/00ISR Number: 3520402-5Report Type:Expedited (15-DaCompany Report #238419
Age:91 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anaemia Macrocytic Leukopenia	Foreign Other	Bactrim	PS	Hoffmann La Roche Inc	ORAL	3 DOSE FORM	
	Mean Cell Volume Abnormal							
	Neutropenia Pancytopenia Thrombocytopenia		Euphytose (Ballota/Crategus/Kola/Passion Flower/Paullinia/Valerian)	SS		ORAL		
			Haldol (Haloperidol)	SS		ORAL		
			Sinemet (Carbidopa/Levodopa)	SS		ORAL		
			Virlix (Cetirizine Hydrochloride) 10 Mg	SS		ORAL		
			Tirofan (Racecadotril) 100 Mg	SS		ORAL		
			Calcium Carbonate.Colecalciferol (Calcium					

				Carbonate/Cholecalci ferol)	C		

Date:06/27/00ISR Number: 3520937-5Report Type:Expedited (15-DaCompany Report #JACFRA2000000413
Age:35 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain Upper Hepatitis Liver Function Test	Foreign Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute	INTRAMUSCULAR	MG, DAILY, IM	
	Abnormal Pyrexia		Mepronizine	SS		ORAL	400 MG,	TOTAL, ORAL
			Nozinan	SS		ORAL	150 MG,	TOTAL, ORAL
			Valium	SS		INTRAMUSCULAR	MG, DAILY, IM	
			Loxapac	SS		INTRAMUSCULAR	MG, DAILY, IM	

Date:06/27/00ISR Number: 3520940-5Report Type:Expedited (15-DaCompany Report #PRIUSA2000002538
Age:44 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death Hospitalization - Initial or Prolonged	Cardiac Arrest Electrolyte Depletion Tardive Dyskinesia	Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute	INTRAVENOUS	10 MG, 1 TIME	(S), IV
			Thorazine	C				
			Depakote	C				
			Cogentin	C				
			Zyprexa	C				
			Klonopin	C				

Date:06/29/00ISR Number: 3522249-2Report Type:Expedited (15-DaCompany Report #00P-083-0091170-00 (0)
Age:85 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agranulocytosis Asthenia Pyrexia	Foreign Health Professional	Depakene	PS	Abbott Laboratories Pharmaceutical Products Div	ORAL	700 MG, 1 IN 1 D, PER ORAL	
			Haloperidol (Haloperidol)	SS		ORAL	20 DROP, 1 IN 1 D, PER ORAL	
			Promazine Hydrochloride (Promazine Hydrochloride)	SS		ORAL	120 DROP, 1 IN 1 D, PER ORAL	

Date:06/30/00ISR Number: 3522973-1Report Type:Expedited (15-DaCompany Report #JACGER2000000597
Age:73 YR Gender:Female I/FU:F

Outcome
Death
Life-Threatening
Hospitalization -
Initial or Prolonged
Required

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Intervention to Prevent Permanent Impairment/Damage	Atrioventricular Block Complete Bundle Branch Block Left Cardiac Failure	Foreign Health Professional	Risperdal	PS	Janssen Research Fdn Div Johnson And Johnson	ORAL	1.5 MG, 2 IN 1 DAY(S), ORAL;1 MG, 2 IN 1 DAY, ORAL	
			Haldol (Haloperidol)	SS			MG ,DAILY	
			Remergil (Mirtazapine)	C				
			Movergan (Selegiline Hydrochoride)	C				
			Madopar (Madopar	C				

Date:07/03/00ISR Number: 3524436-6Report Type:Expedited (15-DaCompany Report #PRIUSA2000006683
Age:32 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Literature Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute Div Ortho Pharm	ORAL	ORAL	
			Amitriptyline (Amitriptyline)	SS		ORAL	ORAL	
			Bupropion (Amfebutamone)	SS		ORAL	ORAL	

Date:07/03/00ISR Number: 3524439-1Report Type:Expedited (15-DaCompany Report #PRIUSA2000006684
Age:41 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Literature Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute Div Ortho Pharm	ORAL	ORAL	
			Benztropine (Benztropine)	SS		ORAL	ORAL	

Date:07/03/00ISR Number: 3524442-1Report Type:Expedited (15-DaCompany Report #PRIUSA2000006685
Age:40 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Literature Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute Div Ortho Pharm	ORAL	ORAL	
			Phenobarbital (Phenobarbital)	SS		ORAL	ORAL	
			Valproic Acid (Valproic Acid)	SS		ORAL	ORAL	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/03/00ISR Number: 3524835-2Report Type:Expedited (15-DaCompany Report #B0083342A
Age:60 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Agranulocytosis	Foreign	Lamictal	PS	Glaxo Wellcome Inc	ORAL		
Hospitalization - Initial or Prolonged	Bone Marrow Depression Leukopenia Pancytopenia Pyrexia Sepsis		Tamoxifen (Formulation Unknown) (Tamoxifen) Haloperidol (Formulation Unknown) Haloperidol	SS SS				

Date:07/05/00ISR Number: 3524294-XReport Type:Expedited (15-DaCompany Report #239349
Age:51 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Aggression Agitation	Foreign Study	Valium	PS	Hoffmann La Roche Inc		15 MG DAILY	
	Aspiration	Health Professional	Haldol (Haloperidol)	SS			20 MG DAILY	
	Blood Creatine Phosphokinase Increased C-Reactive Protein Increased Coma Cyanosis Dyspnoea Grand Mal Convulsion Loss Of Consciousness Obstructive Airways Disorder Respiratory Failure Sensory Disturbance Urinary Incontinence		Neurocil (Methotrimeprazine) Timonil 300 Retard (Carbamazepine) Akineton Retard (Biperiden Hydrochloride) Tavor (Lorazepam) Mono Embolex (Certoparin Sodium)	SS C C C				

Date:07/06/00ISR Number: 3525538-0Report Type:Expedited (15-DaCompany Report #JACGER2000001026
Age:44 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Hospitalization - Initial or Prolonged Required	Alcohol Withdrawal Syndrome Cardiac Failure	Foreign Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute	ORAL	5 MG, 3 IN 1 DAY(S), ORAL	
Intervention to Prevent Permanent Impairment/Damage			Lyogen (Fluphenazine Neurocil (Levomepromazine Maleate) Tavor Laubeel Nifedipin Haemiton (Clonidine)	SS SS C C C C		ORAL ORAL	MG, DIALY,ORAL MG, DAILY, ORAL	

Date:07/06/00ISR Number: 3525540-9Report Type:Expedited (15-DaCompany Report #PRIUSA2000006638
Age:40 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Potassium Decreased Blood Sodium Decreased	Health Professional	Haldol	PS	Rw Johnson Pharmaceutical			

						Research Institute	
40 MG, 1 IN 3 WEEK (S), IM							
			Cozaar (Losartan Potassium)	C			

Date:07/06/00ISR Number: 3525543-4Report Type:Expedited (15-DaCompany Report #JACGER2000001008
Age:49 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Ventricular Fibrillation	Foreign Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute	
INTRAVENOUS 48 MG 1 IN 1 TIME(S), IV INF						
			Catapresan (Clonidine)	SS		
INTRAVENOUS 0.5 MG, 1 IN 1 TIME (S), IV INF						
			Somsanit (Oxybate Sodium)	C		

Date:07/06/00ISR Number: 3525622-1Report Type:Expedited (15-DaCompany Report #JACFRA2000000409
Age:91 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Anaemia Macrocytic Pancytopenia	Foreign Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute Div Ortho Pharm	ORAL
ORAL						
			Euphytose (Euphytose)	SS		ORAL
ORAL						

			Sinemet (Sinemet)	SS		ORAL
ORAL						
			Virlix (Cetirizine Hydrochloride)	SS		ORAL
ORAL						
			Bactrim Forte (Bactrim)	SS		ORAL
ORAL						
			Tiorfan (Acetorphan)	SS		ORAL
ORAL						
			Cacit D3 (Cacit D3)	C		

Date:07/06/00ISR Number: 3525632-4Report Type:Expedited (15-DaCompany Report #JACFRA2000000440
Age:66 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Anaemia Biopsy Bone Marrow Abnormal Bone Marrow Depression	Foreign Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute Div Ortho Pharm	ORAL
MG DAILY ORAL						
	Leukopenia Pancytopenia		Lansoyl (Paraffin, Liquid)	SS		ORAL
ORAL						
	Pyrexia		Noctran (Noctran)	SS		ORAL
MG DAILY ORAL						
	Thrombocytopenia		Tercian (Cyamemazine)	SS		ORAL
MG DAILY ORAL						
			Theralene (Alimemazine Tartrate)	SS		ORAL
ORAL						
			Deroxat (Paroxetine Hydrochloride)	SS		ORAL
20 MG 1 IN 1						
DAY (S) ORAL						
			Insuline Mixtard			

(Initard)	C
Valium (Diazepam)	C
Insulatard (Insulin Human Injection, Isophane)	C
Insuline Actrapid (Insulin)	C
Forlax (Macrogol)	C

Date:07/06/00ISR Number: 3525676-2Report Type:Expedited (15-DaCompany Report #JRFUSA2000000095
Age:52 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Aggression Akathisia Arthralgia Asthenia Bradykinesia Cardiac Arrest Chest Pain Difficulty In Walking Drug Withdrawal Syndrome Feeling Cold Headache Memory Impairment Muscle Rigidity Nausea Overdose Parkinson'S Disease Red Blood Cell Count Decreased Restlessness Sleep Disorder		Haldol Risperdal (Tablet) (Risperidone) Risperdal (Tablet) (Risperidone) Risperdal (Tablet) (Risperidone) Risperdal (Tablet) (Risperidone)	PS SS SS SS SS	Rw Johnson Pharmaceutical Research Institute Div Ortho Pharm	ORAL ORAL ORAL ORAL ORAL	2 MG 4 IN 1 DAY(S) 3 MG 2 IN 1 DAY(S) 7 MG DAILY 6 MG DAILY 7.5 MG DAILY 8.5 MG DAILY	ORAL ORAL ORAL ORAL ORAL ORAL ORAL ORAL

	Tachycardia		Ativan (Lorazepam)	SS		ORAL 2 MG 4 IN 1
	Tardive Dyskinesia					DAY (S) ORAL
	Tremor Weight Decreased White Blood Cell Count Increased		Olanzapine (Olanzapine)	C		

Date:07/06/00ISR Number: 3525706-8Report Type:Expedited (15-DaCompany Report #JACFRA2000000394
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Agitation Neonatal Anxiety Benign Congenital Hypotonia	Foreign	Haldol	PS	Rw Johnson Pharmaceutical Research Institute Div Ortho Pharm		MG, DAILY,	
	Complications Of Maternal Exposure To Therapeutic Drugs Crying Delusion Feeding Problem In Newborn Hypertonia Neonatal Disorder Small For Dates Baby						UTERINE	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/07/00ISR Number: 3526596-XReport Type:Expedited (15-DaCompany Report #JACGER2000000597
Age:73 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Atrioventricular Block	Foreign	Haldol	PS	Rw Johnson			
Life-Threatening	Complete	Health			Pharmaceutical			
Hospitalization -	Bundle Branch Block Left	Professional			Research Institute			
Initial or Prolonged	Cardiac Failure				Div Ortho Pharm			
DAILY								
Required	Electrocardiogram		Risperdal (1 Mg/Ml					
Intervention to	Abnormal		Solution)					
Prevent Permanent			(Risperidone)	SS		ORAL	1.5 MG, 2 IN	
Impairment/Damage							1 DAY (S),	
							ORAL; 1 MG, 2	
							IN 1 DAY (S),	
							ORAL	
			Remergil	C				
			Movergan	C				
			Madopar	C				

Date:07/10/00ISR Number: 3526842-2Report Type:Expedited (15-DaCompany Report #A021140
Age:79 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Cerebral Infarction	Foreign	Zoloft	PS	Pfizer			
Initial or Prolonged	Confusional State	Health			Pharmaceuticals Inc	ORAL	50 MG	
		Professional						
TOTAL:DAILY:O								
		Other						
RAL								
			Clorazepate					
			Dipotassium	SS		ORAL	5.00 MG	
TOTAL:DAILY:O								
RAL								

			Rofecoxib	SS		ORAL

12.00 MG

TOTAL:DAILY:O

RAL

			Haloperidol	SS		

Date:07/11/00ISR Number: 3527186-5Report Type:Direct Company Report #
Age:17 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Dystonia		Haldol	PS		

SEE MEDICAL

RECORD

Date:07/11/00ISR Number: 3527187-7Report Type:Direct Company Report #
Age:47 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Life-Threatening	Chest Discomfort		Haldol (Halperidol)	PS		
	Suicidal Ideation					

Date:07/11/00ISR Number: 3527734-5Report Type:Expedited (15-DaCompany Report #JACGER2000001030
Age:28 YR Gender:Male I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Blood Creatine Phosphokinase Increased
	Gait Disturbance
	Hyperhidrosis

		Muscle Rigidity Parkinsonism Sinus Tachycardia	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
		Tremor	Foreign Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute Div Ortho Pharm	ORAL
MG, DAILY,							
ORAL							
				Leponex (Clozapine)	SS		ORAL
MG, DAILY,							
ORAL							
				Fluanxol (Flupentixol Dihydrochloride)	SS		ORAL
MG, DAILY,							
ORAL							
				Tavor (Lorazepam)	C		
				Akineton (Biperiden Hydrochloride)	C		
				Zyprexa (Olanzapine)	C		

Date:07/11/00ISR Number: 3527737-0Report Type:Expedited (15-DaCompany Report #JRFBEL2000001665
Age:6 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization - Initial or Prolonged	Blood Creatine Phosphokinase Increased Chromaturia Myoglobinuria	Foreign Literature Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute Div Ortho Pharm	ORAL
MG, DAILY,						
	Rhabdomyolysis					
ORAL	0.8					
MG, 2 IN 1						
DAY (S), ORAL						
			Clonazepam (Clonazepam)	C		
			Diazepam (Diazepam)	C		

			Phenobarbital (Phenobarbital)	C		
			Biperiden (Biperiden)	C		

Date:07/11/00ISR Number: 3527766-7Report Type:Expedited (15-DaCompany Report #JACGER2000001027
Age:52 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Life-Threatening Required Intervention to Prevent Permanent Impairment/Damage	Aspiration Loss Of Consciousness Respiratory Failure	Foreign Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute Div Ortho Pharm	ORAL	MG, DAILY, ORAL
			Valium (Diazepam)	SS		ORAL	DAILY, ORAL
			Timonil Retard (Carbamazepine)	C			
			Akineton Retard (Biperiden Hydrochloride)	C			
			Tavor (Lorazepam)	C			
			Mono-Embolex (Heparin-Fraction, Sodium Salt)	C			
			Neurocil (Levomepromazine				

			Maleate)	C			ORAL
MG, DAILY,							
ORAL							

Date:07/13/00ISR Number: 3529403-4Report Type:Expedited (15-DaCompany Report #JRFBEL2000001711
Age:44 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Chills Dysarthria Dyskinesia Dysphagia	Foreign Literature Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute Div Ortho Pharm	ORAL	600 MG, 1 IN	1 TIME(S),
	Extrapyramidal Disorder Oculogyration Sedation Suicide Attempt Torticollis					ORAL		

Date:07/13/00ISR Number: 3529576-3Report Type:Direct Company Report #
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dermatitis		Haloperidol	PS		ORAL	1MG, 0.5MG	
	Pruritus					BID, ORAL		
			Sulfamethoxazole/Trimethoprim Ds	C				

Date:07/18/00ISR Number: 3531359-5Report Type:Expedited (15-DaCompany Report #JAKYO41864
Age:59 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Depressed Level Of Consciousness	Foreign Health	Haldol	PS	Rw Johnson Pharmaceutical			

	Extrapyramidal Disorder Nervous System Disorder	Professional			Research Institute Div Ortho Pharm	ORAL	MG, DAILY,
	Tardive Dyskinesia					ORAL	
			Risperidone (Tablet) (Risperidone)	SS		ORAL	MG, DAILY,
						ORAL	
			Thioridazine Hydrochloride (Thioridazine)	SS		ORAL	MG, DAILY,
						ORAL	
			Fluphenazine (Fluphenazine)	SS			
INTRAMUSCULAR	25 MG, 1 IN 4						
WEEK(S), IM							
			Haloperidol Decanoate (Injection) (Haloperidol Decanoate)	SS			
			Biperiden Hydrochloride (Biperiden Hydrochloride)	C			
			Brotizolam (Tablet) (Brotizolam)	C			
			Promethazine Hydrochloride (Promethazine)	C			

			Clonazepam (Clonazepam)	C		

Date:07/21/00ISR Number: 3534014-0Report Type:Expedited (15-DaCompany Report #240198
Age:29 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Aggression Anxiety	Foreign Literature	Valium	PS	Hoffmann La Roche Inc	
40 MG DAILY 9 DAY						
Required Intervention to	Blood Creatine Phosphokinase Increased	Health Professional	Clopixol (Zuclopenthixol)	SS		
INTRAMUSCULAR INTRAMUSCULAR 2 DAY						
Prevent Permanent Impairment/Damage	Confusional State Depressed Level Of		Haloperidol (Haloperidol)	SS		
30 MG DAILY 12 DAY						
	Consciousness Disorientation Disturbance In Attention Dysphagia Electrocardiogram Abnormal Excitability Hallucination, Auditory Hyperhidrosis Hyperpyrexia Leukocytosis Muscle Rigidity Mutism Neuroleptic Malignant Syndrome Oral Intake Reduced Psychotic Disorder Social Avoidant Behaviour Staring Tachycardia Tremor Waxy Flexibility					

Date:07/21/00ISR Number: 3534719-1Report Type:Expedited (15-DaCompany Report #A025123
Age:68 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hypertension Respiratory Disorder Shock	Foreign Consumer	Norvasc	PS	Pfizer Agricultural Div	ORAL	10.00 MG TOTAL; DAILY;	
			Haloperidol	SS		ORAL		

Date:07/24/00ISR Number: 3533634-7Report Type:Direct Company Report #
Age:71 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Face Oedema		Zyprexa 10mg Lilly	PS	Lilly	ORAL	10MG PO HS	
	Pneumonia		Haloperidol 5mg	SS		ORAL	5MG HS PO	
			Albuterol	C				
			Folic Acid	C				
			Multivilamin	C				
			Benztropine	C				
			Gabapentin	C				
			Thiamine	C				

			Vit E	C		
			Ipratropium	C		
			Gabapentin	C		
			Benztropine	C		
			Docusate	C		

Date:07/25/00ISR Number: 3534575-1Report Type:Direct Company Report #
Age:66 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Muscle Spasms Syncope		Haldol-	PS				

Date:07/27/00ISR Number: 3536538-9Report Type:Expedited (15-DaCompany Report #PHBS2000FR02247
Age:77 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death Life-Threatening Hospitalization - Initial or Prolonged	Antinuclear Antibody Positive Mouth Haemorrhage Purpura Rash Maculo-Papular Rash Morbilliform Skin Lesion Stevens-Johnson Syndrome Thrombocytopenia Toxic Epidermal Necrolysis	Foreign Health Professional Other	Exelon Haldol (Haloperidol)(Haloperidol) Zyloric (Allopurinol) (Allopurinol) Tablet Nimotop(Nimodipine) Tablet Solupred (Prednisolone Sodium Sulfobenzoate)(Prednisolone Sodium	PS SS SS SS	Novartis Pharmaceuticals Corp	ORAL ORAL ORAL ORAL	1.5 MG, QD, 10 MG, QD, 30 MG, BID,	ORAL ORAL ORAL ORAL

			Sulfobenzoate)	SS		ORAL
20 MG, QD,						
ORAL						
			Cortancyl (Prednisone) Tablet	C		

Date:07/28/00ISR Number: 3537669-XReport Type:Expedited (15-DaCompany Report #JACFRA2000000503
Age:90 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Fall Malaise	Foreign Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute Div Ortho Pharm	ORAL
MG, DAILY,						
ORAL						

Date:07/28/00ISR Number: 3537794-3Report Type:Expedited (15-DaCompany Report #FLUV00300005064
Age:67 YR Gender:Female I/FU:F

Outcome	PT
Other	Hyperhidrosis Laboratory Test Abnormal Muscle Rigidity Neuroleptic Malignant

		Syndrome Pyrexia					
			Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
			Foreign Health	Luvox	PS	Solvay Pharmaceuticals	ORAL
150 MG DAILY							
PO			Professional				
			Other	Serenace (Haloperidol)	SS		ORAL
2 MG DAILY PO							
				Risperdal (Risperidone)	SS		ORAL
1 MG DAILY PO							

Date:07/31/00ISR Number: 3539084-1Report Type:Expedited (15-DaCompany Report #2000-07-0838
Age:52 YR Gender:Male I/FU:I

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Other		Condition Aggravated Delusion	Consumer Other	Trilafon	PS	Schering Corp Sub Schering Plough Corp	ORAL
4 MG DAILY							
ORAL							
				Haldol Tablets	SS		ORAL
2 MG DAILY							
ORAL							
				Antihypertensive Agent (Nos)	C		

Date:08/01/00ISR Number: 3539936-2Report Type:Periodic Company Report #990615.01
Age:37 YR Gender:Male I/FU:I

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Other		Drug Ineffective Extrapyramidal Disorder	Consumer	Haloperidol	PS	Mylan Pharmaceuticals Inc	ORAL
10 MG Q HS,							
ORAL		Fatigue					

	Therapeutic Response		Tegretol	C		
	Unexpected		Vitamin E & C	C		
			Multivitamins	C		

Date:08/01/00ISR Number: 3539938-6Report Type:Periodic Company Report #C2000-0418.01
Age:57 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Sedation	Consumer	Haloperidol	PS	Mylan	
	Tremor				Pharmaceuticals Inc	ORAL
10MG BID,						
ORAL						
			Depakote	C		
			Dilantin	C		
			Paxil	C		
			Lithium	C		

Date:08/01/00ISR Number: 3539940-4Report Type:Periodic Company Report #C2000-0631.01
Age:37 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Trismus	Consumer	Haloperidol	PS	Mylan	
		Health			Pharmaceuticals Inc	
5 MG Q HS						
		Professional	Sonata Wyeth Ayerst	SS	Wyeth Ayerst	
			Paxil	C		
			Prilosec	C		
			Phenegran	C		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/01/00ISR Number: 3539943-XReport Type:Periodic Company Report #97145.01
Age:76 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Amblyopia	Consumer	Haloperidol	PS	Mylan Pharmaceuticals Inc	ORAL	7 - 10 MG QD	
	Constipation							
	Difficulty In Walking							
	Dry Mouth		Cogentin	C				
	Dysphagia		Phenergan	C				
	Extrapyramidal Disorder		Tylenol	C				
	Insomnia		Vitamins	C				
	Lethargy							
	Muscle Rigidity							
	Speech Disorder							
	Tardive Dyskinesia							

Date:08/01/00ISR Number: 3539945-3Report Type:Periodic Company Report #C2000-0227.01
Age:51 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Fatigue	Health Professional	Haloperidol	PS	Mylan Pharmaceuticals Inc	ORAL	2MG Q HS PRN,	
	Muscle Spasms							
			Climara Transdermal System	C				

Date:08/03/00ISR Number: 3541462-1Report Type:Expedited (15-DaCompany Report #JRFBEL2000001596
Age:39 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Foreign	Haldol	PS	Rw Johnson Pharmaceutical Research Institute Div Ortho Pharm	ORAL		
Hospitalization - Initial or Prolonged	Delusion	Health Professional						
	Dystonia							
	Hallucination, Auditory							
	Malaise		Risperidone (Tablet)					

	Pain	(Risperidone)	SS	ORAL MG, DAILY,
	Schizophrenia			ORAL
	Speech Disorder	Zotepine (Zotepine)	SS	ORAL MG, DAILY,
	Suicidal Ideation			ORAL
	Tongue Disorder	Tiapride Hydrochloride (Tiapride Hydrochloride)	C	
		Levomepromazine Maleate (Levomepromazine Maleate)	C	
		Lorazepam (Lorazepam)	C	
		Biperiden Hydrochloride (Biperiden Hydrochloride)	C	
		Tocopherol Acetate (Tocopherol)	C	
		Flunitrazepam (Flunitrazepam)	C	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/03/00ISR Number: 3541463-3Report Type:Expedited (15-DaCompany Report #JAUK37989
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Akathisia Depression Hallucination, Auditory	Foreign Consumer Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute	INTRAMUSCULAR	100 MG, 1 IN	1 WEEKS(S), IM
			Carbamazepine (Carbamazepine)	C				
			Olanzapine (Olanzapine)	C				
			Procyclidine (Procyclidine)	C				

Date:08/07/00ISR Number: 3544759-4Report Type:Expedited (15-DaCompany Report #JRFUSA2000000095
Age:52 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Aggression Akathisia Amnesia Angina Pectoris Arthralgia Asthenia Bradykinesia Cardiac Arrest Chest Pain Difficulty In Walking Drug Withdrawal Syndrome Dyskinesia Feeling Cold	Health Professional	Risperdal	PS	Janssen Research Fdn Div Johnson And Johnson	ORAL	3 MG, 2 IN 1	DAY (S), ORAL
			Haldol (Tablet) (Haloperidol)	SS		ORAL	2 MG, 4 IN 1	DAY (S), ORAL
			Ativan (Lorazepam)	SS		ORAL	2 MG, 4 IN 1	DAY (S), ORAL
			Olanzapine	C				
			Seroquel	C				

(SEE IMAGE)

Headache
Heart Rate Increased
Joint Stiffness
Malaise
Overdose
Parkinsonism
Psychotic Disorder
Pulse Absent
Restlessness
Sleep Disorder
Tachycardia
Tardive Dyskinesia
Tremor
Weight Decreased

Date:08/09/00ISR Number: 3546750-0Report Type:Expedited (15-DaCompany Report #JRFBEL2000001908
Age:39 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Myocardial Infarction	Foreign Literature Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute Div Ortho Pharm			
			Benztropine (Benztropine)	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/10/00ISR Number: 3547876-8Report Type:Expedited (15-DaCompany Report #JRFUSA2000000095
Age:52 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Aggression Akathisia Arthralgia Asthenia Bradykinesia Cardiac Arrest Cardio-Respiratory Arrest Chest Pain Difficulty In Walking Drug Effect Decreased Drug Withdrawal Syndrome Headache Heart Rate Increased Leukopenia Malaise Memory Impairment Muscle Rigidity Overdose Parkinsonism Peripheral Coldness Pulse Absent Red Blood Cell Count Decreased Restlessness Sleep Disorder	Health Professional	Haldol Risperdal (Tablet) (Risperidone) Ativan (Lorazepam) Risperdal (Tablet) (Risperidone) Risperdal (Tablet) (Risperidone) Risperdal (Tablet) (Risperdone) Risperdal (Tablet) (Risperidone) Risperdal (Tablet) (Risperidone)	PS SS SS SS SS SS SS SS	Rw Johnson Pharmaceutical Research Institute Div Ortho Pharm	ORAL ORAL ORAL ORAL ORAL ORAL ORAL	2 MG, 4 IN 1 3 MG, 2 IN 1 2 MG, 4 IN 1 7 MG, DAILY, 7.5 MG, 1.5 MG, 4 IN 8.5 MG, 6 MG, DAILY,	DAY(S), ORAL DAY(S), ORAL DAY(S), ORAL ORAL DAILY, ORAL 1 DAY(S), ORAL DAILY, ORAL

	Tachycardia					
ORAL						
	Tardive Dyskinesia		Olanzapine			
	Tremor		(Olanzapine)	C		
	Weight Decreased		Seroquel (Seroquel)	C		
	White Blood Cell Count Decreased					

Date:08/14/00ISR Number: 3550467-6Report Type:Expedited (15-DaCompany Report #00J--10323
Age:28 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Anxiety	Foreign	Ludiomil	PS	Novartis		
	Depressed Level Of Consciousness	Health Professional			Pharmaceuticals Corp	ORAL	75 MG, DAILY
Other							
ORAL							
	Dermatitis	Other	Rohypnol Unknown	SS		ORAL	2 MG , DAILY
	Neuroleptic Malignant Syndrome						
ORAL							
			Linton	SS		ORAL	6 G,DAILY,
	Oculomucocutaneous Syndrome						
ORAL							
	Pyrexia		Amitriptyline Hydrochloride	SS		ORAL	150 MG , DAILY, ORAL
	Urinary Retention						
			Hirnamin	SS		ORAL	15 G, DAILY, ORAL
			Depas	SS		ORAL	3 MG , DAILY, ORAL
			Tasmolin	SS		ORAL	.3 G, DAILY, ORAL

Date:08/14/00ISR Number: 3550498-6Report Type:Expedited (15-DaCompany Report #PHBS2000FR02247
Age:77 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Death	Anaemia	Foreign	Exelon	PS	Novartis		
Life-Threatening	Antinuclear Antibody	Health			Pharmaceuticals Corp	ORAL	1.5 MG, QD,
Hospitalization -	Positive	Professional					ORAL
Initial or Prolonged	Bacillus Infection	Other	Haldol (Haloperidol)				
	Epistaxis		(Haloperidol)	SS		ORAL	10 MG, QD,
	Mouth Haemorrhage						ORAL
	Mucosal Haemorrhage		Zyloric				
	Purpura		(Allopurinol)				
	Pyrexia		(Allopurinol)	SS		ORAL	ORAL
	Rash Generalised		Solupred				
	Rash Maculo-Papular		(Prednisolone Sodium				
	Rash Morbilliform		Sulfobenzoate)				
	Respiratory Distress		(Prednisolone Sodium				
	Sepsis		Sulfobenzoate)	SS		ORAL	20 MG, QD,
	Skin Lesion						ORAL
	Skin Necrosis		Renitec (Enalapril				
	Stevens-Johnson Syndrome		Maleate) Tablet	SS		ORAL	ORAL
	Thrombocytopenia		Cortancyl				
	Toxic Epidermal		(Prednisone)				
	Necrolysis		(Prednisone)	SS		ORAL	5 MG, QD,
							ORAL
			Nimotop (Nimodipine)				
			Tablet	SS		ORAL	30 MG, BID,
							ORAL

Date:08/14/00ISR Number: 3550656-0Report Type:Expedited (15-DaCompany Report #A025123
Age:68 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Back Pain Blood Pressure Increased Condition Aggravated Depression Osteoporosis Respiratory Disorder Shock	Foreign Consumer	Norvasc Haloperidol	PS SS	Pfizer Agricultural Div	ORAL ORAL	10.00 MG TOTAL;DAILY;O RAL	

Date:08/15/00ISR Number: 3551034-0Report Type:Expedited (15-DaCompany Report #JACFRA2000000525
Age:76 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death Hospitalization - Initial or Prolonged	Bacillus Infection Dermatitis Bullous Epistaxis Haemorrhage Lip Disorder Pruritus Purpura Pyrexia Rash Maculo-Papular Sepsis Skin Necrosis Thrombocytopenia	Foreign Health Professional	Haldol Cortancyl (Prednisone) Solupred (Prednisolone Sodium Sulfobenzoate) Renitec (Enalapril Maleate) Allopurinol (Allopurinol)	PS SS SS SS SS	Rw Johnson Pharmaceutical Research Institute Div Ortho Pharm	ORAL ORAL ORAL ORAL ORAL ORAL ORAL ORAL	300 MG,1 IN 1 DAY(S), 1 IN 2 DAY(S),ORAL	

			Exelon (Rivastigmine)	SS		ORAL
ORAL						
			Aldactone (Spironolactone)	C		
			Mopral (Omeprazole)	C		
			Miorel (Thiocolchicoside)	C		
			Nimotop (Nimodipine)	C		
			Ikorel (Nicorandil)	C		

Date:08/15/00ISR Number: 3551201-6Report Type:Expedited (15-DaCompany Report #FLUV00300005228
Age:78 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Life-Threatening	Condition Aggravated	Foreign	Luvox	PS	Solvay	
Hospitalization -	Decreased Activity	Health			Pharmaceuticals	ORAL
50 MG DAILY						
Initial or Prolonged	Drug Interaction	Professional				
PO, 100 MG						
	Muscle Rigidity	Other				
DAILY PO, 150						
	Neuroleptic Malignant					
MG DAILY PO						
	Syndrome		Nauzelin			
	Pyrexia		(Domperidone)	SS		ORAL
3 DF DAILY PO						
	Tremor		Gramalil (Tiapride Hydrochloride)	SS		ORAL
3 DF DAILY PO						
			Symmetrel (Amantadine Hydrochloride)	SS		ORAL
2 DF DAILY PO						
			Artane (Trihexyphenidyl Hydrochloride)	SS		ORAL
2 DF DAILY PO						
			Serenace (Haloperidol)	SS		ORAL
0.75 MG DAILY						
PO						
			Merislon			

			(Betahistine Hydrochloride)	C		
			Aponol (Ifenprodil Tartrate)	C		

Date:08/17/00ISR Number: 3551881-5Report Type:Expedited (15-DaCompany Report #C2000-1034.01
Age:85 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Agitation Confusional State	Consumer	Haloperidol	PS	Mylan Pharmaceuticals Inc	
1 DAY						
Other	Delusion Intestinal Obstruction					

Date:08/17/00ISR Number: 3552053-0Report Type:Direct Company Report #
Age:72 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Life-Threatening	Agitation Arrhythmia Hypotension Supraventricular Tachycardia Torsade De Pointes Ventricular Tachycardia		Haloperidol	PS		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/17/00ISR Number: 3552263-2Report Type:Direct Company Report #
Age:46 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Electrocardiogram Abnormal	Health Professional	Haldol	PS		INTRAVENOUS	IV PRN; TOTAL DOSE 97.5 MG	
	Electrocardiogram Qt Prolonged Torsade De Pointes		Respiridone	SS			4 MG QD	

Date:08/18/00ISR Number: 3553878-8Report Type:Expedited (15-DaCompany Report #JACGER2000001319
Age:63 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Bilirubin Increased Hepatic Enzyme Increased Hepatitis	Foreign Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute	INTRAMUSCULAR	1 IN 3 WEEK(S) IM	

Date:08/18/00ISR Number: 3555119-4Report Type:Periodic Company Report #HQ4910208NOV1999
Age:39 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Confusional State Psychomotor Hyperactivity	Consumer	Ativan	PS	Wyeth Ayerst Laboratories Inc	INTRAMUSCULAR	2 MG,	
	Psychotic Disorder					INTRAMUSCULAR		
			Haldol	SS			5 MG	

Date:08/21/00ISR Number: 3554566-4Report Type:Expedited (15-DaCompany Report #JACGER2000001312
Age:82 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Haemorrhagic Stroke	Foreign Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute Div Ortho Pharm	ORAL		
			Amantadin (Amantadine Hydrochloride)	SS		ORAL		
			Nootrop (Piracetam)	SS				

Date:08/21/00ISR Number: 3554932-7Report Type:Expedited (15-DaCompany Report #JACGER2000001352
Age:30 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Atrioventricular Block Second Degree Cardiac Arrest Sinus Arrest	Foreign Health Professional	Risperdal	PS	Janssen Research Fdn Div Johnson And Johnson	ORAL	MG, DAILY,	ORAL
			Haldol (Haloperidol)	SS		ORAL	DAILY,	ORAL
			Zyprexa (Olanzapine)	SS		ORAL	DAILY,	ORAL
			Eunerpan (Melperone Hydrochloride)	SS		ORAL	MG, DAILY,	ORAL

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/22/00ISR Number: 3555291-6Report Type:Expedited (15-DaCompany Report #JACGER2000001352
Age:30 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Atrioventricular Block Sinus Arrest	Foreign Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute Div Ortho Pharm	ORAL	DAILY	ORAL
			Risperdal (Tablet) (Risperidone)	SS		ORAL	DAILY,	ORAL
			Zyprexa (Olanzapine)	SS		ORAL	DAILY,	ORAL
			Eunerpan (Melperone Hydrochloride0	SS		ORAL	DAILY,	ORAL

Date:08/23/00ISR Number: 3556487-XReport Type:Expedited (15-DaCompany Report #M2000.0552/PHBS2000JP07695
Age:50 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anxiety Delusion	Literature Health	Rimactane	PS	Geneva Pharmaceuticals Inc	ORAL	450 MG, QD,	ORAL
	Drug Interaction Feeling Abnormal Hallucination Hallucination, Auditory Headache Insomnia Irritability Persecutory Delusion Restlessness	Professional	Haloperidol (Decanoate) Izoniazid Streptomycin Chlorpromazine	SS C C C				

Date:08/23/00ISR Number: 3556578-3Report Type:Expedited (15-DaCompany Report #8-97029-001J
Age:74 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Hospitalization - Initial or Prolonged	Brain Damage Coma	Consumer	Ativan	PS	Wyeth Ayerst Laboratories Inc	
INTRAMUSCULAR ONCE, INTRAMUSCULAR	Urinary Incontinence		Haldol	SS		
5 MG INJECTION TWICE			Cognex Haldol	C C		

Date:08/24/00ISR Number: 3557660-7Report Type:Expedited (15-DaCompany Report #PRIUSA2000006683
Age:32 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Completed Suicide	Literature	Haldol	PS	Rw Johnson Pharmaceutical Research Institute	
Hospitalization - Initial or Prolonged	Electrocardiogram Qrs Complex Prolonged Grand Mal Convulsion	Health Professional			Div Ortho Pharm	ORAL
ORAL	Intentional Misuse		Amitriptyline	SS		ORAL
ORAL	Intentional Self-Injury		Bupropion (Amfebutamone)	SS		ORAL

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/24/00ISR Number: 3557663-2Report Type:Expedited (15-DaCompany Report #PRIUSA2000006684
Age:41 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Agitation	Literature	Haldol	PS	Rw Johnson			
Hospitalization - Initial or Prolonged	Autonomic Nervous System Imbalance	Health Professional			Pharmaceutical Research Institute			
	Blood Creatinine Increased				Div Ortho Pharm	ORAL		
	Coagulopathy		Cogentin (Benzatropine Mesilate)	SS		ORAL		
	Coma							
	Completed Suicide		Cocaine (Cocaine)	SS		ORAL		
	Disseminated Intravascular Coagulation							
	Haematemesis							
	Hyperglycaemia							
	Intentional Misuse							
	Loss Of Consciousness							
	Muscle Rigidity							
	Mydriasis							
	Pco2 Decreased							
	Pyrexia							
	Tachycardia							
	Thrombocytopenia							
	Toxicologic Test Abnormal							

Date:08/24/00ISR Number: 3557667-XReport Type:Expedited (15-DaCompany Report #PRIUSA2000006685
Age:40 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Literature	Haldol	PS	Rw Johnson			
	Drug Toxicity	Health			Pharmaceutical			
	Intentional Misuse	Professional			Research Institute			
	Loss Of Consciousness				Div Ortho Pharm	ORAL		
			Phenobarbital (Phenobarbital)	SS		ORAL		
			Valproic Acid					

			(Valproic Acid)	SS		ORAL
ORAL						

Date:08/24/00ISR Number: 3557773-XReport Type:Expedited (15-DaCompany Report #JRFBEL2000002039
Age:75 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Electrocardiogram Qt	Literature	Haldol	PS	Rw Johnson	
Required	Corrected Interval	Health			Pharmaceutical	
Intervention to	Prolonged	Professional			Research Institute	
INTRAVENOUS IV	2 DAY					
Prevent Permanent	Hyponatraemia		Propofol (Propofol)	C		
Impairment/Damage	Ventricular Fibrillation					

Date:08/24/00ISR Number: 3557898-9Report Type:Expedited (15-DaCompany Report #8-96295-001J
Age:74 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Agitation	Health	Ativan	PS	Wyeth Ayerst	
Initial or Prolonged	Brain Damage	Professional			Laboratories Inc	
2 MG ONCE,						
	Coma					
INTRAMUSCULAR						
	Medication Error		Haldol	SS		
5 MG X 2						
	Urinary Incontinence					
INJECTIONS						
			Cognex	C		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/25/00ISR Number: 3558044-8Report Type:Periodic Company Report #C2000-0601.01
Age:45 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dermatitis	Consumer	Haloperidol	PS	Mylan Pharmaceuticals Inc	ORAL	1 MG BID,	
			Buspar	C			ORAL	
			Mysoline	C				
			Tegretol	C				
			Lorazepam	C				
			Tylenol	C				
			Centrum	C				

Date:08/25/00ISR Number: 3559235-2Report Type:Expedited (15-DaCompany Report #HQ0144322AUG2000
Age:87 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Confusional State	Health Professional	Artane	PS	Lederle Laboratories Div American Cyanamid Co	ORAL	2 MG 1 X PER	1 DAY
Other	Disorientation	Other					ORAL	6 DAY
	Fall							
	Hallucination, Visual							
	Persecutory Delusion		Haloperidol	SS			6 DAY	
			Valium	C				

Date:08/28/00ISR Number: 3560266-7Report Type:Expedited (15-DaCompany Report #JACFRA2000000545
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Complications Of Maternal Exposure To Therapeutic Drugs	Foreign Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute	ORAL	100 DROP, 3 IN 1 DAY(S),	
	Foetal Growth Retardation							

ORAL; UTERINE			
	Artane (Trihexyphenidyl Hydrochloride)	SS	ORAL
5 MG, 2 IN 1 DAY(S), ORAL; UTERINE			
	Atarax (Hydroxyzine Hydrochloride)	SS	ORAL
100 MG, 1 IN 1 DAY(S), ORAL; UTERINE			
	Largactil (Chlorpromazine Hydrochloride)	SS	ORAL
MG, 3 IN 1 DAY(S), ORAL; UTERINE			
	Levothyrox (Levothyroxine Sodium)	SS	ORAL
MG, DAILY, ORAL; UTERINE			
	...	C	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/29/00ISR Number: 3561359-0Report Type:Expedited (15-DaCompany Report #JACGER2000001319
Age:67 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Bilirubin Increased Hepatitis Liver Function Test Abnormal	Foreign Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute	INTRAMUSCULAR	100 MG, 1 IN	4 WEEK (S), IM

Date:08/29/00ISR Number: 3561642-9Report Type:Expedited (15-DaCompany Report #JACGER2000001371
Age:62 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Creatine Phosphokinase Increased Blood Creatine Phosphokinase Mb	Foreign Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute Div Ortho Pharm	ORAL	DAILY, ORAL	
	Increased Blood Lactate Dehydrogenase Increased		Dipioeron (Unspecified) (Pipamperone)	SS		ORAL	DAILY, ORAL	
	Rhabdomyolysis		Akineton (Biperiden Hydrochloride)	SS		ORAL	DAILY, ORAL	
			Zyprexa (Olanzapine)	SS		ORAL	DAILY, ORAL	

Date:08/31/00ISR Number: 3563243-5Report Type:Expedited (15-DaCompany Report #DEU003391
Age:25 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Conduction Disorder	Foreign Health	Akineton	PS	Knoll Pharmaceutical Co	ORAL	4 MG PO	

			Professional	Haldol	SS		ORAL
5 MG PO							
			Other	Risperdal	SS		ORAL
2 MG PO							

Date:09/01/00ISR Number: 3563903-6Report Type:Expedited (15-DaCompany Report #A029329
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Congenital Anomaly	Angiopathy	Foreign	Atarax	PS	Roerig Div Pfizer Inc	ORAL	100.00 MG	TOTAL, DAILY,
	Complications Of Maternal Exposure To Therapeutic Drugs	Health Professional						
	Foetal Disorder		Trihexphenidyl	SS		ORAL	10.00 MG	TOTAL, DAILY,
	Foetal Growth Retardation							
	Gastrointestinal Disorder							
	Umbilical Cord Abnormality		Haloperidol	SS		ORAL	ORAL	
	Uterine Disorder		Chlorpromazine	SS		ORAL	250MG TOTAL	DAILY ORAL
			Levothyroxine	C				

Date:09/02/00ISR Number: 3564073-0Report Type:Expedited (15-DaCompany Report #FLUV00300005064
Age:67 YR Gender:Female I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Hyperhidrosis
	Muscle Rigidity
	Neuroleptic Malignant Syndrome

Pyrexia

		Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
		Foreign Health	Luvox	PS	Solvay Pharmaceuticals	ORAL
150 MG DAILY						
PO		Professional				
		Other	Serenace (Haloperidol)	SS		ORAL
2 MG DAILY PO						
			Risperdal (Risperidone)	SS		ORAL
1 MG DAILY						
PO						

Date:09/07/00ISR Number: 3567489-1Report Type:Expedited (15-DaCompany Report #A030303
Age:91 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization -	Anaemia Macrocytic	Foreign	Zyrtec	PS	Pfizer Inc	ORAL
ORAL						
Initial or Prolonged	Leukopenia	Health	Haloperidol	SS		ORAL
ORAL						
	Mean Cell Volume Abnormal	Professional	Levodopa-Carbidopa	SS		ORAL
ORAL						
	Neutropenia		Sulfamethoxazole/Trimethoprime	SS		ORAL
	Pancytopenia					
ORAL						
	Thrombocytopenia		Acetorphan	C		
	White Blood Cell Count Decreased		Euphytose	C		
			Calcium/Cholecalciferol/Citric Acid	C		

Date:09/08/00ISR Number: 3569027-6Report Type:Expedited (15-DaCompany Report #JACGER2000001319
Age:67 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization -	Biliary Tract Disorder	Foreign	Haldol	PS	Rw Johnson	

Initial or Prolonged	Blood Bilirubin Increased Hepatitis	Health Professional			Pharmaceutical Research Institute	
INTRAMUSCULAR	100 MG, 1 IN	Liver Function Test				
4 WEEK (S),		Abnormal				
IM						
			Haldol Decanoat (50 Mg/Ml Injection) (Haloperidol Decanoate)	SS		
INTRAMUSCULAR	150 MG, 1 IN					
4 WEEKS(S),						
IM						

Date:09/11/00ISR Number: 3568179-1Report Type:Expedited (15-DaCompany Report #233564
Age:52 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Agranulocytosis		Haldol	PS				16 DAY
Life-Threatening	Anaemia		Innohep	SS				16 DAY
	Cardiac Arrest		Zestril	SS				16 DAY
	Myocardial Infarction		Hypnovel (Inj)	SS	Roche			
	Red Blood Cell Count Increased		Tranxene	SS				16 DAY
			Lasilix	SS				16 DAY
	Respiratory Failure							
	White Blood Cell Count Decreased							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/11/00ISR Number: 3568234-6Report Type:Expedited (15-DaCompany Report #239349
Age:51 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Aggression		Haldol	PS				
	Agitation		Neurocil	SS				
	Balance Disorder		Valium Retard	SS	Roche			
	Blood Creatine Phosphokinase Increased		Timonil 300 Retard	C				
			Akineton Retard	C				2 DAY
	C-Reactive Protein		Tavor	C				1 DAY
	Increased		Mono Embolex	C				16 DAY
	Cyanosis							
	Dysarthria							
	Dyspnoea							
	Grand Mal Convulsion							
	Respiratory Failure							
	Sedation							
	Urinary Incontinence							

Date:09/12/00ISR Number: 3570983-0Report Type:Expedited (15-DaCompany Report #200010901RHF
Age:52 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Agranulocytosis	Foreign	Lasix	PS	Aventis Pharmaceuticals Inc	ORAL	80 MG/DAY PO	16 DAY
Life-Threatening	Cardiac Arrest	Other						
Hospitalization - Initial or Prolonged	Myocardial Infarction		Haloperidol (Haldol)	SS		ORAL	3 U/DAY PO	16 DAY
	Red Blood Cell Count Decreased		Heparin-Fraction, Sodium Salt (Innohep)	SS		SUBCUTANEOUS	SC	16 DAY
	Respiratory Failure		Lisinopril (Zestril) Tablets	SS		ORAL	2.5 MG/DAY PO	16 DAY
			Midazolam Hydrochloride (Hypnovel) Solution For Injection	SS		INTRAVENOUS	IV	16 DAY

			Clorazepate Dipotassium (Tranxene) Tablets	SS		ORAL
150 MG/DAY PO 16 DAY						

Date:09/13/00ISR Number: 3571017-4Report Type:Expedited (15-DaCompany Report #233564
Age:52 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Agranulocytosis	Foreign	Versed	PS	Hoffmann La Roche	
Life-Threatening	Anaemia	Other			Inc	
INTRAVENOUS INTRAVENOUS						
	Cardiac Arrest		Haldol (Haloperidol)	SS		ORAL
DOSE FORM						
	Leukopenia					
DAILY ORAL						
	Lymphocytosis		Innohep (Tinzaparin			
	Myocardial Infarction		Sodium)	SS		
SUBCUTANEOUS SUBCUTANEOUS						
	Neutropenia		Zestril (Lisinopril)			
	Red Blood Cell Count		5 Mg	SS		ORAL
2.5 MG DAILY						
	Increased					
ORAL						
	Respiratory Failure		Tranxene (Clorazepate Dipotassium) 50 Mg	SS		ORAL
150 MG DAILY						
ORAL						
			Lasilix (Furosemide) 40 Mg	SS		ORAL
80 MG DAILY						
ORAL						

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/14/00ISR Number: 3570860-5Report Type:Direct Company Report #
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agitation Condition Aggravated		Haldol	PS		ORAL	PO PRIOR TO ADMISSION	
			Ativan	C				
			Duragesic Patch	C				
			Percocet	C				

Date:09/14/00ISR Number: 3571568-2Report Type:Expedited (15-DaCompany Report #FLUV00300005228
Age:78 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Hospitalization - Initial or Prolonged	Blood Creatine Phosphokinase Increased Condition Aggravated Decreased Activity Drug Interaction Muscle Rigidity Neuroleptic Malignant Syndrome Parkinson'S Disease Pyrexia Tremor	Foreign Health Professional Other	Luvox	PS	Solvay Pharmaceuticals	ORAL	SEE IMAGE	
			Nauzelin (Domperidone)	SS		ORAL	3 DF	DAILY
			Gramalil (Tiapride Hydrochloride)	SS		ORAL	150 MG	DAILY
			Symmetrel (Amantadine Hydrochloride)	SS		ORAL	2 DF	DAILY
			Artane (Trihexyphenidyl Hydrochloride)	SS		ORAL	2 DF	DAILY
			Serenace (Haloperidol)	SS		ORAL	0.75 MG	DAILY
			..	C				
			Merislon (Betahistine Hydrochloride)	C				
			Aponol (Ifenprodil Tartrate)	C				
			..	C				

Date:09/14/00ISR Number: 3571583-9Report Type:Expedited (15-DaCompany Report #JACGER2000001026
Age:43 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Alcohol Withdrawal Syndrome	Foreign Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute	ORAL	5 MG, 3 IN 1	Required
Hospitalization - Initial or Prolonged	Apallic Syndrome							
	Cardiac Arrest							
	Cardiac Failure		Lyogen (Fluphenazine)	SS		ORAL	SEE IMAGE	
Intervention to Prevent Permanent Impairment/Damage	Delirium							
	Hypertension		Neurocil (Levomepromazine Maleate)	C		ORAL	80 MG, 4 IN 1	
	Hypokalaemia							
	Schizophrenia							
	Tachycardia							
			Tavor	C				
			Laubeel	C				
			Nifedipin	C				
			Haemiton	C				
			Ximovan	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/14/00ISR Number: 3571584-0Report Type:Expedited (15-DaCompany Report #JACFRA2000000250
Age:52 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Agranulocytosis	Foreign	Haldol	PS	Rw Johnson Pharmaceutical Research Institute Div Ortho Pharm	ORAL		
Life-Threatening	Cardiac Arrest	Health Professional Other						
	Leukopenia							
			Innohep (Heparin-Fraction, Sodium Salt)	SS		SUBCUTANEOUS	SUBCU	
			Zestril (Lisinopril)	SS		ORAL	MG, DAILY,	ORAL
			Hypnovel (Midazolam Hydrochloride)	SS		INTRAVENOUS	IV	
			Tranxene (Clorazepate Dipotassium)	SS		ORAL	MG, DAILY,	ORAL
			Lasilix (Furosemide)	SS		ORAL	MG, DAILY,	ORAL

Date:09/14/00ISR Number: 3571676-6Report Type:Expedited (15-DaCompany Report #239349
Age:51 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Aggression	Foreign	Valium	PS	Hoffmann La Roche Inc	ORAL	15 MG DAILY	
	Agitation	Study						
	Balance Disorder	Health Professional						
	Blood Creatine Phosphokinase Increased		Haldol (Haloperidol)	SS		ORAL	20 MG DAILY	
			Neurocil					

C-Reactive Protein Increased	(Methotrimeprazine)	SS	
Cyanosis	Timonil 300 Retard (Carbamazepine)	C	
Dysarthria	Akineton Retard (Biperiden Hydrochloride)	C	
Dyspnoea	Tavor (Lorazepam)	C	
Insomnia	Mono Embolex (Certoparin Sodium)	C	
Loss Of Consciousness			
Parkinson'S Disease			
Respiratory Failure			
Sedation			
Stupor			
Tongue Disorder			
Urinary Incontinence			

Date:09/14/00ISR Number: 3571757-7Report Type:Expedited (15-DaCompany Report #JRFUSA2000006910
Age:70 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Delusion Hallucination	Study Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute Div Ortho Pharm			
			Galantamine (12 Mg Tablet) (Galantamine)	SS		ORAL	12 MG, 2 IN 1	DAY (S), ORAL
			Lodine (Etodolac)	C				
			Multivitamins (Multivitamins)	C				

			Zoloft (Sertraline Hydrochloride)	C		

Date:09/15/00ISR Number: 3571943-6Report Type:Direct Company Report #
Age:24 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Required Intervention to Prevent Permanent Impairment/Damage	Condition Aggravated Priapism		Quetiapine Haloperidol Mesoridazine	PS SS SS			50MG / 100MG / 400MG 10 MG; 1 DOSE 50 MG; 1 DOSE

Date:09/15/00ISR Number: 3572551-3Report Type:Expedited (15-DaCompany Report #001-0184-M0000030
Age:91 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Other	Cognitive Disorder Depressed Level Of Consciousness Wheelchair User	Consumer	Benadryl Zoloft (Sertraline Hydrochloride) Haldol Decanoate (Haloperidol Decanoate)	PS SS SS	Parke Davis Div Warner Lambert Co	ORAL	PER ORAL 3 MG

Date:09/15/00ISR Number: 3572819-0Report Type:Expedited (15-DaCompany Report #FLUV00300005064
Age:67 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Autonomic Nervous System Imbalance	Foreign Health	Luvox	PS	Solvay Pharmaceuticals	ORAL	150 MG DAILY

	Hyperhidrosis	Professional				
PO						
	Muscle Rigidity	Other	Serenace			
	Neuroleptic Malignant		(Haloperidol)	SS		ORAL
2 MG DAILY PO						
	Syndrome		Risperdal			
	Pyrexia		(Risperidone)	SS		ORAL
1 MG DAILY PO						
	Stupor					

Date:09/18/00ISR Number: 3573125-0Report Type:Direct Company Report #
Age:50 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Required Intervention to Prevent Permanent Impairment/Damage	Tardive Dyskinesia		Haldol	PS		

Date:09/18/00ISR Number: 3573128-6Report Type:Direct Company Report #
Age:52 YR Gender:Male I/FU:I

Outcome
Hospitalization - Initial or Prolonged
Disability
Required Intervention to Prevent Permanent

Impairment/Damage

	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Tardive Dyskinesia		Haloperidol	PS				
			Haloperidol 2mg Tab	SS				

Date:09/18/00ISR Number: 3573401-1Report Type:Periodic Company Report #INT2000301
Age:66 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Pyrexia	Health	Integrilin	PS	Cor Therapeutics Inc	INTRAVENOUS	INTRAVENOUS	
		Professional	Haldol Injectable Solution	SS		INTRAVENOUS	5 MG Q4H	

INTRAVENOUS

Date:09/19/00ISR Number: 3574705-9Report Type:Direct Company Report #
Age:78 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Bundle Branch Block		Haloperidol	PS		INTRAVENOUS	160 MG IV (TOTAL DOSE REPORTED)	
	Duodenal Ulcer							
	Electrocardiogram Qt Corrected Interval Prolonged							
	Gastrointestinal Arteriovenous Malformation							
	Gastrointestinal Haemorrhage							
	Sinus Bradycardia							
	Torsade De Pointes							
	Ventricular Tachycardia							

Date:09/20/00ISR Number: 3575666-9Report Type:Expedited (15-DaCompany Report #JACFRA2000000586
Age:43 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain Blood Creatine Phosphokinase Increased Constipation Muscle Spasms Myalgia	Foreign Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute	ORAL	0.5 MG, 1 IN 1 DAY(S),	ORAL
			Vesadol (Tablet) (Haloperidol/Buzepide Metiodide)	SS		ORAL	1 TABLET, 3 IN 1 DAY(S),	ORAL

Date:09/20/00ISR Number: 3575682-7Report Type:Expedited (15-DaCompany Report #JRFBEL2000002215
Age:30 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Depression Suicidal Ideation	Foreign Study Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute Div Ortho Pharm	ORAL	3 MG, 1 IN 1 DAY(S),	ORAL

			Risperidone (Tablet) (Resperidone)	SS		ORAL
3 MG, , 1 IN 1 DAY(S), ORAL						

Date:09/20/00ISR Number: 3575685-2Report Type:Expedited (15-DaCompany Report #JRFBEL2000002212
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged Required Intervention to	Benign Congenital Hypotonia Complications Of Maternal Exposure To Therapeutic	Foreign Literature Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute Div Ortho Pharm	
URETHRAL UTERINE						
Prevent Permanent Impairment/Damage	Drugs Feeding Problem In Newborn		Cogentin (Benzatropine Mesilate)	SS		
URETHRAL UTERINE	Hypothermia					

Date:09/22/00ISR Number: 3577048-2Report Type:Direct Company Report #
Age:60 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Blood Creatine Phosphokinase Increased Muscle Rigidity	Health Professional	Simvastatin 20mg Haloperidol Decanoate	PS SS		ORAL
20MG QD PO INTRAMUSCULAR 100 MG Q MO IM	Pyrexia					
	Tremor		Seroquel 100 Mg Astra Zeneca	SS	Astra Zeneca	ORAL
300MG/D ORAL						
			Asa	C		
			Apap	C		
			Benztropine	C		
			Clonazepam	C		

Docusate	C
Lansoprazole	C
Paroxetine	C
Vit E	C

Date:09/22/00ISR Number: 3577067-6Report Type:Direct Company Report #
Age:47 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Tardive Dyskinesia	Health Professional	Haloperidol	PS				

Date:09/22/00ISR Number: 3578306-8Report Type:Expedited (15-DaCompany Report #JACFRA2000000585
Age: Gender:Male I/FU:I

Outcome	PT
Death	Amniotic Cavity Disorder
Congenital Anomaly	Bladder Dilatation
	Complications Of Maternal Exposure To Therapeutic Drugs
	Congenital Anomaly
	Congenital Genitourinary Abnormality
	Intra-Uterine Death

Placental Disorder
Strabismus

Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Foreign Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute	ORAL	0.5 MG,	DAILY, ORAL, UTERINE
	Athymil (Mianserin Hydrochloride)	SS		ORAL	30 MG, 15 MG,	DAILY, ORAL, UTERINE

Date:09/22/00ISR Number: 3578823-0Report Type:Expedited (15-DaCompany Report #JRFUSA2000006910
Age:70 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Delusion Hallucination	Study Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute Div Ortho Pharm			
			Galantamine (12 Mg Tablet) (Galantamine)	SS		ORAL	12 MG, 2 IN 1	DAY(S), ORAL
			Lodine (Etodolac)	C				
			Multivitamins (Multivitamins)	C				
			Zoloft (Sertraline Hydrochloride)	C				

Date:09/25/00ISR Number: 3578453-0Report Type:Expedited (15-DaCompany Report #C2000-1034.01
Age:85 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agitation Confusional State	Consumer	Haloperidol	PS	Mylan Pharmaceuticals Inc			1 DAY
Other	Delusion Gastrointestinal Disorder Insomnia							

Date:09/26/00ISR Number: 3580349-5Report Type:Expedited (15-DaCompany Report #PRIUSA2000004255
Age:76 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardiac Arrest Medication Error	Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute		INTRAVENOUS	10 MG, 1 TIME(S), IV
			Epinephrine (Epinephrine)	SS			1 MG, 1 TIME(S)	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/27/00ISR Number: 3581492-7Report Type:Expedited (15-DaCompany Report #00P-056-0089614-00 (1)
Age:52 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Agranulocytosis	Foreign	Tranxene	PS	Abbott Laboratories			
Life-Threatening	Cardiac Arrest	Health Professional			Pharmaceutical Products Div	ORAL	150 MG, 1 IN	1 D, PER ORAL
			Haloperidol (Haloperidol)	SS		ORAL	3 UNIT, 1 IN	1 D, PER ORAL
			Heparin-Fraction, Sodium Salt (Heparin-Fraction, Sodium Salt)	SS		SUBCUTANEOUS	SUBCUTANEOUS	
			Lisinopril (Lisinopril)	SS		ORAL	2.5 MG, 1 IN	1 D, PER ORAL
			Midazolam Hydrochloride (Midazolam Hydrochloride)	SS		INTRAVENOUS	INTRAVENOUS	
			Furosemide (Furosemide)	SS		ORAL	80 MG, 1 IN 1	D, PER ORAL

Date:09/27/00ISR Number: 3581635-5Report Type:Expedited (15-DaCompany Report #JRFBEL2000002244
Age:23 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Coma	Foreign Health	Haldol	PS	Rw Johnson Pharmaceutical			

			Professional			Research Institute
INTRAVENOUS	130 MG,					
TOTAL, IV						

Date:09/29/00ISR Number: 3584489-6Report Type:Expedited (15-DaCompany Report #JACFRA2000000621
Age:64 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization - Initial or Prolonged	Antinuclear Antibody Positive	Foreign Health	Haldol	PS	Rw Johnson Pharmaceutical	
Required	C-Reactive Protein	Professional			Research Institute	ORAL
5 MG, 1 IN 1						
Intervention to	Increased					
DAY(S), ORAL						
Prevent Permanent	Dermatitis Bullous		Calciparine	SS		
SUBCUTANEOUS	SUBCU					
Impairment/Damage	Leukocytoclastic		Triflucan	SS		ORAL
ORAL						
	Vasculitis		Mopral	SS		ORAL
20 MG, 1 IN 1						
	Pyrexia					
DAY(S), ORAL						
	Rash Erythematous		Oflocet	SS		
INTRAVENOUS	200 MG, 2 IN					
	Rash Papular					
1 DAY(S), IV						
	Rash Pustular					
(SEE IMAGE)						
	Red Blood Cell		Augmentin	SS		
INTRAVENOUS	1 G, 2 IN 1					
	Sedimentation Rate					
DAY(S), IV						
	Increased		Lasilix	C		
	Scab		Lopril	C		
	Skin Discolouration					
	Skin Necrosis					
	Vascular Purpura					

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/29/00ISR Number: 3584589-0Report Type:Expedited (15-DaCompany Report #JRFBEL2000002354
Age:19 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Blood Pressure Abnormal	Foreign	Haldol	PS	Rw Johnson	
Other	Coma	Study			Pharmaceutical	
	Hyperhidrosis	Literature			Research Institute	
INTRAMUSCULAR MG DAILY IM						
	Leukocytosis	Health				
	Pyrexia	Professional				
	Tachycardia					
	Tachypnoea					

Date:09/29/00ISR Number: 3584591-9Report Type:Expedited (15-DaCompany Report #JRFBEL2000002353
Age:54 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Blood Pressure Abnormal	Foreign	Haldol	PS	Rw Johnson	
Other	Coma	Study			Pharmaceutical	
	Hyperhidrosis	Literature			Research Institute	
INTRAMUSCULAR DAILY, IM						
	Neuroleptic Malignant	Health				
	Syndrome	Professional				
	Pyrexia					
	Tachycardia					
	Tachypnoea					

Date:09/29/00ISR Number: 3584783-9Report Type:Expedited (15-DaCompany Report #JACGER2000001510
Age:47 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Atrioventricular Block	Foreign	Haldol	PS	Rw Johnson	
Initial or Prolonged	Complete	Health			Pharmaceutical	
		Professional			Research Institute	
					Div Ortho Pharm	ORAL
MG, DAILY						
,ORAL						
			Ximovan (Zopiclone)	C		
			Tavor (Lorazepam)	C		

Date:10/02/00ISR Number: 3585643-XReport Type:Expedited (15-DaCompany Report #JAKYO43538
Age:59 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Akathisia Cholelithiasis Dyskinesia	Foreign Health Professional	Risperdal	PS	Janssen Research Fdn Div Johnson And Johnson	ORAL	MG, DAILY,	
	Hepatic Function Abnormal						ORAL	
	Salivary Hypersecretion Stomatitis		Bromperidol (Unspecified) (Bromperidol)	SS		ORAL	SEE IMAGE	
			Haloperidol Decanoate (Injection) (Haloperidol Decanoate)	SS		INTRAMUSCULAR	MG, DAILY,	
							INFUSION, MG,	
							DAILY, IM	
			Fluphenazine (Fluphenazine)	SS		INTRAMUSCULAR	25 MG, DAILY,	
							IM	
			Biperiden					

Hydrochloride (Biperiden Hydrochloride)	C
Sennoside (Tablet) (Sennosides)	C
Tolbutamide (Tablet) (Tolbutamide)	C
Magnesium Oxide (Magnesium Oxide)	C
Daio-Kanzo-To (Daiokanzoto)	C

Date:10/03/00ISR Number: 3586629-1Report Type:Expedited (15-DaCompany Report #JACFRA2000000597
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death Congenital Anomaly	Complications Of Maternal Exposure To Therapeutic Drugs Congenital Genitourinary Abnormality Congenital Musculoskeletal Anomaly Intra-Uterine Death	Foreign Health Professional	Haldol Athymil	PS SS	Rw Johnson Pharmaceutical Research Institute	ORAL ORAL	0.5 MG, DAILY, ORAL (SEE IMAGE) 30 MG, DAILY, ORAL (SEE IMAGE)	

Date:10/03/00ISR Number: 3586646-1Report Type:Expedited (15-DaCompany Report #JACFRA2000000585
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death Congenital Anomaly	Complications Of Maternal Exposure To Therapeutic Drugs Foetal Disorder Intra-Uterine Death	Foreign Health Professional	Haldol Athymil (Mianserin	PS	Rw Johnson Pharmaceutical Research Institute	ORAL	0.5 MG DAILY ORAL	

			Hydrochloride)	SS		ORAL
30 MG DIALY						
ORAL						
			Athymil (Mianserin Hydrochloride)	SS		ORAL
15 MG DAILY						
ORAL						
			Athymil (Mianserin Hydrochloride)	SS		
INTRA-UTERINE	UTERINE					

Date:10/03/00ISR Number: 3586972-6Report Type:Expedited (15-DaCompany Report #PRIUSA2000010108
Age:56 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Difficulty In Walking Ecchymosis Fall	Consumer	Haldol	PS	Rw Johnson Pharmaceutical Research Institute	
INTRAMUSCULAR	100 MG, MONTH					
(S), IM	Heart Rate Irregular					
	Hyperglycaemia Laryngitis		Artane (Trihexyphenidyl Hydrochloride)	C		
			Antibiotics (Antibiotics)	C		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/04/00ISR Number: 3587524-4Report Type:Direct Company Report #
Age:18 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hallucination, Auditory		Haloperidol 5 Mg-					
	Muscle Rigidity		Roxane	PS	Roxane			
12 N & H.S.								
			Haloperidol 10 Mg -					
			Geneva	SS	Geneva			
8A & 4P								

Date:10/04/00ISR Number: 3587727-9Report Type:Expedited (15-DaCompany Report #JACFRA2000000615
Age:1 DY Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Caesarean Section	Foreign	Haldol	PS	Rw Johnson			
Initial or Prolonged	Complications Of Maternal	Health			Pharmaceutical			
	Exposure To Therapeutic	Professional			Research Institute			
SEE IMAGE								
	Drugs							
	Foetal Growth Retardation							
	Pregnancy							
	Premature Baby							

Date:10/04/00ISR Number: 3587755-3Report Type:Expedited (15-DaCompany Report #DEU003512
Age:25 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Amnesia	Foreign	Akineton	PS	Knoll Pharmaceutical			
Hospitalization -	Convulsion	Health			Co			
5 MG DAILY								
Initial or Prolonged	Difficulty In Walking	Professional						
OTHER								
	Dysphagia	Other	Serenace	SS		ORAL		
9 MG DAILY PO								
	Dyspnoea		Serenace	SS				
MG DAILY								
	Heart Rate Increased							
OTHER								

	Hyperpyrexia		Neuleptil	SS		ORAL 30 MG DAILY
	Ileus Paralytic					PO
	Muscle Rigidity		Hirnamin	SS		ORAL 25 MG DAILY
	Pyrexia					PO
	Salivary Hypersecretion		Wintermin	SS		MG DAILY
	Stupor					OTHER
			Depas	C		
			Viccilin	C		
			Cravit	C		

Date:10/06/00ISR Number: 3590707-0Report Type:Expedited (15-DaCompany Report #A0061345A
Age:22 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Aggression	Consumer	Lamictal	PS	Glaxo Wellcome Inc	ORAL	100 MG / TWICE PER DAY
	Choking Sensation						/ ORAL
	Convulsion						
	Drug Ineffective		Haloperidol				
	Loss Of Consciousness		(Haloperidol)	SS			
	Neck Pain		Lamictal Tablet				
	Pain In Extremity		(Lamotrigine)	SS		ORAL	150 MG / VARIABLE DOSE
	Paralysis						/ ORAL
	Vomiting						
			Risperidone	C			

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/06/00ISR Number: 3590948-2Report Type:Expedited (15-DaCompany Report #A030372
Age:78 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Difficulty In Walking Movement Disorder	Foreign Consumer	Zoloft	PS	Pfizer Pharmaceuticals Inc	ORAL	100.00 MG	Required
							TOTAL:DAILY:O	
Intervention to Prevent Permanent Impairment/Damage			Haloperidol	SS			RAL	

Date:10/10/00ISR Number: 3591975-1Report Type:Direct Company Report #
Age:53 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Tardive Dyskinesia		Haloperidol	PS				

Date:10/10/00ISR Number: 3592184-2Report Type:Expedited (15-DaCompany Report #B0088720A
Age:78 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Convulsion	Foreign	Zantac	PS	Glaxo Wellcome Inc	ORAL	150 MG /PER	
							DAY/ ORAL	
			Fluoxetine (Fluoxetine)	SS		ORAL	20 MG /PER	
							DAY/ ORAL	
			Haloperidol Tablet (Haloperidol)	SS		ORAL	ORAL	
			Benzhexol Capsule (Benzhexol)	SS		ORAL	ORAL	

Date:10/11/00ISR Number: 3593075-3Report Type:Expedited (15-DaCompany Report #FLUV00300005959
Age:81 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Aortic Valve Incompetence Aortic Valve Replacement	Foreign Health	Luvox	PS	Solvay Pharmaceuticals	ORAL	UNK DAILY PO,	
Other	Electrocardiogram Qt Prolonged	Professional Other					50 MG DAILY PO	
	Endocarditis Ventricular Fibrillation		Serenace (Haloperidol)	SS		ORAL	3 DF DAILY PO	
	Ventricular Tachycardia		Contomin (Chlorpromazine Hydrochloride)	SS		ORAL	0.03 G DAILY	
							PO, 20 MG DAILY PO	
			Hiberna (Promethazine Hydrochloride)	C				
			Evamyl (Lormetazepam)	C				
			Rhythmy (Rilmazafone)	C				
			Rohypnol (Flunitrazepam)	C				
			Depas (Etizolam)	C				
			Miketorin (Amitriptyline Hydrochloride)	C				

Horizon (Diazepam)	C
Ritalin (Methylphenidate Hydrochloride)	C
Alosenn	C
Dogmatyl (Sulpride)	C
Nauzelin (Domperidone)	C
Ganaton	C
Surmontil (Trimipramine)	C
Brovarin (Bromisoval)	C
Isomytal (Amobarbital)	C
Maalox	C
Persantin-L (Dipyridamole)	C
Lasix (Furosemide)	C
Aldactone-A (Spironolactone)	C
Cravit (Levofloxacin)	C
Marzulene (Sodium Gualenate)	C
Warfarin (Warfarin)	C
Akineton (Biperiden Hydrochloride)	C

Date:10/12/00ISR Number: 3594345-5Report Type:Direct Company Report #
Age:59 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Tardive Dyskinesia		Haloperidol Decanoate 100mg/Ml	PS				

Date:10/12/00ISR Number: 3594551-XReport Type:Expedited (15-DaCompany Report #JRFBEL2000002244
Age:23 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Coma	Foreign	Haldol	PS	Rw Johnson			

		Health Professional			Pharmaceutical Research Institute	

INTRAVENOUS 130 MG ,

TOTAL, IV

Date:10/12/00ISR Number: 3594553-3Report Type:Expedited (15-DaCompany Report #JACGBR2000000751
Age:49 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Dermatitis Leukocytoclastic Vasculitis Renal Impairment	Foreign Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute Div Ortho Pharm	ORAL
5 MG, 1 IN 1 DAY(S) ,ORAL						
			Insulin (Insulin)	SS		
			Quinine Sulphate (Quinine Sulfate)	SS		ORAL
300 MG ,NIGHT(S)						

,ORAL

	Zocor (Simvastatin)	C
	Temazepam (Temazepam)	C
	Frusemide (Furosemide)	C
	Enalapril (Enalapril)	C
	Chlorpromazine (Chlorpromazine)	C

Date:10/17/00ISR Number: 3596645-1Report Type:Direct Company Report #
Age:53 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Tardive Dyskinesia		Haldol	PS				

Date:10/18/00ISR Number: 3596571-8Report Type:Direct Company Report #
Age:65 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Condition Aggravated		Haldol	PS			5MG BID	
	Confusional State		Zanaflex	C				
	Depressed Level Of Consciousness		Lorazepam	C				
	Drug Ineffective		Artane	C				
	Hyperhidrosis		Mirapex	C				
	Labile Blood Pressure		Sinemet Cr	C				
	Neuroleptic Malignant Syndrome		Sinemet	C				
	Pyrexia							
	Renal Impairment							
	Tachycardia							
	Tremor							

Date:10/18/00ISR Number: 3597577-5Report Type:Expedited (15-DaCompany Report #A033556
Age:69 YR Gender:Female I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Blood Chloride Increased
	Blood Pressure Decreased
	Condition Aggravated
	Delusional Disorder, Persecutory Type
	Difficulty In Walking
	Dyspnoea
	Extrapyramidal Disorder
	Flat Affect
	Formication
	Gait Disturbance
	Hallucination
	Heart Rate Decreased
	Hyperventilation
	Joint Stiffness
	Mental Impairment
	Metabolic Acidosis
	Movement Disorder
	Pco2 Decreased
	Psychotic Disorder

	Respiratory Alkalosis Sinus Tachycardia Tachypnoea	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
	Vaginal Candidiasis Vaginitis Bacterial	Literature Health	Zoloft	PS	Pfizer Pharmaceuticals Inc	ORAL
50.00 MG						
	Ventricular Extrasystoles	Professional				
TOTAL: DAILY:						
ORAL						
			Quetiapine	SS		ORAL
100.00 MG						
TOTAL: BID:						
ORAL						
			Haloperidol	SS		ORAL
2.00 MG						
TOTAL: DAILY:						
ORAL						

Date:10/19/00ISR Number: 3599001-5Report Type:Expedited (15-DaCompany Report #71128-004
Age:6 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Blood Creatine Phosphokinase Increased	Foreign Literature	Haloperidol	PS	Roxane Laboratories Inc	ORAL
0.3 TO 0.8MG,						
	Chromaturia	Health				
DAILY, ORAL 2 MON						
	Myoglobinuria	Professional	Biperiden Hcl	SS		ORAL
0.3MG, DAILY,						
	Rhabdomyolysis					
PO 2 MON						
			Clonazepam	C		
			Diazepam	C		
			Phenobarbital	C		

Date:10/23/00ISR Number: 3600262-4Report Type:Expedited (15-DaCompany Report #PRIUSA2000010631
Age:18 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Coma Convulsion	Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute	INTRAVENOUS	5 MG, 5 IN 1	DAY (S), IV
			Cogentin	C				
			Ativan	C				
			Valium	C				
			Tylenol	C				

Date:10/23/00ISR Number: 3600461-1Report Type:Expedited (15-DaCompany Report #JRFBEL2000002503
Age:47 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Coma Electroencephalogram Abnormal Stupor	Foreign Literature Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute	INTRAVENOUS	IV	

Date:10/23/00ISR Number: 3600469-6Report Type:Expedited (15-DaCompany Report #JRFBEL2000002502
Age:58 YR Gender:Male I/FU:I

Outcome	PT
Other	Blood Creatine Phosphokinase Increased Delusion Depression

		Hyperhidrosis Hyperreflexia Irritability	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
		Jaundice Muscle Rigidity Neuroleptic Malignant	Foreign Literature Health	Haldol	PS	Rw Johnson Pharmaceutical Research Institute	
INTRAVENOUS	5 MG DAILY IV						
		Syndrome	Professional	Haldol (Haloperidol)	SS		ORAL
MG DAILY ORAL							
		Pyrexia Stupor Suicide Attempt Tremor		Clomipramine (Clomipramine) Alprazolam (Alprazolam) Triazolam (Triazolam) Flunitrazepam (Flunitrazepam) Nitrazepam (Nitrazepam) Amitriptyline (Amitriptyline) Amoxapine (Amoxapine)	C C C C C C C		

Date:10/24/00ISR Number: 3601403-5Report Type:Expedited (15-DaCompany Report #JRFBEL2000002508
Age:86 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Dyspnoea Face Oedema Fatigue Haematoma Haemoglobin Decreased Haemorrhage Oedema Pallor Petechiae Thrombocytopenia	Foreign Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute Div Ortho Pharm	
			Dipiperon (Unspecified) (Pipamperone) Seresta (Oxazepam) Beta-Blocker (Beta Blocking Agents) Seropram (Citalopram Hydrobromide)	SS SS SS C		

Date:10/26/00ISR Number: 3602261-5Report Type:Expedited (15-DaCompany Report #JACFRA2000000688
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Required	Coma Hypertension Hyponatraemia	Foreign Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute	INTRAMUSCULAR	MONTHLY, IM	
Intervention to Prevent Permanent Impairment/Damage	Malaise Vomiting		Tercian (Cyamemazine)	SS		ORAL	MG, DAILY, ORAL	

Date:10/27/00ISR Number: 3609540-6Report Type:Periodic Company Report #8-97127-008J
Age:27 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Insomnia Mental Disorder	Consumer	Ativan	PS	Wyeth Ayerst Laboratories	ORAL	ORAL	
			Artane (Trihexyphenidyl,					

Tablet)	SS
Haldol (Haloperidol, Unspecified)	SS
Xanax (Alprazolam, Unspecified)	SS
Haldol	C
Xanax	C
Symthroid	C
Artane	C
Mellaril	C

Date:10/30/00ISR Number: 3603556-1Report Type:Direct Company Report #
Age:29 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Hyperpyrexia		Haldol Inj (5mg/Ml					
Hospitalization -	Hypertension		Mcneil)	PS	Mcneil			
INTRAVENOUS	3MG IV Q 8H							
Initial or Prolonged	Tachycardia		Versed	C				
Required	Tachypnoea		Zosyn	C				
Intervention to			Dilantin	C				
Prevent Permanent			Albuterol/Atrovent					
Impairment/Damage			Mdi	C				
			Pepcid	C				
			Thiamine	C				
			Folate	C				
			Ec Asa	C				
			Tylenol	C				
			Lac N Lube	C				
			Neosporin	C				
			Oxacillin	C				
			Phenergan	C				
			Mso4	C				
			Ativan	C				
			Pepto Bismol	C				
			Bacitracin	C				
			Cooling Blanket	C				

Date:10/31/00ISR Number: 3605012-3Report Type:Expedited (15-DaCompany Report #00P-056-0099174-00(0)
Age:54 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Hospitalization - Initial or Prolonged	Agitation Condition Aggravated Coordination Abnormal Extrapyramidal Disorder Speech Disorder Stereotypy	Foreign Health Professional	Tranxene	PS	Abbott Laboratories Pharmaceutical Products Div	ORAL
PER ORAL						
			Trihexyphenidyl Hydrochloride(Trihexyphenidyl Hydrochloride)	SS		ORAL
PER ORAL						
			Haloperidol Decanoate (Haloperidol Decanoate)	SS		
INTRAMUSCULAR	INTRA-MUSCULAR					
			Tiapride(Tiapride)	C		
			Hydroxyzine Hydrochloride(Hydroxyzine Hydrochloride)	C		
			Zopiclone(Zopiclone)	C		
			Zolpidem (Zolpidem)	C		
			Bromazepam(Bromazepa			

m) C

Date:11/03/00ISR Number: 3605761-7Report Type:Expedited (15-DaCompany Report #231189
Age:29 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Hepatic Enzyme Increased		Haldol	PS				7 DAY
Initial or Prolonged	Hepatitis		Tercian	SS				7 DAY
	Pyrexia		Rivotril	SS	Roche			14 DAY
			Risperdal	C				

Date:11/06/00ISR Number: 3607441-0Report Type:Periodic Company Report #M2000.0343
Age:37 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dyskinesia		Haloperidol	PS	Geneva Pharmaceuticals Inc	ORAL	5 MG HS, PO	
	Dysphagia							
	Dyspnoea		Sonada	C				
	Muscle Rigidity		Paxil	C				
	Tongue Disorder		Xanax	C				
	Trismus		Lorazepam	C				

Date:11/06/00ISR Number: 3607464-1Report Type:Periodic Company Report #M2000.0301
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Skin Disorder	Consumer	Haloperidol	PS	Geneva Pharmaceuticals Inc	ORAL	ORAL	
			6 Other Unknown Medications	C				

Date:11/06/00ISR Number: 3607468-9Report Type:Periodic Company Report #M2000.0370
Age:52 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Effect Decreased	Consumer	Haloperidol	PS	Geneva Pharmaceuticals Inc	ORAL	1 TAB, HS, PO	
			Ambien	C				
			Zertex	C				
			Milti-Vitamins	C				

Date:11/06/00ISR Number: 3607654-8Report Type:Expedited (15-DaCompany Report #231189
Age:29 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hepatic Enzyme Increased Hepatitis Pyrexia	Foreign Other	Clonopin	PS	Hoffmann La Roche Inc	ORAL	20 DOSE FORM 1 PER DAY ORAL	
			Haldol (Haloperidol)	SS		ORAL	20 MG 2 PER DAY ORAL	
			Tercian (Cyamemazine)	SS		ORAL	20 MG 1 PER DAY ORAL	
			Risperdal (Risperidone)	C				

Date:11/06/00ISR Number: 3607701-3Report Type:Expedited (15-DaCompany Report #JRFBEL2000002572
Age:19 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Blood Creatine Phosphokinase Increased Injury	Foreign Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute		INTRAMUSCULAR MG, DAILY, IM
	Lethargy Sedation		Vegetamin-A (Vegetamin A)	SS		ORAL	DAILY, ORAL
			Flumezin (Fluphenazine)	C			
			Serenace (Haloperidol)	C			
			Akineton (Biperiden Hydrochloride)	C			

Date:11/06/00ISR Number: 3607911-5Report Type:Expedited (15-DaCompany Report #001-0184-M0000030
Age:91 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Death	Choking	Consumer	Benadryl Hcl	PS	Parke Davis Div Warner Lambert Co	ORAL	PER ORAL
Hospitalization - Initial or Prolonged	Coma Dysphagia	Health Professional					
Other	Overdose Tardive Dyskinesia		Haldol Decanoate (Haloperidol Decanoate)	SS			3 MG
			Zoloft (Sertraline Hydrochloride)	SS			

Date:11/07/00ISR Number: 3608594-0Report Type:Expedited (15-DaCompany Report #JACFRA2000000195
Age:29 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Hepatitis Pyrexia Transaminases Increased	Foreign Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute		

					Div Ortho Pharm	ORAL
20 MG, 1 IN 1 DAY(S), ORAL						
			Rivotril (Clonazepam)	SS		ORAL
ORAL						
			Tercian (Cyamemazine)	C		ORAL
20 MG, DAILY, ORAL						
			Risperdal (Risperidone)	C		

Date:11/07/00ISR Number: 3608691-XReport Type:Expedited (15-DaCompany Report #A044-002-002520
Age:78 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Diarrhoea	Foreign	Aricept	PS	Eisai Inc	ORAL	5 MG, 1 IN 1 D, PER ORAL	
	Drug Interaction	Health						
	Hallucination	Professional	Haloperidol	SS		ORAL	5 MG, PER ORAL	
	Sedation							
	Urinary Incontinence		Amiodarone (Amiodarone)	C				
			Digoxine (Digoxin)	C				
			Enalapril(Enalapril)	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/13/00ISR Number: 3610849-0Report Type:Expedited (15-DaCompany Report #JACFRA2000000722
Age:71 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Akinesia	Foreign	Haldol	PS	Rw Johnson			
	Coma	Health			Pharmaceutical			
	Joint Stiffness	Professional			Research Institute	ORAL	ORAL	
		Other	Imovane (Zopiclone)	C				
			Equanil (Meprobamate)	C				
			Trivstatal (Piribedil)	C				

Date:11/13/00ISR Number: 3611066-0Report Type:Expedited (15-DaCompany Report #JAOCAN2000001048
Age:31 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Rhabdomyolysis	Foreign	Haldol	PS	Rw Johnson			
		Health			Pharmaceutical			
		Professional			Research Institute			

Date:11/14/00ISR Number: 3610931-8Report Type:Direct Company Report #
Age:57 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Extrapyramidal Disorder		Haldol Mcneil Pharm	PS	Mcneil Pharm	ORAL	2 MG PRN	TID
Initial or Prolonged	Jaw Disorder						PO	
Required	Reflexes Abnormal		Acyclovir	C				
Intervention to	Tremor		Zantac	C				
Prevent Permanent			Tazocin	C				
Impairment/Damage			Flagyl	C				
			Heparin	C				
			Multivitamins	C				

Date:11/14/00ISR Number: 3611685-1Report Type:Expedited (15-DaCompany Report #JRFBEL2000002679
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abnormal Behaviour Agitation Attention Deficit/Hyperactivity Disorder Feeling Abnormal Hyperventilation Hypoaesthesia Mental Disorder Muscle Rigidity Speech Disorder	Foreign Literature Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute Div Ortho Pharm		10 MG, 1 IN 1 TIME(S), UNKNOWN	

Date:11/15/00ISR Number: 3611306-8Report Type:Expedited (15-DaCompany Report #231189
Age:29 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hepatitis Pyrexia		Haldol Rivotril Tercian Risperdal	PS SS SS C	Roche		7 DAY 14 DAY 7 DAY	

Date:11/15/00ISR Number: 3612788-8Report Type:Expedited (15-DaCompany Report #231189
Age:29 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Acute Psychosis	Foreign	Clonopin	PS	Hoffmann La Roche Inc	ORAL	20 DOSE FORM	1 PER DAY
	Condition Aggravated	Other						
	Hepatic Enzyme Increased							
	Hepatitis							
	Pyrexia		Haldol (Haloperidol)	SS		ORAL	20 MG 2 PER	DAY ORAL
			Tercian (Cyamemazine)	SS		ORAL	20 MG 1 PER	DAY ORAL
			Risperdal (Risperidone)	C				

Date:11/16/00ISR Number: 3613011-0Report Type:Expedited (15-DaCompany Report #00P-056-0099639-00(0)
Age:1 DY Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Benign Congenital Hypotonia	Foreign Health Professional	Tranxene	PS	Abbott Laboratories Pharmaceutical Products Div			
	Complications Of Maternal Exposure To Therapeutic Drugs		Levomepromazine (Levomepromazine)	SS				
	Electroencephalogram Abnormal		Risperidone (Risperidone)	SS				
	Feeding Problem In Newborn		Haloperidol (Haloperidol)	SS				
	Foetal Macrosomia		Diazepam (Diazepam)	SS				
	Gastrointestinal Disorder							
	Hypoglycaemia							
	Leukopenia							
	Neonatal Disorder							
	Premature Baby							
	Sedation							

	Vasodilatation					

Date:11/16/00ISR Number: 3613084-5Report Type:Expedited (15-DaCompany Report #PHNU2000DE02098
Age:69 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Atrioventricular Block First Degree	Foreign Study	Clozaril	PS	Novartis Pharmaceuticals Corp	ORAL	ORAL	
	Cold Sweat	Health Professional	Hypnorex (Lithium Carbonate)	SS		ORAL	ORAL	
	Electrocardiogram Qt Prolonged	Other	Akineton(Biperiden Hydrochloride)	SS		ORAL	ORAL	
	Heart Rate Decreased		Haldol (Haloperidol)	SS		ORAL	ORAL	
	Sick Sinus Syndrome		Saroten	SS		ORAL	ORAL	
	Sinoatrial Block							
	Sinus Bradycardia							

Date:11/17/00ISR Number: 3613551-4Report Type:Expedited (15-DaCompany Report #JACGER2000001712
Age:62 YR Gender:Female I/FU:I

Outcome
Hospitalization -
Initial or Prolonged
Required

Intervention to Prevent Permanent Impairment/Damage	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Electrocardiogram Qt Prolonged Ventricular Fibrillation	Foreign Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute Div Ortho Pharm	ORAL	MG, DAILY,	ORAL
			Eunerpan (Melperone Hydrochloride)	SS		ORAL	MG, DAILY,	ORAL
			Diazepam (Diazepam)	C				
			Orfiril (Valproate Sodium)	C				

Date:11/17/00ISR Number: 3613554-XReport Type:Expedited (15-DaCompany Report #JACGER2000001713
Age:60 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Creatine Phosphokinase Increased Body Temperature Increased Chills Fear Mutism Neuroleptic Malignant Syndrome Stupor	Foreign Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute Div Ortho Pharm	ORAL	MG, DAILY,	ORAL
			Truxa (Chlorprothixene Hydrochloride)	SS		ORAL	MG, DAILY,	ORAL
			Zyprexa (Olanzapine)	SS		ORAL	MG, DAILY,	ORAL
			Ciatyl-Z Acuphase (Zuclopenthixol					

			Acetate)	SS		

INTRAMUSCULAR 150 MG, 1 IN

1 TIME(S), IM

SEE IMAGE

	Fluanxol (Flupentixol Dihydrochloride)	SS		ORAL

MG, DAILY,

ORAL

	Leptilan (Valproate Sodium)	C		
	Orfiril (Valproate Sodium)	C		

Date:11/17/00ISR Number: 3613556-3Report Type:Expedited (15-DaCompany Report #JACGER2000001716
Age:68 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Arrhythmia	Foreign	Haldol	PS	Rw Johnson	
	Atrioventricular Block	Health			Pharmaceutical	
	Bradycardia	Professional			Research Institute	
	Bundle Branch Block Right				Div Ortho Pharm	ORAL

MG, DAILY,

	Cold Sweat					

ORAL

	Electrocardiogram Qt Prolonged		Hypnorex (Lithium Carbonate)	SS		ORAL

MG, DAILY,

	Sick Sinus Syndrome					

ORAL

	Sinus Bradycardia		Akineton (Biperiden Hydrochloride)	SS		ORAL

MG, DAILY,

ORAL

			Leponex (Clozapine)	SS		ORAL MG, DAILY, ORAL
			Saroten (Amitriptyline Hydrochloride)	SS		ORAL MG, DAILY, ORAL
			Fluanxol (Flupentixol)	C		

Date:11/17/00ISR Number: 3613561-7Report Type:Expedited (15-DaCompany Report #JACGER2000001707
Age:82 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Hospitalization - Initial or Prolonged	Bladder Disorder Blood Folate Decreased Pneumonia	Foreign Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute	ORAL MG, DAILY,ORAL
	Polyneuropathy					
	Pulmonary Congestion		Leponex (Clozapine)	SS		ORAL MG, DAILY, ORAL
	Pyrexia					
	Rales Urinary Retention		Seroxat (Paroxetine Hydrochloride)	SS		ORAL MG, DAILY, ORAL
			Noveril (Dibenzepin Hydrochloride)	C		ORAL MG,DAILY, ORAL
			Tavor (Lorazepam)	C		
			Staurodorm (Staurodorm)	C		
			Chloraldurat Red (Chloral Hydrate)	C		
			Chloraldurat Blue(Chloral			

			Hydrate)	C		

Date:11/20/00ISR Number: 3614867-8Report Type:Expedited (15-DaCompany Report #JRFBEL2000002723
Age:55 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Agitation	Foreign	Haldol	PS	Rw Johnson	
	Blood Creatine	Literature			Pharmaceutical	
	Phosphokinase Increased	Health			Research Institute	
	Clonic Convulsion	Professional			Div Ortho Pharm	
MG, DAILY						
	Confusional State		Etizolam (Etizolam)	C		
	Disorientation		Alprazolam			
	Drug Withdrawal Syndrome		(Alprazolam)	C		
	Dyskinesia					
	Dyspnoea					
	Electroencephalogram Abnormal					
	Hyperhidrosis					
	Irritability					
	Muscle Rigidity					
	Pyrexia					
	Tonic Convulsion					
	Tremor					
	Waxy Flexibility					

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/20/00ISR Number: 3615330-0Report Type:Expedited (15-DaCompany Report #HQ3021031OCT2000
Age:60 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Asthenia Blood Thyroid Stimulating Hormone Decreased Thyroid Adenoma Weight Decreased	Health Professional Other	Inderal	PS	Wyeth Ayerst Laboratories	ORAL	160 MG 1X PER 1 DAY ORAL; 40 MG 1 X PER 1 DAY ORAL	3737 DAY
			Propranolol "Ratiopharm" (Propranolol Hydrochloride)	SS		ORAL	160 MG 1 X PER 1 DAY	
			Vesadol (Buzepide Metiodide/Haloperidol)	SS		ORAL	ORAL	588 DAY
			Apranax (Naproxen Sodium)	C			0.3 MG/3 MG ORAL	171 DAY

Date:11/21/00ISR Number: 3615431-7Report Type:Direct Company Report #
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drooling		Clozapine	PS		ORAL	750 MG Q HS PO	
			Haloperidol Decanoate 100mg Q 4 Weeks	SS			INTRAMUSCULAR	100MG Q

MONTHLY IM

				Trihexyphenidyl	C		
				Maalox	C		

Date:11/21/00ISR Number: 3615580-3Report Type:Expedited (15-DaCompany Report #A037001
Age:57 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Depression Medication Error	Foreign Health Professional	Zoloft	PS	Pfizer Pharmaceuticals Inc	ORAL	50.00 MG TOTAL; DAILY;	
			Haloperidol	SS		ORAL	70.00 MG	TOTAL

Date:11/21/00ISR Number: 3615619-5Report Type:Expedited (15-DaCompany Report #JRFBEL2000002722
Age:38 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death Required Intervention to Prevent Permanent Impairment/Damage	Blood Creatine Phosphokinase Increased Myoglobin Blood Increased Myoglobinuria Pulmonary Haemorrhage Renal Impairment Renal Tubular Disorder Respiratory Failure Rhabdomyolysis	Foreign Literature Health Professional	Haldol Flunitrazepam (Flunitrazepam) Ifosfamide (Ifosfamide)	PS SS SS	Rw Johnson Pharmaceutical Research Institute Div Ortho Pharm		7.5 MG, DAILY, DAILY 1500 MG/M2,	2 DAY 2 DAY

			Carboplatin (Carboplatin)	SS		
250 MG/M2						
			Etoposide (Etoposide)	SS		
300 MG/M2						

Date:11/21/00ISR Number: 3615625-0Report Type:Expedited (15-DaCompany Report #JACGER2000001513
Age:67 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Condition Aggravated Jaundice Jaundice Cholestatic Liver Function Test Abnormal Pancreatic Carcinoma	Foreign Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute Div Ortho Pharm		30 MG, DAILY	

Date:11/21/00ISR Number: 3615728-0Report Type:Expedited (15-DaCompany Report #WAES 00110883
Age:32 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Brain Oedema	Foreign	Vivactil	PS	Merck And Co Inc	ORAL	UNKNOWN	ORAL
	Completed Suicide	Literature	Haloperidol Tab	SS		ORAL	UNKNOWN	ORAL
	Drug Interaction Drug Toxicity Intentional Misuse Muscle Necrosis Necrosis Pulmonary Congestion Pulmonary Haemorrhage Pulmonary Oedema							

Date:11/30/00ISR Number: 3618785-0Report Type:Direct Company Report #
Age:40 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abnormal Behaviour Dystonia Hyperphagia Muscle Rigidity Parkinsonism Tremor		Haloperidol	PS				

Date:11/30/00ISR Number: 3618812-0Report Type:Direct Company Report #
Age:23 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anxiety Difficulty In Walking Dysarthria Extrapyramidal Disorder Movement Disorder Muscle Rigidity		Haloperidol	PS				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/30/00ISR Number: 3619914-5Report Type:Expedited (15-DaCompany Report #JRFBEL2000002749
Age:63 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Choking Completed Suicide Dyskinesia	Foreign Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute Div Ortho Pharm			
			Risperidone(Tablet)(Risperidone)	SS		ORAL	DAILY, ORAL	
			Biperiden Hydrochloride (Biperiden Hydrochloride)	C				

Date:11/30/00ISR Number: 3619997-2Report Type:Expedited (15-DaCompany Report #JACFRA2000000741
Age:76 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Condition Aggravated Confusional State Decreased Activity	Foreign Company Representative	Risperdal	PS	Janssen Research Fdn Div Johnson And Johnson	ORAL	1 MG, 1 IN 1	DAY(S), ORAL
	Disorientation Extrapyramidal Disorder Fall Pyrexia		Hald0l (1 Mg Tablet) (Haloperidol)	SS		ORAL	MG, DAILY,	ORAL
			Surmontil (Trimipramine)	SS		ORAL	12.5 , MG, 1	IN 1 DAY(S), ORAL

Date:11/30/00ISR Number: 3620034-4Report Type:Expedited (15-DaCompany Report #JRFBEL2000002132
Age:22 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardio-Respiratory Arrest Gait Disturbance Haemorrhage Hepatocellular Damage Nasopharyngitis Pneumonia Pyrexia Sudden Death	Foreign Health Professional	Risperdal	PS	Janssen Research Fdn Div Johnson And Johnson	ORAL	4 MG, DAILY, ORAL	
			Haloperidol (Haloperidol)	SS		ORAL	5 MG, DAILY, ORAL	
			Bromperidol (Bromperidol)	SS		ORAL	4 MG DAILY, ORAL	
			Biperiden Hydrochloride (Biperiden Hydrochloride)	C				
			Hydroxyzine Pamoate (Hydroxyzine)	C				
			Etizolam (Etizolam)	C				
			Propericiazine (Periciazine)	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/30/00ISR Number: 3620437-8Report Type:Expedited (15-DaCompany Report #S00-GER-01905-01
Age:68 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Tardive Dyskinesia	Foreign Health Professional Other	Celexa	PS	Forest Laboratories Inc	ORAL	20 MG QD PO	
			Cipramil (Citalopram)	SS		ORAL	30 MG QD PO	
			Cipramil (Citalopram)	SS		ORAL	40 MG QD PO	
			Cipramil (Citalopram)	SS		ORAL	20 MG QD PO	
			Cipramil (Citalopram)	SS		ORAL	40 MG QD PO	
			Cipramil (Citalopram)	SS		ORAL	60 MG QD PO	
			Fluanxol "Lundbeck" (Flupentixol Dihydrachloride)	SS		ORAL	20 MG QD PO	
			Fluanxol "Lundbeck" (Flupentixol Dihydrochloride)	SS		ORAL	30 MG QD PO	
			Fluanxol "Lundbech" (Flupentixol Dihydrochloride)	SS		ORAL	25 MG QD PO	
			Risperdal (Risperidone)	SS			2 MG QD	
			Risperdal (Risperidone)	SS			4 MG QD	
			Risperdal (Risperidone)	SS			6 MG QD	
			Risperdal (Risperidone)	SS			4 MG QD	

	Risperdal (Risperidone)	SS
3 MG QD		
	Risperdal (Risperidone)	SS
2 MG QD		
	Haldol (Haloperidol)	SS
5 MG QD		
	Haldol (Haloperidol)	SS
10 MG QD		
	Haldol (Haloperidol)	SS
5 MG QD		
	Haldol (Haloperidol)	SS
3 MG QD		
	Haldol (Haloperidol)	SS
10 MG QD		
	Haldol (Haloperidol)	SS
12.5 MG QD		
	Haldol (Haloperidol)	SS
10 MG QD		
	Haldol (Haloperidol)	SS
5 MG QD		
	Akineton (Biperiden Hydrochloride)	C
	Trevilor (Venlafaxine Hydrochloride)	C

Date:12/04/00ISR Number: 3620743-7Report Type:Expedited (15-DaCompany Report #A0061345A
Age:22 YR Gender:Male I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Aggression
	Choking Sensation
	Convulsion
	Dermatitis
	Drug Ineffective
	Loss Of Consciousness

	Neck Pain Pain In Extremity Vomiting	Report Source	Product	Role	Manufacturer	Route	Dose Duration
		Health Professional	Lamictal	PS	Glaxo Wellcome	ORAL	100MG Twice per day
			Haldol	SS			
			Risperdal	C			

Date:12/04/00ISR Number: 3622135-3Report Type:Expedited (15-DaCompany Report #JACGER2000001810
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Circulatory Collapse Condition Aggravated Depressed Level Of Consciousness Restlessness Tremor	Foreign Consumer Other	Haldol	PS	Rw Johnson Pharmaceutical Research Institute	ORAL	ORAL

Date:12/06/00ISR Number: 3623397-9Report Type:Direct Company Report #
Age:16 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Fall		Haloperidol	PS			2MG BID
	Syncope		Clonidine	C			

Date:12/08/00ISR Number: 3625454-XReport Type:Expedited (15-DaCompany Report #A0061345A
Age:22 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Abnormal Behaviour	Health	Lamictal	PS	Glaxo Wellcome Inc	ORAL	100 MG /

Initial or Prolonged	Aggression	Professional		
TWICE PER DAY				
	Choking Sensation			
/ ORAL				
	Convulsion		Haloperidol	
	Dermatitis		(Formulation	
	Drug Effect Decreased		Unknown)	
	Hydrocephalus		(Haloperidol)	SS
	Neck Pain		Risperidone	C
	Pain In Extremity			
	Vomiting			

Date:12/08/00ISR Number: 3625492-7Report Type:Expedited (15-DaCompany Report #FLUV00300005767
Age:60 YR Gender:Female I/FU:F

Outcome	PT
Other	Anxiety
	Attention
	Deficit/Hyperactivity
	Disorder
	Depressed Level Of
	Consciousness
	Insomnia
	Laboratory Test Abnormal
	Liver Function Test
	Abnormal
	Neuroleptic Malignant
	Syndrome

		Oedema Peripheral Urinary Incontinence Vomiting	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
			Foreign Study	Luvox	PS	Solvay Pharmaceuticals	ORAL
75 MG DAILY							
			Health Professional				
PO, 50 MG DAILY PO							
			Other	Haloperidol	SS		ORAL
3 MG DAILY PO							
				Defekton (Carpipramine Dihydrochloride)	C		
				Levotomin (Levomepromazine Maleate)	C		
				Ubidecarenone	C		
				Nicorandil	C		
				Timiperone	C		
				Flunitrazepam	C		
				Etizolam	C		
				Zopiclone	C		

Date:12/11/00ISR Number: 3626518-7Report Type:Expedited (15-DaCompany Report #00-11-0599
Age:77 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Life-Threatening	Drug Interaction	Health Professional	Proglycem	PS	Baker Norton Pharmaceuticals Inc	ORAL
Hospitalization - Initial or Prolonged	Hyperglycaemia Ketoacidosis Renal Impairment					
200MG QD ORAL						
			Haldol Oral Suspension	SS		ORAL
30 DROPS ORAL						
			Praxilene	C		
			Fonzylane	C		

Date:12/11/00ISR Number: 3626523-0Report Type:Expedited (15-DaCompany Report #A038497
Age:39 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anger Depression Mental Disorder Sensation Of Heaviness Thrombocythaemia White Blood Cell Count Increased	Consumer	Zoloft Haldol Meridia Lithium Benazepril Loratadine	PS SS SS C C C	Pfizer Pharmaceuticals Inc	ORAL ORAL INTRAMUSCULAR	200.00 MG TOTAL: BID: INTRAMUSCULAR	

Date:12/11/00ISR Number: 3626938-0Report Type:Expedited (15-DaCompany Report #PHRM2000FR01805
Age:1 DY Gender:Male I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Abdominal Distension Abdominal Pain Bradycardia Complications Of Maternal Exposure To Therapeutic Drugs Cyst Gastrointestinal

Malformation
Neonatal Disorder

Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Foreign Health Professional	Anafranil	PS	Novartis Pharmaceuticals Corp	TRANSPLACENTAL	TRANSPLACENTAL	
Other	Haldol(Haloperidol)	SS		TRANSPLACENTAL	TRANSPLACENTAL	
	Xanax(Alprazolam)	SS		TRANSPLACENTAL	TRANSPLACENTAL	

Date:12/11/00ISR Number: 3626982-3Report Type:Expedited (15-DaCompany Report #JACFRA2000000806
Age:86 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Bradycardia	Foreign Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute	ORAL	15 MG, DAILY,	ORAL
		Other	Aldactazine (Aldactazine)	SS		ORAL	ORAL	
			Speciafoldine (Folic Acid)	SS		ORAL	5 MG , 3 IN 1	DAY (S), ORAL
			Tanakan (Ginkgo Tree Leaves Extract)	SS		ORAL	40 MG , 3 IN	1 DAY (S) , ORAL
			Cogenex 10 Mg					

			(Tacrine Hydrochloride)	SS		ORAL
MG, DAILY,						
ORAL						
			...	C		

Date:12/11/00ISR Number: 3626983-5Report Type:Expedited (15-DaCompany Report #JACFRA2000000808
Age:80 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Bradykinesia Dementia Extrapyramidal Disorder Fall	Foreign Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute Div Ortho Pharm	ORAL
2 MG, 3 IN 1 DAY(S), ORAL						
			Temesta (Lorazepam)	SS		ORAL
TABLE, DAILY, ORAL						
			Seropram (Citalopram Hydrobromide)	SS		ORAL
TABLE, DAILY, ORAL						
			Stilnox (Zolpidem)	SS		
MG, DAILY, ORAL						
			Sandocal(Calcium Glubionate)	C		
			Dedrogly(Calcifediol)	C		
			Aspegic (Acetylsalicylate Lysine)	C		
			Hydrocortisone (Hydrocortisone)	C		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/11/00ISR Number: 3627154-9Report Type:Expedited (15-DaCompany Report #HQ4565007DEC2000
Age:80 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Extrapyramidal Disorder Parkinson'S Disease	Health Professional	Ativan	PS	Wyeth Ayerst Laboratories	ORAL	2 TABLETS	DAILY
		Other	Haldol (Haloperidol)	SS		ORAL		52 DAY
			Seropram (Citalopram Hydrobromide)	C				
			Stilnox (Zolpidem)	C				
			Sandocal (Calcium Glubionate)	C				
			Dedrogyl (Calcifediol)	C				
			Aspegic (Acetylsalicylate Lysine)	C				
			Hydrocortisone	C				

Date:12/12/00ISR Number: 3627004-0Report Type:Periodic Company Report #990882.01
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Withdrawal Syndrome Headache	Consumer	Lorazepam	PS	Mylan Pharmaceuticals Inc	ORAL	2MG QID, ORAL	
	Tremor		Haloperidol Tablets 2mg Geneva	SS	Geneva			
			Risperdal	C				

Date:12/12/00ISR Number: 3627820-5Report Type:Expedited (15-DaCompany Report #FLUV00300006313
Age:37 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardiac Arrest	Foreign	Luvox	PS	Solvay			

	Depressed Level Of Consciousness Disseminated Intravascular Coagulation Hypotension Hypoventilation Multi-Organ Failure Neuroleptic Malignant Syndrome Pyrexia	Health Professional Other	Serenace (Haloperidol) Wintermin (Chlorpromazine Hydrochloride) Depakene (Valproate Sodium) Akineton (Biperiden Hydrochloride) Rohypnol (Flunitrazepam)	SS SS SS C C	Pharmaceuticals	ORAL 50 MG DAILY PO, 25 MG DAILY PO ORAL 27 MG DAILY PO ORAL 100 MG DAILY PO ORAL 1800 MG DAILY PO

Date:12/13/00ISR Number: 3629052-3Report Type:Expedited (15-DaCompany Report #001201-SK842
Age:86 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Hospitalization - Initial or Prolonged	Bradycardia	Foreign Other	Aldactazide	PS	Searle Pharmaceuticals Inc	ORAL UNKNOWN PO

			Cognex (Tacrine Hydrochloride)	SS		ORAL
UNKNOWN	PO					
			Haldol (Haloperidol)	SS		ORAL
UNKNOWN	PO					
			Speciafoldine (Folic Acid)	SS		ORAL
UNKNOWN	PO					
			Tanakan (Ginkgo)	SS		ORAL
UNKNOWN	PO					

Date:12/18/00ISR Number: 3633139-9Report Type:Expedited (15-DaCompany Report #2000037456FR
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization - Initial or Prolonged	Bradycardia Complications Of Maternal Health Exposure To Therapeutic Drugs Cyst Gastrointestinal Malformation Neonatal Disorder Premature Baby	Foreign	Xanax	PS	Pharmacia And Upjohn Co	
TRANSPLACENTAL	ORAL					
Congenital Anomaly		Professional Other	Anafranil(Clomipramine Hydrochloride)	SS		
TRANSPLACENTAL	ORAL					
			Haldol(Haloperidol)	SS		
TRANSPLACENTAL	ORAL					

Date:12/18/00ISR Number: 3633738-4Report Type:Expedited (15-DaCompany Report #DEU003714
Age:24 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Death	C-Reactive Protein Increased	Foreign	Akineton	PS	Knoll Pharmaceutical Co	
Hospitalization - Initial or Prolonged	Dystonia Laboratory Test Abnormal Neuroleptic Malignant	Health Professional Other	Serenace	SS		ORAL
INTRAMUSCULAR	5 MG DAILY IM					
12 MG DAILY						
PO						
15 MG DAILY			Serenace	SS		ORAL

	Syndrome					
PO						
	Pneumonia		Serenace	SS		ORAL
18 MG DAILY						
	Respiratory Failure					
PO						
	Salivary Hypersecretion		Vegetamin A	SS		ORAL
1 DF DAILY PO						
	Stupor		Wintermin	SS		ORAL
25 MG DAILY						
PO						
			Linton	C		
			Tasmolin	C		
			Magnesium	C		
			Contomin	C		
			Rohypnol	C		
			Artane	C		
			Parlodel	C		
			Alosenn	C		

Date:12/22/00ISR Number: 3636566-9Report Type:Expedited (15-DaCompany Report #EMADSS2000002052
Age:45 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Aggression Insomnia	Foreign Study Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute Div Ortho Pharm	
SEE IMAGE						
			Risperidone (Tablet) (Risperidone)	SS		
SEE IMAGE						

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/26/00ISR Number: 3638148-1Report Type:Expedited (15-DaCompany Report #JRFUSA2000000095
Age:52 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Accidental Overdose Aggression Akathisia Asthenia Body Temperature Decreased Bradykinesia Cardiac Arrest Chest Pain Convulsion Drug Effect Decreased Drug Withdrawal Syndrome Headache Hyperhidrosis Memory Impairment Parkinsonism Pyrexia Red Blood Cell Count Decreased Sleep Disorder Suicidal Ideation Tachycardia Tardive Dyskinesia Weight Decreased White Blood Cell Count Decreased	Consumer Health Professional	Risperdal Haldol (Tablet) (Haloperidol) Ativan (Lorazepam) Olanzapine (Olanzapine) Seroquel (Seroquel) Zyprexa (Olanzapine) Remeron (Mirtazapine)	PS SS SS C C C C	Janssen Research Fdn Div Johnson And Johnson	ORAL ORAL ORAL	3 MG, 7MG, 6MG, 7.5MG, 8.5MG, 1.5MG, 4 IN 1 , 2 IN 1 DAY(S), 2 MG, 4 IN 1 DAY(S), ORAL 2 MG, 4 IN 1 DAY(S), ORAL

Date:12/26/00ISR Number: 3638624-1Report Type:Expedited (15-DaCompany Report #A039421
Age:66 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dehydration	Health Professional	Zoloft	PS	Pfizer Pharmaceuticals Inc	ORAL	25.00 MG	
Required	Dysarthria							
Intervention to Prevent Permanent Impairment/Damage	Electroencephalogram							
	Abnormal							
	Hypotension		Risperidal	SS		ORAL	1.00 MG	
	Lethargy							
			Haldol	SS				
			Hydrodiuril	SS		ORAL	25.00 MG	
			Aricept	C				
			Levaquin	C				
			Ativan	C				
			Mellaril	C				
			Diovan	C				
			Timoptic	C				
			Ecotrin	C				
			Multivitamin	C				
			Vitamin E	C				
			Prozac	C				

TOTAL:DAILY:O

RAL

INTRAMUSCULAR 4.00 MG

TOTAL:PRN:INT

RAMUSCULAR

TOTAL:DAILY:O

RAL

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/26/00ISR Number: 3639316-5Report Type:Expedited (15-DaCompany Report #PHBS2000JP10906
Age:74 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Circadian Rhythm Sleep Disorder	Foreign Literature	Ludiomil	PS	Novartis Pharmaceuticals Corp	ORAL	10 MG DAY	
	Clonic Convulsion	Health Professional	Tetramide (Mianserin Hydrochloride) Tablet	SS		ORAL	10 MG DAY	
	Convulsion							
	Delirium							
	Hallucinations, Mixed							
	Hyperhidrosis							
	Pyrexia							
	Serotonin Syndrome		Serenace (Haloperidol) Tablet	SS		ORAL	0.75 MG DAY	ORAL

Date:12/29/00ISR Number: 3639475-4Report Type:Expedited (15-DaCompany Report #NSADSS2000003009
Age:77 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Hospitalization - Initial or Prolonged	Dehydration Diabetes Mellitus Ketoacidosis	Foreign Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute	ORAL	30 DROP,	DAILY, ORAL
	Renal Impairment		Haldol Decanoate (Injection) (Haloperidol Decanoate)	SS		INTRAMUSCULAR	IM	
			Proglycem (Diazoxide)	SS			200 MG, DAILY	

Date:01/02/01ISR Number: 3640469-3Report Type:Expedited (15-DaCompany Report #NSADSS2000003005
Age:49 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Aggression	Literature	Haldol	PS	Rw Johnson Pharmaceutical Research Institute	INTRAMUSCULAR	5 MG, IM; 10 MG, IM	
	Anxiety	Health						
	Cardio-Respiratory Arrest	Professional						
	Coma							
	Cyanosis		Lorazepam	C				
	Disorientation		Diphenhydramine	C				
	Nausea							
	Restlessness							

Date:01/03/01ISR Number: 3641459-7Report Type:Expedited (15-DaCompany Report #PHBS2000JP04474
Age:24 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Respiratory Failure	Foreign	Parlodel (Bromocriptine Mesilate)	PS	Novartis Pharmaceuticals Corp	ORAL	2.5 MG/D ORAL	
		Health						
		Professional						
		Other	Serenace (Haloperidol)	SS		ORAL	12 MG/D ORAL; 15 MG/D ORAL; 18 MG/D ORAL	
			Akineton (Biperiden Hydrochloride)	SS		ORAL	6 MG/D ORAL	
			Wintermin					

			(Chlorpromazine Hydrochloride)	SS			ORAL 25 MG/D ORAL
			Vegetamin A (Chlorpromazine Hydrochloride, Promethazine) Tablet	SS			ORAL 1 TAB/D ORAL
			Artane (Trihexyphenidyl Hydrochloride)	C			ORAL 6 MG/D ORAL
			Dantrolene (Dantrolene)	C			

Date:01/04/01ISR Number: 3641919-9Report Type:Direct Company Report #
Age:48 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Torsade De Pointes		Haloperidol	PS				
Required Intervention to Prevent Permanent Impairment/Damage			Lorazepam	C				
			Nicotine Transdermal Patch	C				
			Temazepam	C				
			Doxepin	C				
			Fluoxetine	C				
			Triamcinolone	C				
			Estrogens	C				
			Ensure	C				
			Furosemide	C				
			Acetaminophen/Codeine	C				
			Docusate	C				
			Risperidone	C				
			Cefazolin	C				
			Folic Acid	C				
			Thiamine	C				
			Mvi	C				

Date:01/05/01ISR Number: 3641958-8Report Type:Direct Company Report #
Age:68 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Disability Required Intervention to Prevent Permanent Impairment/Damage	Balance Disorder Difficulty In Walking Memory Impairment Psychotic Disorder Speech Disorder		(Halcyon)-Haloperidol	PS			5MG 3 X/DAY	3 WK

Date:01/08/01ISR Number: 3644022-7Report Type:Expedited (15-DaCompany Report #HQ5542404JAN2001
Age:97 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Abnormal Behaviour Anxiety Confusional State Sleep Disorder	Foreign Health Professional Other	Ativan Haldol (Haloperidol) Imovane (Zopiclone) Cordipatch (Glyceryl Trinitrate)	PS SS SS C	Wyeth Ayerst Laboratories	ORAL ORAL	2 MG DAILY 2 MG/ML ORAL	

			Zovirax (Aciclovir)	C			
			Koretic (Hydrochlorothiazide /Quinapril Hydrochloride)	C			
			Rabeprazole (Rabeprazole)	C			
			Forlax (Macrogol)	C			
			Gaviscon "Smith Kline Beecham" (Aluminium Hydroxide Gel, Dried/Magnesium Trisilicate)	C			
			Motilium (Domperidone)	C			

Date:01/10/01ISR Number: 3645720-1Report Type:Expedited (15-DaCompany Report #NSADSS2001000056
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hepatic Failure Psychotic Disorder	Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute	ORAL		

ORAL

Date:01/11/01ISR Number: 3646530-1Report Type:Expedited (15-DaCompany Report #00-11-0599
Age:77 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Hospitalization - Initial or Prolonged	Dehydration Drug Interaction Hyperglycaemia Ketoacidosis Overdose Renal Impairment	Foreign Health Professional	Proglycem Haldol Oral Suspension Praxilene Fonzylane	PS SS C C	Baker Norton Pharmaceuticals Inc	ORAL ORAL	200MG QD 30 DROPS	ORAL ORAL

Date:01/12/01ISR Number: 3647374-7Report Type:Expedited (15-DaCompany Report #EMADSS2001000051
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Convulsion Encephalopathy Memory Impairment Pyrexia Urinary Tract Infection	Foreign Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute Div Ortho Pharm			
			Nozinan (Levomepromazine)	C				
			Solian (Amisulpride)	C				

Date:01/16/01ISR Number: 3648128-8Report Type:Direct Company Report #
Age:25 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Agitation		Haloperidol	PS				
INTRAMUSCULAR							2MG Q 6 HOURS	
	Condition Aggravated							
PRN. MAY USE								
IM FORM								
			Gabapentin	C				
			Olanzapine	C				
			Lansoprazole	C				

			Mirtazapine	C		
			Propranolol	C		
			Ibuprofen	C		
			Salmetrol Inhaler	C		
			Benztropine	C		

Date:01/16/01ISR Number: 3648227-0Report Type:Direct Company Report #
Age:16 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Dyspnoea		Haloperidol	PS		OTHER	5MG Q 4 H PRN	
	Speech Disorder		Risperidone	SS		ORAL	1 MG BID	
	Throat Tightness		Lithium	C				
	Tongue Oedema		Melatonin	C				
			Multivitamin	C				

Date:01/16/01ISR Number: 3648938-7Report Type:Expedited (15-DaCompany Report #02333
Age:40 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Literature	Phenobarbital	PS		ORAL	ORAL	
	Intentional Misuse		Valproic Acid	SS		ORAL	ORAL	
			Haloperidol	SS				

Date:01/16/01ISR Number: 3649034-5Report Type:Expedited (15-DaCompany Report #EMADSS2001000073
Age:75 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Potassium Abnormal	Foreign	Haldol	PS	Rw Johnson Pharmaceutical Research Institute	ORAL	20 MG, DAILY, ORAL	
	Dyspnoea	Health Professional						
	Fluid Overload							
	Hyponatraemia	Other						

	Malaise					

Date:01/17/01ISR Number: 3649438-0Report Type:Expedited (15-DaCompany Report #2000UW03450
Age:16 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agitation	Health Professional	Seroquel	PS	Astrazeneca Pharmaceuticals Lp	ORAL	100 MG BID PO	
	Dermatitis Contact							
	Drug Interaction		Zyprexa	SS			5 MG BID	
	Dystonia		Effexor	SS				
	Pruritus		Haloperidal	SS			INTRAMUSCULAR	10 MG IM
	Torticollis							
	Vomiting							
	Weight Increased							

Date:01/18/01ISR Number: 3651089-9Report Type:Expedited (15-DaCompany Report #EMADSS2001000045
Age: Gender:Male I/FU:I

Outcome
Hospitalization - Initial or Prolonged
Congenital Anomaly
Required Intervention to

Prevent Permanent
Impairment/Damage

	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Abdominal Distension		Haldol	PS	Rw Johnson Pharmaceutical Research Institute Div Ortho Pharm	OTHER	UNK, UTERINE	
	Abdominal Mass							
	Abdominal Pain							
	Bradycardia							
	Complications Of Maternal Exposure To Therapeutic Drugs		Tardyferon (Ferrous Sulfate)	C				
	Cyst		Zymafluor (Sodium Fluoride)	C				
	Electrocardiogram Abnormal		Xanax (Alprazolam)	C				
	Feeding Problem In Newborn		Anafranil (Clomipramine Hypochloride)	C				
	Foetal Growth Retardation							
	Neonatal Disorder							
	Small For Dates Baby							
	Small Intestinal Anastomosis							
	Vomiting							

Date:01/19/01ISR Number: 3650629-3Report Type:Direct Company Report #
Age:45 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Neuroleptic Malignant Syndrome		Olanzapine	PS		ORAL	20MG,20M QD	
			Haloperidol 5mg/Ml Inj, Soln	SS		INTRAMUSCULAR	2.5MG Q6H IM	

Date:01/19/01ISR Number: 3650644-XReport Type:Direct Company Report #
Age:54 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Hospitalization - Initial or Prolonged	Neuroleptic Malignant Syndrome		Risperidone 4MG,4MG QD	PS		ORAL
			Haloperidol Tablet 2MG PO	SS		ORAL
			Haloperidol 5mg/Ml Inj, Soln , IM	SS		INTRAMUSCULAR

2MG,Q4H, PRN

Date:01/22/01ISR Number: 3652386-3Report Type:Expedited (15-DaCompany Report #EMADSS2001000104
Age:75 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Asthenia Atrial Fibrillation Blood Pressure Decreased Dizziness Dyspnoea Exertional Heart Rate Increased Insomnia Palpitations	Foreign Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute			
			Risperdal (1 Mg/Ml Solution)(Risperidone)	SS			2 M., 1 DAILY	
			Artane (Trihexyphenidyl Hydrochloride)	SS				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/23/01ISR Number: 3652278-XReport Type:Expedited (15-DaCompany Report #A0061345A
Age:22 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Aggression		Lamictal	PS	Glaxo Wellcome	ORAL	100MG Twice per day	
	Choking Sensation							
	Convulsion		Haldol	SS				
	Dermatitis		Risperdal	C				
	Disturbance In Attention							
	Drug Ineffective							
	Loss Of Consciousness							
	Neck Pain							
	Pain In Extremity							
	Paralysis							
	Weight Increased							

Date:01/23/01ISR Number: 3653372-XReport Type:Expedited (15-DaCompany Report #EMADSS2001000164
Age:37 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Gestational Diabetes Pregnancy	Foreign Health Professional	Haldol Decanate	PS	Rw Johnson Pharmaceutical Research Institute	INTRAMUSCULAR	50 MG, 1 IN	21 DAY(S), IM
			Nozinan (Levomepromazine)	C				
			Akineton (Biperiden Hydrochloride)	C				

Date:01/23/01ISR Number: 3653752-2Report Type:Expedited (15-DaCompany Report #HQ5882512JAN2001
Age:56 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Alcohol Withdrawal Syndrome	Literature	Ativan	PS	Wyeth Ayerst Laboratories			
	Arrhythmia		Advil (Ibuprofen,					

	Atrial Flutter	Unspec)	SS
	Cyanosis	Atenolol (Atenolol)	SS
	Drug Level Above	Diazepam (Diazepam,	
	Therapeutic	Tablet, Unspec)	SS
	Hyperhidrosis	Dixyrazine	
	Muscle Spasms	(Dixyrazine,)	SS
	Musculoskeletal Stiffness	Haloperidol	
	Pyrexia	(Haloperidol,)	SS
	Tachycardia	Ibuprofen	
		(Ibuprofen,)	SS
		Orudix (Ketoprofen,	
		Unspec)	SS
		Tramadol (Tramadol,	
		)	SS

Date:01/25/01ISR Number: 3653991-0Report Type:Direct Company Report #
Age:69 YR Gender:Male I/FU:I

Outcome	PT
Life-Threatening	Acute Psychosis
	Balance Disorder
	Blood Creatine
	Phosphokinase Increased

		Blood Creatinine Increased Condition Aggravated	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
		Confusional State		Haloperidol	PS		
REFER TO							
		Oral Intake Reduced					
SUMMARY							
		Parkinsonism		Lithium Carbonate	SS		
		Pneumonia					
		Respiratory Arrest					
		Speech Disorder					

Date:01/29/01ISR Number: 3657257-4Report Type:Expedited (15-DaCompany Report #2001041167CH
Age:85 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization - Initial or Prolonged	Inappropriate Antidiuretic Hormone Secretion	Foreign Health Professional Other	Aldactazide	PS	Searle Pharmaceuticals Inc	
			Haloperidol (Haloperidol)	SS		ORAL
5 MG, QD,						
ORAL						
			Lisinopril (Lisinopril)	SS		ORAL
5MG/DAY, ORAL						
			Prednisolone	C		
			Clomethiazole (Clomethiazole)	C		

Date:01/30/01ISR Number: 3659274-7Report Type:Expedited (15-DaCompany Report #WAES 01018225
Age:85 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Other	Inappropriate Antidiuretic Hormone Secretion	Foreign Other	Prinivil	PS	Merck Research Laboratories Div Merck Co Inc	ORAL
5 MG						
			Buthiazide	SS		ORAL
			Haloperidol	SS		ORAL

Acenocoumarol	C
Clomethiazole	C
Prednisone	C
Spironolactone	C

Date:02/01/01ISR Number: 3658239-9Report Type:Direct Company Report #
Age:82 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Inappropriate Antidiuretic Hormone Secretion	Health Professional	Haloperidol	PS		ORAL	5 MG BID, BID	

Date:02/01/01ISR Number: 3659883-5Report Type:Expedited (15-DaCompany Report #NSADSS2001001866
Age:19 YR Gender:Female I/FU:I

Outcome
Death Hospitalization - Initial or Prolonged

Required Intervention to Prevent Permanent Impairment/Damage	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Cardiac Disorder Coma Electrocardiogram Abnormal Sinus Tachycardia	Health Professional	Risperdal	PS	Janssen Research Fdn Div Johnson And Johnson	ORAL	2 MG, 2 IN 1 DAY(S), ORAL; 3 MG, ORAL	
			Haldol (Injection) (Haloperidol)	SS		INTRAMUSCULAR	5, IM	
			Ativan (Lorazepam)	C				

Date:02/01/01ISR Number: 3660612-XReport Type:Expedited (15-DaCompany Report #EMADSS2001000175
Age:89 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Hepatitis	Foreign Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute	ORAL	0.5 MG, ORAL	
			Augmentin (Clavulin)	SS		ORAL	33 G, 1 DAILY, ORAL	
			Gardenal (Phenobarbital)	SS		ORAL	75 MG, 1 DAILY, ORAL	
			Kardegic (Acetylsalicylate Lysine)	SS		ORAL	160 MG, 1 DAILY, ORAL	

Date:02/01/01ISR Number: 3660614-3Report Type:Expedited (15-DaCompany Report #EMADSS2001000150
Age:68 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Antinuclear Antibody Positive	Foreign Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute	ORAL	DAILY, ORAL	
	Blood Immunoglobulin A Increased		Anafranil (Clomipramine Hydrochloride)	SS			25 MG, ORAL	
	Blood Immunoglobulin G Increased		Largactil (Chlorpromazine Hydrochloride)	SS		ORAL	25 MG, ORAL	
	Cerebrovascular Disorder		Depamide (Valpromide)	SS		ORAL	300, ORAL	
	Extrapyramidal Disorder		Aspegic (Acetylsalicylate Lysine)	C				
	Haemorrhage		Mepronizine	C				
	Laboratory Test Abnormal		Artane (Trihexyphenidyl Hydrochloride)	C				
			Seresta (Oxazepam)	C				
			Zocor (Simvastatin)	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/01/01ISR Number: 3660620-9Report Type:Expedited (15-DaCompany Report #DEU003868
Age:33 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Disability	Aggression Agitation Anxiety Attention Deficit/Hyperactivity Disorder Condition Aggravated Hydronephrosis Neurogenic Bladder Urinary Tract Infection	Foreign Health Professional Other	Akineton Serenace Rohypnol Lendormin Depas	PS SS C C C	Knoll Pharmaceutical Co	ORAL	2 MG DAILY PO	

Date:02/05/01ISR Number: 3662808-XReport Type:Expedited (15-DaCompany Report #EMADSS2001000217
Age:52 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agranulocytosis	Foreign Health Professional	Risperdal Haldol (Unspecified) (Haloperidol) Lepticur (Tropatepine Hydrochloride) Theralene (Alimemazine Tartrate) Imovane (Zopiclone) Tercian (Cyamemazine)	PS SS SS SS SS SS	Janssen Research Fdn			

Date:02/07/01ISR Number: 3662203-3Report Type:Expedited (15-DaCompany Report #EMADSS2001000054
Age:75 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Hospitalization - Initial or Prolonged	Bradycardia Coma Dyskinesia	Foreign Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute			

	Extrapyramidal Disorder				Div Ortho Pharm	ORAL	
ORAL							
	Grand Mal Convulsion		Tinset (Unspecified)				
	Hyperpyrexia		(Oxatomide)	SS		ORAL	
2 IN 1 DAILY,							
	Metabolic Acidosis						
ORAL 4 DAY							
	Mydriasis		Effexor (Venlafaxine				
	Serotonin Syndrome		Hydrochloride)	C			
	Tachycardia						

Date:02/07/01ISR Number: 3662326-9Report Type:Expedited (15-DaCompany Report #NSADSS2001001866
Age:19 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Coma	Health	Risperdal	PS	Janssen Research Fdn	ORAL	SEE IMAGE	
Hospitalization - Initial or Prolonged	Electrocardiogram	Professional	Haldol (Injection)	SS				
	Abnormal		Ativan (Lorazepam)	C				
Required	Electrocardiogram T Wave							
Intervention to	Inversion							
Prevent Permanent	Heart Disease Congenital							
Impairment/Damage	Sinus Tachycardia							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/08/01ISR Number: 3662820-0Report Type:Expedited (15-DaCompany Report #NSADSS2001002465
Age:50 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Chest Pain	Health	Risperdal	PS	Janssen Research Fdn	ORAL	3 MG 2 IN 1	
	Myocardial Infarction	Professional					DAY(S) ORAL	
	Nasal Congestion		Haldol (Injection) (Haloperidol)	SS			INTRAMUSCULAR	25 MG 1 IN 2 WEEK(S) IM
			Trazodone (Trazodone)	C				
			Cogentin (Benzatropine Mesilate)	C				

Date:02/09/01ISR Number: 3664260-7Report Type:Expedited (15-DaCompany Report #JRFUSA2000000095
Age:52 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Aggression	Consumer	Risperdal	PS	Janssen Research Fdn	ORAL	3 MG, 2 IN 1 DAY(S), ORAL	
Required Intervention to Prevent Permanent Impairment/Damage	Akathisia	Health					; 7 MG, DAILY, ORAL ; 6 MG, DAILY, ; 7.5 MG, DAILY, ORAL ; 8.5 MG, DAILY, ORAL ;	
	Arthralgia	Professional						
	Asthenia							
	Body Temperature Decreased		Risperdal(Tablet) (Risperidone)	SS		ORAL		
	Bone Marrow Depression							
	Bradykinesia							
	Cardiac Arrest							
	Chest Pain							

	Confusional State					
1.5 MG, 4 IN						
	Convulsion		Haldol(Tablet)			
	Difficulty In Walking		(Haloperidol)	SS		ORAL
2 MG, 4 IN 1						
	Drug Withdrawal Syndrome					
DAY(S), ORAL						
	Dyskinesia		Ativan(Lorazepam)	SS		ORAL
2 MG, 4 IN 1						
	Headache					
DAY(S), ORAL						
	Hyperhidrosis		Olanzapine	C		
	Memory Impairment		Seroquel	C		
	Parkinsonism		Zyprexa(Olanzapine)	C		
	Peripheral Coldness		Remeron(Mirtazapine)	C		
	Psychotic Disorder					
	Pulse Absent					
	Pyrexia					
	Red Blood Cell Count Decreased					
	Sleep Disorder					
	Suicidal Ideation					
	Tachycardia					
	Tardive Dyskinesia					
	Weight Decreased					
	White Blood Cell Count Decreased					

Date:02/12/01ISR Number: 3664043-8Report Type:Periodic Company Report #HQ9368703AUG2000
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Drug Level Above Therapeutic	Health Professional	Effexor	PS	Wyeth Ayerst Laboratories	
			Haldol (Haloperidol)	SS		

Date:02/12/01ISR Number: 3664586-7Report Type:Expedited (15-DaCompany Report #FLUV00300006313
Age:37 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Blood Pressure Decreased Cardiac Arrest	Foreign Health	Luvox	PS	Solvay Pharmaceuticals	ORAL	50 MG DAILY	
	Depressed Level Of Consciousness	Professional					PO, 25 MG DAILY PO	
	Disseminated Intravascular Coagulation		Serenace (Haloperidol)	SS		ORAL	9 MG DAILY PO	
	Hypopnoea Multi-Organ Failure Neuroleptic Malignant Syndrome		Wintermin (Chlorpromazine Hydrochloride)	SS		ORAL	100 MG DAILY PO	
	Pyrexia		Depakene (Valproate Sodium)	SS		ORAL	600 MG DAILY PO	
			Akineton (Biperiden Hydrochloride)	C				

Date:02/13/01ISR Number: 3664802-1Report Type:Expedited (15-DaCompany Report #US_981214565
Age:24 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abortion Spontaneous Pregnancy Vaginal Haemorrhage	Study Health Professional	Haloperidol	PS			2 MG/DAY	

Date:02/13/01ISR Number: 3665029-XReport Type:Expedited (15-DaCompany Report #PHBS2001JP00910
Age:3 DY Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Clonic Convulsion	Foreign	Ritalin Tab	PS				
	Complications Of Maternal Exposure To Therapeutic Drugs	Health Professional Other	Anafranil(Clomipramine Hydrochloride) Tablet	SS				
	Convulsion Neonatal		Wintermin(Chlorpromazine Hydrochloride)	SS				
TRANSPLACENTAL	TRANSPLACENTA Jaundice Neonatal							
L	Neonatal Disorder		Serenace(Haloperidol)	SS				
			Contomin(Chlorpromazine Hydrochloride)	SS				
TRANSPLACENTAL	TRANSPLACENTA							
L			Artane(Trihexyphenidyl Hydrochloride)	SS				
TRANSPLACENTAL	TRANSPLACENTA							
L								

Date:02/16/01ISR Number: 3666104-6Report Type:Direct Company Report #
Age:85 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Balance Disorder		Haldol	PS			7-8 MG/DAY	
	Muscle Rigidity							
	Parkinsonism							
	Tremor							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/16/01ISR Number: 3667530-1Report Type:Expedited (15-DaCompany Report #PHBS2001JP00910
Age:3 DY Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Clonic Convulsion	Foreign	Anafranil(Clomipramine Hydrochloride)					
	Complications Of Maternal Exposure To Therapeutic Drugs	Health Professional Other	Tablet	PS		TRANSPLACENTAL	TRANSPLACENTAL	
	Convulsion Neonatal		Ritaline(Methylphenidate Hydrochloride)					
	Crying							
	Dyskinesia Neonatal		Tablet	SS		TRANSPLACENTAL	TRANSPLACENTAL	
	Jaundice Neonatal							
			Wintermin(Chlorpromazine Hydrochloride)	SS		TRANSPLACENTAL	TRANSPLACENTAL	
			Serenace(Haloperidol)	SS		TRANSPLACENTAL	TRANSPLACENTAL	
			Contomin(Chlorpromazine Hydrcochloride)	SS		TRANSPLACENTAL	TRANSPLACENTAL	
			Artane(Trihexyphenidyl Hydrochloride)	SS		TRANSPLACENTAL	TRANSPLACENTAL	

Date:02/20/01ISR Number: 3666690-6Report Type:Expedited (15-DaCompany Report #239349
Age:51 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Aggression		Valium Tablets	PS	Roche			
	Agitation		Haldol	SS				

	Blood Creatine	Neurocil	SS
	Phosphokinase Increased	Timonil 300 Retard	C
	C-Reactive Protein	Akineton Retard	C
2 DAY			
	Increased	Tavor	C
1 DAY			
	Cyanosis	Mono Embolex	C
16 DAY			
	Dysarthria		
	Dyspnoea		
	Gait Disturbance		
	Loss Of Consciousness		
	Respiratory Failure		
	Tongue Disorder		
	Urinary Incontinence		

Date:02/20/01ISR Number: 3666731-6Report Type:Direct Company Report #
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Neuroleptic Malignant Syndrome		Haldol	PS		ORAL	5MG PO BID	
			Olanzapine	SS				
			Cogentin	C				
			Ativan	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/21/01ISR Number: 3668962-8Report Type:Periodic Company Report #JRFUSA1999000190
Age:28 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - SEE IMAGE	Aggression	Consumer	Risperdal	PS	Janssen Research Fdn	ORAL		
Initial or Prolonged	Alopecia		Haldol (Tablet) (Haloperidol)	SS		ORAL		
	Anxiety							
	Condition Aggravated		Zinc (Zinc)	C				
	Convulsion							
	Coordination Abnormal							
	Dermatitis							
	Dystonia							
	Gastrointestinal Disorder							
	Headache							
	Hepatocellular Damage							
	Herpes Zoster							
	Hypersensitivity							
	Hypertension							
	Injury							
	Insomnia							
	Muscular Weakness							
	Sedation							
	Tachycardia							
	Thinking Abnormal							

Date:02/21/01ISR Number: 3669005-2Report Type:Periodic Company Report #JRFUSA2000001403
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - SEE IMAGE	Diarrhoea	Health	Risperdal	PS	Janssen Research Fdn	ORAL		
Initial or Prolonged	Hyponatraemia	Professional	Haldol Decanoate (Injection) (Haloperidol Decanoate)	SS		INTRAMUSCULAR	100 MG, 1 IN	
Required Intervention to Prevent Permanent Impairment/Damage							2 WEEK(S), IM	
			Cogentin (Benzatropine Mesilate)	C				

Date:02/21/01ISR Number: 3669439-6Report Type:Expedited (15-DaCompany Report #239349
Age:51 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Aggression	Study	Valium	PS	Hoffmann La Roche Inc	ORAL	15 MG DAILY	
	Agitation	Health						
	Blood Creatine Phosphokinase Increased	Professional	Haldol (Haloperidol)	SS			20 MG DAILY	
	Cyanosis		Neurocil (Methotrimeprazine)	SS				
	Dyspnoea							
	Loss Of Consciousness		Timonil 300 Retard (Carbamazepine)	C				
	Obstructive Airways Disorder		Akineton Retard (Biperiden Hydrochloride)	C				
	Parkinsonism							
	Respiratory Failure		Tavor (Lorazepam)	C				
	Sedation		Mono Embolex (Certoparin Sodium)	C				
	Stupor							
	Urinary Incontinence							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/21/01ISR Number: 3669677-2Report Type:Periodic Company Report #JRFUSA2000000014
Age:20 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Condition Aggravated	Consumer	Risperdal	PS	Janssen Research Fdn	ORAL	1 MG. 1 IN 1	DAY(S), ORAL
			Haldol	SS		ORAL		
			Cogentin(Benzatropine Mesilate)	C				
			Ativan(Lorazepam)	C				

Date:02/21/01ISR Number: 3669683-8Report Type:Periodic Company Report #JRFUSA2000000064
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hypotension	Health	Risperdal	PS	Janssen Research Fdn	ORAL	2 MG 1 IN 2	DAY(S), ORAL
Required Intervention to Prevent Permanent Impairment/Damage	Neuroleptic Malignant Syndrome	Professional	Haldol Decanoate	SS			100 MG, 1 IN	1 MONTH(S) IM
			Haldol	SS				ORAL
			Klonopin (Clonazepam)	C				
			Depakote (Valproate Semisodium)	C				

Date:02/21/01ISR Number: 3669685-1Report Type:Periodic Company Report #JRFUSA2000000095
Age:52 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Asthenia	Consumer	Risperdal	PS	Janssen Research Fdn	ORAL	3 MG. 2 IN 1	

Initial or Prolonged	Cardiac Arrest					
DAY(S), ORAL						
Required	Chest Pain		Haloperidol	SS		ORAL
2 MG, 4 IN 1						
Intervention to	Extrapyramidal Disorder					
DAY(S), ORAL						
Prevent Permanent	Feeling Of Body		Avitan(Lorazepam)	C		
Impairment/Damage	Temperature Change		Olanzapine			
	Headache		(Olanzapine)	C		
	Sensory Disturbance					
	Tachycardia					

Date:02/21/01ISR Number: 3669786-8Report Type:Expedited (15-DaCompany Report #EMADSS2001000371
Age:25 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Malaise	Foreign	Haldol	PS	Rw Johnson	
Initial or Prolonged	Muscular Weakness	Health			Pharmaceutical	
	Sedation	Professional			Research Institute	
	Tachycardia				Div Ortho Pharm	ORAL
ORAL						
			Tercian			
			(Cyamemazine)	SS		ORAL
2, ORAL						
			Zoloft	SS		ORAL
50 MG, DAILY,						
ORAL						

Date:02/21/01ISR Number: 3669806-0Report Type:Expedited (15-DaCompany Report #EMADSS2001000370
Age:51 YR Gender:Female I/FU:I

Outcome	PT	Report Source
Hospitalization -	Hepatitis	Foreign
Initial or Prolonged		Health

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Professional

Dose	Duration	Product	Role	Manufacturer	Route
		Haldol	PS	Rw Johnson Pharmaceutical Research Institute	ORAL
10 DROPS, 1 IN 1 DAY(S), ORAL					
		Ertythromycin (Erythromycin Estolate)	SS		ORAL
1200 MG, 1 IN 1 DAY(S), ORAL					

Date:02/21/01ISR Number: 3669810-2Report Type:Expedited (15-DaCompany Report #EMADSS2001000363
Age:55 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization - Initial or Prolonged	Hypothermia	Foreign Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute	
HALOPERIDOL REPLACED HALOPERIDOL DECOANOATE						
			Nozinan (Levomepromazine)	SS		
			Lysanxia (Prazepam)	C		
			Parkinane (Trihexyphenidyl Hydrochloride)	C		
			Haldol Decanoas (Haloperidol Decanoate)	C		

Date:02/21/01ISR Number: 3669813-8Report Type:Expedited (15-DaCompany Report #EMADSS2001000500
Age:63 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hypersensitivity	Foreign Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute Div Ortho Pharm	ORAL	ORAL	

Date:02/21/01ISR Number: 3673806-4Report Type:Periodic Company Report #JRFUSA1999001216
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Condition Aggravated	Consumer	Risperdal	PS	Janssen Research Fdn	ORAL	ORAL	
Initial or Prolonged	Dizziness		Haldol	SS		ORAL	ORAL	
	Malaise							

Date:02/22/01ISR Number: 3668433-9Report Type:Direct Company Report #
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hypotension		Haldol	PS		ORAL	5 MG TID ORAL	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/23/01ISR Number: 3669787-XReport Type:Expedited (15-DaCompany Report #NSADSS2001002956
Age:65 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Atrioventricular Block Complete	Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute	
INTRAVENOUS 5 MG, PRN, IV						
	Meningitis		Lorazepam			
	Sinus Tachycardia		(Lorazepam)	SS		
INTRAVENOUS 2 MG, PRN, IV						

Date:02/23/01ISR Number: 3670208-1Report Type:Expedited (15-DaCompany Report #NSADSS20010003731
Age:25 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Aggression	Foreign	Risperdal	PS	Janssen Research Fdn	ORAL
SEE IMAGE						
Hospitalization -	Cardiac Arrest	Health	Haloperidol	SS		
INTRAMUSCULAR 10 MG, 1 IN 8						
Initial or Prolonged		Professional				
HOUR(S), IM						
			Diacepam	SS		
INTRAMUSCULAR 20 MG, 1 IN 8						
HOUR(S), IM						
			Levopromacine	SS		
INTRAMUSCULAR 25 MG, 1 IN 8						
HOUR(S), IM						

Date:02/26/01ISR Number: 3670534-6Report Type:Expedited (15-DaCompany Report #US_010259401
Age:47 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Anaemia	Study	Haloperidol	PS		
1 DSG FORM/1						
Initial or Prolonged	Blood Chloride Decreased	Health				
AT BEDTIME						
	Blood Ketone Body Absent	Professional	Benzotropine			

	Blood Potassium Decreased		(Benzatropine			
	Blood Sodium Decreased		Mesilate)	SS		
1 DSG FORM/1						
	Chest Pain					
AT BEDTIME						
	Condition Aggravated					
	Diabetes Mellitus					
	Gastrointestinal					
	Haemorrhage					
	Hypoaesthesia					
	Malaise					
	Muscle Spasms					
	Nausea					
	Rectal Haemorrhage					
	Vision Blurred					
	Vomiting					
	Weight Decreased					

Date:02/26/01ISR Number: 3671264-7Report Type:Expedited (15-DaCompany Report #EMADSS2001000370
Age:58 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hepatic Enzyme Increased Hepatitis Hyperbilirubinaemia	Foreign Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute	ORAL	10 DROPS, 1	IN 1 DAY(S),
						ORAL		
			Ertythromycin (Erythromycin Estolate)	SS		ORAL	1200 MG, 1 IN	1 DAY(S),
						ORAL		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/26/01ISR Number: 3675811-0Report Type:Periodic Company Report #A005840
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Agitation	Health Professional	Zoloft	PS	Pfizer Pharmaceuticals Inc		100.00 MG	TOTAL: DAILY
	Depression							
	Hallucination							
	Hostility		Haldol	SS			4.00 MG	TOTAL: DAILY
			Calcium Supplement	C				
			Premarin	C				
			Multivitamin	C				

Date:02/27/01ISR Number: 3671290-8Report Type:Direct Company Report #
Age:68 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Aspiration		Haldol (Haloperidol)	PS			5 MG IM / PO	
Life-Threatening	Dyspnoea						Q 4 HRS PRN	
Hospitalization - Initial or Prolonged	Muscle Rigidity		Clozaril	SS		ORAL	25 MG PO Q PM / DC'D	
	Neuroleptic Malignant Syndrome							
	Oxygen Saturation						AFTER ONE DOSE	
	Decreased		Sinemet	C				
	Pneumonia		Effexor	C				
	Pyrexia		Lipitor	C				
			Inderal	C				
			Asa	C				
			Exelon	C				
			Depakote	C				

Date:02/27/01ISR Number: 3671665-7Report Type:Expedited (15-DaCompany Report #2010781
Age:52 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Health	Oxycontin	PS	Purdue Pharma Lp	ORAL	PO	
Other	Anxiety	Professional	Vistaril					
	Back Pain	Other	(Hydroxizine					
	Coma		Pamoate)	SS		ORAL	PO	
	Drug Toxicity		Haldol (Haloperidol)	SS		ORAL	PO	
	Dyspnoea		Hydrocodone	SS			UNKNOWN	
	Hyperhidrosis		Ibuprofen	SS			UNKNOWN	
	Myocardial Ischaemia		Celebrex (Celecoxib)	SS		ORAL	PO	
			Klonopin					
			(Clonazepam)	C		ORAL	PO	

Date:02/28/01ISR Number: 3671053-3Report Type:Direct Company Report #
Age:32 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Confusional State		Risperdal 2 Mg Po					
Hospitalization -	Dysarthria		Bid	PS		ORAL	2 MG BID PO	
Initial or Prolonged	Extrapyramidal Disorder		Zyprexa 10 Mg X 1					
Required	Hallucination, Visual		Dose	SS		ORAL	10 MG MS PO	
Intervention to	Heart Rate Increased		Trazodone 100 Mg Hs	SS			100 MG HS	
Prevent Permanent	Pyrexia		Haldol 5 Mg 1m X 1	SS			INTRAMUSCULAR	5 MG IM X 1
Impairment/Damage	Restlessness		Effexor 75 Mg Xr Po					
	Speech Disorder		Qd	SS		ORAL	75 MG XR PO	
							QD	

			Benztropine 2 Mg Po Bid	SS		ORAL
2 MG PO BID						
			Cogentin	C		
			Effexor	C		
			Wellbutrin	C		
			Gabapentin	C		
			Paxil	C		
			Compazine	C		
			Meclizine	C		
			Trazodone	C		
			Acyclovir	C		
			Thiamine	C		
			Mvi	C		
			Unasyin	C		

Date:02/28/01ISR Number: 3675915-2Report Type:Expedited (15-DaCompany Report #01020405
Age:72 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Drug Hypersensitivity	Consumer	Enbrel 25 Mg	PS		SUBCUTANEOUS	25 MG, BIW,	
Initial or Prolonged	Erythema	Health				SUBCUTANEOUS		
	Nervous System Disorder	Professional	Haloperidol	SS				
	Oedema Peripheral		Celecoxib	C				
	Pain In Extremity		Omeprazole	C				
	Pyrexia		Paroxetine	C				
	Renal Impairment							

Date:02/28/01ISR Number: 3677522-4Report Type:Periodic Company Report #A001056
Age:13 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Abdominal Pain	Health	Zoloft	PS	Pfizer			
	Agitation	Professional			Pharmaceuticals Inc	ORAL	25.00 MG	
	Drug Ineffective							TOTAL: DAILY
	Dysgeusia							ORAL

	Hypertonia		Lithium	SS		ORAL 300.00 MG
	Muscle Twitching					TOTAL:DAILY:ORAL
	Myalgia					
	Osteoarthritis		Neurontin	SS		ORAL 900.00 MG
	Pain					TOTAL:TID:ORAL
	Thinking Abnormal					
	Vasodilatation		Haldol	SS		ORAL 1.00 MG TOTAL:BID:ORAL
			Adderall	C		
			Tenex	C		
			Claritin	C		

Date:02/28/01ISR Number: 3677600-XReport Type:Periodic Company Report #A023481
Age:43 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Hospitalization - Initial or Prolonged	Akathisia	Literature	Zoloft	PS	Pfizer Pharmaceuticals Inc	ORAL ORAL
	Depression	Health				
	Hallucination	Professional	Haloperidol	SS		ORAL ORAL
	Hostility	Other	Fluoxetine	C		
	Suicidal Ideation		Lorazepam	C		
	Suicide Attempt					

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/28/01ISR Number: 3677602-3Report Type:Periodic Company Report #A023487
Age:43 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Coma	Other	Zoloft	PS	Pfizer Pharmaceuticals Inc			
	Confusional State							
	Intentional Misuse		Haldol	SS				
	Suicide Attempt		Congentin	SS				

Date:02/28/01ISR Number: 3677609-6Report Type:Periodic Company Report #A023514
Age:32 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Coma	Other	Zoloft	PS	Pfizer Pharmaceuticals Inc			
	Intentional Misuse							
	Sedation		Haldol	SS				
	Suicide Attempt		Artane	SS				
			Restoril	SS				

Date:02/28/01ISR Number: 3678017-4Report Type:Periodic Company Report #A020879
Age:79 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Blood Caffeine Increased	Other	Zoloft	PS	Pfizer Pharmaceuticals Inc			
	Completed Suicide							
	Injury Asphyxiation		Haloperidol	SS				
			Risperdal	SS				
			Other Medication (Unspecified)	SS				
			Vicks Vaporub	C				
			Nicobid	C				
			Meclizine	C				

Date:02/28/01ISR Number: 3679340-XReport Type:Periodic Company Report #A033243
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Other	Agitation Feeling Of Relaxation	Consumer	Zoloft	PS	Pfizer Pharmaceuticals Inc
			Haldol	SS	

Date:03/01/01ISR Number: 3672529-5Report Type:Expedited (15-DaCompany Report #01P-087-0102964-00
Age:37 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardiac Arrest Depressed Level Of Consciousness	Foreign Health Professional	Depakene	PS	Abbott Laboratories Pharmaceutical Products Div	ORAL	1800 MG, 1 IN 1 D, PER ORAL	
	Disseminated Intravascular Coagulation Hypotension Multi-Organ Failure Neuroleptic Malignant Syndrome Pyrexia Respiratory Depression	Other	Fluvoxamine Maleate (Fluvoxamine Maleate) Haloperidol (Haloperidol) Chlorpromazine	SS		ORAL	25 MG, 1 IN 1 D, PER ORAL 27 MG, 1 IN 1 D, PER ORAL	

			Hydrochloride (Chlorpromazine Hydrochloride)	SS		ORAL	100 MG, 1 IN 1 D, PER ORAL
			Biperiden Hydrochloride (Biperiden Hydrochloride)	C			
			Flunitrazepam (Fluitrazepam)	C			

Date:03/05/01ISR Number: 3674176-8Report Type:Expedited (15-DaCompany Report #2001042521FR
Age:56 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Aortic Aneurysm Pain	Foreign Health	Ambien	PS	Lorex Pharmaceuticals	ORAL	ORAL
	Retroperitoneal Fibrosis	Professional Other	Celebrex (Celecoxib)	SS		ORAL	200 MG, QD, ORAL
			Trimebutine Maleate	SS		ORAL	ORAL
			Haloperidol	SS		ORAL	ORAL
			Bromazepam	SS		ORAL	12 MG, QD, ORAL

Date:03/05/01ISR Number: 3674605-XReport Type:Expedited (15-DaCompany Report #NSADSS2001003731
Age:25 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Death	Aggression	Foreign	Risperdal	PS	Janssen Research Fdn	ORAL	SEE IMAGE
Hospitalization - Initial or Prolonged	Cardiac Arrest	Health Professional	Haloperidol (Haloperidol)	SS		INTRAMUSCULAR	10 MG, 1 IN 8

HOUR(S), IM

	Diacepam	SS

INTRAMUSCULAR 20 MG, 1 IN 8

HOUR(S), IM

	Levopromacine	SS

INTRAMUSCULAR 25 MG, 1 IN 8

HOUR(S), IM

	..	SS
	..	SS

Date:03/05/01ISR Number: 3674621-8Report Type:Expedited (15-DaCompany Report #EMADSS2001000500
Age:63 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Life-Threatening	Hypersensitivity	Foreign	Haldol	PS	Rw Johnson	
Other		Health			Pharmaceutical	
		Professional			Research Institute	
					Div Ortho Pharm	ORAL

5MG NIGHT(S)

ORAL:2.5 MG,

NIGHT(S),

ORAL

	Fentanyl (Fentanyl)	C
	Amitriptyline (Amitriptyline)	C
	Mexaforme(Clioquinol)	C
	Prednisolone (Prednisolone)	C
	Diclofenac (Diclofenac)	C

			Atenolol (Atenolol)	C		
			Candesartan (Candesartan)	C		
			Frusemide (Furosemide)	C		
			Co-Codamol (Panadeine Co)	C		
			Co-Danthramer (Dorbanex)	C		

Date:03/08/01ISR Number: 3676659-3Report Type:Expedited (15-DaCompany Report #EMADSS2001000789
Age:81 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Acute Psychosis Aggression Delirium Persecutory Delusion	Foreign Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute	ORAL	11 DROPS, DAILY,	ORAL
			Mst Morphine (Morphine Sulfate)	SS		ORAL	30 MG, DAILY,	ORAL
			Novalgin	C				

Date:03/08/01ISR Number: 3676671-4Report Type:Expedited (15-DaCompany Report #EMADSS2001000835
Age:41 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Bone Marrow Depression	Foreign Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute Div Ortho Pharm	ORAL	1, DAILY,	ORAL
			Zyprexa (Olanzapine)	SS		ORAL		ORAL

Date:03/08/01ISR Number: 3676673-8Report Type:Expedited (15-DaCompany Report #NSADSS2001004354
Age:50 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Required	Erythema Skin Ulcer	Foreign Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute		INTRAMUSCULAR	50 MG, IM
Intervention to Prevent Permanent Impairment/Damage			Linton (Haloperidol)	C				
			Serenace (Haloperidol)	C				
			Neuleptil (Periciazine)	C				
			Hirnamin (Levomepromazine)	C				
			Benzalin (Nitrazepam)	C				
			Rohypnol (Flunitrazepam)	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/09/01ISR Number: 3678179-9Report Type:Expedited (15-DaCompany Report #2011349
Age:82 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Aggression	Foreign	Ms Contin	PS	Purdue Frederick Co	ORAL	30 MG QD PO	
	Persecutory Delusion	Health	Haloperidol	SS		ORAL	PO	
	Psychotic Disorder	Professional Company Representative Other	Novalgin (Metamizol)	C				

Date:03/12/01ISR Number: 3678796-6Report Type:Direct Company Report #
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Bronchospasm		Haldol 1mg	PS		ORAL	1 MG Q 8H	
	Muscle Spasms						ORALLY	
			Accupril	C				
			Albuterol	C				
			Alprazolam	C				
			Baclofen	C				
			Calcium	C				
			Diltiazem	C				
			Hydroxyurea	C				
			Ibuprofen	C				
			Isosorbide Mono	C				
			Morphine Sulfate	C				
			M-V	C				
			Neurontin	C				
			Prednisone	C				
			Metamucil	C				
			Vit E	C				
			Zoloft	C				

Date:03/12/01ISR Number: 3682716-8Report Type:Expedited (15-DaCompany Report #NSADSS2001004800
Age: Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Death	Consumer	Haldol	PS	Rw Johnson Pharmaceutical Research Institute Div Ortho Pharm			

Date:03/13/01ISR Number: 3679073-XReport Type:Expedited (15-DaCompany Report #255517
Age:18 YR Gender:Female I/FU:I

Outcome	PT
Life-Threatening	Alanine Aminotransferase Increased
	Blood Creatinine Increased
	Blood Lactate Dehydrogenase Increased
	Blood Potassium Increased
	Haematocrit Decreased
	Haemoglobin Decreased
	Hyponatraemia
	Pancytopenia
	Platelet Count Decreased

		Prothrombin Time Prolonged						
		Red Blood Cell Count	Report Source	Product	Role	Manufacturer	Route	
Dose	Duration							
		Decreased		Bactramin	PS	Roche		
11	DAY							
		White Blood Cell Count		Serenace	SS			
25	DAY							
		Decreased		Hicaliq	C			
25	DAY							
				Neoamiyu	C			
25	DAY							
				Neolamin Multi V	C			
25	DAY							
				Gastrozepin	C			
25	DAY							
				Adelavin	C			
25	DAY							
				Magnesium Sulfate	C			
25	DAY							
				Foscavir	C			
4	DAY							
				Sandimmun	C			
14	DAY							
				Prednisolone Sodium Succinate (For Inj)	C			
25	DAY							
				Fungizone	C			
25	DAY							
				Mucosta	C			
25	DAY							
				Tenormin	C			
25	DAY							
				Renivace	C			
25	DAY							
				Rize	C			
25	DAY							
				Rohypnol	C			
25	DAY							

Date:03/13/01ISR Number: 3679570-7Report Type:Direct Company Report #
Age: Gender:Male I/FU:I

Outcome		PT	Report Source	Product	Role	Manufacturer	Route	
Dose	Duration							

Life-Threatening	Neuroleptic Malignant		Haloperiodol 5mg	PS	
INTRAVENOUS 5MG IV					
	Syndrome		Cefotetan	C	
			Enoxaparin	C	
			Lansoprazole	C	
			Sucaralfate	C	
			Lorazepam	C	

Date:03/13/01ISR Number: 3679854-2Report Type:Direct Company Report #
Age:38 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Confusional State		Quetiapine	PS		ORAL
NOT A						
Initial or Prolonged	Diabetes Mellitus					
RELIABLE PT						
Other	Diabetic Ketoacidosis					
PO						
	Disorientation		Valproic Acid	SS		
	Thrombocytopenia		Risperidone	SS		
			Haldol	SS		
			Benztropine	SS		

Date:03/13/01ISR Number: 3680952-8Report Type:Expedited (15-DaCompany Report #EMADSS2001001017
Age:70 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Akathisia	Foreign	Haldol	PS	Rw Johnson	
Initial or Prolonged	Depressed Level Of	Health			Pharmaceutical	
	Consciousness	Professional			Research Institute	
	Dyskinesia	Other			Div Ortho Pharm	

THERAPY DATES

NOT SPECIFIED

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/14/01ISR Number: 3681149-8Report Type:Expedited (15-DaCompany Report #NSADSS2001004862
Age:67 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Death	Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute			

Date:03/14/01ISR Number: 3681819-1Report Type:Expedited (15-DaCompany Report #EMADSS2001000994
Age:87 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Cerebral Atrophy Delirium Disorientation	Foreign Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute			
			Ditropan (Oxybutynin)	SS		ORAL	1 TABLE, 1 IN	1 DAY(S),

ORAL

Date:03/14/01ISR Number: 3682248-7Report Type:Expedited (15-DaCompany Report #255517
Age:18 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Alanine Aminotransferase Increased	Foreign Study	Bactrim	PS	Hoffmann La Roche Inc	INTRAVENOUS		
	Blood Chloride Abnormal	Health Professional				DRIP	12 AMPULE	
	Blood Creatinine Increased					INTRAVENOUS	DAILY	
	Blood Glucose Increased					DRIP		
	Blood Lactate		Serenace					

	Dehydrogenase Increased	(Haloperidol)	SS	ORAL 2.25 MG DAILY
	Blood Potassium Increased			ORAL
	Haematocrit Decreased	Hicaliq (Calcium Gluconate/Glucose/Magnesium Sulfate/Potassium Acetate/Potassium	C	
	Haemoglobin Decreased	Neoamiyu	C	
	Hyponatraemia	Neolamin Multi V (Multivitamin Nos)	C	
	Pancytopenia	Gastrozepin (Pirenzipine Hydrochloride)	C	
	Platelet Count Decreased	Adelavin (Flavin Adenin Dinucleotide)	C	
	Pneumocystis Jiroveci Pneumonia	Magnesium Sulfate (Magnesium Sulfate)	C	
	Prothrombin Time Prolonged	Foscavir (Foscarnet Sodium)	C	
	Red Blood Cell Count Decreased	Sandimmun (Cyclosporine)	C	
	Vomiting	Prednisolone Sodium Succinate (For Inj) (Prednisolone Sodium Succinate (For Inj)	C	
	White Blood Cell Count Decreased	Fungizone (Amphotericin B)	C	
		Mucosta (Rebamipide)	C	
		Tenormin (Atenolol)	C	

			Renivace (Enalaprilum)	C		
			Rize (Clotiazepam)	C		
			Rohypnol (Flunitrazepam)	C		

Date:03/14/01ISR Number: 3682746-6Report Type:Expedited (15-DaCompany Report #2001041167CH
Age:85 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Inappropriate Antidiuretic Hormone Secretion	Foreign Health Professional Other	Aldactazide	PS	Searle Pharmaceuticals Inc			
			Haloperidol (Haloperidol)	SS		ORAL	5 MG, QD, ORAL	
			Lisinopril (Lisinopril)	SS		ORAL	5 MG/DAY, ORAL	
			Prednisolone	C				
			Clomethiazole (Clomethiazole)	C				

Date:03/16/01ISR Number: 3681916-0Report Type:Expedited (15-DaCompany Report #255517
Age:18 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Hyponatraemia		Bactar Tablets	PS	Roche			
	Nausea		Bactramin	SS	Roche			
							11	DAY
	Pancytopenia		Serenace	SS				
							25	DAY
	Vomiting		Hicaliq	C				
							25	DAY
			Neoamiyu	C				
							25	DAY
			Neolamin Multi V	C				
							25	DAY

					Gastrozepin	C	
25	DAY						
					Adelavin	C	
25	DAY						
					Magnesium Sulfate	C	
25	DAY						
					Foscavir	C	
4	DAY						
					Sandimmun	C	
14	DAY						
					Prednisolone Sodium Succinate (For Inj)	C	
25	DAY						
					Fungizone	C	
25	DAY						
					Mucosta	C	
25	DAY						
					Tenormin	C	
25	DAY						
					Renivace	C	
25	DAY						
					Rize	C	
25	DAY						
					Rohypnol	C	

Date:03/16/01ISR Number: 3683510-4Report Type:Expedited (15-DaCompany Report #EMADSS2001000944
Age:56 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Pain Retroperitoneal Fibrosis	Foreign Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute Div Ortho Pharm	ORAL	3 TABLE, 1 IN	1 DAY(S),
			Stilnox (Zolpidem)	SS		ORAL	10 MG, DAILY,	ORAL

				Debridat (Trimebutine Maleate)	SS		
10 MG PER DAY							
				Lexomil (Bromazepam)	SS		ORAL
12 MG, DALY,							
ORAL							
				Celebrex (Celecoxib)	SS		ORAL
200 MG,							
DAILY, ORAL							

Date:03/19/01ISR Number: 3684471-4Report Type:Expedited (15-DaCompany Report #EMADSS2001001002
Age:35 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
	Urticaria	Foreign Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute	
INTRAMUSCULAR 1 AMP, TOTAL,						
IM						
			Metamizol	C		
			Tramal	C		

Date:03/19/01ISR Number: 3684510-0Report Type:Expedited (15-DaCompany Report #255517
Age:18 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Life-Threatening	Alanine Aminotransferase Increased	Foreign Study	Bactrim	PS	Hoffmann La Roche Inc	ORAL
ORAL						
	Hyponatraemia Pancytopenia Vomiting	Health Professional	Bactramin (Sulfamethoxazole / Trimethoprim)	SS		
INTRAVENOUS						DRIP
12 AMPULE						
DAILY						

INTRAVENOUS

DRIP

	Serenace (Haloperidol)	SS	ORAL

2.25 MG DAILY

ORAL

	Hicaliq (Calcium Gluconate / Glucose / Magnesium Sulfate/ Potassium Acetate / Potassium Phosphate,	C
	Neoamiyu (Amino Acids Nos)	C
	Neolamin Multi V (Multivitamin Nos)	C
	Gastrozepin (Pirenzipine Hydrochloride)	C
	Adelavin (Flavin Adenin Dinucleotide)	C
	Magnesium Sulfate (Magnesium Sulfate)	C
	Foscavir (Foscarnet Sodium)	C
	Sandimmun (Cyclosporine)	C
	Prednisolone Sodium Succinate (For Inj) (Prednisolone Sodium Succinate (For Inj))	C

Fungizone (Amphotericin B)	C
Mucosta (Rebamipide)	C
Tenormin (Atenolol)	C
Renivace (Enalaprilum)	C
Rize (Clotiazepam)	C
Rohypnol (Flunitrazepam)	C

Date:03/23/01ISR Number: 3689983-5Report Type:Expedited (15-DaCompany Report #NSADSS2001007292
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dermatitis Pruritus	Foreign Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute	INTRAMUSCULAR	IM	
			Chlorpromazine (Chlorpromazine)	C				
			Fluoxetine (Fluoxetine)	C				

Date:03/26/01ISR Number: 3689547-3Report Type:Direct Company Report #
Age:34 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Hospitalization - Initial or Prolonged Disability Required Intervention to Prevent Permanent Impairment/Damage	Hypersensitivity Parkinson'S Disease		Haldol	PS				

Date:03/26/01ISR Number: 3690091-8Report Type:Expedited (15-DaCompany Report #A105258
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Abnormal Behaviour	Consumer	Zoloft	PS	Pfizer			
Required	Drug Level Above				Pharmaceuticals Inc			
100.00 MG								
Intervention to	Therapeutic							
TOTAL								
Prevent Permanent	Dyskinesia		Benadryl	SS				
Impairment/Damage	Eating Disorder		Cogentin	SS				
	Hallucination		Haldol	SS				
	Intentional Misuse		Seroquel	C				
	Muscle Rigidity							
	Overdose							
	Tremor							
	Trismus							

Date:03/27/01ISR Number: 3690553-3Report Type:Expedited (15-DaCompany Report #NSADSS2001005841
Age:46 YR Gender:Male I/FU:I

Outcome
Hospitalization -
Initial or Prolonged

Required Intervention to Prevent Permanent Impairment/Damage	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Infection Pruritus Psychotic Disorder	Consumer	Haldol	PS	Rw Johnson Pharmaceutical Research Institute			
			Klonopin (Clonazepam)	C				
			Benadryl (Diphenhydramine Hydrochloride)	C				

Date:03/29/01ISR Number: 3692568-8Report Type:Expedited (15-DaCompany Report #EMADSS2001001071
Age:30 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Confusional State Dyspnoea Hypertonia	Foreign Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute	INTRAMUSCULAR	10 MG/ML,	TOTAL, IM
	Pyrexia Tachycardia Tremor		Sinogan (Levomepromazine)	SS		INTRAMUSCULAR	25 MG,	TOTAL, IM
			Seropram (Citalopram Hydrobromide)	C				
			Ludiomil (Maprotiline Hydrochloride)	C				
			Diazepam	C				
			...	C				

Date:04/03/01ISR Number: 3694499-6Report Type:Expedited (15-DaCompany Report #257312
Age:75 YR Gender:Female I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Aortic Valve Incompetence Aphasia

Disability	Atrial Fibrillation
	Back Injury
	Back Pain
	Bladder Disorder
	Blood Culture Positive
	Blood Pressure Decreased
	C-Reactive Protein Increased
	Cardiomegaly
	Cerebral Artery Embolism
	Cerebral Atrophy
	Circulatory Collapse
	Compression Fracture
	Constipation
	Culture Urine Positive
	Cystitis
	Dementia
	Depression
	Dizziness
	Embolism
	Escherichia Infection
	Fall

	Heart Rate Increased						
	Hypoaesthesia						
	Intervertebral Disc Protrusion	Report Source	Foreign	Product	Role	Manufacturer	Route
Dose	Duration			Valium Tablets	PS	Roche	
7 DAY							
	Mental Disorder Due To A General Medical Condition	Health Professional		Cipramil	SS		
				Haldol	SS		
	Mitral Valve Incompetence			Tramal	SS		
15 DAY							
	Monoparesis			Musaril	C		
14 DAY							
	Nausea			Vigantoletten	C		
	Nervous System Disorder			L-Thyroxin	C		
	Pyrexia			Ximovan	C		
7.5 MG FROM							
	Sedation						
02 DEC 2000.							
	Sepsis			Bifiteral	C		
	Spinal Cord Compression			Mono Embolex	C		
15 DAY							
	Spinal Fracture			Paracetamol	C		
15 DAY							
	Tricuspid Valve Incompetence						
	Urinary Retention						
	Urinary Tract Infection						
	White Blood Cell Count Increased						

Date:04/03/01ISR Number: 3694808-8Report Type:Direct Company Report #
Age:47 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization -	Dysphagia		Haloperidol (Geneva)	PS	Geneva	ORAL
15 MG PO AM	YR					
Initial or Prolonged	Dyspnoea		Zoloft	SS		ORAL
100 MG PO QD						
	Tongue Oedema		Benztropine	C		
			Risperidone	C		
			Naproxen	C		

Date:04/03/01ISR Number: 3694949-5Report Type:Direct Company Report #
Age:76 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Mental Impairment		Paroxetine	PS			20 MG QD	
			Haloperidol	SS			2 MG Q NS	
			Tylenol #2	C				
			Fosinopril	C				
			Ibuprofen	C				
			Hctz	C				
			Sinemet Cr	C				

Date:04/04/01ISR Number: 3696993-0Report Type:Expedited (15-DaCompany Report #NSADSS2001007203
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Bradycardia	Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute	INTRAVENOUS	1; 5 MG IV	

Date:04/04/01ISR Number: 3697004-3Report Type:Expedited (15-DaCompany Report #NSADSS2001009210
Age: Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Congenital Anomaly	Cleft Lip And Palate Complications Of Maternal Exposure To Therapeutic Drugs	Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute Div Ortho Pharm	ORAL	3.5 MG, ORAL	

Date:04/04/01ISR Number: 3699768-1Report Type:Expedited (15-DaCompany Report #257312
Age:75 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Disability	Aphasia Atrial Fibrillation Bladder Disorder Cardiomegaly Cerebral Artery Embolism Circulatory Collapse Compression Fracture Constipation Culture Positive Culture Urine Positive Cystitis Dizziness Embolism Escherichia Infection Fall Heart Rate Increased Intervertebral Disc Protrusion Monoparesis	Foreign Study Health Professional	Valium Cipramil (Citalopram) Haldol (Haloperidol) Musaril (Tetrazepam) Tramal (Tramadol Hydrochloride) Vigantoletten (Cholecalciferol) L-Thyroxin (Levothyroxine Sodium) Ximovan (Zopiclone)	PS SS SS SS SS C C C	Hoffmann La Roche Inc	ORAL	4 MG DAILY ORAL 20 MG DAILY ORAL 4 MG DAILY ORAL 50 MG DAILY ORAL 100 MG DAILY ORAL	

	Nausea		Bifiteral		
	Photopsia		(Lactulose)	C	
	Pulmonary Hypertension				
	Pyrexia				
	Renal Disorder				
	Sedation				
	Sepsis				
	Spinal Cord Compression				
	Spinal Fracture				
	Urinary Retention				

Date:04/06/01ISR Number: 3700454-XReport Type:Expedited (15-DaCompany Report #NSADSS2001004354
Age:50 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Skin Reaction	Foreign	Haldol	PS	Rw Johnson	
Required	Skin Ulcer	Health			Pharmaceutical	
INTRAMUSCULAR 50 MG, IM		Professional			Research Institute	
Intervention to			Linton (Haloperidol)	C		
Prevent Permanent			Serenace			
Impairment/Damage			(Haloperidol)	C		
			Neuleptil			
			(Periciazine)	C		
			Hirnamin			
			(Levomepromazine)	C		
			Benzalin			
			(Nitrazepam)	C		
			Rohypnol			

(Flunitrazepam)	C
Promethazine Hydrochloride	
(Promethazine Hydrochloride)	C
Biperiden	
(Biperiden)	C
Chinese Medicine	C

Date:04/06/01ISR Number: 3700899-8Report Type:Periodic Company Report #71131-002
Age:31 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Amblyopia Medication Error	Health Professional	Haloperidol	PS	Roxane Laboratories Inc	ORAL	5MG, BID, PO	3 MON
	Muscle Rigidity Vision Blurred		Haloperidol Decanoate Injection	SS		INTRAMUSCULAR	100MG, Q 4 WEEKS, IM	
						INJECTION		3 MON
			Benztropine Mesylate	C				

Date:04/06/01ISR Number: 3700906-2Report Type:Periodic Company Report #71131-002
Age:31 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Amblyopia Muscle Rigidity	Health Professional	Haloperidol	PS	Roxane Laboratories Inc	ORAL	5MG,BID,PO	
			Haloperidol Decanoate Injection	SS		INTRAMUSCULAR	100MG, Q4 WEEKS, IM	
						INJECTION		
			Benztropine Mesylate	C				

Date:04/09/01ISR Number: 3701394-2Report Type:Expedited (15-DaCompany Report #A106741
Age:87 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Condition Aggravated	Foreign	Zyrtec	PS	Pfizer Inc	ORAL	10.00 MG TOTAL: DAILY:
	Eczema	Consumer					
	Pruritus						
	Scratch		Hydroxyzine	SS		ORAL	ORAL 100.00 MG TOTAL: DAILY:
	Skin Fissures						
	Skin Necrosis						
	Xerosis		Haloperidol	SS			
			Paroxetine	SS		ORAL	ORAL 20.00 MG TOTAL: DAILY:
							ORAL
			Ginko	C			

Date:04/09/01ISR Number: 3701761-7Report Type:Expedited (15-DaCompany Report #A106621
Age:17 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Required Intervention to Prevent Permanent Impairment/Damage	Liver Function Test Abnormal	Consumer	Zeldox	PS	Pfizer Medicinal Product Research And Development	ORAL	80.00 MG TOTAL: BID:
							ORAL

Haldol	SS
Zyprexa	C
Depakote	C
Serevent	C
Topamax	C
Zoloft	C
Prevacid	C
Flovent	C

Date:04/10/01ISR Number: 3702200-2Report Type:Expedited (15-DaCompany Report #NSADSS2001010130
Age:88 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Movement Disorder	Consumer	Risperdal	PS	Janssen Research Fdn	ORAL	ORAL	
Hospitalization - Initial or Prolonged	Muscle Rigidity Pneumonia Tongue Disorder Weight Decreased		Haldol (Injection) (Haloperidol) Ativan (Lorazepam)	SS C			INTRAMUSCULAR	2 MG, 1 IN 1 DAY (S), IM

Date:04/10/01ISR Number: 3702565-1Report Type:Expedited (15-DaCompany Report #NSADSS2001008270
Age:67 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Atrial Fibrillation Respiratory Arrest	Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute		INTRAVENOUS	5 MG, 1 IN 1 TIME(S), IV

Date:04/10/01ISR Number: 3702566-3Report Type:Expedited (15-DaCompany Report #NSADSS2001005827
Age:42 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required	Pelvic Pain	Health	Haldol	PS	Rw Johnson			

Intervention to Prevent Permanent Impairment/Damage	Professional	Pharmaceutical Research Institute	ORAL

10 MG, DAILY,
ORAL; 6 MG, 1

IN 1

NIGHT(S),ORAL

Lithium (Lithium)	C
Risperdal (Risperidone)	C
Colace (Docusate Sodium	C

Date:04/10/01ISR Number: 3702778-9Report Type:Expedited (15-DaCompany Report #EMADSS2001001668
Age:75 YR Gender:Female I/FU:I

Outcome	PT
Life-Threatening	Aphasia
Hospitalization - Initial or Prolonged	Atrial Fibrillation
Required	Back Pain
Intervention to Prevent Permanent Impairment/Damage	Blood Pressure Decreased
	Cerebral Artery Embolism
	Constipation
	Cystitis Escherichia
	Dizziness
	Embolism

		Fall Fatigue Hypoaesthesia	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
		Loss Of Consciousness Mitral Valve Incompetence Paresis Sepsis Spinal Fracture Urinary Retention Urinary Tract Infection Vomiting	Foreign Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute Div Ortho Pharm	
				Tramal (Tramadol Hydrochloride)	SS		ORAL
100 MG, ORAL							
				Cipramil (Citalopram)	SS		ORAL
20 MG, DAILY,							
ORAL							
				Diazepam (Diazepam)	SS		ORAL
SEE IMAGE							
				Tetrazepam (Tetrazepam)	SS		ORAL
50 MG, ORAL							
				Colecalciferol (Colecalciferol)	C		
				Thyroxin (Levothyroxine Sodium)	C		
				Ximovan (Zopiclone)	C		
				Bifiteral (Lactulose)	C		

Date:04/10/01ISR Number: 3702779-0Report Type:Expedited (15-DaCompany Report #EMADSS2001001747
Age:24 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization - Initial or Prolonged	Drug Ineffective Enuresis Urinary Incontinence	Foreign Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute Div Ortho Pharm	
INTRAVENOUS	25 MG, DAILY,					
IV						
			Valium (Diazepam)	SS		
INTRAVENOUS	SEE IMAGE					
			Benperidol			

			(Benperidol)	SS		
			Clozapine (Clozapine)	SS		

Date:04/11/01ISR Number: 3703871-7Report Type:Expedited (15-DaCompany Report #NSADSS2001009787
Age:27 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Electrocardiogram Qt Prolonged Torsade De Pointes Ventricular Fibrillation	Foreign Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute		530 MG, 24 HOUR(S)	
			Cocaine (Cocaine)	SS				

Date:04/11/01ISR Number: 3703872-9Report Type:Expedited (15-DaCompany Report #NSADSS2001007292
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dermatitis Pruritus	Foreign Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute	INTRAMUSCULAR	IM	
			Chlorpromazine (Chlorpromazine)	C				

			Fluoxetine (Fluoxetine)	C		

Date:04/11/01ISR Number: 3703964-4Report Type:Expedited (15-DaCompany Report #2001000791-FJ
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Encephalopathy Neuroleptic Malignant Syndrome	Foreign Study Health Professional	Prograf (Amitriptyline Hydrochloride)	PS SS	Fujisawa Healthcare Inc	
INTRAVENOUS	UNK DOSE BID - TWICE A DAY INTRAVENOUS					
			(Haloperidol)	SS		
INTRAVENOUS	UNK DOSE BID - TWICE A DAY INTRAVENOUS					

Date:04/12/01ISR Number: 3704403-XReport Type:Expedited (15-DaCompany Report #081-0981-M0100222
Age:86 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged Other	Condition Aggravated Drug Interaction Hepatitis	Foreign Health Professional	Lipitor	PS	Pfizer Ireland Pharmaceuticals, Tablet Plant	ORAL
10 MG (DAILY), PER ORAL						
			Haloperidol	SS		ORAL
3 "DF" DAILY, PER ORAL						

	Chlorpromazine	SS	ORAL

3 "DF" DIALY,

PER ORAL

Trihexyphenidyl	SS	ORAL

2 MG (DAILY),

PER ORAL

Brotizolam	SS	ORAL

0.25 MG

(DAILY), PER

ORAL

Alfacalcidol	C
Mizoribine	C
Amlodipine	C
Famotidine	C
Simvastatin	C
Prednisolone	C
Dipyridamole	C
Pravastatin	C
Furosemide	C

Date:04/13/01ISR Number: 3704560-5Report Type:Expedited (15-DaCompany Report #PHNU2001DE00848
Age:65 YR Gender:Male I/FU:F

Outcome	PT
Other	Ascites
	Hepatic Cirrhosis
	Hypoproteinaemia
	Metastasis
	Metastatic Neoplasm
	Neoplasm Malignant
	Pancreatic Carcinoma
	Peritoneal Disorder

Renal Disorder

		Report Source	Product	Role	Manufacturer	Route	Dose
Duration							
		Foreign Health	Clozaril	PS	Novartis Pharmaceuticals Corp	ORAL	500 MG/DAY,
ORAL							
		Professional					
		Other	Glianimon (Benperidol)	SS			
			Truxal(Chlorprothixene Hydrochloride)	SS			
			Haldol(Haloperidol)	SS			
			Pantozol	C			
			Lactulose	C			
			Lefax	C			

Date:04/16/01ISR Number: 3706159-3Report Type:Expedited (15-DaCompany Report #PHBS2001JP00910
Age:3 DY Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose
Duration							
Other	Complications Of Maternal Exposure To Therapeutic	Foreign Health	Ritalin Tab	PS	Novartis Pharmaceuticals Corp		
TRANSPLACENTAL	TRANSPLACENTA						
	Drugs	Professional					
L							
	Convulsion Neonatal	Other	Anafranil(Clomipramine Hydrochloride)				
	Dyskinesia						
	Jaundice Neonatal		Tablet	SS			
TRANSPLACENTAL	TRANSPLACENTA						
L							
			Wintermin(Chlorpromazine Hydrochloride)	SS			
TRANSPLACENTAL	TRANSPLACENTA						
L							
			Serenace(Haloperidol)	SS			
TRANSPLACENTAL	TRANSPLACENTA						
L							
			Contomin(Chlorpromaz				

			ine	SS		
TRANSPLACENTAL	TRANSPLACENTA					
L						
			Artane (Trihexyphenidyl Hydrochloride)	SS		
TRANSPLACENTAL	TRANSPLACENTA					
L						

Date:04/17/01ISR Number: 3706967-9Report Type:Expedited (15-DaCompany Report #081-0981-M0100222
Age:86 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Interaction	Foreign Health Professional	Lipitor	PS	Pfizer Ireland Pharmaceuticals,			
Other	Hepatic Function Abnormal				Tablet Plant	ORAL	10 MG	(DAILY), PER
						ORAL		
			(Haloperidol)	SS		ORAL	(3 "DF"	DAILY), PER
						ORAL		
			(Chlorpromazine)	SS		ORAL	(3 "DF"	DAILY), PER
						ORAL		
			Trihexyphenidyl)	SS		ORAL	2 MG (DAILY),	
						PER ORAL		
			(Brotizolam)	SS		ORAL	0.25 MG	(DAILY), PER

ORAL			Alfacalcidol	C			
			Mizoribine	C			
			Amlodipine	C			
			Famotidine	C			
			Simvastatin	C			
			Prednisolone	C			
			Dipyridamole	C			
			Pravastatin	C			
			Furosemide	C			

Date:04/17/01ISR Number: 3707186-2Report Type:Expedited (15-DaCompany Report #FLUV00301000004
Age:34 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blood Alkaline Phosphatase Increased	Foreign Health	Luvox	PS	Solvay Pharmaceuticals	ORAL	150 MG DAILY	
	Fall	Professional					PO	
	Gamma-Glutamyltransferase Increased	Other	Linton (Haloperidol)	SS		ORAL	12 MG DAILY	
	Injury Loss Of Consciousness		Hirnamin (Levomepromazine)	SS		ORAL	200 MG DAILY	
			Anafranil (Clomipramine Hydrochloride)	SS		ORAL	150 MG DAILY	
			Tegretol (Carbamazepine)	SS		ORAL	800 MG DAILY	
			Limas (Lithium Carbonate)	SS		ORAL	1200 MG DAILY	

PO

Date:04/18/01ISR Number: 3707248-XReport Type:Expedited (15-DaCompany Report #JRFUSA2000000095
Age:52 YR Gender:Male I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Aggression
	Akathisia
	Arthralgia
	Asthenia
	Body Temperature Decreased
	Bone Marrow Depression
	Bradykinesia
	Cardiac Arrest
	Chest Pain
	Confusional State
	Convulsion
	Difficulty In Walking
	Drug Withdrawal Syndrome
	Dyskinesia
	Feeling Cold
	Headache
	Hyperhidrosis
	Leukopenia
	Memory Impairment
	Overdose
	Parkinsonism

	Psychotic Disorder Pulse Absent Pyrexia	Report Source	Product	Role	Manufacturer	Route Dose Duration
	Red Blood Cell Count Decreased	Consumer Health	Risperdal (Tablet) (Risperidone)	PS	Janssen Research Fdn	ORAL 3 MG, 2 IN 1
	Sleep Disorder	Professional				DAY(S), ORAL
	Suicidal Ideation Tachycardia		Haldol (Tablet) Haloperidol	SS		ORAL 2 MG, 4 IN 1
	Tardive Dyskinesia					DAY(S), ORAL
	Tremor		Ativan (Lorazepam)	SS		ORAL 2 MG, 4 IN 1
	Weight Decreased					DAY(S), ORAL
			Olanzapine (Olanzapine)	C		
			Seroquel (Seroquel)	C		
			Zyprexa (Olanzapine)	C		
			Remeron (Mirtazapine)	C		

Date:04/18/01ISR Number: 3707257-0Report Type:Expedited (15-DaCompany Report #NSADSS2001010130
Age:88 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Death Hospitalization - Initial or Prolonged	Muscle Rigidity Pneumonia Tongue Disorder	Consumer	Haldol	PS	Rw Johnson Pharmaceutical Research Institute	INTRAMUSCULAR 2 MG, 2 IN 1
	Weight Decreased					DAY, IM
			Risperdal (Unspecified) (Risperidone)	SS		ORAL ORAL
			Ativan (Lorazepam)	C		

Date:04/18/01ISR Number: 3707793-7Report Type:Expedited (15-DaCompany Report #NSADSS2001008394
Age:50 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Asthenia	Foreign	Risperdal	PS	Janssen Research Fdn	ORAL	6 MG, DAILY, ORAL	
Required Intervention to Prevent Permanent Impairment/Damage	Cardiac Arrest	Literature						
	Chromosome Abnormality	Health Professional	Haldol (Unspecified0 (Haloperidol)	SS			7.5 MG, DAILY,	
	Electrocardiogram Qt Prolonged							
	Myocarditis		Chlorpromazine Hydrochloride (Chlorpromazine Hydrochloride)	SS			300 MG, DAILY	
	Oral Intake Reduced							
	Pneumonia							
	Torsade De Pointes							
	Ventricular Tachycardia		Flunitrazepam	C				
			Levomepromazine	C				

Date:04/18/01ISR Number: 3707953-5Report Type:Expedited (15-DaCompany Report #FLUV00301001684
Age:68 YR Gender:Female I/FU:I

Outcome	PT
Life-Threatening	Blood Alkaline Phosphatase Increased
	Blood Creatine Phosphokinase Increased
	Clonic Convulsion
	Depressed Level Of Consciousness

Diarrhoea Drug Interaction Hepatic Enzyme Increased	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hyperhidrosis Hyponatraemia	Foreign Other	Luvox	PS	Solvay Pharmaceuticals	ORAL	1 DF QD PO
Hypotension		Topalgic (Tramadol)	SS		ORAL	2 DF DAILY PO
Joint Stiffness Lung Disorder Multi-Organ Failure		Anafranil (Clomipramine Hydrochloride)	SS		ORAL	100 MG QD PO 10 YR
Neuroleptic Malignant Syndrome		Hadol (Haloperidol)	SS		ORAL	30 GTT DAILY PO
Pyrexia Respiratory Distress Serotonin Syndrome		Theralene (Alimemazine Tartrate)	SS		ORAL	UNK DAILY
Tachycardia						PO
Tremor		Celebrex (Celecoxib)	SS		ORAL	1 DF QD PO
		Seropram (Citalopram Hydrobromide)	SS		ORAL	2 DF DAILY PO A FEW YEARS
		Mepronizine ( )	SS		ORAL	1 DF DAILY PO A FEW YEARS

Date:04/20/01ISR Number: 3708659-9Report Type:Expedited (15-DaCompany Report #NSADSS2001010396
Age:23 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Belligerence Brain Oedema Hallucination	Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute	
35 MG, DAILY						
			Cogentin (Benzatropine Mesilate)	C		
			Seropuel	C		
			Vitamins	C		
			Omega 3 (Fish Oil)	C		

Date:04/20/01ISR Number: 3708668-XReport Type:Expedited (15-DaCompany Report #NSADSS2001010615
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Medication Error	Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute	
INTRAMUSCULAR 500 MG, IM						

Date:04/20/01ISR Number: 3708850-1Report Type:Expedited (15-DaCompany Report #EMADSS2001002178
Age:68 YR Gender:Female I/FU:I

Outcome	PT
Life-Threatening Required Intervention to Prevent Permanent Impairment/Damage	Clonic Convulsion Depressed Level Of Consciousness Diarrhoea Hyperhidrosis Hyponatraemia

		Hypotension Multi-Organ Failure Muscle Rigidity	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
		Neuroleptic Malignant Syndrome Pyrexia	Foreign Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute	ORAL
30 DROPS, DAILY ORAL		Respiratory Distress					
		Serotonin Syndrome Tachycardia		Topalgic (Tramadol Hydrochloride)	SS		
THERAPY DATES AND DOSE NOT SPECIFIED		Toxicologic Test Abnormal Tremor					
				Anafranil (Clomipramine Hydrochloride)	SS		
DOSE NOT STATED							
				Celebrex (Celecoxib)	SS		ORAL
1 DAILY ORAL							
				Seropam (Citalopram Hydrobromide)	SS		ORAL
1 , DAILY ORAL							
				Mepronizine (Mepronizine)	SS		ORAL
2, DAILY, ORAL							
				Theralene (Alimemazine Tartrate)	SS		ORAL
100 MG , DAILY, ORAL							
				Floxyfral (Fluvoxamine Maleate)	SS		ORAL
100 MG , DAILY ORAL							

Date:04/20/01ISR Number: 3708861-6Report Type:Expedited (15-DaCompany Report #EMADSS2001002304
Age:56 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death Hospitalization - Initial or Prolonged	Depressed Level Of Consciousness	Foreign Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute			

EXACT THERAPY

DATES UNKNOWN

- 1997 OR

1998

Date:04/20/01ISR Number: 3709070-7Report Type:Expedited (15-DaCompany Report #2001052544FR
Age:68 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Alanine Aminotransferase Increased	Foreign Health Professional Other	Celebrex	PS	Gd Searle And Co	ORAL	ORAL	
	Aspartate Aminotransferase Increased		Topalgic 'Houde' (Tramadol Hydrochloride)	SS		ORAL	ORAL	
	Blood Creatine Phosphokinase Increased		Anafranil (Clomipramine Hydrochloride)	SS		ORAL	100 MG, QD,	
	Hyponatraemia						ORAL	
	Neuroleptic Malignant Syndrome		Halidol (Haloperidol)	SS		ORAL	30 DROPS,	
	Serotonin Syndrome						ORAL	
			Theralene (Alimemazine					

			Tartrate)	SS		ORAL
ORAL						
			Floxyfral (Fluvoxamine Maleate)	SS		ORAL
ORAL						
			Seropram (Citalopram Hydrobromide)	SS		ORAL
ORAL						
			Mepronizine (Meprobamate, Aceprometazine)	SS		ORAL
ORAL						

Date:04/23/01ISR Number: 3708864-1Report Type:Expedited (15-DaCompany Report #EMADSS2001002177
Age:73 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Coma Drug Interaction Hypercapnia Hypoxia	Foreign Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute	ORAL	15 DROP, DAILY, ORAL	
	Overdose Sedation		Equantil (Meprobamate)	SS			THERAPY DATES AND DOSE NOT SPECIFIED	
			Largactil (Chlorpromazine Hydrochloride)	SS			THERAPY DATES NOT SPECIFIED	
			Melleril (Thioridazine Hydrochloride)	SS		ORAL	50 MG DAILY	ORAL
			Teralithe (Lithium Carbonate)	SS				

Effexor (Venlafaxine Hydrochloride)	C	
Aspirine (Acetylsalicylic Acid)	C	
Tanakan (Ginkgo Tree Leaves Extract)	C	
Levothyrox (Levothyroxine Sodium)	C	

Date:04/23/01ISR Number: 3709119-1Report Type:Expedited (15-DaCompany Report #081-0981-M0100222
Age:86 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged Other	Alanine Aminotransferase Increased Aspartate Aminotransferase Increased Blood Alkaline Phosphatase Increased Blood Lactate Dehydrogenase Increased Drug Interaction Gamma-Glutamyltransferase Increased Hepatic Function Abnormal	Foreign Health Professional	Lipitor (Haloperidol) (Chlorpromazine) (Trihexyphenidyl) (Brotizolam)	PS SS SS SS SS	Pfizer Ireland Pharmaceuticals, Tablet Plant	ORAL ORAL ORAL ORAL ORAL	10 MG (DAILY) PER ORAL (3 "DF" DAILY), PER ORAL (3 "DF" DAILY), PER ORAL 2 MG (DAILY), PER ORAL 0.25 MG

(DAILY), PER

ORAL

(Alfacalcidol)	C	
(Mizoribine)	C	
(Amlodipine)	C	
(Famotidine)	C	
(Prednisolone)	C	
(Dipyridamole)	C	
(Pravastatin)	C	
(Furosemide)	C	

Date:04/23/01ISR Number: 3709232-9Report Type:Expedited (15-DaCompany Report #EMADSS2001001628
Age:87 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Eczema Pruritus	Foreign Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute			
			Tanakan (Ginkgo Tree Leaves Extract)	SS		ORAL	3 CAP,	DAILY,
			Zyrtec (Cetirizine Hydrochloride)	SS		ORAL	10 MG,	DAILY,
			Atarax (Hydroxyzine Hydrochloride)	SS		ORAL	100 MG,	DAILY,
			Deroxat (Paroxetine Hydrochloride)	SS		ORAL	20 MG,	DAILY,

ORAL

Date:04/23/01ISR Number: 3709284-6Report Type:Expedited (15-DaCompany Report #NSADSS2001008394
Age:50 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Required Intervention to	Asthenia Cardiac Arrest Chromosome Abnormality Decreased Appetite	Foreign Literature Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute Div Ortho Pharm		7.5 MG DIALY	
Prevent Permanent Impairment/Damage	Electrocardiogram Qt Prolonged Myocarditis		Risperidone (Unspecified) (Risperidone)	SS		ORAL	SEE IMAGE	
	Oral Intake Reduced Pneumonia Torsade De Pointes Ventricular Tachycardia		Chlorpromazine Hydrochloride (Chlorpromazine Hydrochloride)	SS			SEE IMAGE	
			Flunitrazepam (Flunitrazepam)	C				
			Levomepromazine (Levomepromazine)	C				

Date:04/23/01ISR Number: 3709380-3Report Type:Expedited (15-DaCompany Report #NSADSS2001010785
Age:25 YR Gender:Male I/FU:I

Outcome
Life-Threatening
Disability
Required
Intervention to

Prevent Permanent Impairment/Damage

	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Apallic Syndrome Blood Creatinine Increased	Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute			
INTRAMUSCULAR							IM	
	Blood Glucose Decreased Blood Potassium Increased		Haldol (Tablet) (Haloperidol)	SS		ORAL		
ORAL								
	Blood Urea Increased Brain Damage Cardiac Arrest Joint Contracture		Haldol Decanoate (Injection) (Haloperidol Decanoate)	SS				
INTRAMUSCULAR							IM	
	Lethargy Oral Intake Reduced Pain Weight Decreased							

Date:04/25/01ISR Number: 3710772-7Report Type:Direct Company Report #
Age:35 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Breath Holding Dyskinesia		Haloperidol 4mg Iv Q 4 Hr	PS				
INTRAVENOUS							4MG IV	Q 4 HR

Date:04/26/01ISR Number: 3712442-8Report Type:Expedited (15-DaCompany Report #NSADSS2001011245
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Unevaluable Event	Study Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute Div Ortho Pharm	ORAL		

50 MG, 1 IN 1

NIGHT(S),

ORAL

Depakote (Valproate Semisodium) C

Date:04/27/01ISR Number: 3713143-2Report Type:Expedited (15-DaCompany Report #PHRM2001FR01106
Age:68 YR Gender:Female I/FU:I

Outcome	PT
Life-Threatening	Alanine Aminotransferase Increased
	Aspartate Aminotransferase Increased
	Blood Alkaline Phosphatase Increased
	Blood Creatine Phosphokinase Increased
	Depressed Level Of Consciousness
	Diarrhoea
	Drug Interaction
	Dyshidrosis
	Hyponatraemia
	Hypotension
	Multi-Organ Failure

		Muscle Contractions Involuntary Muscle Rigidity Pyrexia Respiratory Distress Serotonin Syndrome Tachycardia Tremor	Report Source Foreign Health Professional Other	Product	Role	Manufacturer	Route
Dose	Duration						
				Anafranil	PS	Novartis Pharmaceuticals Corp	ORAL
100 MG PER DAY,	ORAL						
				Topalgic "Houde" (Tramadol Hydrochloride)	SS		ORAL
2DF PER DAY,	ORAL						
				Haldol (Haloperidol) Solution	SS		ORAL
30 DF PER DAY,	ORAL						
				Theralene (Alimemazine Tartrate)	SS		ORAL
ORAL							
				Floxyfral (Fluvoxamine Maleate)	SS		ORAL
1 DF PER DAY,	ORAL						
				Celebrex (Celecoxib)	SS		ORAL
1 DF PER DAY,	ORAL						
				Serorpam (Citalopram Hydrobromide) Tablet	SS		ORAL
2 DF PER DAY,	ORAL						
				Mepronizine (Meprobamate, Aceprometazine) Tablet	SS		ORAL
1 DF PER DAY,	ORAL						

Date:04/27/01ISR Number: 3713517-XReport Type:Expedited (15-DaCompany Report #NSADSS2001008394
Age:50 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Asthenia Cachexia Cardiac Arrest Electrocardiogram Qt Prolonged Inflammation Myocarditis Oral Intake Reduced Pneumonia Respiratory Disorder Schizophrenia Torsade De Pointes Ventricular Tachycardia	Foreign Literature Health Professional	Risperdal Haldol (Unspecified) (Haloperidol) Chlorpormazine Hydrochloride Flunitrazepam Levomepromazine	PS SS SS C C	Janssen Research Fdn	ORAL	2MG, DAILY, 7.5; 5.25 MG, DAILY 300; 200; 300 MG, DAILY	

Date:04/30/01ISR Number: 3714402-XReport Type:Expedited (15-DaCompany Report #HQ0164626APR2001
Age:37 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hypotension Hypothermia	Health Professional Other	Artane	PS	Lederle Laboratories Div American Cyanamid Co	ORAL	5 MG 1XPER 1 DAY	
			Depakine (Valproate Sodium)	SS		ORAL	1000 MG 1X	

PER 1 DAY

ORAL

			Haldol (Haloperidol)	SS	ORAL

1 MG 1XPER 1

DAY ORAL

			Neurontin (Gabapantin)	SS	ORAL

1600 MG 1 X

PER 1 DAY

ORAL

			Tranxene (Clorazepate Dipotassium)	SS	ORAL

ORAL

Date:05/02/01ISR Number: 3715530-5Report Type:Expedited (15-DaCompany Report #NSADSS2001011369
Age:40 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Death	Coma Encephalitis Meningitis	Consumer	Haldol	PS	Rw Johnson Pharmaceutical Research Institute	
UNKNOWN						
			Ativan (Lorazepam)	SS		
UNKNOWN						
			Compazine (Prochlorperazine Edisylate)	C		
			Prozac (Fluoxetine Hydrochloride)	C		
			Paxil (Paroxetine Hydrochloride)	C		

Date:05/02/01ISR Number: 3715557-3Report Type:Expedited (15-DaCompany Report #NSADSS2001011411
Age:47 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					

Hospitalization - Initial or Prolonged	Unevaluable Event	Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute Div Ortho Pharm	

UNKNOWN 10 MG, 2 IN 1

DAY(S),

Date:05/02/01ISR Number: 3716745-2Report Type:Periodic Company Report #PRIUSA2000001292
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Convulsion	Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute	
INTRAMUSCULAR IM						

Date:05/02/01ISR Number: 3716747-6Report Type:Periodic Company Report #PRIUSA2000001293
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Convulsion	Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute	
INTRAMUSCULAR IM						
			Effexor (Venlafaxine Hydrochloride)	C		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/02/01ISR Number: 3716749-XReport Type:Periodic Company Report #PRIUSA2000006643
Age:48 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Disability	Extrapyramidal Disorder	Consumer Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute	INTRAMUSCULAR	IM	
			Depakote (Valproate Semisodium)	C				
			Neurontin (Gabapentin)	C				
			Seroquel (Seroquel)	C				

Date:05/02/01ISR Number: 3716751-8Report Type:Periodic Company Report #PRIUSA2000009391
Age:41 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Injection Site Reaction	Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute	INTRAMUSCULAR	IM	
			Depakote (Valproate Semisodium)	C				
			Cogentin (Benzatropine Mesilate)	C				

Date:05/02/01ISR Number: 3717344-9Report Type:Expedited (15-DaCompany Report #EMADSS2001001687
Age:31 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Chills Drug Interaction Extrapyramidal Disorder Hypokinesia	Foreign Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute Div Ortho Pharm	ORAL	SEE IMAGE	
			Fluoxetine (Fluoextine)	SS		ORAL	20 MG, ORAL	

			Amitriptyline (Amitriptyline)	C		
			Prothazin (Promethazine Hydrochloride)	C		
			Pantozol (Pantoprazole Sodium)	C		

Date:05/03/01ISR Number: 3717194-3Report Type:Expedited (15-DaCompany Report #EMADSS2001002469
Age:85 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Delirium Urinary Incontinence	Foreign Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute	ORAL
10 U, DAILY, ORAL						
			Fluindione (Fluindione)	C		
			Nicardipine(Nicardipine)	C		
			Digoxine (Digoxin)	C		
			Furosemide			

			(Fuosemide)	C			
			Benazepril (Benazepril)	C			

Date:05/03/01ISR Number: 3717199-2Report Type:Expedited (15-DaCompany Report #EMADSS2001002490
Age:41 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Alanine Aminotransferase Increased Aspartate Aminotransferase Increased Dermatitis Eosinophilia Face Oedema Gamma-Glutamyltransferase Increased Hyperkeratosis Pruritus White Blood Cell Count Increased	Foreign Health Professional	Haldol Largactil(Chlorpromazine Hydrochloride) Heptaminol(Heptaminol) Lepticur (Tropatepine Hydrochloride) Niflugel (Niflumic Acid)	PS SS C C C	Rw Johnson Pharmaceutical Research Institute	IM; ORAL		

Date:05/04/01ISR Number: 3718191-4Report Type:Expedited (15-DaCompany Report #EMADSS2001002575
Age:37 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hypotension Hypothermia	Foreign	Haldol Depakine (Valproate Sodium) Parkinane (Trihexyphenidyl Hydrochloride)	PS SS SS	Rw Johnson Pharmaceutical Research Institute Div Ortho Pharm	ORAL ORAL	1 MG, 1 IN 1 5 MG, DAILY,	DAILY,

ORAL

	Tranxene (Clorazepate Dipotassium)	SS

2 TABLETS PER

DAY

Date:05/04/01ISR Number: 3718192-6Report Type:Expedited (15-DaCompany Report #NSADSS2001008394
Age:50 YR Gender:Female I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Asthenia
	Cachexia
	Cardiac Arrest
	Chromosome Analysis Abnormal
	Electrocardiogram Qt Prolonged
	Inflammation
	Myocarditis
	Oral Intake Reduced
	Pneumonia
	Respiratory Disorder

		Schizophrenia Torsade De Pointes Ventricular Tachycardia	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
			Foreign Literature Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute Div Ortho Pharm	
7.5; 5.25 MG, DAILY							
				Risperidone (Risperidone)	SS		ORAL
2; 12; 5; 9 MG, DAILY, ORAL							
				Chlorpromazine Hydrochloride (Chlorpromazine Hydrochloride)	SS		
300; 200; 300 MG, DAILY							
				Flunitrazepam (Flunitrazepam)	C		
				Levomepromazine (Levomepromazine)	C		

Date:05/07/01ISR Number: 3719154-5Report Type:Expedited (15-DaCompany Report #081-0981-M0100222
Age:86 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization - Initial or Prolonged Other	Drug Interaction Hepatitis	Foreign Health Professional	Lipitor	PS	Pfizer Ireland Pharmaceuticals, Tablet Plant	ORAL
10 MG (DAILY), PER ORAL						
			Haloperidol	SS		ORAL
(3 "DF"						

DAILY), PER

ORAL

	Chlorpromazine	SS	ORAL

(3 "DF"

DAILY) PER

ORAL

	Trihexyphenidyl	SS	ORAL

2 MG (DAILY),

PER ORAL

	Brotizolam	SS	ORAL

0.25 MG

(DAILY), PER

ORAL

	(Alfacalcidol)	C
	(Mizoribine)	C
	(Amlodipine)	C
	(Famotidine)	C
	(Prednisolone)	C
	(Dipyridamole)	C
	(Pravastatin)	C
	(Furosemide)	C

Date:05/10/01ISR Number: 3721502-7Report Type:Expedited (15-DaCompany Report #EMADSS2001002783
Age:64 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Neutropenia	Foreign Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute Div Ortho Pharm	ORAL

30 MG, DAILY,

ORAL						
			Heparin	C		
			Dobutrex (Dobutamine Hydrochloride)	C		

Date:05/10/01ISR Number: 3721504-0Report Type:Expedited (15-DaCompany Report #EMADSS2001002178
Age:68 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Clonic Convulsion	Foreign	Haldol	PS	Rw Johnson			
Required	Depressed Level Of	Health			Pharmaceutical			
Intervention to	Consciousness	Professional			Research Institute	ORAL	30 DROPS,	
Prevent Permanent	Diarrhoea						DAILY, ORAL	
Impairment/Damage	Hyperhidrosis		Topalgic (Tramadol					
	Hypotension		Hydrochloride)	SS				
	Multi-Organ Failure		Anafranil					
	Muscle Rigidity		(Clomipramine					
	Neuroleptic Malignant		Hydrochloride)	SS				
	Syndrome		Celebrex (Celecoxib)	SS		ORAL	1, DAILY,	
	Respiratory Distress						ORAL	
	Serotonin Syndrome		Seropram (Citalopram					
	Tachycardia		Hydrobromide)	SS		ORAL	1, DAILY,	
	Tremor						ORAL	
			Mepronizine					
			(Mepronizine)	SS		ORAL	2, DAILY,	
							ORAL	
			Theralene					
			(Alimemazine					
			Tartrate)	SS		ORAL	100 MG,	
							DAILY, ORAL	
			Floxyfral					
			(Fluvoxamine					
			Maleate)	SS		ORAL	100 MG,	

DAILY, ORAL

Date:05/14/01ISR Number: 3723723-6Report Type:Expedited (15-DaCompany Report #PHEH1990US01495
Age:17 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Accident	Health	Clozaril	PS	Novartis			
Hospitalization -	Coma	Professional			Pharmaceuticals Corp	ORAL	SEE IMAGE	
Initial or Prolonged	Convulsion		Lithium(Lithium)	SS				
	Coordination Abnormal		Haldol (Haloperidol)					
	Dermatitis		(Haloperidol)	SS				
	Encephalopathy		Artane					
	Fall		(Trihexypenidyl					
	Head Injury		Hydrochloride	SS			"HIGH DOSE"	
	Hypotension		Thorazine	SS			HIGH DOSE	
	Loss Of Consciousness						UNK	
	Nephropathy Toxic							
	Orthostatic Hypotension							
	Pyrexia							
	Simple Partial Seizures							
	Syncope							
	Tachycardia							
	White Blood Cell Count Increased							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/14/01ISR Number: 3723776-5Report Type:Expedited (15-DaCompany Report #NSADSS2001009210
Age: Gender:Unknown I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Congenital Anomaly	Cleft Lip Cleft Palate Complications Of Maternal Exposure To Therapeutic Drugs Foetal Disorder	Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute Div Ortho Pharm	ORAL	3.5 MG, ORAL	

Date:05/15/01ISR Number: 3723600-0Report Type:Expedited (15-DaCompany Report #01P-056-0106430-00
Age:37 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hypotension Hypothermia	Foreign Health Professional	Depakene	PS	Abbott Laboratories Pharmaceutical Products Div	ORAL	1000 MG, 1 IN 1 D, PER ORAL;	DURATION: YEARS
			Tranxene (Tranxene) (Clorazepate Dipotassium)	SS		ORAL	20 MG, 1 IN 1 D, PER ORAL;	DURATION: YEARS
			Haloperidol (Haloperidol)	SS		ORAL	1 MG, 1 IN 1 D, PER ORAL;	

DURATION:

YEARS

			Trihexyphenidyl Hydrochloride (Trihexyphenidyl Hydrochloride)	SS	ORAL

5 MG, 1 IN 1

D, PER ORAL;

DURATION:

YEARS

Date:05/17/01ISR Number: 3724473-2Report Type:Direct Company Report #
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Agitation		Haloperidol	PS				
Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Confusional State Drug Ineffective Hypertension Multiple Sclerosis Pyrexia Tachycardia							
			Risperidone	SS				
			Lorazepam	C				
			Ranitidine	C				
			Naficillin	C				
			Lactalose	C				
			Mvi	C				
			Thiamine	C				
			Folate	C				
			Heparin	C				

INTRAVENOUS 1MG IV Q 6H

PRN

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/17/01ISR Number: 3724482-3Report Type:Direct Company Report #
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required	Hypotension		Procainamide	PS		ORAL	500 MG PO Q	
Intervention to	Hypoxia							6H
Prevent Permanent	Respiratory Failure		Haldol	SS				
INTRAVENOUS	5MG IV Q 6 HR							
Impairment/Damage	Sepsis		Apap	C				
	Tachyarrhythmia		Ampho B	C				
			Lorazepam	C				
			Feso4	C				
			Furosemide	C				
			Hydrocortisone	C				
			Insulin	C				
			Metoprolol	C				
			Omeprazole	C				
			Vanco	C				

Date:05/17/01ISR Number: 3724680-9Report Type:Expedited (15-DaCompany Report #2001COU0724
Age:81 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Accidental Exposure	Health	Coumadin	PS	Dupont Merck			
	Cerebrovascular Accident	Professional			Pharmaceutical Co	ORAL	1.5 MG QD PO	
			Haldol (Haloperidol)	SS				
			Cogentin (Benzatropine Mesilate)	SS		ORAL	PO	
			Cardizem Cd (Diltiazem Hydrochloride)	SS				
			Therevac - Sb (Docusate Sodium)	C				
			Seroquel (Quetiapine Fumarate)	C				
			Senokot (Senna Fruit)	C				
			Pepcid (Famotidine)	C				

Ni (Multivitamin)	C
Lopressor (Metoprolol Tartrate)	C
Lasix (Furosemide)	C
Lanoxin (Digoxin)	C
Ni (Insulin)	C
Ni (Glipizide)	C
Actos (Pioglitazone Hcl)	C

Date:05/17/01ISR Number: 3724749-9Report Type:Expedited (15-DaCompany Report #NSADSS2001008394
Age:50 YR Gender:Female I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Cardiac Arrest
Required Intervention to Prevent Permanent Impairment/Damage	Chromosome Abnormality
	Electrocardiogram Qt Prolonged
	Myocarditis
	Oral Intake Reduced
	Pneumonia

Torsade De Pointes
Ventricular Tachycardia

Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Foreign	Risperdal	PS	Janssen Research Fdn	ORAL	SEE IMAGE	
Literature	Haldol (Unspecified)					
Health	(Haloperidol)	SS			SEE IMAGE	
Professional	Chlorpromazine Hydrochloride (Chlorpromazine Hydrochloride)	SS			SEE IMAGE	
	Flunitrazepam (Flunitrazepam)	C				
	Levomepromazine (Levomepromazine)	C				

Date:05/18/01ISR Number: 3724567-1Report Type:Direct Company Report #
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Electrocardiogram		Haloperidol	PS			INTRAVENOUS	10 MG
Required Intervention to Prevent Permanent Impairment/Damage	IV Q6 Abnormal Electrocardiogram Qt Prolonged		Acyclovir	C				
			Albuterol	C				
			Cefepime	C				
			Chlorothiazide	C				
			Tobra	C				
			Cotrimoxazole	C				
			Clonidine	C				
			Fluconazole	C				
			Furosemide	C				
			Vanco	C				
			Primaxin	C				
			Insulin Reg.	C				
			Mycophenolate	C				
			Mylanta	C				
			Nystatin	C				
			Omeprazole	C				
			Pancrelipase	C				
			Prednisone	C				
			Sertraline	C				

Date:05/18/01ISR Number: 3724782-7Report Type:Direct Company Report #
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Abdominal Distension		Haloperidol	PS				
Initial or Prolonged	Autonomic Nervous System Imbalance							
Required Intervention to Prevent Permanent Impairment/Damage	Body Temperature Increased							
	Clonic Convulsion							
	Coma							
	Muscle Rigidity							
	Opisthotonus							
	Sedation							
	Tetanus							
	White Blood Cell Count Increased							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/18/01ISR Number: 3725813-0Report Type:Expedited (15-DaCompany Report #HQ0856514MAY2001
Age:54 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Condition Aggravated Malaise Orthostatic Hypotension	Health Professional Other	Artane	PS	Lederle Laboratories Div American Cyanamid Co	ORAL	5 MG ORAL	,SEVERAL YEARS
			Esperal (Disulfiram)	SS		ORAL	ORAL SEVERAL	YEARS
			Haldol (Haloperidol)	SS		INTRAMUSCULAR	IM SEVERAL	YEARS
			Noctran 10 (Acepromazine/Acepromazine/Clorazepate Dipotassium,)	SS		ORAL	10 MG 1 X PER 1 DAY ORAL	SEVERAL YEARS
			Xanax (Alprazolam)	SS		ORAL	.25 MG ORAL	SEVERAL YEARS

Date:05/22/01ISR Number: 3726880-0Report Type:Expedited (15-DaCompany Report #2001000791-FJ
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dermatitis Encephalopathy Face Oedema Mouth Haemorrhage	Foreign Study Health Professional	Prograf (Amitriptyline Hydrochloride)	PS	Fujisawa Healthcare Inc			

Neuroleptic Malignant Unknown Strength SS
INTRAVENOUS BID-TWICE A
Syndrome
DAY

INTRAVENOUS

(Haloperidol)
Unknown Strength SS
INTRAVENOUS BID-TWICE A

DAY

INTRAVENOUS

Date:05/24/01ISR Number: 3728523-9Report Type:Expedited (15-DaCompany Report #NSADSS2001014251
Age:86 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anuria Coma Condition Aggravated	Consumer	Haldol	PS	Rw Johnson Pharmaceutical Research Institute	INTRAVENOUS	5 MG;2.5 MG; 5 MG, IV	

Date:05/24/01ISR Number: 3728595-1Report Type:Expedited (15-DaCompany Report #EMADSS2001003045
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Pancreatitis	Foreign Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute			

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/24/01ISR Number: 3728596-3Report Type:Expedited (15-DaCompany Report #NSADSS2001008394
Age:50 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage (SEE IMAGE)	Asthenia Cardiac Arrest Electrocardiogram Qt Prolonged Myocarditis Oral Intake Reduced Pneumonia Ventricular Tachycardia	Foreign Literature Health Professional	Haldol Risperidone (Risperidone) Chlorpromazine Hydrochloride (Chlorpromazine Hydrochloride) Flunitrazepam (Flunitrazepam) Levomepromazine (Levomepromazine)	PS SS SS C C	Rw Johnson Pharmaceutical Research Institute Div Ortho Pharm	ORAL	7.5 MG, DAILY 2 MG, DAILY, ORAL (SEE IMAGE) 300 MG, DAILY (SEE IMAGE)	

Date:05/24/01ISR Number: 3728693-2Report Type:Expedited (15-DaCompany Report #PHBS2001DE04940
Age:19 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Binge Eating Hunger Hyperphagia Weight Increased	Foreign Literature Health Professional Other	Clozaril Haloperidol Chlorprothixene Clopenthixol	PS SS SS SS	Novartis Pharmaceuticals Corp		450 MG/D	

Date:05/25/01ISR Number: 3728425-8Report Type:Direct Company Report #
Age:29 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Aspiration		Zyprexa 10mg	PS		ORAL	10 MG PO QD	
Hospitalization -	Coma		Haldol 5 Mg/Ml Inj	SS			2 MG IM Q 4	
Initial or Prolonged	Metabolic Acidosis						HOURS PRN	
Required	Pyrexia							
Intervention to	Shock							
Prevent Permanent								
Impairment/Damage								

Date:05/29/01ISR Number: 3730482-XReport Type:Expedited (15-DaCompany Report #EMADSS2001003087
Age:81 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	C-Reactive Protein	Foreign	Haldol	PS	Rw Johnson			
Initial or Prolonged	Increased	Health			Pharmaceutical			
	Confusional State	Professional			Research Institute			
	Fall		Laroxyl Roche					
	Hypokalaemia		(Amitriptyline					
	Hypoproteinaemia		Hydrochloride)	SS				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/30/01ISR Number: 3730643-XReport Type:Expedited (15-DaCompany Report #2001-05-1273
Age:58 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Dyskinesia	Foreign	Trilafon	PS	Schering Corp Sub			
Other	Meigs' Syndrome	Health			Schering Plough Corp		4-16 MG (SEE IMAGE)	
	Muscle Twitching	Professional						
	Visual Disturbance		Haldol	SS				
			Propavan Tablets	SS			25-50 MG (SEE IMAGE)	
			Tryptizol Tablets	SS			50-100 MG (SEE IMAGE)	
			Seroxat Tablets	SS			10-30 MG (SEE IMAGE)	
			Nozinan Tablets	SS			25-50 MG HS	

Date:06/01/01ISR Number: 3732279-3Report Type:Expedited (15-DaCompany Report #EMADSS2001003233
Age:36 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Apallic Syndrome	Foreign	Haldol	PS	Rw Johnson			
	Electrocardiogram Qt Prolonged	Health			Pharmaceutical			
		Professional			Research Institute		INTRAMUSCULAR	200 MG, DAILY, IM
	Ventricular Tachycardia							

Date:06/05/01ISR Number: 3734077-3Report Type:Expedited (15-DaCompany Report #NSADSS2001015993
Age:29 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Hospitalization - Initial or Prolonged Required	Deep Vein Thrombosis Disorientation Hypertension	Foreign Literature Other	Haldol	PS	Rw Johnson Pharmaceutical Research Institute	
INTRAMUSCULAR IM						
Intervention to Prevent Permanent ORAL	Leukocytosis Neuroleptic Malignant		Haldol *Unspecified) (Haloperidol)	SS		ORAL
Impairment/Damage	Syndrome Pneumonia Aspiration Sepsis Speech Disorder		Haldol (Unspecified) (Haloperidol) Olanzapine Lorazepam	SS C C		

Date:06/05/01ISR Number: 3734106-7Report Type:Expedited (15-DaCompany Report #J081-002-000749
Age:82 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Bronchitis Acute	Foreign	Aricept	PS	Eisai Inc	ORAL
3 MG, 1 IN 1						
	Bronchospasm	Health				
D, PER ORAL;						
	Dehydration	Professional				
5 MG , 1 IN 1						
	Eating Disorder Symptom					
D, PER ORAL						
	Haematuria		Serenace			
	Muscle Rigidity		(Haloperidol)	SS		
5 MG,						
	Neuroleptic Malignant Syndrome		Akineton (Biperiden Hydrochloride)	C		
	Pneumonia Aspiration		Tetramide (Mianserin			
	Respiratory Failure		Hydrochloride)	C		
	Restlessness		Pantosin			
	Vomiting		(Pantethine)	C		
	White Blood Cells Urine Positive		Laxoberon (Sodium Picosulfate)	C		
			Symmetrel (Amantadine			

			Hydrochloride)	C		

Date:06/05/01ISR Number: 3734138-9Report Type:Expedited (15-DaCompany Report #NSADSS2001008394
Age:50 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - SEE IMAGE	Asthenia	Foreign	Risperdal	PS	Janssen Research Fdn	ORAL		
Initial or Prolonged Required SEE IMAGE	Cardiac Arrest Decreased Appetite	Literature Health	Haldol (Unspecified) (Haloperidol)	SS				
Intervention to Prevent Permanent Impairment/Damage SEE IMAGE	Dehydration Electrocardiogram Qt Prolonged Myocarditis Pneumonia Torsade De Pointes Ventricular Tachycardia	Professional	Chlorpromazine Hydrochloride (Chlorpromazine Hydrochlorride) Flunitrazepam (Flunitrazepam) Levomepromazine (Levomepromazine)	SS C C				

Date:06/07/01ISR Number: 3735938-1Report Type:Expedited (15-DaCompany Report #J081-002-000749
Age:82 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Neuroleptic Malignant Syndrome Oral Intake Reduced Pneumonia Aspiration Urine Abnormality	Foreign Health Professional	Aricept Serenace (Haloperidol) Tetramide (Mianserin Hydrochloride) Pantosin (Pantethine)	PS SS C C	Eisai Inc	ORAL	3 MG, 1 IN 1 D, PER ORAL INTRAMUSCULAR 5 MG, INTRA-MUSCULAR	

			Laxoberon (Sodium Picosulfate)	C		
			Symmetrel (Amantadine Hydrochloride)	C		

Date:06/07/01ISR Number: 3735943-5Report Type:Expedited (15-DaCompany Report #10854453
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Blood Albumin Decreased	Study	Fluphenazine Hcl	PS	Apothecon Inc Div			
Hospitalization -	Blood Albumin Increased	Health			Bristol Myers Squibb			
Initial or Prolonged	Blood Alkaline Phosphatase Increased	Professional						
	Blood Bilirubin Increased		Protonix (Pantoprazole Sodium)	SS				
	Cardiac Arrest							
	Diabetes Insipidus							
	Electrocardiogram St Segment Abnormal		Haldol (Haloperidol)	SS				
	Hypotension							
	Neuroleptic Malignant Syndrome		Pepcid	C				
	Renal Failure Acute		Ativan	C				
	Renal Tubular Necrosis		Phenytoin	C				
	Rhabdomyolysis		Clonazepam	C				
			Risperdal	C				
						INTRAMUSCULAR	12.5 MILLIGRAM, 1/TOTAL IM	
						INTRAVENOUS	40 MILLIGRAM, 1 DAY IV	
						INTRAVENOUS	5 MILLIGRAM, AS NECESSARY IV	

Colace	C
Isoflurane	C
Aquamephyton	C
Versed	C
Norcuron	C
Lidocaine	C
Etomidate	C
Anectine	C
Tylenol	C
Chloral Hydrate	C
Potassium Phosphate, Dibasic	C
Neostigmine	C
Glycopyrrolate	C
Potassium Chloride	C
Magnesium Sulfate	C
Labetalol	C
Calcium Chloride	C
Morphine	C
Mannitol	C
Propofol	C
Reglan	C
Depakote	C
Fentanyl Citrate	C
Flagyl	C
Vancomycin	C
Rocephin	C

Date:06/08/01ISR Number: 3736274-XReport Type:Expedited (15-DaCompany Report #A110358
Age:54 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Interaction Drug Level Below Therapeutic Mania Psychotic Disorder	Health Professional	Geodon	PS	Pfizer Central Research	ORAL	PO	
			Haldol	SS		ORAL	ORAL	
			Vioxx	C				
			Synthroid	C				
			Anafranil	C				
			Benztropine	C				
			Depakote	C				
			Ambien	C				

Date:06/11/01ISR Number: 3737996-7Report Type:Expedited (15-DaCompany Report #2001CG00570
Age:47 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	C-Reactive Protein	Foreign	Prilosec	PS	Astrazeneca Lp	ORAL	20 MG QD PO	
	Increased	Health	Sabril	SS				
	Cholestasis	Professional	Lamictal	SS		ORAL	150 MG QD PO	
	Hepatic Failure	Other	Haldol	SS		ORAL	7 MG QD PO	
	International Normalised		Gardinal "Specia"	SS		ORAL	10 MG QD PO	
	Ratio Increased		Seresta	SS		ORAL	10 MG PO	
	Mouth Haemorrhage		Revotril	C				
	Pyrexia							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/11/01ISR Number: 3740425-0Report Type:Periodic Company Report #NSADSS2001001541
Age:40 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Extrapyramidal Disorder	Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute	INTRAMUSCULAR	50 MG, IM	
			Haldol (Unspecified) (Haloperidol)	SS		ORAL	5 MG, 1 IN 1 NIGHT(S), ORAL	
			Cogentin (Benzatropine Mesilate)	C				
			Lipitor (Atorvastatin)	C				
			Celexa (Citalopram Hydrobromide)	C				
			Oral Hypoglycemic (Hypoglycemics)	C				

Date:06/11/01ISR Number: 3740427-4Report Type:Periodic Company Report #PRIUSA2000006040
Age:73 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Confusional State Hallucination Neuroleptic Malignant Syndrome	Consumer	Haldol	PS	Rw Johnson Pharmaceutical Research Institute	INTRAMUSCULAR	2 TIME(S), IM	
			Antibiotics (Antibiotics)	C				

Date:06/11/01ISR Number: 3740429-8Report Type:Periodic Company Report #PRIUSA2000009984
Age:55 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Disability	Disturbance In Attention Dyskinesia	Consumer	Haldol	PS	Rw Johnson Pharmaceutical Research Institute	ORAL
0.5 MG, ORAL						
			Risperdal (Risperidone)	C		

Date:06/13/01ISR Number: 3739326-3Report Type:Expedited (15-DaCompany Report #NSADSS2001016096
Age:32 YR Gender:Female I/FU:I

Outcome	PT
Death	Acute Respiratory Distress Syndrome
Hospitalization - Initial or Prolonged	Atrioventricular Block
	Candidiasis
	Cardiac Arrest
	Fungal Infection
	Haematoma
	Hepatic Congestion
	Hepatic Haemorrhage
	Hepatic Necrosis
	Hepatic Steatosis
	Hepatomegaly
	Hyperkalaemia
	Hypertrophy

		Hypotension Mental Impairment Neuroleptic Malignant Syndrome Oxygen Saturation Decreased	Report Source Health Professional	Product	Role	Manufacturer	Route
Dose	Duration						
INTRAVENOUS	IV	Pyrexia		Pantoprazole	SS		
INTRAVENOUS	40 MG, 1 IN 1 DAY(S), IV	Renal Failure Acute Renal Tubular Necrosis		Pantoprazole	SS		
INTRAMUSCULAR	12.5 MG, 1 IN 1 TIME(S), IM	Splenomegaly Ventricular Fibrillation		Morphine	C		
				Vasopressin	C		
				Vecuronium	C		
				Dopamine	C		
				Insulin Injectino (Insulin)	C		
				Enoxaparin Sodium (Heparin-Fraction, Sodium Salt)	C		
				Vancomycin	C		
				Metoprolol	C		
				Ranitidine	C		
				Albuterol (Salbutamol)	C		
				Atrovent (Ipratropium Bromide)	C		
				Insulin Iletin I Regular (Insulin)	C		
				Zosyn (Pip/Tazo)	C		
				Diflucan (Fluconazole)	C		
				Gentamicin Sulfate	C		
				Sodium Bicarbonate	C		
				Calcium Gluconate	C		
				Dantrolene	C		
				Dextrose (Glucose Injection)	C		
				Ceftriaxone	C		
				Isoflurane	C		
				Sevoflurane	C		

Versed (Midazolam Hydrochloride)	C
Fentanyl Citrate	C
Scopolamine (Hyoscine)	C
Rocuronium	C
Ibuprophen	C
Acetaminophen (Paracetamol)	C
Diphenhydramine	C
Calcium Chloride Anhydrous	C
Cefazolin	C
Lorazepam	C
Acetazolamide	C
Magnesium Sulfate	C
Furosemide	C
Mannitol	C
Potassium Phosphate Dibasic	C

			Potassium Chloride	C			
			Eprex (Epoetin Alfa)	C			

Date:06/13/01ISR Number: 3739330-5Report Type:Expedited (15-DaCompany Report #NSADSS2001016102
Age:29 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Life-Threatening	Blood Pressure Decreased	Health	Haldol	PS	Rw Johnson		
Hospitalization -	Cardiac Arrest	Professional			Pharmaceutical		
Initial or Prolonged	Dyspnoea				Research Institute		
INTRAVENOUS	PRN,						10 MG,
Disability	Electrocardiogram St						
IV							
	Segment Abnormal		Depakote (Valproate				
	Nervous System Disorder		Semisodium)	C			
	Neuroleptic Malignant		Clonazepam	C			
	Syndrome		Risperdal	C			
	Renal Failure Acute						
	Rhabdomyolysis						

Date:06/14/01ISR Number: 3739757-1Report Type:Expedited (15-DaCompany Report #A110358
Age:54 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Condition Aggravated	Health	Geodon	PS	Pfizer Central		
Initial or Prolonged	Drug Interaction	Professional			Research	ORAL	
120.00 MG							
	Mania						
TOTAL:BID:ORA							
	Psychotic Disorder						
L							
			Haldol	SS		ORAL	
ORAL							
			Vioxx	C			
			Synthroid	C			
			Anafranil	C			
			Benztropine	C			
			Depakote	C			
			Ambien	C			

Date:06/14/01ISR Number: 3739794-7Report Type:Expedited (15-DaCompany Report #01P-114-0107676-00
Age:74 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Cognitive Disorder	Foreign	Biaxin	PS	Abbott Laboratories	ORAL	250 MG, 2 IN 1 D,F PER	
	Delirium	Literature						
	Disorientation	Health					ORAL	
	Extrapyramidal Disorder	Professional	Haloperidol					
	Hallucination		(Haloperidol)	SS			INTRAVENOUS	INTRAVENOUS
	Hypokinesia		Metronidazole					
	Joint Stiffness		(Metronidazole)	C				
	Muscle Rigidity		Ranitidine Bismuth					
	Pallor		Citrate (Ranitidine					
	Paranoia		Bismuth Citrates)	C				
	Renal Impairment		Iron Preparations	C				
	Speech Disorder		Pravastatin					
			(Pravastatin)	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/15/01ISR Number: 3740554-1Report Type:Expedited (15-DaCompany Report #71128-005
Age:68 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dehydration Extrapyramidal Disorder Ileus Paralytic	Literature Health Professional	Haloperidol	PS	Roxane Laboratories Inc	ORAL	0.5 MG, TID, ORAL	4 DAY
			Benztropine Injection	SS		INTRAVENOUS	2MG, TWICE ONLY, INTRAVENOUSLY	
			Cardizem Xl	C				
			Synthroid	C				
			Premarin	C				

Date:06/18/01ISR Number: 3741894-2Report Type:Expedited (15-DaCompany Report #NSADSS2001016691
Age:63 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Intestinal Perforation Uterine Cancer	Foreign Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute Div Ortho Pharm	ORAL	24 MG ORAL	
			Propitan (Pipamperone)	SS			150	
			Mellaril (Thioridazine Hydrochloride)	SS			150	
			Chlorpromazine (Chloropromazine)	SS			50	
			Fluphenazine (Fluphenazine)	SS		INTRAMUSCULAR	25 MG , 2 IN	

1 MONTH(S) IM

	Perphenazine (Perphenazine)	SS
12		
	Phenytoin (Phenytoin)	SS
150		
	Phenobarbital (Phenobarbital)	SS
48		
	Promethazine (Promethazine)	SS
75		
	Levomepromazine (Levomepromazine)	SS
250		
	Trihexyphenidyl (Trihexyphenidyl)	SS
6		
	Zotepine (Zotepine)	SS
100		
	Fluphenazine (Fluphenazine)	SS

INTRAMUSCULAR 50 MG 1 IN 1

MONTH(S) IM

	Nitrazepam (Nitrazepam)	SS
10		
	Sennoside (Sennoside)	SS

Date:06/19/01ISR Number: 3741439-7Report Type:Direct Company Report #
Age:68 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Neuroleptic Malignant Syndrome		Haloperidol	PS	UNKNOWN			

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/19/01ISR Number: 3742447-2Report Type:Direct Company Report #
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Intubation		Haldol	PS			INTRAVENOUS	7MG IV X1
Hospitalization -	Respiratory Depression		Lorazepam	SS			INTRAVENOUS	2MG IV X1
Initial or Prolonged			Ec Aspirin	C				
Required			Colace	C				
Intervention to			Ranitidine	C				
Prevent Permanent			Heparin	C				
Impairment/Damage			Mvi	C				
			Thiamine	C				
			Colchicine	C				
			Levaquin	C				

Date:06/19/01ISR Number: 3743150-5Report Type:Expedited (15-DaCompany Report #NSADSS2001008394
Age:50 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Asthenia	Foreign	Risperdal	PS	Janssen Research Fdn	ORAL	2 MG, DAILY,	
Initial or Prolonged	C-Reactive Protein	Literature					ORAL (SEE	
Required	Increased	Health					IMAGE)	
Intervention to	Cardiac Arrest	Professional	Haldol (Unspecified)					
Prevent Permanent	Decreased Appetite		(Haloperidol)	SS			7.5 MG, DAILY	
Impairment/Damage	Electrocardiogram Qt						(SEE IMAGE)	
	Prolonged		Chlorpromazine					
	Inflammation		Hydrochloride					
	Myocarditis		(Chlorpromazine					
	Pneumonia		Hydrochloride)	SS			300 MG, DAILY	
	Torsade De Pointes						(SEE IMAGE)	
	Ventricular Tachycardia		Flunitrazepam					
			(Flunitrazepam)	C				
			Levomepromazine					
			(L-Evomepromazine)	C				

Date:06/21/01ISR Number: 3744010-6Report Type:Expedited (15-DaCompany Report #A105258
Age:34 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Abnormal Behaviour	Consumer	Zoloft	PS	Pfizer			
Required	Drug Level Above	Health			Pharmaceuticals Inc		100.000 MG	
Intervention to	Therapeutic	Professional						TOTAL
Prevent Permanent	Dyskinesia		Benadryl	SS				
Impairment/Damage	Hallucination		Cogentin	SS				
	Muscle Rigidity		Haldol	SS				
	Overdose		Seroquel	C				
	Psychotic Disorder							
	Tremor							
	Trismus							
	Wolff-Parkinson-White Syndrome							

Date:06/21/01ISR Number: 3744604-8Report Type:Expedited (15-DaCompany Report #EMADSS2001003630
Age:25 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Shock	Foreign	Haldol	PS	Rw Johnson			
	Sudden Death	Health			Pharmaceutical			
		Professional			Research Institute			START DATE

NOT SPECIFIED

Rohypnol (Flunitrazepam)	SS	

START DATE

NOT SPECIFIED

Nozinan (Levomepromazine)	SS	

START DATE

NOT SPECIFIED

Date:06/21/01ISR Number: 3744876-XReport Type:Expedited (15-DaCompany Report #NSADSS2001008394
Age:50 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Asthenia Cachexia Cardiac Arrest Dehydration Electrocardiogram Qt Prolonged Myocarditis Oral Intake Reduced Pneumonia Torsade De Pointes Ventricular Tachycardia	Foreign Literature Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute Div Ortho Pharm		7.5 MG, DAILY 5.25 MG, DAILY	
			Risperidone (Unspecified) (Risperidone)	SS		ORAL	2 MG, DAILY, ORAL/12 MG, DAILY, ORAL/ 5 MG DAILY, ORAL 3 MG, 300 MG, DAILY/ 200 MG DAILY/300 MG,	
			Chlorpromazine Hydrochloride	SS				

DAILY

				Flunitrazepam	C		
				Levomepromazine	C		

Date:06/22/01ISR Number: 3745299-XReport Type:Expedited (15-DaCompany Report #PHRM2001FR01488
Age:38 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Sudden Death	Foreign	Tegretol	PS	Novartis			
	Ventricular Arrhythmia	Health			Pharmaceuticals Corp	ORAL	ORAL	
		Professional	Haldol (Haloperidol)	SS			INTRAMUSCULAR	INTRAMUSCULAR
		Other	Barnetil	SS		ORAL	ORAL	
			Tranxene	SS		ORAL	ORAL	

Date:06/25/01ISR Number: 3745262-9Report Type:Expedited (15-DaCompany Report #262522
Age:55 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Neuroleptic Malignant Syndrome		Rivotril	PS	Roche			
			Haldol	SS				18 DAY
	Pyrexia		Tercian	SS				18 DAY
	Rhabdomyolysis							

Date:06/25/01ISR Number: 3746368-0Report Type:Expedited (15-DaCompany Report #NSADSS2001018709
Age:73 YR Gender:Female I/FU:I

Outcome	PT
Death	Blindness
	Catatonia

		Confusional State					
		Dysphagia					
		Neuroleptic Malignant	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
		Syndrome	Consumer	Haldol	PS	Rw Johnson	
		Paranoia				Pharmaceutical	
		Starvation				Research Institute	
INTRAMUSCULAR	0.5 MG, IM						
		Tardive Dyskinesia		Zoloft (Sertraline			
				Hydrochloride)	C		
				Restoril (Temazepam)	C		

Date:06/25/01ISR Number: 3746834-8Report Type:Expedited (15-DaCompany Report #EMADSS2001003698
Age:46 YR Gender:Male I/FU:I

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Death		Congestive Cardiomyopathy	Foreign	Haldol	PS	Rw Johnson	
		Deep Vein Thrombosis	Health			Pharmaceutical	
		Mitral Valve Prolapse	Professional			Research Institute	
		Pulmonary Embolism				Div Ortho Pharm	ORAL
5 MG, 1 IN 1							
		Pulmonary Veno-Occlusive					
DAILY, ORAL							
		Disease		Xanax (Alprazolam)	C		
				Imovane (Zopiclone)	C		
				Vitamins	C		
				Catapressan			
				(Clonidine)	C		

Date:06/25/01ISR Number: 3746835-XReport Type:Expedited (15-DaCompany Report #NSADSS2001017662
Age:60 YR Gender:Female I/FU:I

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Hospitalization -		Depression	Foreign	Haldol	PS	Rw Johnson	
Initial or Prolonged		Malaise	Health			Pharmaceutical	
			Professional			Research Institute	
						Div Ortho Pharm	
				Risperidone	SS		ORAL
ORAL							
				Alosenn	C		
				Antibiotics-Resistan			

			t Lactic Acid			
			Bacteriae	C		
			Magnesium Oxide	C		
			Etizolam	C		
			Milnacipran	C		

Date:06/25/01ISR Number: 3746836-1Report Type:Expedited (15-DaCompany Report #EMADSS2001003584
Age:47 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Thrombocytopenia	Foreign Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute Div Ortho Pharm	ORAL	5 MG, 1 IN 1	DAY(S), ORAL
			Trihexyphenidyl	C				
			Paroxetine	C				
			Diclofenac	C				
			Tetrazepam	C				
			Tramadol	C				
			Staltor (Cerivastatin)	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/25/01ISR Number: 3747322-5Report Type:Expedited (15-DaCompany Report #EMADSS2001003648
Age:35 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Intestinal Obstruction Rectal Haemorrhage	Foreign Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute	INTRAMUSCULAR	100 MG/ML, 1	IN 30 DAY(S),
						IM		
			Tercian (Cyamemazine)	SS		ORAL	2,	DAILY,
						ORAL		
			Dexoxat (Paroxetine Hydrochloride)	C				
			Stilnox (Zolpidem)	C				
			Forlax (Macrogol)	C				
			Eurobiol (Pancreatin)	C				

Date:06/26/01ISR Number: 3748076-9Report Type:Expedited (15-DaCompany Report #262522
Age:55 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Neuroleptic Malignant Syndrome	Foreign Other	Clonopin	PS	Hoffmann La Roche Inc	ORAL		
						ORAL		
	Pyrexia		Haldol (Haloperidol)	SS		ORAL		
						ORAL		
	Rhabdomyolysis		Tercian (Cyamemazine)	SS		ORAL		
						ORAL		

Date:06/26/01ISR Number: 3748274-4Report Type:Expedited (15-DaCompany Report #A001-002-004751
Age:75 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Agitation	Consumer	Aricept	PS	Eisai Inc	ORAL	PER ORAL	
	Aphasia		Zoloft (Sertraline Hydrochloride)	SS		ORAL	50 MG, PER ORAL	
	Belligerence							
	Blindness							
	Catatonia		Proventil (Salbutamol)	SS				
	Confusional State		Haldol (Haloperidol)	SS		ORAL	PER ORAL	
	Constipation		Restoril (Temazepam)	C				
	Decreased Appetite		Zithromax (Azithromycin)	C				
	Dehydration		Antibiotics	C				
	Dementia							
	Disorientation							
	Dry Mouth							
	Dysphagia							
	Flight Of Ideas							
	Hallucination							
	Hallucination, Auditory							
	Lethargy							
	Neuroleptic Malignant Syndrome							
	Paranoia							
	Personality Change							
	Pneumonia							
	Raynaud'S Phenomenon							
	Sjogren'S Syndrome							
	Starvation							
	Tremor							
	Weight Decreased							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/27/01ISR Number: 3748798-XReport Type:Expedited (15-DaCompany Report #EMADSS2001003899
Age:84 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abnormal Behaviour Cerebellar Syndrome Fall	Foreign Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute Div Ortho Pharm	ORAL		
			Celebrex (Celecoxib)	C				
			Xanax (Alprazolam)	C				
			..	C				

Date:06/27/01ISR Number: 3749469-6Report Type:Expedited (15-DaCompany Report #HQ2446122JUN2001
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Mental Disorder Murder	Consumer	Effexor	PS	Wyeth Ayerst Laboratories	ORAL	75 MG 1 X PER	1 DAY, ORAL
			Cogentin (Benzatropine Mesilate)	SS			2 MG	
			Colace (Docusate Sodium)	SS			200 MG	
			Haldol (Haloperidol)	SS			2 MG	
			Trazodone (Trazodone)	SS			200 MG 1 X	PER 1 DAY

Date:06/28/01ISR Number: 3749937-7Report Type:Expedited (15-DaCompany Report #2001061492FR
Age:84 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Cerebellar Syndrome	Foreign	Celebrex	PS	Gd Searle And Co	ORAL	200 MG, QD,	
	Fall	Health Professional Other	Haldol (Haloperidol)	SS				
			Xanax	C				

Date:06/29/01ISR Number: 3750305-2Report Type:Direct Company Report #
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Medication Error		Haloperidol 5 Mg/ Ml American Pharmaceutical Partners	PS	American Pharmaceutical Partners			

Date:07/02/01ISR Number: 3751012-2Report Type:Expedited (15-DaCompany Report #WAES 01062113
Age:68 YR Gender:Female I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Abdominal Distension
	Confusional State
	Dehydration
	Drug Interaction
	Dyskinesia

	Dystonia						
	Ileus Paralytic						
	Intestinal Dilatation	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Pyrexia	Literature	Cogentin	PS	Merck And Co Inc	INTRAVENOUS	2 MG/1X/IV
		Health	Haloperidol	SS		ORAL	0.5 MG/TID/PO
		Professional	Cardizem Sr	C			
			Premarin	C			
			Synthroid	C			
			Verapamil	C			

Date:07/02/01ISR Number: 3751060-2Report Type:Expedited (15-DaCompany Report #A044-002-003055
Age:65 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Bradycardia	Foreign	Aricept	PS	Eisai Inc	ORAL	10 MG, 1 IN 1 D, PER ORAL
	Loss Of Consciousness	Health					
	Nodal Arrhythmia	Professional	Verapamil	SS		ORAL	240 MG, PER ORAL
	Sinus Arrhythmia						
	Urinary Incontinence		Haloperidol	SS		ORAL	5 DOSAGE FORMS, 5 IN 1 D, PER ORAL

Date:07/02/01ISR Number: 3751243-1Report Type:Expedited (15-DaCompany Report #01P-087-0108135-00
Age:37 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Death Required Intervention to	Cardiac Arrest	Foreign	Depakene	PS	Abbott Laboratories Pharmaceutical Products Div	ORAL	600 MG, 1 IN
	Depressed Level Of Consciousness	Health Professional					

Prevent Permanent Impairment/Damage	Disseminated Intravascular Coagulation Multi-Organ Failure Neuroleptic Malignant Syndrome Pyrexia	Other	Fluvoxamine Maleate	SS		ORAL 1 D, PER ORAL SEE IMAGE
			Haloperidol	SS		ORAL 9 MG, 1 IN 1 D, PER ORAL
			Chlorpromazine Hydrochloride	SS		ORAL 100 MG, 1 IN 1 D, PER ORAL
			Biperiden Hydrochloride	C		

Date:07/02/01ISR Number: 3751539-3Report Type:Expedited (15-DaCompany Report #2001-05-1273
Age:58 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Disability Other	Anxiety Condition Aggravated Decreased Activity Eyelid Ptosis Meigs' Syndrome Mental Disorder Muscle Twitching Psychotic Disorder Speech Disorder Tardive Dyskinesia Tremor Visual Acuity Reduced	Foreign Health Professional	Trilafon	PS	Schering Corp Sub Schering Plough Corp	4-16 MG (SEE IMAGE)
			Haldol	SS		2 MG BID (SEE IMAGE)
			Propavan Tablets	SS		25-50 MG (SEE IMAGE)
			Tryptizol Tablets	SS		50-100 MG (SEE IMAGE)
			Nozinan Tablets	SS		25-50 MG HS
			Litarex Tablets	SS		84 MG BID
			Seroxat Tablets	SS		10-30 MG (SEE IMAGE)
			Flunitrazepam Tablets	C		

Disipal Tablets C

Date:07/04/01ISR Number: 3752020-8Report Type:Expedited (15-DaCompany Report #A114732
Age:75 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Abnormal Behaviour	Consumer	Zoloft	PS	Pfizer			
Disability	Agitation				Pharmaceuticals Inc			
	Asthenia						25.00 MG	
							TOTAL	
	Balance Disorder		Haldol	SS		ORAL	0.50 MG	
	Blindness						TOTAL:ORAL	
	Blood Pressure Decreased		Aricept	SS				
	Catatonia		Restoril	SS			15.00 MG	
	Confusional State						TOTAL	
	Constipation		Zithromax	C				
	Decreased Appetite							
	Diarrhoea							
	Difficulty In Walking							
	Dysphagia							
	Hallucinations, Mixed							
	Lethargy							
	Neuroleptic Malignant Syndrome							
	Paranoia							
	Starvation							
	Tooth Disorder							
	Vision Blurred							
	Visual Disturbance							
	Weight Decreased							

Date:07/05/01ISR Number: 3752523-6Report Type:Direct Company Report #
Age:25 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Other		Body Temperature		Haldol (Injection)	PS		
INTRAMUSCULAR	5MG IM STAT	Increased Muscle Rigidity Nervousness					

Date:07/05/01ISR Number: 3752634-5Report Type:Direct Company Report #
Age:46 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Coordination Abnormal		Haloperidol Conc.	PS			10MG BID	
Initial or Prolonged			Decanoate	SS			250MG Q3W IM	
			Olanzapine	SS		ORAL	10MG DAILY PO	
			Lithium Citrate	C				
			Sertraline	C				
			Docusate Sodium	C				
			Lactulose	C				

Date:07/06/01ISR Number: 3753584-0Report Type:Direct Company Report #
Age:77 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Bladder Disorder		Risperidone 0.5mg	PS		ORAL	0.5MG-0.75	
Initial or Prolonged							DAILY ORAL	

			Haloperidol 0.5mg	SS		ORAL
0.5MG-2MG DAILY ORAL						
			Donepezil	C		
			Trazodone	C		
			Bupropion	C		
			Metoprolol	C		

Date:07/09/01ISR Number: 3754672-5Report Type:Expedited (15-DaCompany Report #JAFRA31345
Age:77 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Bundle Branch Block Left	Foreign	Droleptan (Solution)			
Hospitalization - (27-SEP-93):D	Cardiac Arrest	Health	(Droperidol)	PS		
Initial or Prolonged OSE:20DROPS	Computerised Tomogram	Professional				
	Abnormal		Haldol (Solution)			
	Drug Toxicity		(Haloperidol)	SS		
(27-SEP-93) :DOSE: 30	Electroencephalogram					
	Abnormal					
DROPS						
	Epilepsy		Renitec (Tablet)			
	Respiratory Arrest		(Enalapril)	SS		
( ): DOSE:1/2 TABLETS FOR A FEW MONTHS						

Date:07/09/01ISR Number: 3755091-8Report Type:Expedited (15-DaCompany Report #A114732
Age:75 YR Gender:Female I/FU:F

Outcome	PT
Death	Abnormal Behaviour
Disability	Agitation
	Asthenia
	Blindness
	Catatonia

Confusional State
Constipation
Decreased Appetite
Dehydration
Dementia
Diarrhoea
Difficulty In Walking
Discomfort
Disorientation
Dysphagia
Eating Disorder
Feeling Abnormal
Feeling Cold
Flight Of Ideas
Hallucinations, Mixed
Lethargy
Mental Impairment
Muscle Rigidity
Neuroleptic Malignant
Syndrome
Pharyngitis Streptococcal
Pulse Absent
Road Traffic Accident
Speech Disorder
Starvation
Vision Blurred
Visual Disturbance

Weight Decreased

Dose	Duration	Report Source	Product	Role	Manufacturer	Route
		Consumer	Zoloft	PS	Pfizer Pharmaceuticals Inc	
50.00 MG						
TOTAL						
			Azithromycin	SS		ORAL
500.00 MG						
TOTAL DAILY:						
ORAL						
			Aricept	SS		
			Haldol	SS		ORAL
0.50 MG						
TOTAL: ORAL						
			Restoril	C		
			Antibiotic Unspecified	C		
			Proventil	C		

Date:07/09/01ISR Number: 3755374-1Report Type:Expedited (15-DaCompany Report #971028-008012934
Age:23 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Death	Cardio-Respiratory Arrest	Foreign Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute	
INTRAMUSCULAR	10 MG, ONCE,					
IM						
			Droperridol (Droperidol)	SS		
INTRAMUSCULAR	50 MG, ONCE,					
IM						
			Levomerpromazine	C		
			Zuclopenthixol	C		
			Valproate Sodium	C		

Date:07/09/01ISR Number: 3755375-3Report Type:Expedited (15-DaCompany Report #970305-008010646
Age:77 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death Hospitalization - Initial or Prolonged	Atrophy Bundle Branch Block Cardiac Arrest Cardiac Disorder Convulsion Nervous System Disorder Respiratory Arrest	Foreign Study Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute	ORAL	30 DROP, 1 IN	I DAY (S),
			Droperidol Solution	SS		ORAL	10 DROP, I IN	1 DAY (S),
			Droperidol Solution	SS		ORAL	20 DROP,	NIGHT (S),
			Enalapril	SS		ORAL	ORAL	

Date:07/09/01ISR Number: 3755404-7Report Type:Expedited (15-DaCompany Report #JAFRA35307
Age:23 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardio-Respiratory Arrest	Foreign	Droleptan (Solution 5 Mg/Ml) (Droperidol)	PS		INTRAMUSCULAR	50 MG, 1 IN 1	TIME(S), IM
			Haldol (Solution 5/					

			Mg/Ml) (Haloperidol)	SS		
INTRAMUSCULAR	10 MG, 1 IN 1					
TIME(S) IM						
			Nozinan (Solution 25 Mg/Ml) (Levomepromazine)	C		
			Clopixol Action Prolongee (Ampoule 200 Mg) (Zuclopenthixol)	C		
			Clopixol (Tablet 10 Mg) (Zuclopenthixol)	C		
			Depakine (Tablet 500 Mg) (Valproate Sodium)	C		

Date:07/11/01ISR Number: 3756744-8Report Type:Expedited (15-DaCompany Report #EMADSS2001003233
Age:36 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Apallic Syndrome	Foreign	Haldol	PS	Rw Johnson Pharmaceutical Research Institute			
Disability (DATES TO BE	Brain Hypoxia	Health						
Other CONFIRMED)	Bronchitis Acute	Professional						
Required Intervention to Prevent Permanent Impairment/Damage	Coma							
	Electrocardiogram Qt Prolonged		Carbamazepine	C				
	Fall							
	Loss Of Consciousness							
	Pyrexia							
	Ventricular Fibrillation							
	Ventricular Tachycardia							

Date:07/11/01ISR Number: 3756745-XReport Type:Expedited (15-DaCompany Report #EMADSS2001004102
Age:65 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Bradycardia	Foreign	Haldol	PS	Rw Johnson Pharmaceutical			
	Convulsion	Health						

	Malaise	Professional			Research Institute	ORAL
5 U, DAILY,						
	Sinus Arrhythmia					
ORAL						
	Syncope		Verapamil	C		
	Urinary Incontinence		Aricept (Donepezil Hydrochloride)	C		

Date:07/11/01ISR Number: 3756776-XReport Type:Expedited (15-DaCompany Report #01P-056-0108471-00
Age:38 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Sudden Death	Foreign	Tranxene	PS	Abbott Laboratories	
	Ventricular Arrhythmia	Health Professional			Pharmaceutical Products Div	ORAL
1IN 1 D, PER						
ORAL		Other				
			Sultopride	SS		ORAL
PER ORAL						
			Haloperidol	SS		
INTRAMUSCULAR INTRAMUSCULAR						
			Carbamazepine	SS		ORAL
PER ORAL						

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/16/01ISR Number: 3758394-6Report Type:Direct Company Report #
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Hallucination		Haloperidol	PS		ORAL	0.5 MG PO QHS	
Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Neuroleptic Malignant Syndrome		Geodon	SS		ORAL	80 MG PO BID	

Date:07/18/01ISR Number: 3760264-4Report Type:Direct Company Report #
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Medication Error		Haloperidol	PS				
			Haldol	SS	Ortho Mcneil			

Date:07/19/01ISR Number: 3762218-0Report Type:Expedited (15-DaCompany Report #PHBS2001JP00910
Age:3 DY Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Clonic Convulsion	Foreign	Ritalin	PS	Novartis Pharmaceuticals Corp			
	Complications Of Maternal	Literature					TRANSPLACENTAL	
	Exposure To Therapeutic Drugs	Health Professional	Anafranil (Clomipramine Hydrochloride)					
	Convulsion Neonatal	Other						
	Dyskinesia		Tablet	SS			TRANSPLACENTAL	
	Jaundice Neonatal		Wintermin (Chlorpromazine Hydrochloride)	SS			TRANSPLACENTAL	
	Neonatal Disorder							
			Serenace (Haloperidol)	SS			TRANSPLACENTAL	

			Contomin (Chlorpromazine Hydrochloride)	SS			
TRANSPLACENTAL							
			Artane (Trihexyphenidyl Hydrochloride)	SS			
TRANSPLACENTAL							

Date:07/19/01ISR Number: 3762597-4Report Type:Expedited (15-DaCompany Report #NSADSS2001020630
Age:48 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Death	Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute Div Ortho Pharm			
			Zyprexa (Olanzapine)	SS		ORAL		
ORAL								

Date:07/20/01ISR Number: 3762533-0Report Type:Expedited (15-DaCompany Report #2013472
Age:90 YR Gender:Female I/FU:I

Outcome	PT
Death	Anuria
	Asthenia
	Atrial Fibrillation

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Cardiac Failure Congestive							
	Cerebrovascular Accident	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Dementia	Health	Ms Contin	PS			INTRAMUSCULAR	MG UNKNOWN IM
	Hypertension	Professional	Risperdal	SS		ORAL	.5 MG TID PO	
	Weight Decreased		Haldol (Haloperidol)	SS			INTRAMUSCULAR	MG PRN IM
			Ciprofloxacin	SS			MG UNKNOWN	
			Depakene (Valproic Acid)	SS				
			Trazodone Hcl	SS			MG UNKNOWN	
			Clonidine Hcl	SS			TRANSDERMAL	MG UNKNOWN TD

Date:07/20/01ISR Number: 3762535-4Report Type:Expedited (15-DaCompany Report #2013474
Age:90 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Agitation	Health	Morphine Sulfate (Similar To Andas 74-769 And 74-862)	PS			INTRAMUSCULAR	MG Q3H IM
	Anuria	Professional						
	Asthenia							
	Cerebrovascular Accident		Risperdal	SS		ORAL	.5 MG TID PO	
	Oral Intake Reduced		Haldol (Haloperidol)	SS			INTRAMUSCULAR	MG PRN IM
	Refusal Of Treatment By		Ciprofloxacin	SS			MG UNKNOWN	
	Patient		Depakene (Valproic Acid)	SS				
	Weight Decreased		Trazodone Hcl	SS			MG UNKNOWN	
			Clonidine Hcl	SS			TRANSDERMAL	MG UNKNOWN TD

Date:07/20/01ISR Number: 3762836-XReport Type:Expedited (15-DaCompany Report #EMADSS2001000217
Age:52 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agranulocytosis	Foreign Health Professional	Risperdal	PS	Janssen Research Fdn	ORAL	6 MG, DAILY , ORAL	
			Haldol (Unspecified) (Haloperidol)	SS			6 MG, DAILY, ORAL	
			Lepticur (Tropatepine Hydrochloride)	SS		ORAL	5 MG, DAILY, ORAL	
			Theralene (Alimemazine Tartrate)	SS		ORAL	0.5, DAILY, ORAL	
			Imovane (Zopiclone)	SS		ORAL	170 MG, DAILY, ORAL	
			Tercian (Cyamemazine)	SS		ORAL		

Date:07/23/01ISR Number: 3762585-8Report Type:Direct Company Report #USP 54164
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Medication Error		Medrol	PS	Pharmacia Corporation			
			Haldol	SS	Ortho-Mcneil			

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/23/01ISR Number: 3764076-7Report Type:Expedited (15-DaCompany Report #2001AP02861
Age:48 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardiac Arrest	Foreign	Seroquel	PS	Astrazeneca Lp	ORAL	75 MG DAILY	
Life-Threatening	Cyanosis	Health Professional					PO	
	Hypotension		Seroquel "Zeneca"	SS		ORAL	150 MG DAILY	
	Pallor	Other					PO	
	Polydipsia		Seroquel "Zeneca"	SS		ORAL	225 MG DAILY	
	Tachycardia						PO	
	Ventricular Extrasystoles		Alesion	SS		ORAL	20 MG DAILY	
							PO	
			Levotomin	SS				
			Adalat	SS		ORAL	20 MG DAILY	
							PO	
			Tegretol	SS		ORAL	200 MG DAILY	
							PO	
			Cysvon	SS		ORAL	10 MG DAILY	
							PO	
			Rohypnol	SS		ORAL	2 MG DAILY PO	
			Serenace	SS		ORAL	9 MG DAILY PO	
			Serenace	SS		ORAL	6 MG DAILY PO	
			Serenace	SS		ORAL	3 MG DAILY PO	
			Cystantin	C				
			Daiokanzoto	C				
			Laxoberon	C				
			Alosenn	C				
			Sunailin	C				

Sennoside	C
Marzulene S	C
Triphedinon	C
Anatensol	C
Pantosin	C

Date:07/25/01ISR Number: 3764395-4Report Type:Direct Company Report #
Age:69 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required	Convulsion		Haloperidol 10mg	PS				
INTRAMUSCULAR							2-3	Q3-6 HRS
Intervention to	Myocardial Infarction							
IM								
Prevent Permanent	Pyrexia							
Impairment/Damage								

Date:07/26/01ISR Number: 3765459-1Report Type:Direct Company Report #USP 54183
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Medication Error		Haloperidol Lactate	PS	American Pharmaceutical Partners			
			Haloperidol Decanoate	SS				

Date:07/26/01ISR Number: 3766250-2Report Type:Expedited (15-DaCompany Report #2001AP02034
Age:57 YR Gender:Female I/FU:I

Outcome
Hospitalization -
Initial or Prolonged

Disability

PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Blood Glucose Increased	Foreign	Seroquel	PS	Astrazeneca Lp	ORAL	75 MG DAILY	
Convulsion	Health					PO	
Cystitis	Professional	Seroquel	SS		ORAL	150 MG DAILY	
Decubitus Ulcer	Other					PO	
Dehydration		Seroquel	SS		ORAL	300 MG DAILY	
Delusion						PO	
Hallucination		Seroquel	SS		ORAL	600 MG DAILY	
Muscle Rigidity						PO	
Neuroleptic Malignant		Serenace	SS		ORAL	45 MG DAILY	
Syndrome						PO	
Oral Intake Reduced		Serenace	SS			40.5 MG DAILY	
Pneumonia		Serenace	SS		ORAL	36 MG DAILY	
Sedation						PO	
Speech Disorder		Serenace	SS		ORAL	31.5 MG DAILY	
						PO	
		Serenace	SS		ORAL	27 MG DAILY	
						PO	
		Halomonth	SS			INTRAMUSCULAR	100 MG DAILY
						IM	
		Levotomin	SS			50 MG DAILY	
		Artane	C				
		Solanax	C				
		Benzalin	C				

			Sennasid	C		
			Pantosin	C		
			Minzain	C		

Date:07/26/01ISR Number: 3766482-3Report Type:Expedited (15-DaCompany Report #K200100123
Age:39 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Disability	Convulsion	Foreign Health	Kemadrin	PS	Monarch Pharmaceuticals Inc	
INTRAMUSCULAR 10 MG,						
		Professional				
INTRAMUSCULAR						
		Other	Haloperidol (Haloperidol) Injection	SS		
INTRAMUSCULAR INTRAMUSCULAR						

Date:07/26/01ISR Number: 3766483-5Report Type:Expedited (15-DaCompany Report #K200100124
Age:45 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Disability	Epilepsy	Foreign Health	Kemadrin	PS	Monarch Pharmaceuticals Inc	
INTRAMUSCULAR 10 MG						
		Professional				
INTRAMUSCULAR						
		Other	Haloperidol (Haloperidol)	SS		
INTRAMUSCULAR INTRAMUSCULAR						
			Metodril (Methaqualone, Diphenhydramine Hydrochloride)	C		
			Valproate Sodium (Valproate Sodium)	C		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/30/01ISR Number: 3767729-XReport Type:Expedited (15-DaCompany Report #01-0052
Age:34 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Anaphylactic Shock	Other	Ponstel	PS	First Horizon Pharmaceutical Corp	ORAL	250 MG, TID,	
Hospitalization - Initial or Prolonged	Atelectasis						PO	
	Cardiac Failure							
	Diarrhoea		Serenace					
	Disseminated		(Haloperidol)	SS			33MG, TID, PO	
	Intravascular Coagulation		Limas (Lithium					
	Duodenal Ulcer		Carbonate)	SS		ORAL	200MG;TID;PO	
	Enteritis		Depas (Etizolam)	C				
	Haemodialysis		Artane					
	Hypogammaglobulinaemia		(Trihexyphenidyl					
	Hypoproteinaemia		Hydrochloride)	C				
	Oesophagitis		Silece					
	Pleural Effusion		(Flunitrazepam)	C				
	Pneumonia		Impromen					
	Pulmonary Embolism		(Bromperidol)	C				
	Pulmonary Mycosis		Remark (Betahistine					
	Rash Erythematous		Mesilate)	C				
	Renal Failure Acute							
	Rhabdomyolysis							
	Sepsis							
	Staphylococcal Infection							

Date:07/31/01ISR Number: 3768342-0Report Type:Direct Company Report #
Age:24 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Back Pain		Haldol One Single					
	Neuroleptic Malignant		Dose 5mg	PS		ORAL	5MG PO	
	Syndrome		Risperdal 2mg One @					
	Urine Abnormality		Hs	SS			1 DOSE 7/26 1	
							DOSE 7/27	

Date:07/31/01ISR Number: 3768494-2Report Type:Direct Company Report #
Age:64 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Cardiac Arrest		Haloperidol	PS				
			Lorazepam	SS				

Date:07/31/01ISR Number: 3768617-5Report Type:Expedited (15-DaCompany Report #DEU004344
Age:64 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Neuroleptic Malignant Syndrome	Other	Akineton	PS	Abbott Laboratories Pharmaceutical Products Div	ORAL	3 MG DAILY PO	
	Upper Respiratory Tract Infection		Serenace	SS		ORAL	6 MG DAILY PO	

Date:07/31/01ISR Number: 3769099-XReport Type:Expedited (15-DaCompany Report #PHBS2001JP00910
Age:4 DY Gender:Male I/FU:F

Outcome	PT
Other	Complications Of Maternal Exposure To Therapeutic

	Drugs Convulsion Neonatal Drug Withdrawal Syndrome Neonatal	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
	Dyskinesia Jaundice Neonatal	Foreign Literature	Ritalin Tab	PS	Novartis Pharmaceuticals Corp	
TRANSPLACENTAL	TRANSPLACENTA					
		Health				
L						
		Professional Other	Anafranil (Clomipramine Hydrochloride)	SS		
TRANSPLACENTAL	TRANSPLACENTA					
L						
			Wintermin (Chlorpromazine Hydrochloride)	SS		
TRANSPLACENTAL	TRANSPLACENTA					
L						
			Serenace (Haloperidol)	SS		
TRANSPLACENTAL	TRANSPLACENTA					
L						
			Contomin (Chlorpromazine Hydrochloride)	SS		
TRANSPLACENTAL	TRANSPLACENTA					
L						
			Artane (Trihexyphenidyl Hydrochloride)	SS		
TRANSPLACENTAL	TRANSPLACENTA					
L						

Date:08/01/01ISR Number: 3769650-XReport Type:Expedited (15-DaCompany Report #NSADSS2001021953
Age:35 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization -	Dermatitis Atopic	Foreign	Haldol	PS	Rw Johnson	

Initial or Prolonged	Stevens-Johnson Syndrome	Health Professional	Pharmaceutical Research Institute Div Ortho Pharm	ORAL

10 MG, DAILY,

ORAL

Carbamazepine(Carbamazepine)	C
Chlorpromazine (Chlorpormazine)	C

Date:08/02/01ISR Number: 3770420-7Report Type:Expedited (15-DaCompany Report #10854453
Age: Gender:Male I/FU:F

Outcome	PT
Life-Threatening	Agitation
Hospitalization - Initial or Prolonged	Aspartate Aminotransferase Increased
	Asthenia
	Blood Albumin Increased
	Blood Alkaline Phosphatase Increased
	Blood Calcium Increased
	Blood Chloride Increased
	Blood Magnesium Decreased
	Cardiac Arrest
	Diabetes Insipidus
	Dyspnoea
	Hypernatraemia

		Hypocalcaemia Hypotension Neuroleptic Malignant Syndrome Pyrexia Renal Failure Acute Renal Tubular Necrosis Rhabdomyolysis	Report Source Study Health Professional	Product	Role	Manufacturer	Route
Dose	Duration						
INTRAMUSCULAR MILLIGRAM,1/ TOTAL IM	12.5			Fluphenazine Hcl	PS	Apothecon Inc Div Bristol Myers Squibb	
INTRAVENOUS MILLIGRAM,1 DAY IV	40			Protonix (Pantoprazole Sodium)	SS		
INTRAVENOUS IV	5 MILLIGRAM,			Haldol (Haloperidol)	SS		
				Pepcid	C		
				Vancomycin	C		
				Rocephin	C		
				Flagyl	C		
				Ativan	C		
				Fentanyl Citrate	C		
				Phenytoin	C		
				Depakote	C		
				Clonazepam	C		
				Risperdal	C		
				Propofol	C		
				Colace	C		
				Chloral Hydrate	C		
				Tylenol	C		
				Anectine	C		
				Etomidate	C		
				Lidocaine	C		
				Norcuron	C		
				Versed	C		
				Aquamephyton	C		
				Isoflurane	C		
				Mannitol	C		
				Morphine	C		
				Calcium Chloride	C		

			Labetalol	C		
			Magnesium Sulfate	C		
			Potassium Chloride	C		
			Glycopyrrolate	C		
			Neostigmine	C		
			Potassium Phosphate, Dibasic	C		
			Reglan	C		

Date:08/03/01ISR Number: 3770856-4Report Type:Direct Company Report #
Age:41 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Dysphagia Dystonia Respiratory Arrest		Haloperidol 5mg Po By Geneva	PS	Geneva	ORAL	5MG PO X 1	DOSE
			Ativan 2mg Po	SS			2 MG PO X 1	DOSE
			Seroquel	C				
			Trazodone	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/09/01ISR Number: 3774238-0Report Type:Expedited (15-DaCompany Report #HQ3884731JUL2001
Age:51 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blood Creatine Phosphokinase Increased	Study	Protonix Iv	PS	Wyeth Ayerst Laboratories	INTRAVENOUS	80 MG 1X PER	1 DAY,
	Staphylococcal Sepsis							
	Tachypnoea					INTRAVENOUS		
			Haldol (Haloperidol)	SS			10 MG, 2	DOSES
			Phenegan (Promethazine Hydrochloride)	SS			25 MG, ONE	DOSE
			Suxamethonium (Suxamethonium)	SS				

Date:08/09/01ISR Number: 3774396-8Report Type:Expedited (15-DaCompany Report #EMADSS2001004599
Age:77 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Blood Bilirubin Increased	Foreign	Haldol	PS	Rw Johnson Pharmaceutical Research Institute Div Ortho Pharm			
Hospitalization - Initial or Prolonged	Hepatic Failure	Health Professional						
	Hyperpyrexia							
	Pneumonia					ONE TREATMENT		
	Prothrombin Time Shortened					ONLY		
			Strangyl (Trimipramine)	C				
			Fluoxetin 20 (Fluoxetine)	C				
			Ximovan (Zopiclone)	C				

Date:08/13/01ISR Number: 3775110-2Report Type:Direct Company Report #
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Ileus Paralytic		Zyprexa 7.5 Mg Lilly	PS		ORAL	7.5 MG HS	
			Haloperidol 5 Mg	SS		ORAL	5 MG TID PO	
			Quetiapine	C				

Date:08/14/01ISR Number: 3777340-2Report Type:Expedited (15-DaCompany Report #2001AP02861
Age:48 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardiac Arrest	Foreign	Seroquel	PS	Astrazeneca Lp	ORAL	75 MG DAILY	
Life-Threatening	Hypotension	Health					PO	
	Polydipsia	Professional	Seroquel "Zeneca"	SS	Zeneca	ORAL	150 MG DAILY	
	Sudden Death	Other					PO	
	Tachycardia		Alesion	SS		ORAL	20 MG DAILY	
	Ventricular Extrasystoles						PO	
			Seroquel "Zeneca"	SS	Zeneca	ORAL	225 MG DAILY	
							PO	
			Levotomin	SS				
			Tegretol	SS		ORAL	200 MG DAILY	
							PO	
			Rohypnol	SS		ORAL	2 MG DAILY PO	
			Serenace	SS		ORAL	6 MG DAILY PO	
			Serenace	SS		ORAL	3 MG DAILY PO	

	Serenace	SS	ORAL
9 MG DAILY PO			
	Cysvon	SS	ORAL
10 MG DAILY			
PO			
	Adalat	SS	ORAL
20 MG DAILY			
PO			
	Triphedinon	C	
	Daiokanzoto	C	
	Alosenn	C	
	Sennoside	C	
	Sunailin	C	
	Laxoberon	C	
	Cystanin	C	
	Anatensol	C	
	Marzulene	C	
	Pantosin	C	

Date:08/14/01ISR Number: 3781982-8Report Type:Direct Company Report #USP 54298
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Confusional State		Haldol	PS	Mcneil			
	Medication Error							
	Sedation							

Date:08/16/01ISR Number: 3778485-3Report Type:Direct Company Report #
Age:83 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Depressed Level Of		Buspar	PS				
	Consciousness		Haldol	SS				
	Dysarthria		Aricept	C				

Date:08/16/01ISR Number: 3778917-0Report Type:Direct Company Report #
Age:22 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Aggression		Quetiapine	PS			600 MG	
	Agitation		Haldol	SS			12 MG	
	Condition Aggravated							
	Irritability							

Date:08/20/01ISR Number: 3780160-6Report Type:Direct Company Report #USP 54229
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Medication Error		Haldol	PS	Ortho-Mcneil			

Date:08/22/01ISR Number: 3782057-4Report Type:Expedited (15-DaCompany Report #01P-167-0109885-00
Age: Gender:Female I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Blood Creatine Phosphokinase Increased
	Condition Aggravated
	Infection
	Myasthenic Syndrome

	Neuroleptic Malignant Syndrome Restlessness	Report Source	Product	Role	Manufacturer	Route	Dose Duration
		Foreign Health Professional	Depakote (Divalproex Sodium) (Divalproex Sodium)	PS			1250 MG, 1 IN 1 D
		Other	Haloperidol	SS			

Date:08/22/01ISR Number: 3782204-4Report Type:Expedited (15-DaCompany Report #NSADSS2001024233
Age:95 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Other	Abnormal Behaviour Cardiac Arrest Dementia Depression	Consumer	Haldol Reminyl (Galantamine)	PS SS		ORAL	4 MG, 1 IN 1 DAY(S), ORAL

Date:08/23/01ISR Number: 3782450-XReport Type:Direct Company Report #
Age:24 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Required Intervention to Prevent Permanent Impairment/Damage	Blood Creatine Phosphokinase Increased Malaise Myalgia		Haloperidol Deconate 100mg	PS		INTRAMUSCULAR	100MG Q3 WEEKS INTRAMUSCULAR
			Risperdal 2mg Jannsen	SS		ORAL	2MG AM&HS ORAL
			Folic Acid Lorazepam	C C			

Thiamine	C
Multi Vit	C
Acetaminophen	C
Lorazepam	C
Pseudodophrine	C
Benztropine	C
Buspirone	C
Haldol Decanoate	C
Lithobid	C
Risperdal	C

Date:08/24/01ISR Number: 3783078-8Report Type:Expedited (15-DaCompany Report #EMADSS2001004599
Age:77 YR Gender:Female I/FU:F

Outcome	PT
Death	Alanine Aminotransferase
Hospitalization -	Increased
Initial or Prolonged	Aspartate
	Aminotransferase
	Increased
	Blood Bilirubin Increased
	Blood Lactate
	Dehydrogenase Increased
	Hepatic Failure
	Hyperpyrexia
	Nervous System Disorder
	Neuroleptic Malignant

	Syndrome Pneumonia					
		Report Source	Product	Role	Manufacturer	Route
Dose Duration						
		Foreign	Haldol (20mg Tablet)			
		Health	(Haloperidol)	PS		
ONE TREATMENT						
		Professional				
ONLY						
			Strangyl			
			(Trimipramine)	C		
			Fluoxetin 20			
			(Fluoxetine)	C		
			Ximovan (Zopiclone)	C		

Date:08/24/01ISR Number: 3783118-6Report Type:Expedited (15-DaCompany Report #NSADSS2001024190
Age:59 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Catatonia	Consumer	Haldol Decanoate			
Initial or Prolonged	Cognitive Disorder		(Injection)			
	Dyskinesia		(Haloperidol			
	Embolism		Decanoate)	PS		
100 - 150 MG						
	Muscular Weakness					
EVERY 3 -4						
	Upper Respiratory Tract					
WEEKS.						
	Infection		Coumadin (Warfarin			
	Weight Increased		Sodium)	C		
			Artane			
			(Trihexyphenidyl			
			Hydrochloride)	C		

Date:08/31/01ISR Number: 3787083-7Report Type:Expedited (15-DaCompany Report #01-0052
Age:34 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Anaphylactic Shock	Other	Pontal (Mefenamic			
Hospitalization -	Atelectasis		Acid 250mg Capsules)	PS		ORAL
250 MG, BID,						

Initial or Prolonged PO	Cardiac Failure			
	Diarrhoea	Serenace		
	Disseminated	(Haloperidol)	SS	ORAL 33MG, TID, PO
	Intravascular Coagulation	Limas (Lithium		
	Duodenal Ulcer	Carbonate)	SS	ORAL 200 MG, TID,
	Enteritis			PO
	Erythema	Depas (Efizolam)	C	
	Haematemesis	Artane		
	Haemodialysis	(Trihexyphenidyl		
	Liver Function Test	Hydrochloride)	C	
	Abnormal	Silece		
	Melaena	(Flunitrazepam)	C	
	Muscular Weakness	Impromen		
	Oesophagitis	(Bromperidol)	C	
	Oliguria	Remark (Betahistine		
	Pleural Effusion	Mesilate)	C	
	Pulmonary Embolism			
	Pulmonary Mycosis			
	Renal Failure Acute			
	Rhabdomyolysis			
	Sepsis			
	Shock			
	Staphylococcal Infection			
	Vomiting			

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/31/01ISR Number: 3787830-4Report Type:Periodic Company Report #A118139
Age:37 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Pyrexia	Health	Ziprasidone Po	PS			80.00 MG	
		Professional						TOTAL:BID
		Company	Trileptal	SS				
		Representative	Haldol	SS				

Date:09/05/01ISR Number: 3788701-XReport Type:Expedited (15-DaCompany Report #10968907
Age:26 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Creatine Phosphokinase Increased	Foreign Health	Moditen Tabs (Fluphenazine Hcl)	PS		ORAL	100 MILLIGRAM, ORAL	
	Blood Creatinine Increased	Professional Company						
	Haemoglobinaemia	Representative	Modecate Inj (Fluphenazine Decanoate)	SS				
	Oliguria	Other						
	Pyrexia						INTRAMUSCULAR	150 MILLIGRAM, 3/TOTAL IM
			Nozinan (Methotrimeprazine)	SS		ORAL	200 MILLIGRAM, 1 DAY ORAL	
			Largactil (Chloropromazine)	SS		ORAL	100 MILLIGRAM, 1	

DAY ORAL

		Phenergan (Promethazine Hcl)	SS
INTRAMUSCULAR	50 MILLIGRAM,		
1 DAY IM			
		Haldol (Haloperidol)	SS
10 MILLIGRAM,			
1 DAY ORAL			
		Dipiperon (Pipamperone Hcl)	C
		Clopixol (Zuclopenthixol Hcl)	C
		Depakine (Valproate Sodium)	C
		Rivotril (Clonazepam)	C
		Rohypnol (Flunitrazepam)	C
		Lepticur (Tropatepine Hcl)	C

Date:09/06/01ISR Number: 3788059-6Report Type:Expedited (15-DaCompany Report #B0119047A
Age:67 YR Gender:Female I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Abnormal Behaviour
	Aphasia
	Gastric Outlet Obstruction
	Gastric Ulcer
	Gastritis
	Hyponatraemia
	Necrosis

Weight Decreased

		Report Source	Product	Role	Manufacturer	Route	Dose	Duration
			Raniplex	PS	Glaxo Wellcome	ORAL		
			Valsartan	SS		ORAL	1UNIT per day	
			Haloperidol	SS		ORAL	15UNIT per day	
			Clobazam	C		ORAL	3UNIT per day	

Date:09/06/01ISR Number: 3789295-5Report Type:Expedited (15-DaCompany Report #PHRM2001FR01916
Age:67 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abnormal Behaviour	Foreign	Tareg (Valsartan) Capsule	PS		ORAL	80 MG/DAY, ORAL	
	Gastric Outlet Obstruction	Health Professional						
	Gastric Ulcer	Other	Haldol (Haloperidol) Solution	SS		ORAL	15 DROPS/DAY, ORAL	
	Gastritis							
	Hyponatraemia							
	Necrosis		Raniplex (Ranitidine) Unknown	SS		ORAL	ORAL	
	Weight Decreased							
			Urbanyl (Clobazam)	C				

Date:09/13/01ISR Number: 3792745-1Report Type:Expedited (15-DaCompany Report #HQ5788410SEP2001
Age:44 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Condition Aggravated	Foreign	Temesta (Lorazepam, Unspec)	PS			2.5-5 MG	
	Constipation	Health						

		Ileus Paralytic	Professional			
DAILY						
			Other	Haldol (Haloperidol,)		SS
10 MG	10	DAY				
				Haldol (Haloperidol,)		SS
15 MG	76	DAY				
				Haldol (Haloperidol,)		SS
5 MG	3	DAY				
				Haldol (Haloperidol,)		SS
20 MG	5	DAY				
				Leponex "Novartis" (Clozapine,)		SS
200 MG	10	DAY				
				Leponex "Novartis" (Clozapine,)		SS
250 MG	10	DAY				
				Leponex "Novartis" (Clozapine,)		SS
125 MG	7	DAY				
				Leponex "Novartis" (Clozapine,)		SS
150 MG	3	DAY				
				Haldol (Haloperidol,)		SS
12.5 MG	6	DAY				
				..		C
				...		C
				Duphalac (Lactulose)		C
				Clopixol (Zuclophenthixol Decanoate)		C
				Augmentin (Amoxicillin Sodium/Clavulanate Potassium)		C
				Vioxx (Rofecoxib)		C

				Risperdal (Risperidone)	C		
				Zyprexa (Olanzapine)	C		
				...	C		
				..	C		
				...	C		

Date:09/13/01ISR Number: 3792756-6Report Type:Direct Company Report #
Age:82 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Grand Mal Convulsion		Haloperidol	PS		INTRAVENOUS	IV	
			Neurontin	C				
			Percocet	C				

Date:09/14/01ISR Number: 3793302-3Report Type:Direct Company Report #
Age:92 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Required	Neuroleptic Malignant Syndrome Sedation		Haldol (5 Mg/Ml)-(1ml Ampules) (Ortho Mcneil)	PS	Ortho-Mcneil	INTRAVENOUS	15MG IV X 1	
Intervention to Prevent Permanent Impairment/Damage	Sepsis		Ciprofloxacin	C				
			Acetaminophen	C				

Date:09/14/01ISR Number: 3794281-5Report Type:Expedited (15-DaCompany Report #EMADSS2001005241
Age:26 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Required	Oliguria Pyrexia	Foreign Health Professional	Haldol (Solution) (Haloperidol)	PS		INTRAVENOUS IV	10 MG, DAILY,	
Intervention to			Nozinan					

Prevent Permanent Impairment/Damage	(Levomepromazine)	C
	Largactil (Chlorpromazine Hydrochloride)	C
	Modecate (Fluphenazine Decanoate)	C
	Phenergan (Promethazine Hydrochloride)	C
	Moditen (Fluphenazine Hydrochloride)	C
	Dipiperon (Pipamperone)	C
	Clopixol (Zuclopenthixol Decanoate)	C
	Depakine (Valproate Sodium)	C
	Rivotril (Clonazepam)	C
	Rohypnol (Flunitrazepam)	C

			Lepticur (Tropatepine Hydrochloride)	C		

Date:09/14/01ISR Number: 3794312-2Report Type:Expedited (15-DaCompany Report #EMADSS2001005196
Age:67 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Required	Abnormal Behaviour Bone Marrow Depression Gastric Outlet Obstruction Hyponatraemia Vasculitis Necrotising	Foreign Health Professional	Haldol (2 Mg/Ml Solution) (Haloperidol)	PS		ORAL	15 DROPS, DAILY, ORAL	Intervention to Prevent Permanent Impairment/Damage
			Raniplex (Ranitidine)	SS			75 MG, DAILY	
			Tareg (Valsartan)	SS		ORAL	80 MG, DAILY, ORAL	
			Urbanyl (Clobazam)	C				

Date:09/18/01ISR Number: 3795284-7Report Type:Expedited (15-DaCompany Report #EMADSS2001005240
Age:44 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardio-Respiratory Arrest Liver Function Test Abnormal Metabolic Acidosis Pyrexia Respiratory Failure	Foreign Health Professional	Haldol (Unspecified) (Haloperidol)	PS		ORAL	10 MG DAILY, ORAL	
			Eritumine (Clotiapine)	SS		ORAL	SEE IMAGE	
			Leponex (Clozapine)	SS			STANDARD DAILY DOSE (PRIOR TO	

HOSPITALISATI

ON): 400 MG/

INTRAVENOUS SEE IMAGE

150 MG

9 MG

5 MG

Temesta (Lorazepam)	SS
Promazine (Promazine)	SS
Midazolam (Midazolam)	SS
Olanzapine (Olanzapine)	SS
Fraxiparine (Heparin Fraction, Calcium Salt)	C
Morphine (Morphine)	C
Seretide (Salmeterol Xinafoate)	C

Date:09/19/01ISR Number: 3795445-7Report Type:Direct Company Report #
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Neuroleptic Malignant Syndrome		Haloperidol	PS				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/19/01ISR Number: 3795637-7Report Type:Direct Company Report #
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Respiratory Disorder		Phenobarbital	PS		INTRAVENOUS	1 GM IV	
			Haloperidol	SS			VARIABLE	
							(HIGH DOSES)	
			Lorazepam	SS				
			Lasix	C				
			Digoxin	C				
			Kcl	C				
			Amiodarone	C				
			Mvi	C				
			Bumex	C				
			Folic Acid	C				
			Thiamine	C				
			Enalaprilat	C				
			Lovenox	C				
			Metoprolol	C				
			Famotidine	C				

Date:09/19/01ISR Number: 3795770-XReport Type:Expedited (15-DaCompany Report #01P-167-0110705-00
Age:40 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Extrapyramidal Disorder	Foreign Health Professional Other	Depakote (Divalproex Sodium) (Divalproex Sodium)	PS		ORAL	750 MG, 1 IN 1 D, PER ORAL	
			Haloperidol	SS		INTRAVENOUS	INTRAVENOUS	
			Nitrazepam	C				

Date:09/19/01ISR Number: 3796127-8Report Type:Expedited (15-DaCompany Report #200115166GDS
Age:52 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Immunoglobulin A Decreased	Foreign Health Professional Other	Baycol	PS				
			Cercin	SS				
			Benidipine Hydrochloride	SS				
			Zolpidem Tartrate	SS				
			Maprotiline	SS				
			Haloperidol	SS				
			Nitrazepam	SS				
			Imipramine Hydrochloride	SS				
			Amoxapine	SS				
			Rebamipide	SS				
			Verapamil Hydrochloride	SS				

Date:09/20/01ISR Number: 3795875-3Report Type:Direct Company Report #
Age:75 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Confusional State		Haloperidol	PS		ORAL	1 MG BID PO	
	Disorientation							
	Dysphemia							
	Parkinsonism							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/21/01ISR Number: 3797585-5Report Type:Expedited (15-DaCompany Report #HQ5902512SEP2001
Age:94 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Agranulocytosis	Health	Seresta (Oxazepam,					
	Asthenia	Professional	Unspec)	PS		ORAL	10 MG 1X PER	
	Delirium	Other					1 DAY ORAL	
	Depression		Athymil (Mianserin					
	Hallucination		Hydrochloride)	SS			30 MG 1X PER	
	Leukopenia						1 DAY	294 DAY
	Lung Disorder		Forlax (Macrogol,)	SS				
	Lymphopenia		Haldol (Haloperidol,					
	Malaise		)	SS			292 DAY	
	Neutrophil Count Decreased							
	Viral Infection							

Date:09/25/01ISR Number: 3798438-9Report Type:Expedited (15-DaCompany Report #EMADSS2001005511
Age:68 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Akinesia	Foreign	Haldol (Solution)					
Initial or Prolonged	Eyelid Oedema	Health	(Haloperidol)	PS		ORAL	40 MG, DAILY,	
	Oedema Peripheral	Professional					ORAL, 50 MG,	
							DAILY, ORAL	
			Stablon (Tianeptine)	SS				

Date:09/25/01ISR Number: 3798450-XReport Type:Expedited (15-DaCompany Report #EMADSS2001005519
Age:35 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Hospitalization -	Blood Creatine	Foreign	Haldol (Haloperidol)	PS		ORAL
10 MG, 1 IN 1						
Initial or Prolonged	Phosphokinase Increased	Health				
DAY(S), ORAL						
	Blood Lactate	Professional	Tercian			
	Dehydrogenase Increased		(Cyamemazine)	SS		ORAL
200 MG, 1 IN						
1 DAY(S),						
ORAL						

Date:09/26/01ISR Number: 3798900-9Report Type:Direct Company Report #
Age:46 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Required	Dystonia		Haloperidol			
Intervention to			Decanoate	PS		
INTRAMUSCULAR 150 MG IM						
Prevent Permanent						
EVERY 3 WEEKS						
Impairment/Damage			Haloperidol			
			Concentrate	SS		ORAL
5 MG PO BID						
			Olanzapine	C		
			Benztropine	C		
			Mvi	C		
			Fes04	C		
			Haldol Dec	C		
			Lorazepam	C		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/26/01ISR Number: 3798912-5Report Type:Direct Company Report #
Age:37 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Fear		Gabapentin (300 Mg)	PS		ORAL	600 MG BID PO	
	Sedation		Haloperidol (5 Mg)	SS		ORAL	5 MG BID PO	3 MON
			Benztropine	C				
			Depakote	C				
			Haldol Decanoate	C				

Date:09/26/01ISR Number: 3799363-XReport Type:Direct Company Report #
Age:45 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Neuroleptic Malignant Syndrome		Chlorpromazine 100mg	PS			100MG QAM + 200MG HS	
			Haloperidol 5-10mg	SS			INTRAMUSCULAR	5-10MG 1 PRN
			Seroquel	C				
			Zyprexa	C				
			Eskalith	C				
			Cleocin	C				
			Pepcid	C				

Date:09/26/01ISR Number: 3799921-2Report Type:Direct Company Report #
Age:43 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Agitation		Haloperidol Decanoate	PS		INTRAMUSCULAR	100MG IM Q 4 WKS	
	Eye Rolling							
	Grand Mal Convulsion							
	Hyperhidrosis		Haloperidol					

	Movement Disorder		Concentrate	SS		ORAL
15MG PO BID 1 YR						
	Tongue Paralysis		Phenytoin	C		
	Tremor		Gabapentin	C		
			Depakote	C		
			Quetiapine	C		
			Benztropine	C		
			Atorvastatin	C		
			Amantadine	C		

Date:09/27/01ISR Number: 3800069-9Report Type:Direct Company Report #
Age:43 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Extrapyramidal Disorder		Haloperidol Dec Clinic Inj 1 D	PS		
			Amantadine	C		
			Acyclovir	C		

Date:09/27/01ISR Number: 3800447-8Report Type:Expedited (15-DaCompany Report #EMADSS2001005534
Age:39 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Congestive Cardiomyopathy	Foreign	Haldol Decanoate			
	Sudden Death	Health	(Injection)			
		Professional	(Haloperidol Decanoate)	PS		

DATES, DOSE

AND FREQUENCY

				Procyclidine (Procyclidine)	C		

Date:09/28/01ISR Number: 3802312-9Report Type:Expedited (15-DaCompany Report #DEU004484
Age:49 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dysphagia	Foreign	Biperiden	PS				
	Oesophageal Stenosis	Literature	Chlorpromazine	SS				
	Pneumonia Aspiration	Health Professional	Haloperidol	SS				
	Post Procedural Complication	Other						
	Regurgitation Of Food							

Date:09/28/01ISR Number: 3807417-4Report Type:Expedited (15-DaCompany Report #01P-087-0102964-00
Age:37 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardiac Arrest	Foreign	Depakene (Valproic Acid) (Valproic Acid)	PS		ORAL	600 MG, 1 IN	1 D, PER ORAL
Required Intervention to Prevent Permanent Impairment/Damage	Depressed Level Of Consciousness	Health Professional						
	Disseminated Intravascular Coagulation	Other	Fluvoxamine Maleate	SS		ORAL	25 MG 1 IN 1 D, PER ORAL	
	Hypotension							
	Multi-Organ Failure							
	Neuroleptic Malignant Syndrome						50 MG 1IN 1 D PER ORAL	
	Pyrexia		Haloperidol	SS		ORAL	9 MG, 1 IN 1 D, PER ORAL	
	Respiratory Disorder							
			Chlorpromazine					

			Hydrochloride	SS		ORAL
100 MG, 1 IN 1 D, PER ORAL						
			Biperiden Hydrochloride	C		
			Flunitrazepam	C		

Date:10/01/01ISR Number: 3802574-8Report Type:Expedited (15-DaCompany Report #01P-167-0109885-00
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Blood Creatine Phosphokinase Increased	Foreign Health	Depakote (Divalproex Sodium) (Divalproex			
	Infection	Professional	Sodium)	PS		
1250 MG, 1 IN						
	Myasthenic Syndrome	Other				
1 D						
	Neuroleptic Malignant Syndrome		Haloperidol	SS		
	Restlessness					

Date:10/01/01ISR Number: 3804162-6Report Type:Expedited (15-DaCompany Report #LBID00201003889
Age:59 YR Gender:Male I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Abnormal Behaviour
	Constipation
	Diarrhoea
	Disorientation
	Disturbance In Attention

	Electroencephalogram Abnormal Encephalopathy Medication Error Memory Impairment Obsessive Thoughts Paranoia Urinary Incontinence	Report Source Literature Health Professional	Product Lithium, Manufacturer Unknown (Lithium) Olanzapine (Olanzapine) Haloperidol (Haloperidol) (Carbamazepine)	Role PS SS SS C	Manufacturer	Route ORAL ORAL ORAL	Dose Duration 900 MG DAILY PO 5 MG DAILY PO 20 MG DAILY PO

Date:10/02/01ISR Number: 3803703-2Report Type:Expedited (15-DaCompany Report #DEU004506
Age:52 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged Other	Selective Iga Immunodeficiency	Foreign Other	Vasolan Certa Bendipine Zolpidem Maprotiline Haloperidol Nitrazepam Imipramine Amoxapine Diazepam Rebamipide	PS SS SS SS SS SS SS SS SS SS SS			

Date:10/03/01ISR Number: 3805988-5Report Type:Expedited (15-DaCompany Report #002-0945-M0100118
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Other	Blood Creatine	Foreign	Gabapentin				

	Phosphokinase Increased	Health Professional	(Gabapentin)	PS		ORAL PER ORAL
			Haloperidol (Haloperidol)	SS		
			(Unspecified Medications)	C		

Date:10/03/01ISR Number: 3807902-5Report Type:Expedited (15-DaCompany Report #2014362
Age:49 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Death	Brain Hypoxia	Health Professional	Oxycontin Cr Tablets , 80 Mg (Oxycodone Hydrochloride)	PS		ORAL 80 MG BID PO
Hospitalization - Initial or Prolonged	Bronchopneumonia					
	Granuloma	Other				
	Hepatic Congestion		Robaxin (Methocarbamol)	SS		ORAL 1500 MG TID
	Lung Disorder					
	Lymphadenopathy					PO
	Nervous System Disorder		Soma (Carisoprodol)	SS		ORAL MG PO
	Renal Disorder		Codeine	SS		ORAL MG PO
	Respiratory Failure		Ativan (Lorazepam)	SS		3 MG PRN
			Haldol (Haloperidol)	SS		
			Morphine Sulfate (Similar To Nda 19-516)	SS		

			Atenolol	C			
			Aspirin (Acetysalicylic Acid)	C			
			Lomotil	C			
			Fluoxetine Hydrochloride	C			
			Zocor (Simvastatin)	C			
			Clonazepam	C			
			Temazepam	C			

Date:10/04/01ISR Number: 3805292-5Report Type:Expedited (15-DaCompany Report #EMADSS2001005294
Age:94 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Agranulocytosis	Foreign	Haldol Faible (0.5 Mg/Ml Solution)					
	Asthenia	Health						
	Leukopenia	Professional	(Haloperidol)	PS				
	Lower Respiratory Tract Infection		Seresta (Oxazepam)	SS		ORAL	10 MCG DAILY,	ORAL
	Lymphopenia		Athymil (Mianserin Hydrochloride)	SS		ORAL	10 MCG DAILY	ORAL
	Malaise							
	Viral Infection							
			Forlax (Macrogol)	C				

Date:10/05/01ISR Number: 3806104-6Report Type:Direct Company Report #
Age:40 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cerebral Artery Occlusion		Haloperidol 5mgml	PS		INTRAVENOUS		
	Neuroleptic Malignant Syndrome					BOLUS INTRAVENOUS	2MG Q2HRS X3	BOL

Date:10/05/01ISR Number: 3807344-2Report Type:Expedited (15-DaCompany Report #200115166GDS
Age:52 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Immunoglobulin A Decreased	Foreign	Baycol	PS				
	Muscle Rigidity	Health Professional	Cercin	SS				
	Palindromic Rheumatism	Other	Benidipine Hydrochloride	SS				
	Swelling		Zolpidem Tartrate	SS				
			Maprotiline	SS				
			Haloperidol	SS				
			Nitrazepam	SS				
			Imipramine Hydrochloride	SS				
			Amoxapine	SS				
			Rebamipide	SS				
			Verapamil Hydrochloride	SS				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/08/01ISR Number: 3807006-1Report Type:Expedited (15-DaCompany Report #HQ3884731JUL2001
Age:50 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Bacterial Infection	Study	Protonix					
Other	Blood Creatine Phosphokinase Increased		(Pantoprazole, Injection)	PS		INTRAVENOUS	80 MG 1 X PER	1 DAY,
	Blood Culture Positive							
	Gram Stain Positive							
	Pyrexia		Haldol (Haloperidol)	SS			10 MG, 2	DOSES
	Staphylococcal Infection							
	Tachypnoea		Phenergan					
	Thrombophlebitis Septic		(Promethazine Hydrochloride, Unspec)	SS			25 MG, ONE	DOSE
			Suxamethonium (Suxamethonium)	SS				

Date:10/08/01ISR Number: 3807633-1Report Type:Expedited (15-DaCompany Report #NSADSS2001029545
Age:49 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Literature	Haldol (Unspecified)					
		Health	(Haloperidol)	PS		ORAL	ORAL	
		Professional	Amitriptyline (Amitriptyline)	SS				

Date:10/08/01ISR Number: 3807636-7Report Type:Expedited (15-DaCompany Report #NSADSS2001029538
Age:38 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Death	Death	Literature	Haldol (Unspecified)			
		Health	(Haloperidol)	PS		ORAL
ORAL						
		Professional	Benztropine (Benztropine)	SS		
			Clozapine (Clozapine)	SS		

Date:10/08/01ISR Number: 3807641-0Report Type:Expedited (15-DaCompany Report #NSADSS2001029546
Age:41 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Completed Suicide	Literature	Haldol (Unspecified)			
		Health	(Haloperidol)	PS		ORAL
ORAL						
		Professional	Lithium (Lithium)	SS		

Date:10/08/01ISR Number: 3807645-8Report Type:Expedited (15-DaCompany Report #NSADSS2001029537
Age:37 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Death	Literature	Haldol			
		Health	(Haldoperidol)	PS		ORAL
ORAL						
		Professional	Ethanol (Ethanol)	SS		
			Lorazepam (Lorazepam)	SS		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/08/01ISR Number: 3807648-3Report Type:Expedited (15-DaCompany Report #NSADSS2001029547
Age:21 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Literature	Haldol (Haloperidol)	PS		ORAL	ORAL	
		Health Professional	Benztropine (Benztropine)	SS				
			Gabapentin (Gabapentin)	SS				

Date:10/10/01ISR Number: 3806493-2Report Type:Direct Company Report #
Age:39 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Bradycardia		Propranolol 120mg Twice A Day	PS		ORAL	120MG TWICE A DAY BID PO	
			Haloperidol 10 Mg Im	SS		INTRAMUSCULAR	10 MG IM STAT	
			Lorazepam 4 Mg Im	SS		INTRAMUSCULAR	4 MG IM	
			Tolteradine	C				

Date:10/10/01ISR Number: 3807877-9Report Type:Expedited (15-DaCompany Report #081-0073-M0100004
Age:40 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Coma	Foreign	Phenytoin					
	Condition Aggravated	Literature	(Phenytoin)	PS			300 MG	
	Drug Interaction	Health	Carbamazepine					
	Gingival Hyperplasia	Professional	(Carbamazepine)	SS			500 MG	
	Grand Mal Convulsion		Haloperidol					
	Inappropriate		(Haloperidol)	SS			6.5 MG	
	Antidiuretic Hormone		Levomepromazine					

	Secretion		(Levomepromazine)	SS			
185 MG							
	Vomiting		Biperiden				
			(Biperiden)	SS			
9 MG							
			Clonazepam				
			(Clonazepam)	SS			
3 MG							

Date:10/10/01ISR Number: 3809335-4Report Type:Expedited (15-DaCompany Report #A030706
Age:91 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Depressed Level Of Consciousness	Consumer	Zoloft Tablets	PS				
Hospitalization - Initial or Prolonged	Dysphagia	Health Professional	Haldol	SS				
Required Intervention to Prevent Permanent Impairment/Damage	Foreign Body Aspiration		Benadryl	SS				
	Overdose							
	Tardive Dyskinesia							

Date:10/11/01ISR Number: 3809947-8Report Type:Expedited (15-DaCompany Report #EMADSS2001005845
Age:1 DY Gender:Male I/FU:I

Outcome	PT
Other	Complications Of Maternal Exposure To Therapeutic Drugs
	Jaundice Neonatal

Postmature Baby
Ventricular Septal Defect

Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Foreign Health Professional	Haldol (Solution) (Haloperidol)	PS		INTRA-UTERINE	0.5 MG, DAILY, UTERINE	

Date:10/11/01ISR Number: 3809957-0Report Type:Expedited (15-DaCompany Report #NSADSS2001021953
Age:35 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dermatitis Atopic Stevens-Johnson Syndrome	Foreign Health Professional	Haldol (Tablet)(Haloperidol)	PS		ORAL	10 MG, DAILY, ORAL	
			Carbamazepine (Carbamazepine)	C				
			Chlorpromazine (Chlorpromazine)	C				

Date:10/11/01ISR Number: 3810900-9Report Type:Periodic Company Report #C2000-1891.01
Age:15 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Anxiety Panic Attack	Consumer	Haloperidol Tablets 0.5 Mg Mylan	PS	Mylan	ORAL	1MG BID, ORAL	
			Clonazepam	C				
			Lorazepam	C				
			Paroxetine	C				
			Sertraline	C				

Date:10/11/01ISR Number: 3810901-0Report Type:Periodic Company Report #C2001-1029.01
Age:16 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Asthenia	Consumer	Haloperidol Tablets					
	Hypotonia		0.5 Mg Mylan	PS	Mylan	ORAL	0.5MG Q AM,	
	Muscle Rigidity						1MG Q HS,	
	Parkinsonian Gait						ORAL	
	Tardive Dyskinesia		Chlorpromazine	C				
			Divalproex Sodium	C				

Date:10/16/01ISR Number: 3810155-5Report Type:Expedited (15-DaCompany Report #EWC011028522
Age:28 YR Gender:Male I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Abdominal Distension
	Abdominal Tenderness
	Blood Creatine Phosphokinase Increased
	Blood Creatinine Increased
	Blood Urea Increased
	Diarrhoea
	Pyrexia
	Renal Disorder

	Ultrasound Scan Abnormal Vomiting White Blood Cell Count Increased	Report Source Foreign Study Health Professional Other	Product Haloperidol Biperiden	Role PS C	Manufacturer	Route	Dose Duration 5 MG/DAY

Date:10/16/01ISR Number: 3810296-2Report Type:Expedited (15-DaCompany Report #HQ3884731JUL2001
Age:51 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Life-Threatening Other	Blood Creatine Phosphokinase Increased Culture Positive	Study	Protonix (Pantoprazole, Injection)	PS		INTRAVENOUS	80 MG 1 X PER 1 DAY,
	Gram Stain Negative Gram Stain Positive					INTRAVENOUS	
	Haematocrit Decreased Implant Site Infection		Haldol (Haloperidol,)	SS		INTRAVENOUS	5 MG X 2,
	Sepsis Sputum Abnormal Staphylococcal Infection Tachypnoea Thrombophlebitis Septic		Phenergan (Promethazine Hydrochloride, Unspec)	SS		INTRAVENOUS	25 MG X 1,
			Suxamethonium (Suxamethonium,)	SS		INTRAVENOUS	50 MG TO 100 MG X 2,
			Midazolam (Midazolam)	C		INTRAVENOUS	

Propofol (Propofol)	C	
Morphine Sulfate (Morphine Sulfate)	C	
Isoflurane (Isoflurane)	C	
Dilantin (Phenytoin Sodium)	C	
Potassium Chloride (Potassium Chloride)	C	
Lidocaine (Lidocaine)	C	
Famotidine (Famotidine)	C	
Acetaminophen (Paracetamol)	C	
Etomidate (Etomidate)	C	

Date:10/17/01ISR Number: 3810776-XReport Type:Expedited (15-DaCompany Report #EMADSS2001005870
Age:21 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Akathisia Laceration	Foreign Study Health Professional	Haldol (Tablet) (Haloperidol)	PS		ORAL	10, ORAL; 8, ORAL; 6, ORAL; 4, ORAL	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/17/01ISR Number: 3810779-5Report Type:Expedited (15-DaCompany Report #EMADSS2001005883
Age:62 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Ileus Paralytic	Foreign Study Health Professional	Haldol (Unspecified) (Haloperidol)	PS		ORAL	10MG, DAILY, ORAL; 20MG DAILY, ORAL; 15MG, DAILY, ORAL; 10MG,	
			Leponex (Clozapine)	SS		ORAL	300 MG,DAILY,ORAL ; 900 MG, DAILY,ORAL ; 800	
			Glianimon (Benperidol)	SS		ORAL	10 MG, DAILY, ORAL	
			Melleril Ret (Thioridazine Hydrochloride)	SS		ORAL	400 MG, DAILY, ORAL ; 600 MG, DAILY, ORAL	
			Akineton Ret (Biperiden Hydrochloride)	SS		ORAL	4 MG, DAILY, ORAL	

			Gastrozepin (Pirenzepine Dihydrochloride)	SS		ORAL

100 MG,

DAILY, ORAL

; 150 MG,

DAILY, ORAL

Date:10/19/01ISR Number: 3812835-4Report Type:Expedited (15-DaCompany Report #DEU004542
Age:62 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Ileus Paralytic	Foreign	Akineton Retard	PS		ORAL	4 MG OD PO	
Initial or Prolonged		Health	Leponex "Novartis"	SS	Novartis	ORAL	100 MG TID PO	
		Professional	Leponex "Novartis"	SS	Novartis	ORAL	300 MG TID PO	
		Other	Leponex "Novartis"	SS	Novartis	ORAL	800 MG DAILY	
							PO	
			Haldol	SS		ORAL	10 MG DAILY	
							PO	
			Haldol	SS		ORAL	15 MG DAILY	
							PO	
			Glianimon	SS		ORAL	10 MG DAILY	
							PO	
			Melleril - Slow Release "Novartis"	SS	Novartis	ORAL	200 MG TID PO	
			Gastrozepin	SS		ORAL	50 MG TID PO	
			Gastrozepin	SS		ORAL	50 MG BID PO	
			Melleril - Slow Release "Novartis"	SS	Novartis	ORAL	200 MG BID PO	
			Haldol	SS		ORAL	10 MG DAILY	

PO

Haldol	SS			ORAL

20 MG DAILY

PO

Leponex "Novartis"	SS	Novartis		ORAL

700 MG DAILY

PO						
				Euglucon N	C	
				Glucobay	C	

Date:10/22/01ISR Number: 3812477-0Report Type:Expedited (15-DaCompany Report #EMADSS2001006043
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Hepatic Enzyme Increased Serum Ferritin Increased	Foreign Health Professional	Vesadol (Tablet) (Haloperidol/Buzepide Metiodide)	PS		

Date:10/24/01ISR Number: 3814180-XReport Type:Expedited (15-DaCompany Report #EMADSS2001006021
Age:61 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Bronchopneumonia	Foreign	Haldol (Injection)			
	Cardio-Respiratory Arrest	Health	(Haloperidol)	PS		
INTRAVENOUS 10 MG, 2 IN 1 DAY (S), IV	Coma	Professional				
	Fatigue		Timonil (Carbamazepine)	C		
	Neuroleptic Malignant Syndrome		Euthyrox (Levothyroxine Sodium)	C		
			Adalat Sl (Nifedipine)	C		

Date:10/25/01ISR Number: 3815480-XReport Type:Expedited (15-DaCompany Report #EMADSS2001006088
Age:23 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Weight Increased	Foreign Health Professional	Haldol (Haloperidol)	PS		

Date:10/26/01ISR Number: 3816582-4Report Type:Expedited (15-DaCompany Report #NSADSS2001032058
Age:53 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Abdominal Distension	Foreign	Haldol (Haloperidol)	PS		ORAL	6 MG, 1 IN 1	
	Asthenia	Literature						DAY(S) ORAL
	Blood Creatine Phosphokinase Increased	Health Professional	Impromen (Bromperidol)	SS		ORAL	18 MG, 1 IN 1	
	Blood Sodium Decreased							DAY(S), ORAL
	Depressed Level Of Consciousness		Akineton (Biperiden Hydrochloride)	C				
	Malaise		Rohypnol (Flunitrazepam)	C				
	Thirst		Benzalin (Nitrazepam)	C				
	Vomiting							
	Water Intoxication							

Date:10/29/01ISR Number: 3817132-9Report Type:Expedited (15-DaCompany Report #01P-167-0110705-00
Age:53 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to								

Prevent Permanent
Impairment/Damage

	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Dysphagia Extrapyramidal Disorder Eye Movement Disorder	Foreign Health Professional	Depakote (Divalproex Sodium) (Divalproex Sodium)	PS		ORAL	750 MG, 1 IN	
	Musculoskeletal Stiffness	Other					1 D, PER ORAL	
			Haloperidol	SS				
INTRAMUSCULAR							5 MG, 1 IN 1 D,	
INTRA-MUSCULAR								
			Nitrazepam	C				
			Lorazepam	C				
			Paracetamol	C				

Date:10/31/01ISR Number: 3818994-1Report Type:Expedited (15-DaCompany Report #NSADSS2001029538
Age:38 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Brain Oedema Coma	Literature Health	Haldol (Unspecified) (Haloperidol)	PS		ORAL	ORAL	
	Dry Skin Haemorrhagic Stroke Hyperthermia Malignant Hypotension Medication Error Miosis Pulmonary Congestion Pupillary Reflex Impaired	Professional	Benztropine (Benztropine) Valproate (Valproate Sodium)	SS C				

Date:10/31/01ISR Number: 3818997-7Report Type:Expedited (15-DaCompany Report #NSADSS2001029545
Age:49 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Aggression	Literature	Haldol(Haloperidol)	PS		ORAL	ORAL	
	Cardiac Arrest	Health Professional	Amitriptyline(Amitriptyline)	SS				
	Completed Suicide							
	Lethargy							
	Overdose							
	Respiratory Depression							

Date:10/31/01ISR Number: 3818999-0Report Type:Expedited (15-DaCompany Report #NSADSS2001029546
Age:41 YR Gender:Male I/FU:F

Outcome	PT
Death	Agitation
	Blood Pressure Diastolic Decreased
	Blood Pressure Systolic Increased
	Clonic Convulsion
	Completed Suicide
	Drug Level Below Therapeutic
	Heart Rate Increased
	Mental Impairment
	Pyrexia
	Respiratory Rate

		Increased Tremor Ventricular Fibrillation					
			Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
			Literature	Haldol(Haloperidol)	PS		ORAL
ORAL							
			Health Professional	Lithium (Lithium)	SS		

Date:10/31/01ISR Number: 3819000-5Report Type:Expedited (15-DaCompany Report #NSADSS2001029547
Age:21 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Death	Aspiration	Literature	Haldol (Haloperidol)	PS		ORAL
ORAL						
Required	Completed Suicide	Health	Benztropine(Benztrop			
Intervention to	Dialysis	Professional	ine)	SS		
Prevent Permanent	Heart Rate Increased		Gabapentin(Gabapenti			
Impairment/Damage	Pneumonia		n)	SS		
	Posture Abnormal					
	Renal Failure					
	Respiratory Failure					
	Rhabdomyolysis					

Date:10/31/01ISR Number: 3819001-7Report Type:Expedited (15-DaCompany Report #NSADSS2001029537
Age:37 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Death	Abnormal Behaviour	Literature	Haldol (Haloperidol)	PS		
INTRAMUSCULAR	5 MG, IM					
	Aggression	Health	Ethanol (Ethanol)	SS		
	Agitation	Professional	Lorazepam			
	Alcohol Withdrawal		(Lorazepam)	SS		
INTRAMUSCULAR	2, IM					
	Syndrome					
	Alcoholic Liver Disease					
	Brain Hypoxia					
	Cardiac Arrest					
	Encephalopathy					
	Hallucination					
	Intentional Misuse					

Date:11/01/01ISR Number: 3819881-5Report Type:Direct Company Report #
Age:55 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Neuroleptic Malignant		Risperidone 1 Mg	PS		ORAL	1 MG BID ORAL	
Hospitalization - Initial or Prolonged Disability Required Intervention to Prevent Permanent Impairment/Damage	Syndrome		Haldol 5 Mg	SS		INTRAMUSCULAR	5 MG IM OR PO	

Date:11/02/01ISR Number: 3820042-4Report Type:Expedited (15-DaCompany Report #NSADSS2001029484
Age:29 YR Gender:Male I/FU:I

Outcome	PT
Death	Aspiration
	Bradycardia
	Cardiac Arrest

		Completed Suicide Confusional State Sedation Tachycardia Vomiting	Report Source Literature Health Professional	Product Risperdal (Unspecified) (Risperidone) Haldol (Haloperidol) Benztropine (Benztropine)	Role PS SS SS	Manufacturer	Route ORAL

Dose Duration

ORAL

Date:11/05/01ISR Number: 3820691-3Report Type:Expedited (15-DaCompany Report #02707
Age:37 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Death	Drug Abuser Overdose	Literature	Lorazepam Haloperidol	PS SS		

Dose Duration

Date:11/05/01ISR Number: 3821929-9Report Type:Expedited (15-DaCompany Report #K200100124
Age:45 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Disability	Convulsion	Foreign Health Professional Other	Kemadrin (Procyclidine) Tablet, 5 Mg Haloperidol (Haloperidol) Injection Metodril (Methaqualone, Diphenhydramine Hydrochloride) Valproate Sodium (Valproate Sodium)	PS SS C C		

Dose Duration

INTRAMUSCULAR 10 MG

INTRAMUSCULAR

Date:11/05/01ISR Number: 3821930-5Report Type:Expedited (15-DaCompany Report #K200100123
Age:39 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Convulsion	Foreign Health Professional	Kemadrin (Procyclidine)Tablet, 10 Mg	PS		INTRAMUSCULAR	10 MG,	
		Other	Haloperidol (Haloperidol) Injection	SS		INTRAMUSCULAR		

Date:11/06/01ISR Number: 3821458-2Report Type:Expedited (15-DaCompany Report #2000037456FR
Age: Gender:Female I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Abdominal Pain
Congenital Anomaly	Bradycardia
	Bronchitis
	Complications Of Maternal Exposure To Therapeutic Drugs
	Feeding Problem In

	Newborn						
	Gastrointestinal Malformation						
	Growth Retardation	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Hypotonia	Foreign	Xanax (Alprazolam)				
	Neonatal Disorder	Other	Tablet	PS		ORAL	ORAL
	Psychomotor Retardation		Anafranil				
	Small For Dates Baby		(Clomipramine				
	Vomiting		Hydrochloride)	SS		ORAL	ORAL
			Haldol (Haloperidol)	SS		ORAL	ORAL

Date:11/07/01ISR Number: 3822567-4Report Type:Expedited (15-DaCompany Report #NSADSS2001029484
Age:29 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Death	Aspiration	Literature	Haldol (Haloperidol)	PS			
	Bradycardia	Health	Risperdal				
	Cardiac Arrest	Professional	(Risperidone)	SS		ORAL	ORAL
	Confusional State		Benztropine				
	Sedation		(Benztropine)	SS			
	Tachycardia						
	Vomiting						

Date:11/07/01ISR Number: 3822658-8Report Type:Expedited (15-DaCompany Report #NSADSS2001032994
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Dizziness	Consumer	Haldol (Unspecified)				
	Fall		(Haloperidol)	PS			2 MG, 3 IN 1
	Vertigo						DAILY,
							UNKNOWN

Date:11/07/01ISR Number: 3823581-5Report Type:Expedited (15-DaCompany Report #EMADSS2001006043
Age:43 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Alanine Aminotransferase Increased Aspartate Aminotransferase Increased Asthenia Gamma-Glutamyltransferase Increased Lipase Increased Serum Ferritin Increased	Foreign Health Professional	Vesadol (Tablet) (Haloperidol/Buzepide Metiodide) Pentasa (Mesalazine)	PS C				

Date:11/07/01ISR Number: 3824286-7Report Type:Expedited (15-DaCompany Report #NSADSS2001033049
Age:40 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Disability	Neuroleptic Malignant Syndrome Osteosis	Foreign Literature Health Professional	Haldol Decanoate (Injection) (Haloperidol)	PS		INTRAMUSCULAR	IM	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/08/01ISR Number: 3821806-3Report Type:Direct Company Report #
Age:37 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Myocardial Infarction		Haldol	PS				
Hospitalization - Initial or Prolonged	Neuroleptic Malignant Syndrome		Ritonavir	C				
			Saquinavir	C				
Required Intervention to Prevent Permanent Impairment/Damage			Nevaripine	C				
			Gemfibrozolw	C				
			Gliberide	C				
			Enalapril	C				
			Provastatin	C				

Date:11/08/01ISR Number: 3821820-8Report Type:Direct Company Report #
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Bradykinesia		Haldol	PS		ORAL	5 MG II TABS	QHS ORAL
	Sedation							
	Tremor		Risperidal	SS		ORAL	1 MG BID ORAL	

Date:11/08/01ISR Number: 3822494-2Report Type:Direct Company Report #
Age:48 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dystonia		Haloperidol	PS				
	Tremor							

Date:11/08/01ISR Number: 3824375-7Report Type:Expedited (15-DaCompany Report #HQ7880131OCT2001
Age:39 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Dysarthria	Health	Prazine (Promazine					
Hospitalization -	Dysphagia	Professional	Hydrochloride,					

Initial or Prolonged	Hyperreflexia Hypertonia Hyponatraemia Overdose Speech Disorder	Other	Tablet) Baldriparan (Crataegus Extract/Humulus Lupulus Extract/Valerian	PS SS	ORAL ORAL

"90",

OVERDOSE 1 DAY

			Haldol (Haloperidol,)	SS	ORAL

1 DAY

Date:11/09/01ISR Number: 3823200-8Report Type:Direct Company Report #
Age:6 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Extrapyramidal Disorder Medication Error		Haldol Injectible 1ml -5mg- Mcneil	PS	Mcneil	INTRAMUSCULAR	2MG/	

NOW/INTRAMUSC

ULAR

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/13/01ISR Number: 3823661-4Report Type:Periodic Company Report #M2001.0236
Age:47 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dysphagia Dyspnoea	Health Professional	Haloperidol 5 Mg Tablet, Geneva Manufacturer	PS	Geneva Pharmaceuticals, Inc.	ORAL	15 MG PO AM	HD YR
			Benztropine Tpo	C				
			Risperidone 2mg	C				
			Naproxen 375 Mg	C				

Date:11/13/01ISR Number: 3823686-9Report Type:Periodic Company Report #M2001.0268
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Depression Suicidal Ideation	Consumer	Haloperidol 2 Mg Tablet	PS	Geneva Manufacturer		2 TABLETS DAILY	
			Tegretol	C				
			Celexa	C				
			Zyprexa	C				
			Levothyroxin	C				

Date:11/13/01ISR Number: 3826133-6Report Type:Expedited (15-DaCompany Report #A126193
Age:39 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Aggression Akathisia Anxiety	Foreign Health Professional	Ziprasidone Po	PS		ORAL	160.00 MG TOTAL:DAILY:O	

	Blood Creatine	Haloperidol	SS	ORAL 15.00 MG TOTAL:DAILY:ORAL
	Phosphokinase Increased			
	Chills			
	Condition Aggravated	Atosil	C	
	Crying	Acc	C	
	Fall	Tavor	C	
	Klebsiella Infection	Leponex	C	
	Neuroleptic Malignant	Truxal	C	
	Syndrome	Dicton	C	
	Parkinson'S Disease	Imovane Zopiclon	C	
	Psychotic Disorder			
	Swelling			
	Tremor			
	Urinary Tract Infection			
	Vomiting			

Date:11/13/01ISR Number: 3826166-XReport Type:Expedited (15-DaCompany Report #DEU004533
Age:53 YR Gender:Male I/FU:I

Outcome	PT
Life-Threatening	Abdominal Distension
	Anhidrosis
	Asthenia
	Blood Sodium Decreased
	Depressed Level Of Consciousness

	Dysuria Electrolyte Imbalance Hypotonia	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Polydipsia	Foreign	Akineton	PS		ORAL	9 MG DAILY PO
	Pupillary Light Reflex	Health	Serenace	SS		ORAL	6 MG DAILY PO
	Tests Abnormal	Professional	Impromen	SS			18 MG DAILY
	Pupillary Reflex Impaired	Other	Flunitrazepam	SS			2 MG DAILY
	Schizophrenia		Benzalin	SS			10 MG DAILY
	Vomiting Water Intoxication						

Date:11/13/01ISR Number: 3826168-3Report Type:Expedited (15-DaCompany Report #DEU004532
Age:29 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Life-Threatening	Aggression	Foreign	Akineton	PS		ORAL	6 MG DAILY PO
	Asthenia	Health	Serenace	SS		ORAL	12 MG DAILY
	Blood Sodium Decreased	Professional					PO
	Depressed Level Of	Other	Barnetil	SS			150 MG DAILY
	Consciousness		Rohypnol	SS			2 MG DAILY
	Impulsive Behaviour Persecutory Delusion Polydipsia Restlessness Vomiting Water Intoxication						

Date:11/13/01ISR Number: 3827588-3Report Type:Expedited (15-DaCompany Report #EMADSS2001000045
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain Bradycardia	Foreign Health	Haldol (Unspecified) (Haloperidol)	PS			INTRA-UTERINE	UTERINE
Congenital Anomaly	Bronchiolitis	Professional	Xanax (Alprazolam)	SS			INTRA-UTERINE	UTERINE
Required Intervention to Prevent Permanent Impairment/Damage	Bronchitis Complications Of Maternal Exposure To Therapeutic Drugs Cyst Foetal Growth Retardation Gastrointestinal Malformation Hypotonia Neonatal Disorder Psychomotor Retardation Small For Dates Baby Vomiting Neonatal		Anafranil (Clomipramine Hydrochloride) Tardyferon (Ferrous Sulfate) Zymafluor (Sodium Fluoride)	SS C C			INTRA-UTERINE	UTERINE

Date:11/14/01ISR Number: 3825290-5Report Type:Expedited (15-DaCompany Report #PHBS2001JP11159
Age:20 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Hypersensitivity Infectious Mononucleosis	Foreign Literature Health Professional Other	Tegretol (Carbamazepine) Tablet Serenace (Haloperidol) Tablet	PS SS		ORAL ORAL	600 MG/DAY, 6 MG/DAY,	

ORAL

			Akineton (Biperiden Hydrochloride) Tablet	SS		ORAL

3 MG/DAY,

ORAL

Date:11/15/01ISR Number: 3824687-7Report Type:Direct Company Report #
Age:53 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Unevaluable Event		Haloperidol Deconate 50mg/Ml 55390-0412-05 Mfd By Bedford Labs	PS	Bedford Labs	
INTRAMUSCULAR 50MG 1/MONTH						

IM

Date:11/16/01ISR Number: 3825919-1Report Type:Expedited (15-DaCompany Report #NSADSS2001033843
Age:17 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Injury	Consumer	Haldol (Tablet)			
	Medication Error		(Haloperidol)	PS		ORAL
0.5 MG/ML,						
ORAL						
			Propulsid (Unspecified) (Cisapride)	SS		ORAL
ORAL						

Date:11/16/01ISR Number: 3826946-0Report Type:Expedited (15-DaCompany Report #A126281
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						

Required	Condition Aggravated	Foreign	Ziprasidone Po	PS		ORAL
80.00 MG						
Intervention to	Delirium	Consumer				
TOTAL:BID:ORA						
Prevent Permanent	Hallucination					
L						
Impairment/Damage			Haloperidol	SS		

Date:11/16/01ISR Number: 3827043-0Report Type:Expedited (15-DaCompany Report #EMADSS2001006508
Age:52 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardiac Arrest	Foreign	Haldol (Haloperidol)	PS		ORAL	25 MG, DAILY,	
Life-Threatening	Fall	Health					ORAL	
	Haemodialysis	Professional	Oxazepam (Oxazepam)	SS		ORAL	15 MG, DAILY,	
	Pulmonary Oedema						ORAL	
			Saroten (Amitriptyline Hydrochloride)	SS		ORAL	75 MG, DAILY,	
							ORAL	
			Motilium (Domperidone)	SS			20	
			Multivitamin (Multivitamins)	C				
			Kreon (Pancreatin)	C				
			Pantozol (Pantoprazole Sodium)	C				
			Doxycyclin (Doxycyclin)	C				

Date:11/16/01ISR Number: 3827582-2Report Type:Expedited (15-DaCompany Report #EMADSS2001006515
Age:26 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Death	Accommodation Disorder	Foreign	Haldol (Unspecified)				
Life-Threatening	Headache	Health	(Haloperidol)	PS		ORAL	5 MG, 3 IN 1
	Intentional Self-Injury	Professional					DAY(S), ORAL;
	Sleep Disorder						SEE IMAGE
			Nozinan (Levomepromazine)	SS		ORAL	25 MG, 3 IN 1
							DAY(S), ORAL

Date:11/16/01ISR Number: 3827584-6Report Type:Expedited (15-DaCompany Report #EMADSS2001006505
Age:44 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Condition Aggravated	Foreign	Haldol (10 Mg Tablet)				
Other	Constipation	Health					
	Ileus Paralytic	Professional	(Haloperidol)	PS		ORAL	10 MG, ORAL;
							SEE IMAGE
			Leponex (Clozapine)	SS		ORAL	150 MG, ORAL;
							SEE IMAGE
			Temesta (Lorazepam)	C			
			Vioxx (Rofecoxib)	C			

Date:11/16/01ISR Number: 3827585-8Report Type:Expedited (15-DaCompany Report #EMADSS2001006504
Age:39 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Condition Aggravated	Foreign	Haldol (Haloperidol)	PS		ORAL	30;15; 20 MG,

Initial or Prolonged	Fall	Health			
DAILY, ORAL					
	Neuroleptic Malignant	Professional	Zeldox	SS	ORAL
80;160; MG,					
	Syndrome				
DAILY, ORAL					
	Parkinson'S Disease		Truxal		
	Schizophrenia, Paranoid		(Chlorprothixene		
	Type		Hydrochloride)	C	
	Urinary Retention		Dociton		
	Urinary Tract Infection		(Propranol-Ol		
			Hydrochloride)	C	
			Zopiclone		
			(Zopiclone)	C	
			Atosil		
			(Isopremethazine		
			Hydrochloride)	C	
			Acc 200		
			(Acetylcysteine)	C	

Date:11/19/01ISR Number: 3825859-8Report Type:Expedited (15-DaCompany Report #WAES 01111661
Age:21 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Completed Suicide		Cogentin	PS	Merck & Co., Inc	ORAL
			Haloperidol	SS		
			Gabapentin	SS		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/19/01ISR Number: 3825861-6Report Type:Expedited (15-DaCompany Report #WAES 01111658
Age:38 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Death		Cogentin	PS	Merck & Co., Inc	ORAL		
			Clozapine	SS				
			Haloperidol	SS				

Date:11/19/01ISR Number: 3827583-4Report Type:Expedited (15-DaCompany Report #001-0945-M0101301
Age:58 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Abdominal Pain	Literature	Gabapentin					
Hospitalization - Initial or Prolonged	Aggression	Health Professional	(Gabapentin)	PS				
	Agitation		Haloperidol					
Other	Aspartate		(Haloperidol)	SS			15 MG (5 MG,	
	Aminotransferase							TID)
	Increased		Olanzapine					
	Blood Albumin Increased		(Olanzapine)	SS				
	Blood Calcium Decreased		Nortriptyline					
	Blood Creatine		(Nortriptyline)	SS				
	Phosphokinase Increased		Zolpedem (Zolpidem)	SS				
	Blood Pressure Increased		Fluoxetine	SS				
	Blood Sodium Increased		Multivitamins					
	Cardiac Arrest		(Ergocalciferol,					
	Chest X-Ray Abnormal		Ascorbic Acid, Folic					
	Constipation		Acid, Thiamine					
	Delirium		Hydrochloride,	SS				
	Dry Skin		Unspecified					
	Dysuria		Laxatives	SS				
	Excoriation		Clomipramine					
	Haematuria		(Clomipramine)	SS			25 MG (DAILY)	
	Haemodialysis		Benztropine					
	Headache		(Benzatropine					
	Heart Rate Increased		Mesilate)	SS			4 MG (BID)	
	Insomnia		Buspirone Sr					
	Lethargy		(Buspirone)	SS			100 MG	

	Metabolic Acidosis		
(DAILY)			
	Multi-Organ Failure	Clonazepam	
	Muscle Rigidity	(Clonazepam)	SS
1.5 MG (TID)			
	Neuroleptic Malignant Syndrome		
	Proteinuria		
	Prothrombin Time Prolonged		
	Renal Failure		
	Respiratory Rate Increased		
	Serotonin Syndrome		
	Tachypnoea		
	Urinary Casts		
	White Blood Cell Count Increased		

Date:11/20/01ISR Number: 3828142-XReport Type:Expedited (15-DaCompany Report #EMADSS2001006505
Age:44 YR Gender:Female I/FU:F

Outcome
Hospitalization -
Initial or Prolonged

Other

	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Ileus Paralytic	Foreign Health Professional	Haldol (10 Mg Tablet) (Haloperidol)	PS		ORAL	10 MG, ORAL;	
							SEE IMAGE	
			Leponex (Clozapine)	SS		ORAL	150 MG, ORAL;	
							SEE IMAGE	
			Temesta (Lorazepam)	C				
			Vioxx (Rofecoxib)	C				

Date:11/20/01ISR Number: 3830787-8Report Type:Periodic Company Report #PHEH2000US11337
Age:51 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Drug Level Above Therapeutic	Health Professional	Clozaril (Clozapine)(Clozapine) Tablet	PS		ORAL	100 MG, BID,	
	Electrocardiogram Qt Prolonged						ORAL	
	Eosinophilia		Haldol (Haloperidol)	SS				
	Lethargy							
	Leukocytosis							
	Nausea							
	Neutrophilia							
	Vomiting							

Date:11/23/01ISR Number: 3829224-9Report Type:Expedited (15-DaCompany Report #PHRM2000FR01805
Age:1 DY Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain	Foreign	Anafranil					
	Benign Congenital	Health	(Clomipramine					

	Hypotonia	Professional	Hydrochloride)	PS	
TRANSPLACENTAL	TRANSPLACENTA				
	Bradycardia	Other			
L					
	Bronchitis		Haldol (Haloperidol)	SS	
TRANSPLACENTAL	TRANSPLANCENT				
	Complications Of Maternal				
AL					
	Exposure To Therapeutic		Xanax (Alprazolam)	SS	
TRANSPLACENTAL	TRANSPLACENTA				
	Drugs				
L					
	Cyst				
	Developmental				
	Coordination Disorder				
	Gastrointestinal				
	Malformation				
	Growth Retardation				
	Neonatal Disorder				
	Strabismus				

Date:11/26/01ISR Number: 3829688-0Report Type:Expedited (15-DaCompany Report #WAES 01111658
Age:38 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Death	Literature	Tab Cogentin Unk	PS		ORAL
PO						
			Clozapine	SS		
			Haloperidol	SS		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/26/01ISR Number: 3830043-8Report Type:Expedited (15-DaCompany Report #WAES 01111661
Age:21 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Death	Completed Suicide	Literature	Tab Cogentin	PS		ORAL	PO
		Health Professional	Haloperidol	SS			
			Gabapentin	SS			

Date:11/27/01ISR Number: 3830576-4Report Type:Expedited (15-DaCompany Report #PHEH2001US09499
Age:50 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Life-Threatening Hospitalization - Initial or Prolonged	Blood Chloride Decreased Blood Potassium Decreased Condition Aggravated	Health Professional Company	Trileptal (Oxcarbazepine) Tablet	PS		ORAL	SEE IMAGE
	Delusion Hyponatraemia	Representative	Haldol Decanoate (Haloperidol Decanoate)	SS			
			Lorazepam	C			
			Cogentin (Benzatropine Mesilate)	C			
			Serentil (Mesoridazine)	C			

Date:11/27/01ISR Number: 3830651-4Report Type:Direct Company Report #
Age:37 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Death	Apallic Syndrome		Haldol	PS			
Life-Threatening	Myocardial Infarction		Ritonavir	C			
Hospitalization - Initial or Prolonged	Neuroleptic Malignant Syndrome		Saquinavir	C			
			Neveripine	C			
Required Intervention to Prevent Permanent Impairment/Damage			Gemfibrozole	C			
			Gliburide	C			
			Enalapril	C			
			Provastatin	C			

Date:11/28/01ISR Number: 3832391-4Report Type:Expedited (15-DaCompany Report #EMADSS2001006673
Age:47 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Coma	Foreign	Haldol (Haloperidol)	PS		INTRAMUSCULAR	IM	
Other Required Intervention to Prevent Permanent Impairment/Damage	Hyponatraemia Inappropriate Antidiuretic Hormone Secretion	Health Professional	Mirtrazapine (Mirtazapine)	C				
			Clonazepam (Clonazepam)	C				
			Procyclidine (Procyclidine)	C				
			Lansoprazole (Lansoprazole)	C				
			Picolax (Sodium Picosulfate)	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/29/01ISR Number: 3832101-0Report Type:Expedited (15-DaCompany Report #PHBS2001JP11159
Age:20 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Alanine Aminotransferase Increased Aspartate Aminotransferase Increased Hepatic Function Abnormal Infectious Mononucleosis Lymphadenopathy Lymphocyte Morphology Abnormal Pruritus Pyrexia Rash Generalised Skin Test Positive	Foreign Literature Health Professional Other	Tegretol (Carbamazepine) Tablet Serenace (Haloperidol) Tablet Akineton (Biperiden Hydrochloride) Tablet	PS SS SS		ORAL ORAL ORAL	600 MG/DAY, 6 MG/DAY, 3 MG/DAY,	

Date:11/29/01ISR Number: 3832533-0Report Type:Direct Company Report #
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Medication Error		Ketorolac Tomethamine Msz/Usp Haloperidol Msz/Usp	PS SS	Abbott		30MG/ML 1 ML 5MG/ML 1 ML	VIAL VIAL

Date:11/30/01ISR Number: 3833005-XReport Type:Expedited (15-DaCompany Report #NSADSS2001035561
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Arrhythmia	Health	Haldol (Injection)					
	Pallor	Professional	Haloperidol)	PS				
INTRAVENOUS							5 MG IV	
	Skin Discolouration							

Date:12/04/01ISR Number: 3834684-3Report Type:Expedited (15-DaCompany Report #EMADSS2001006876
Age:61 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Burning Sensation	Foreign	Haldol (Unspecified)					
	Drug Hypersensitivity	Health	(Haloperidol)	PS		ORAL		
ORAL								
Other	Extrapyramidal Disorder	Professional	Fentanyl					
	Feeling Hot		(Unspecified)					
	Parkinsonism		(Fentanyl)	SS				
0.2 MG								
	Restlessness		Dipidolor (10 Mg/Ml					
	Sleep Disorder		Injection)					
			(Piritramide)	SS				
5 MG								
			Propofol (Propofol)	SS				
INTRAVENOUS							200 MG,IV	
			Stangyl					
			(Trimipramine					
			Maleate)	SS		ORAL		
ORAL								

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/04/01ISR Number: 3834714-9Report Type:Expedited (15-DaCompany Report #EMADSS2001006706
Age:21 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Required	Dermatitis Exfoliative Erythema Rash Pustular	Foreign Health Professional	Haldol(5 Mg Tablet)(Haloperidol)	PS		ORAL	5 MG, 2 IN 1	DAY(S), ORAL
Intervention to Prevent Permanent Impairment/Damage			Risperdal(Solution)(Risperdone)	SS		ORAL	8 MG, DAILY, ORAL	
			Tercian(Cyamemazine)	C				
			Depamide(Valpromide)	C				
			Parkinane(Trihexyphenidyl Hydrochloride)	C				

Date:12/05/01ISR Number: 3835417-7Report Type:Direct Company Report #
Age:63 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Torsade De Pointes		Haloperidol Haldol	PS				

Date:12/05/01ISR Number: 3835699-1Report Type:Expedited (15-DaCompany Report #EWC011028522
Age:28 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Distension Abdominal Tenderness Alanine Aminotransferase Increased Blood Creatine Increased Blood Urea Increased Cardiomegaly Diarrhoea Neuroleptic Malignant Syndrome	Foreign Study Health Professional Other	Haloperidol Biperiden	PS C			5 MG/DAY	

	Pyrexia					
	Renal Disorder					
	Vomiting					
	White Blood Cell Count Increased					

Date:12/05/01ISR Number: 3835740-6Report Type:Expedited (15-DaCompany Report #EMADSS2001006957
Age:29 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Schizophrenia Thrombocytopenia	Foreign Health Professional	Haldol (20 Mg/Ml Solution) (Haloperidol)	PS		ORAL	175 DROP, DAY (S), ORAL

Date:12/06/01ISR Number: 3837157-7Report Type:Expedited (15-DaCompany Report #EMADSS2001007085
Age:70 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Cerebrovascular Accident Coma Overdose	Foreign Health Professional	Haldol (Solution) (Haloperidol)	PS		ORAL	10 DROPS, 1 IN 1 DAY(S), ORAL

			Tranxene (Clorazepate Dipotassium)	SS		ORAL	25 MG, 1 IN 1 DAY*S), ORAL
			Tiapridal (Tiapride)	C			
			Effexor 25 Mg (Venlafaxine Hydrochloride	C			
			Laroxyl (Amitriptyline Hydrochloride)	C			

Date:12/07/01ISR Number: 3836813-4Report Type:Expedited (15-DaCompany Report #PHBS2001JP11372
Age:82 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Alanine Aminotransferase Increased	Foreign Health	Lochol (Fluvastatin Sodium)	PS		ORAL	20 MG, QD, ORAL
	Aspartate Aminotransferase Increased	Professional Other	Bromperidol (Bromperidol)	SS			6 MG/DAY
	Blood Creatine Phosphokinase Increased		Haloperidol (Haloperidol)	SS			0.75 MG/DAY
	C-Reactive Protein Increased		Nicergoline (Nicergoline)	C			
	Myalgia		Panaldine (Ticlopidine Hydrochloride)	C			
	Neuroleptic Malignant Syndrome		Casanmil	C			
	Pyrexia		Lanirapid (Metildigoxin)	C			
	White Blood Cell Count Increased		Tiapride Hydrochloride (Tiapride Hydrochloride)	C			
			Nitorol	C			

Date:12/07/01ISR Number: 3837630-1Report Type:Expedited (15-DaCompany Report #NSADSS2001033049
Age:43 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Disability	Decubitus Ulcer Dysphagia Extrapyramidal Disorder	Foreign Literature Health	Haldol Decanoate (Injection) (Haloperidol)	PS		INTRAMUSCULAR	IM	
	Gastric Ulcer Haematuria Neuroleptic Malignant Syndrome Osteosis Pneumonia Pyrexia Salivary Hypersecretion	Professional	Fludecasin (Fluphenazine Decanoate)	SS		INTRAMUSCULAR	5, IM	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/11/01ISR Number: 3837762-8Report Type:Expedited (15-DaCompany Report #HQ3884731JUL2001
Age:51 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Bacteraemia	Study	Protonix					
Other	Blood Creatine Phosphokinase Increased		(Pantoprazole, Injection)	PS		INTRAVENOUS	80 MG 1X PER	1 DAY,
	Catheter Related Complication					INTRAVENOUS		
	Haematocrit Decreased		Haldol (Haloperidol)	SS		INTRAVENOUS	5 MG X 2,	
	Hyperpyrexia					INTRAVENOUS		
	Staphylococcal Infection		Phenergan					
	Tachypnoea		(Promethazine Hydrochloride,					
	Thrombophlebitis Septic		Unspec)	SS		INTRAVENOUS	25 MG X 1,	
						INTRAVENOUS		
			Suxamethonium (Suxamethonium)	SS		INTRAVENOUS	50MG TO 100	MG X 2,
						INTRAVENOUS		
			Midazolam (Midazolam)	C				
			Propofol (Propofol)	C				
			Morphine Sulfate (Morphine Sulfate)	C				
			Isoflurane (Isoflurane)	C				
			Dilantin (Phenytoin Sodium)	C				
			Potassium Chloride (Potassium Chloride)	C				
			Lidocaine (Lidocaine)	C				
			Famotidine (Famotidine)	C				
			Acetaminophen					

			(Paracetamol)	C		
			Etomidate (Etomidate)	C		
			Pantoprazole	C		

Date:12/12/01ISR Number: 3840220-8Report Type:Expedited (15-DaCompany Report #01-1953
Age:83 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Grand Mal Convulsion	Foreign	Loxitane (Loxapac)					
Hospitalization -	Somnolence	Health	Capsules	PS	Wyeth Ayerst	ORAL	15 MG 1 X PER	Initial or Prolonged
		Professional					1 DAY, ORAL	305 DAY
		Company Representative	Risperdal (Risperidone), Manufacturer Unknown	SS		ORAL	500 UG 1 X PER 1 DAY, ORAL	28 DAY
			Serenase (Haloperidol)	SS		ORAL	2 MG 1 X PER 1 DAY, ORAL	305 DAY
			Zyprexa (Olanzapine)	SS		ORAL	2.5 MG 1 X PER 1 DAY, ORAL	301 DAY

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/13/01ISR Number: 3839354-3Report Type:Expedited (15-DaCompany Report #EMADSS2001007171
Age:60 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardiac Failure	Foreign Health Professional	Haldol (Haloperidol)	PS				

Date:12/13/01ISR Number: 3839401-9Report Type:Expedited (15-DaCompany Report #APCDSS2001001467
Age:71 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Cardiac Arrest Injection Site Reaction Muscle Disorder Oedema Peripheral	Foreign Health Professional Company Representative	Haldol Decanoate (100 Mg/Ml Injection) (Haloperidol Decanoate)	PS		INTRAMUSCULAR	SEE IMAGE	

Date:12/13/01ISR Number: 3839403-2Report Type:Expedited (15-DaCompany Report #EMADSS2001007112
Age:83 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Grand Mal Convulsion Somnolence	Foreign Health Professional	Haldol (Unspecified) (Haloperidol)	PS		ORAL	2 MG, DAILY,	ORAL
			Risperidone (Unspecified) (Risperidone)	SS		ORAL	500 MCG,	DAILY, ORAL
			Loxapac (Loxapine Succinate)	SS		ORAL	15 MG, DAILY.	ORAL
			Olanzapine					

			(Olanzapine)	SS		ORAL
2.5 MG, DAILY, ORAL						

Date:12/13/01ISR Number: 3839834-0Report Type:Expedited (15-DaCompany Report #EMADSS2001007085
Age:70 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Cerebrovascular Accident Coma Overdose Paralysis Somnolence	Foreign Health Professional	Haldol (Solution) (Haloperidol)	PS		ORAL	10 DROPS, 1 IN 1 DAY(S), ORAL
			Tranxene (Clorazepate Dipotassium)	SS		ORAL	25 MG, 1 IN 1 DAY(S), ORAL
			Tiapridal (Tiapride)	C			
			Effexor 25 Mg (Venlafaxine Hydrochloride)	C			
			Laroxyl (Amitriptyline Hydrochloride)	C			

Date:12/14/01ISR Number: 3840943-0Report Type:Expedited (15-DaCompany Report #EMADSS2001007112
Age:83 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Grand Mal Convulsion Somnolence	Foreign Health Professional	Risperidone (Unspecified) (Risperidone)	PS		ORAL	500 MCG,	DAILY, ORAL
			Haldol(Unspecified)(Haloperidol)	SS		ORAL	2 MG, DAILY,	ORAL
			Loxapac(Loxapine Succinate)	SS		ORAL	15 MG, DAILY,	ORAL
			Olanzapine(Olanzapin e)	SS		ORAL	2.5 MG,	DAILY, ORAL

Date:12/14/01ISR Number: 3841026-6Report Type:Expedited (15-DaCompany Report #2001110021
Age:80 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death Other	Apallic Syndrome Blood Pressure Decreased	Foreign Health	Doral (Quazepam) Tablets	PS		ORAL	15 MG/D, PO	
	Cardiac Arrest	Professional	Haloperidol Tablets	SS		ORAL	9 MG/D, PO	
	Condition Aggravated		Biperiden Hcltablets	SS		ORAL	3 MG/D, PO	
	Dementia Depressed Level Of Consciousness Heart Rate Decreased Mouth Breathing Respiratory Depression							

Date:12/17/01ISR Number: 3839886-8Report Type:Direct Company Report #
Age:28 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Electroencephalogram Abnormal		Haldol Decanoate 150 Mg Im 11-1-01 (Prior To Admission)	PS		INTRAMUSCULAR	150 MG IM	

Date:12/17/01ISR Number: 3840721-2Report Type:Expedited (15-DaCompany Report #EMADSS2001006911
Age:36 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Creatine Phosphokinase Increased	Foreign Health	Haldol (Injection) (Haloperidol)	PS		INTRAVENOUS	12.5 MG, 1 IN	
Other	Sepsis	Professional						1 DAY (S), IV
			Dipiperon (Pipamperone)	SS		ORAL		PRN, ORAL
			Remergil (Mirtazapine)	C				
			Tavor (Lorazepam)	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/17/01ISR Number: 3841704-9Report Type:Direct Company Report #
Age:74 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Pyrexia		Haloperidol	PS		ORAL	2.5MG PO BID	
			Lithium	C				
			Digoxin	C				
			Sinemet	C				
			Asa	C				
			Cogentin	C				
			Seroquel	C				
			Zoloft	C				
			Lactulose	C				
			Macrodactin	C				

Date:12/18/01ISR Number: 3841296-4Report Type:Expedited (15-DaCompany Report #EMADSS2001007245
Age:90 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Test Abnormal	Foreign	Haldol (Solution)					
	Faecaloma	Health	(Haloperidol)	PS				
	Hepatic Function Abnormal	Professional	Di-Antalvic (Aporex)	SS				
			Diovenor (Diosmin)	SS				
			Stilnox (Zolpidem)	SS				
			Coversyl (Perindopril)	C				
			Lasilix (Furosemide)	C				

Date:12/18/01ISR Number: 3841419-7Report Type:Expedited (15-DaCompany Report #PHBS2001JP11372
Age:82 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Creatine Phosphokinase Increased	Foreign Health	Lochol (Fluvastatin Sodium) Capsule	PS		ORAL	20 MG, QD, ORAL	
	C-Reactive Protein Increased	Professional Other	Bromperidol					

	Myalgia	(Bromperidol)	SS	ORAL 6 MG/DAY,
	Neuroleptic Malignant Syndrome			ORAL
	Pyrexia	Haloperidol (Haloperidol)	SS	ORAL 0.75 MG/DAY,
	White Blood Cell Count Increased			ORAL
		Panaldine (Ticlopidine Hydrochloride)	C	
		Casanmil	C	
		Lanirapid Hydrochloride (Tiapride Hydrochloride)	C	
		Nitorol	C	
		Nicergoline (Nicergoline)	C	

Date:12/18/01ISR Number: 3841644-5Report Type:Expedited (15-DaCompany Report #2001120003
Age:92 YR Gender:Female I/FU:I

Outcome	PT
Life-Threatening	Depressed Level Of Consciousness

	Eating Disorder Medication Error Somnolence	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
		Foreign Health Professional	Doral (Quazepam) Tablets	PS		ORAL
1) 10 MG/D, PO; 2) 20 MG/D, PO						
			Promethazine Hcl	SS		ORAL
25 MG/D, PO						
			Haloperidol	SS		ORAL
0.75 MG/D, PO						
			Zopiclone	SS		ORAL
7.5 MG/D, PO						

Date:12/19/01ISR Number: 3842301-1Report Type:Expedited (15-DaCompany Report #NSADSS2001037757
Age:26 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Agitation Respiratory Depression	Foreign Consumer	Haldol (Tablet) (Haloperidol)	PS		ORAL
1 TABLE, ORAL						
			Valium (Diazepam)	SS		ORAL
2 TABLE, ORAL						
			Alcohol (Ethanol)	SS		ORAL
ORAL						

Date:12/20/01ISR Number: 3843291-8Report Type:Direct Company Report #
Age:24 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Hallucination, Auditory		Haldol Decanoate	PS		
INTRAMUSCULAR 75MG IM						
	Suicidal Ideation		Lithium Carbonate	SS		ORAL
600-600-300MG PO (SEE						

IMAGE)

Date:12/20/01ISR Number: 3843571-6Report Type:Expedited (15-DaCompany Report #EMADSS2001007260
Age:50 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Cardiac Arrest Shock	Foreign Health Professional	Haldol (Injection) (Haloperidol)	PS			7 MG/HR OVER 60 HRS.	
			Bevitol (Thiamine Hydrochloride)	C				
			Zantac (Ranitidine Hydrochloride)	C				
			Calcium Chloride	C				
			Midazolam	C				

Date:12/20/01ISR Number: 3843755-7Report Type:Expedited (15-DaCompany Report #DEU004506
Age:96 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Arthralgia Selective Iga	Foreign Health	Vasolan	PS		ORAL	120 MG DAILY PO	
Other	Immunodeficiency	Professional Other	Certa	SS		ORAL	0.15 MG BID PO	
			Coniel	SS		ORAL	4 MG DAILY PO	
			Myslee	SS		ORAL	5 MG DAILY PO	
			Ludiomil	SS		ORAL	25 MG DAILY PO	
			Haloperidol	SS		ORAL	1.5 MG DAILY PO	

			Nitrazepam	SS		ORAL	5 MG Q8HR PO
			Tofranil	SS		ORAL	40 MG Q6HR PO
			Amoxapine	SS		ORAL	25 MG Q8HR PO
			Diazepam	SS		ORAL	5 MG Q8HR PO
			Rebamipide	SS		ORAL	100 MG Q8HR PO
			Loxonin	SS		ORAL	30 MG DAILY PO

Date:12/24/01ISR Number: 3844400-7Report Type:Expedited (15-DaCompany Report #NSADSS2001038538
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Drug Interaction	Health Professional	Haldol (Haloperidol)	PS			
	Electrocardiogram Qt Prolonged		Seroquel (Seroquel)	SS		ORAL	
			Paxil (Paroxetine Hydrochloride)	C			

Date:12/26/01ISR Number: 3844938-2Report Type:Expedited (15-DaCompany Report #01P-056-0114023-00
Age:70 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Akinesia	Foreign	Tranxene (Clorazepate Dipotassium)				
	Cerebrovascular Accident	Health Professional	(Clorazepate Dipotassium)	PS		ORAL	SEE IMAGE
	Coma	Other	Haloperidol	SS		ORAL	10 UNIT, 1 IN 1 D, PER
	Overdose						
	Somnolence						

ORAL

Amitriptyline Hydrochloride	C
Tiapride	C
Venlafaxine Hydrochloride	C

Date:12/26/01ISR Number: 3845122-9Report Type:Expedited (15-DaCompany Report #A126193
Age:39 YR Gender:Female I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Aggression
	Akathisia
	Anxiety
	Bacterial Infection
	Blood Creatine Phosphokinase Increased
	Chills
	Contusion
	Cystitis Klebsiella
	Echolalia
	Fear
	Hallucination, Auditory
	Head Injury
	Intentional Self-Injury
	Nausea
	Parkinsonism
	Pyrexia
	Schizophrenia

	Self-Injurious Ideation Tremor Urinary Retention	Report Source	Product	Role	Manufacturer	Route Dose Duration
	Urinary Tract Infection	Foreign	Ziprasidone Po	PS		ORAL 160. 00 MG
	Vomiting	Health				TOTAL:DAILY:O
	X-Ray Limb Abnormal	Professional				RAL
			Haloperidol	SS		ORAL 15.00 MG TOTAL:DAILY:O RAL
			Atosil	C		
			Acc	C		
			Tavor	C		
			Leponex	C		
			Truxal	C		
			Dicton	C		
			Imovane Zopiclon	C		

Date:12/27/01ISR Number: 3848498-1Report Type:Periodic Company Report #2001000016-AP
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Other	Injection Site Inflammation Injection Site Mass Injection Site Pain	Health Professional	Haloperidol Deconoate (Haloperidol Deconaoate) 100.00 M.	PS		INTRAMUSCULAR 100 MILLIGRAMS MONTHLY INTRAMUSCULAR
			Depakote	C		
			Lithium Carbonate	C		
			Procardia	C		
			Trazedone	C		

Date:12/28/01ISR Number: 3846644-7Report Type:Expedited (15-DaCompany Report #EMADSS2001007427
Age:74 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dementia Epilepsy Extrapyramidal Disorder Fall Psychotic Disorder	Foreign Health Professional	Haldol Faible (0.5 Mg/Ml Solution) (Haloperidol)	PS		ORAL	0.5 ML, DAILY, ORAL	
			Loxen (Nicardipine Hydrochloride)	C				
			Vasteral (Trimetazidine Dihydrochloride)	C				
			Anafranil (Clomipramine Hydrochloride)	C				
			Neo-Mercazole (Carbimazole)	C				
			L-Thyoxin (Levothyroxine Sodium)	C				
			Orocal Vitamine (Calcium Carbonate)	C				
			Lexomil (Bromazepam)	C				
			Mopral (Omeprazole)	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/28/01ISR Number: 3846807-0Report Type:Expedited (15-DaCompany Report #A126193
Age:39 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Aggression	Foreign	Ziprasidone Po	PS		ORAL	160.00 MG	TOTAL;DAILY;O
	Anxiety	Health						
	Bacterial Infection	Professional						
	Blood Creatine Phosphokinase Increased		Haloperidol	SS		ORAL	15.00 MG	TOTAL;DAILY;O
	Chills							
	Contusion		Atosil	C				
	Fall		Acc	C				
	Hallucination, Auditory		Tavor	C				
	Klebsiella Infection		Leponex	C				
	Neuroleptic Malignant Syndrome		Truxal	C				
	Parkinson'S Disease		Dicton	C				
	Pyrexia		Imovane Zopiclon	C				
	Tremor							
	Urinary Retention							
	Urinary Tract Infection							
	Vomiting							

Date:12/31/01ISR Number: 3846937-3Report Type:Expedited (15-DaCompany Report #EMADSS2001007245
Age:90 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain	Foreign	Haldol (Solution) (Haloperidol)	PS				
	Faecaloma	Health	Di-Antalvic (Aporex)	SS				
	Hepatic Function Abnormal	Professional	Diovenor (Diosmin)	SS				
	Liver Disorder		Stilnox (Zolpidem)	SS				
	Vomiting		Coversyl (Perindopril)	C				
			Lasilix (Furosemide)	C				

Date:01/02/02ISR Number: 3847389-XReport Type:Expedited (15-DaCompany Report #2001UW16417
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Drug Interaction	Other	Seroquel	PS				
	Electrocardiogram Qt Prolonged		Haldol	SS				
			Paxil	C				

Date:01/03/02ISR Number: 3847839-9Report Type:Expedited (15-DaCompany Report #2001AP05471
Age:54 YR Gender:Male I/FU:F

Outcome	PT
Death	Blood Pressure Decreased
Life-Threatening	Computerised Tomogram Abnormal
Hospitalization - Initial or Prolonged	Gastric Haemorrhage
Required Intervention to Prevent Permanent Impairment/Damage	Gastrointestinal Haemorrhage
	Gastrointestinal Necrosis
	Hyperthermia Malignant
	Loss Of Consciousness
	Mesenteric Artery

	Embolism Metabolic Acidosis Neuroleptic Malignant Syndrome	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Oesophageal Haemorrhage	Foreign	Seroquel "Zeneca"	PS		ORAL	400 MG DAILY
	Psychomotor Hyperactivity	Health					PO
	Respiratory Rate	Professional	Seroquel "Zeneca"	SS		ORAL	300 MG DAILY
	Increased	Other					PO
	Sepsis		Lodopin	SS		ORAL	150 MG DAILY
	Septic Shock						PO
	Shock		Lodopin	SS		ORAL	100 MG DAILY
	Stress Ulcer						PO
	Tachycardia		Levotomin	SS		ORAL	100 MG DAILY
	Tongue Biting						PO
			Levotomin	SS		ORAL	50 MG DAILY
							PO
			Cosminal	SS		ORAL	5 MG DAILY PO
			Anafranil	SS		ORAL	75 MG DAILY
							PO
			Akineton	C			
			Artane	C			
			Hiberna	C			
			Rohypnol	C			
			Forsenid	C			

Date:01/03/02ISR Number: 3848315-XReport Type:Expedited (15-DaCompany Report #2001000107-AP
Age:62 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration

Death Life-Threatening Other	Tachycardia		Haloperidol Injection (Haloperidol Injection) 5.00 Milligrar	PS			
INTRAVENOUS	1 MILLILITRES						
UNK FREQUENCY							
INTRAVENOUS							

Date:01/03/02ISR Number: 3848318-5Report Type:Periodic Company Report #2001000108-AP
Age:55 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Tachycardia		Haloperidol Injection (Haloperidol Injection) 5.00 Milligrams	PS				
INTRAVENOUS	1 MILLILITRES							
UNK FREQUENCY								
INTRAVENOUS								

Date:01/04/02ISR Number: 3848615-3Report Type:Direct Company Report #CTU 158372
Age:50 YR Gender:Male I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Aphasia Cogwheel Rigidity Confusional State Coordination Abnormal Disturbance In Attention Drooling

	Neuroleptic Malignant Syndrome Paranoia	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
	Psychotic Disorder Pulmonary Embolism		Haloperidol 2 Mg Tablets Geneva	PS	Geneva	ORAL
2 MG PO TID						
			Haldol 5 Mg	SS		OTHER
PO OR IM Q 4 HR PRN						
			Coreg	C		
			Clonazepam	C		
			Plavix	C		
			Furosemide	C		
			Altace	C		
			Coumadin	C		

Date:01/04/02ISR Number: 3849144-3Report Type:Expedited (15-DaCompany Report #PHBS2001JP11372
Age:82 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	C-Reactive Protein Increased	Foreign Health	Lochol (Fluvastatin Sodium) Capsule	PS		ORAL
20 MG, QD, ORAL						
	Myalgia	Professional				
	Neuroleptic Malignant Syndrome	Other	Bromperidol (Bromperidol)	SS		ORAL
6 MG/DAY, ORAL						
			Haloperidol (Haloperidol)	SS		ORAL
0.75 MG/DAY, ORAL						
			Nicergoline (Nicergoline)	C		
			Panaldine (Ticlopidine Hydrochloride)	C		
			Casanmil	C		
			Lanirapid			

	(Metildigoxin)	C
	Tiapride Hydrochloride (Tiapride Hydrochloride)	C
	Nitorol	C

Date:01/04/02ISR Number: 3849866-4Report Type:Direct Company Report #CTU 158392
Age:27 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Tremor	Health Professional	Haloperidol 2mg Tab Geneva	PS	Geneva	ORAL	2MG PO BID	

Date:01/07/02ISR Number: 3849062-0Report Type:Direct Company Report #CTU 158491
Age:78 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Neuroleptic Malignant Syndrome		Haloperidol	PS			.5MG BID	
			Olanzapine	SS			2.5MG QD	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/08/02ISR Number: 3849978-5Report Type:Expedited (15-DaCompany Report #EMADSS2002000011
Age:90 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Confusional State	Foreign	Haldol Faible					
	Drug Interaction	Health	(Haloperidol)	PS		ORAL	15 DROPS,	
	Dysstasia	Professional					DAILY, ORAL	
	Renal Impairment	Other	Di-Antalvic					
	Somnolence		(Aporex)	SS		ORAL	1 CAP, 6 IN 1	DAY(S), ORAL
			Xanax (Alprazolam)	SS		ORAL	0.25 MG,	DAILY, ORAL
			Vastarei (Trimetazidine)	C				
			Mopral (Omeprazole)	C				
			Diffu-K (Potassium Chloride)	C				
			Deroxat (Paroxetine Hydrochloride)	C				
			Azopt (Brinzolamide)	C				
			Tobrex (Tobramycin Sulfate)	C				
			Ciloxan (Ciprofloxacin Hydrochloride)	C				
			Xalatan (Latanoprost)	C				

Date:01/09/02ISR Number: 3851051-7Report Type:Expedited (15-DaCompany Report #EMADSS2002000012
Age:25 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Body Temperature Increased	Foreign Health	Haldol Decanoate (Unspecified)					
	Clonic Convulsion	Professional	Haloperidol Decanoate)	PS				
	Mydriasis						INTRAMUSCULAR	2 AMP, 1 IN

Psychomotor Retardation

30 DAY (S),

Somnolence

IM

			Haldol (5 Mg Tablet) (Haloperidol)	SS		ORAL

5 MG DAILY,

ORAL

			Tiapridal (Tiapride)	SS		ORAL

100 MG, 3 IN

1 DAY (S),

ORAL

			Lamictal (Lamotrigine)	C		
			Parkinane (Trihexyphenidyl Hydrochloride)	C		

Date:01/10/02ISR Number: 3850047-9Report Type:Expedited (15-DaCompany Report #US-BRISTOL-MYERS SQUIBB COMPANY-11658093
Age:68 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Lung Infiltration		Modecate Inj	PS	Apothecon	INTRAMUSCULAR	"18 years 48 weeks 4 days"	19 YR
			Di-Antalvic	SS		ORAL	"1 week 6 days"	2 WK
			Doliprane	SS		ORAL	3 DAY	

				Haldol	SS		ORAL
"21 years 48 weeks 4 days"	22	YR					
				Seglor	SS		ORAL
"7 weeks 6 days"	8	WK					
				Voltarene	SS		ORAL
"1 week 6 days"	2	WK					

Date:01/10/02ISR Number: 3851739-8Report Type:Expedited (15-DaCompany Report #EMADSS2001007586
Age: Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Convulsion	Foreign	Haloperidol					
Other		Health	(Unspecified)					
		Professional	(Haloperidol)	PS				
			Lamotrigine					
			(Lamotrigine)	C				

Date:01/11/02ISR Number: 3851958-0Report Type:Expedited (15-DaCompany Report #M2002.0022
Age:50 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Confusional State	Health	Haloperidol 2 Mg					
	Neuroleptic Malignant Syndrome	Professional	Tablets, Geneva Manufacturer	PS	Geneva Manufacturer	ORAL	2 MG	PO TID
	Paranoia		Haldol 5 Mg	SS		ORAL	PO OR IM	Q 4 HR. PRN
	Psychotic Disorder							
	Pulmonary Embolism		Coreg	C				
			Clonazepam	C				
			Plavix	C				
			Furosemide	C				
			Altace	C				
			Coumadin	C				

Date:01/14/02ISR Number: 3851984-1Report Type:Direct Company Report #CTU 159056
Age:72 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Acute Coronary Syndrome		Haloperidol	PS			18MG OVER	<24
Initial or Prolonged	Anoxic Encephalopathy						HR	
	Respiratory Failure							
	Torsade De Pointes							

Date:01/14/02ISR Number: 3852639-XReport Type:Expedited (15-DaCompany Report #M2002.0022
Age:50 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Neuroleptic Malignant Syndrome	Health Professional	Haloperidol 2 Mg Tablets, Geneva Manufacturer	PS			2 MG PO TID	
	Pulmonary Embolism		Haldol 5 Mg	SS			PO OR IM Q 4	
							HR. PRN	
			Coreg	C				
			Clonazepam	C				
			Plavix	C				
			Furosemide	C				
			Altace	C				
			Coumadin	C				

			Qhs	C		

Date:01/16/02ISR Number: 3853379-3Report Type:Direct Company Report #CTU 159324
Age:24 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blood Prolactin Increased		Haldol Decanoate	PS		INTRAMUSCULAR	75 MG IM	
	Hallucination, Auditory		Lithium Carbonate	SS		ORAL	600-600-300	MG PO
	Homicidal Ideation							
	Suicidal Ideation		Haldol Decanoate	C				

Date:01/16/02ISR Number: 3853381-1Report Type:Direct Company Report #CTU 159325
Age:28 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Electroencephalogram Abnormal		Haldol Decanoate 150 Mg	PS		INTRAMUSCULAR	150 MG IM	

Date:01/17/02ISR Number: 3854174-1Report Type:Expedited (15-DaCompany Report #EMADSS2002000142
Age:68 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Interstitial Lung Disease	Foreign Health Professional	Haldol (Unspecified) (Haloperidol)	PS		ORAL	ORAL	
			Di-Antalvic (Aproex)	SS		ORAL	ORAL	
			Doliprane (Paracetamol)	SS		ORAL	ORAL	
			Modecate (Fluphenazine Decanoate)	SS		ORAL	ORAL	

			Seglor (Dihydroergotamine Mesilate)	SS		ORAL
ORAL						
			Voltarene (Diclofenac Sodium)	SS		ORAL
ORAL						

Date:01/17/02ISR Number: 3854203-5Report Type:Expedited (15-DaCompany Report #EMADSS2002000208
Age:61 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Hepatitis	Foreign Health Professional	Haldol (Unspecified) (Haloperidol)	PS		ORAL
ORAL 3 DAY			Erythromycin (Erythromycin)	C		

Date:01/17/02ISR Number: 3855181-5Report Type:Expedited (15-DaCompany Report #EMADSS2002000218
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Anaphylactic Shock	Foreign Health Professional	Haldol (Injection) (Haloperidol)	PS		
1 VIAL						

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/18/02ISR Number: 3855760-5Report Type:Expedited (15-DaCompany Report #HQ3884731JUL2001
Age:51 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Bacteraemia	Study	Protonix					
Hospitalization - Initial or Prolonged	Catheter Related Complication		(Pantoprazole, Injection)	PS				
						INTRAVENOUS	80 MG 1X PER	
Other	Haematocrit Decreased							1 DAY,
	Hyperpyrexia					INTRAVENOUS		
	Procedural Site Reaction		Haldol (Haloperidol,					
	Staphylococcal Infection		)	SS		INTRAVENOUS	5 MG X 2,	
	Tachypnoea					INTRAVENOUS		
	Thrombophlebitis Septic		Phenergan (Promethazine Hydrochloride, Unspec)	SS		INTRAVENOUS	25 MG X 1,	
						INTRAVENOUS		
			Suxamethonium (Suxamethonium)	SS		INTRAVENOUS	50 MG TO 100	MG X 2,
						INTRAVENOUS		
			Midazolam (Midazolam)	C				
			Propofol (Propofol)	C				
			Morphine Sulfate (Morphine Sulfate)	C				
			Isoflurane (Isoflurane)	C				
			Dilantin (Phenytoin Sodium)	C				
			Potassium Chloride (Potassium Chloride)	C				
			Lidocaine (Lidocaine)	C				
			Famotidine (Famotidine)	C				

			Acetaminophen (Paracetamol)	C		
			Etomidate (Etomidate)	C		

Date:01/22/02ISR Number: 3857817-1Report Type:Expedited (15-DaCompany Report #EMADSS2002000074
Age:89 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Sedation	Foreign Health Professional	Haldol (Injection) (Haloperidol)	PS			25MG THEN Other 25MG	1.5 HOURS LATER
			Diazepam (Diazepam)	C				

Date:01/23/02ISR Number: 3856155-0Report Type:Expedited (15-DaCompany Report #304707
Age:53 YR Gender:Female I/FU:I

Outcome	PT
Death	Pneumonia
	Respiratory Distress
	Respiratory Failure
	Stevens-Johnson Syndrome
	Toxic Epidermal

Necrolysis

Dose	Duration	Report Source	Product	Role	Manufacturer	Route
			Dormicum	PS	Roche	
1	DAY					
			Unat	SS	Roche	
27	DAY					
			Remestan	SS	Roche	
19	DAY					
			Hepa-Merz	SS		
1	DAY					
			Tutofusin Bg	SS		
24	DAY					
			Aldactone	SS	Roche	
29	DAY					
			Pantozol	SS		
29	DAY					
			Haldol	SS		
25	DAY					
			Hepa-Merz	SS		
28	DAY					
			Eugalac	SS		
1	DAY					
			Tromcardin Forte	SS		
23	DAY					
			Humanalbumin	SS		
3	DAY					
			Natriumchlorid	SS		
1	DAY					
			Polybion	SS		
1	DAY					
			Bifiteral	SS		
5	DAY					
			Placebo	SS	Roche	
17	DAY					
			Quantalan	SS		
3	DAY					
			Eunerpan	SS		
4	DAY					
			Lactulose	SS		
9	DAY					

Date:01/23/02ISR Number: 3857786-4Report Type:Expedited (15-DaCompany Report #PHBS2001JP11372
Age:82 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Alanine Aminotransferase Increased	Foreign Health Professional Other	Lochol (Fluvastatin Sodium)	PS		ORAL	20 MG, QD, ORAL	
	Blood Creatine Phosphokinase Increased		Bromperidol (Bromperidol)	SS		ORAL	6 MG/DAY, ORAL	
	Bronchitis							
	C-Reactive Protein Increased		Haloperidol (Haloperidol)	SS		ORAL	0.75 MG/DAY, ORAL	
	Myalgia							
	Neuroleptic Malignant Syndrome		Nicergoline (Nicergoline)	C				
	Pneumonia		Panaldene (Ticlopidine Hydrochloride)	C				
	Pyrexia		Casanmil	C				
	White Blood Cell Count Increased		Lanirapid (Metildigoxin)	C				
			Tiapride Hydrochloride (Tiapride Hydrochloride)	C				
			Nitorol	C				

Date:01/24/02ISR Number: 3859999-4Report Type:Expedited (15-DaCompany Report #PHRM2002FR00518
Age:68 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Interstitial Lung Disease	Foreign Health Professional Other	Voltarene (Diclofenac Sodium) Enteric-Film-Coated Tablet	PS		ORAL	ORAL	
			Di-Antalvic					

			(Dextropropoxyphene Hydrochloride, Paracetamol)	SS			ORAL
ORAL							
			Doliprane (Paracetamol)	SS			ORAL
ORAL							
			Haldol (Haloperidol)	SS			ORAL
ORAL							
			Modecate "Sanofi Winthrop" (Fluphenazine Decanoate)	SS			ORAL
ORAL							
			Seglor (Dihydroergotamine Mesilate)	SS			ORAL
ORAL							

Date:01/24/02ISR Number: 3860926-4Report Type:Expedited (15-DaCompany Report #081-0981-M0200032
Age:60 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Chromaturia Dialysis	Foreign Health	Atorvastatin (Atorvastatin)	PS		ORAL	PER ORAL	
Other	Loss Of Consciousness Rhabdomyolysis	Professional	(Haloperidol) (Brotizolam) (Diazepam)	SS C C				

Date:01/25/02ISR Number: 3860274-2Report Type:Expedited (15-DaCompany Report #304707
Age:53 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Acute Respiratory Distress Syndrome Enanthema	Foreign Study Health	Dormicum (Midazolam Hydrochloride Or Midazolam Maleate)	PS		INTRAVENOUS	5 MG DAILY	
	Infection	Professional				INTRAVENOUS		
	Pneumonia		Remestan (Temazepam)	SS		ORAL	1 DOSE FORM 1	

	Respiratory Failure			
PER DAY ORAL				
	Stevens-Johnson Syndrome	Unat (Torsemide Or		
	Toxic Epidermal	Torsemide Sodium)	SS	ORAL
5 MG ORAL				
	Necrolysis	Hepa-Merz		
		(Ornithine)	SS	
INTRAVENOUS	INTRAVENOUS			
		Tutofusin Bg		
		(Glucose/Magnesium		
		Chloride/Potassium		
		Phosphate,		
		Monobasic/Sodium	SS	
INTRAVENOUS	500 ML DAILY			
INTRAVENOUS				
		Aldactone		
		(Spironolactone)	SS	ORAL
100 MG 2 PER				
DAY ORAL				
		Pantozol		
		(Pantoprazole)	SS	ORAL
40 MG 1 PER				
DAY ORAL				
		Haldol (Haloperidol)	SS	ORAL
30 DROP 1 PER				
DAY ORAL				
		Hepa-Merz		
		(Ornithine)	SS	ORAL
1 DOSE FORM 1				
PER DAY ORAL				
		Eugalac (Lactulose)	SS	ORAL
20 ML 1 PER				
DAY ORAL				
		Tromcardin Forte		
		(Magnesium		
		Aspartate/Potassium		

		Aspartate)	SS	ORAL
14 DOSE FORM				
1 PER DAY				
ORAL				
		Humanalbumin (Albumin Human) 20%	SS	
INTRAVENOUS	100 ML DAILY			
INTRAVENOUS				
		Natriumchlorid (Sodium Chloride)	SS	
INTRAVENOUS	100 ML DAILY			
INTRAVENOUS				
		Polybion (Biotin/Vitamin B Complex)	SS	
INTRAVENOUS	2 DOSE FORM			
DAILY				
INTRAVENOUS				
		Bifiteral (Lactulose)	SS	ORAL
20 ML 1 PER				
DAY ORAL				
		Placebo (Placebo)	SS	ORAL
1 DOSE FORM 1				
PER DAY ORAL				
		Quantalan (Cholestyramine Resin)	SS	ORAL
1 DOSE FORM 3				
PER DAY ORAL				
		Eunerpan (Melperone)	SS	ORAL
5 ML 1 PER				
DAY ORAL				
		Lactulose (Lactulose)	SS	ORAL
20 ML 1 PER				
DAY ORAL				

Date:01/28/02ISR Number: 3858867-1Report Type:Expedited (15-DaCompany Report #US-BRISTOL-MYERS SQUIBB COMPANY-11658093
Age:68 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Acute Respiratory		Modecate Inj	PS	Apothecon	INTRAMUSCULAR	"18 years 48	
Initial or Prolonged	Distress Syndrome						weeks 4 days"	19 YR
	Lung Infiltration		Di-Antalvic	SS		ORAL	"1 week 6	
							days"	2 WK
			Doliprane	SS		ORAL	3	DAY
			Haldol	SS		ORAL	"21 years 48	
							weeks 4 days"	22 YR
			Seglor	SS		ORAL	"7 weeks 6	
							days"	8 WK
			Voltarene	SS		ORAL	"1 week 6	
							days"	2 WK
			Trihexyphenidyl	C				
			Fluvoxamine	C				
			Heptaminol	C				
			Lactulose	C				
			Etidronate Disodium	C				
			Fluphenazine	C				
			Calcifediol	C				
			Tricalcium Phosphate	C				
			Alprazolam	C				

Date:01/28/02ISR Number: 3860440-6Report Type:Direct Company Report #CTU 160197
Age:33 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Hyperpyrexia		Haloperidol-Im Injection	PS		LAST DOSE	22-Aug-2005	10:49 AM

6/12/01(POSSI

BLY)

			Trazodone	C		
			Mellaril	C		
			Tegretol	C		
			Risperdal	C		

Date:01/28/02ISR Number: 3861150-1Report Type:Expedited (15-DaCompany Report #EMADSS2002000142
Age:68 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Abdominal Pain Acinetobacter Infection	Foreign Health	Haldol (Unspecified) (Haloperidol)	PS		ORAL	ORAL
	Acute Respiratory Distress Syndrome Alveolitis	Professional	Di-Antalvic (Aporex)	SS		ORAL	ORAL
			Doliprane (Paracetamol)	SS		ORAL	ORAL
	Condition Aggravated Hypoxia Lung Disorder		Modecate (Fluphenazine Decanoate)	SS		ORAL	ORAL
	Pulmonary Hypertension Pyrexia Urinary Retention		Seglor (Dihydroergotamine Mesilate)	SS		ORAL	ORAL
			Voltarene (Diclofenac Sodium)	SS		ORAL	ORAL
			Dedrogyl (Calcified-Iol)	C			
			Parkinane (Trihexyphenidyl Hydrochloride)	C			
			Floxyfral (Fluvoxamine Maleate)	C			
			Hept-A-Myl (Heptaminol Hydrochloride)	C			
			Duphalac (Lactulose)	C			
			Didronel (Etidronate				

			Disodium)	C		
			Ostram (Calcium Phosphate)	C		
			Xanax (Alprazolam)	C		

Date:01/28/02ISR Number: 3861151-3Report Type:Expedited (15-DaCompany Report #EMADSS2002000347
Age:68 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blister Oedema	Foreign Health Professional	Haldol (Unspecified) (Haloperidol)	PS		ORAL	1 MG, DAY(S), ORAL	
			Exelon (Rivastigmine)	C				
			Trisequens (Trisekvens)	C				
			Nisis (Valsartan)	C				
			Tanakan (Ginkgo Tree Leaves Extract)	C				
			Elisor (Pravastatin Sodium)	C				

Date:01/30/02ISR Number: 3862575-0Report Type:Expedited (15-DaCompany Report #NSADSS2001013546
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Hospitalization -	Breath Sounds Decreased Convulsion	Health Professional	Haldol (Injection) (Haloperidol)	PS				
Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Heart Rate Increased Hyperpyrexia Hypotension Hypoxia Muscle Twitching Neuroleptic Malignant Syndrome Pneumonia Respiratory Rate Increased Tremor		Synthroid (Levothyroxine Sodium) Kefzol (Cefazolin Sodium)	C C				
						INTRAMUSCULAR	IM	

Date:02/01/02ISR Number: 3864896-4Report Type:Expedited (15-DaCompany Report #DEU003391
Age:25 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Conduction Disorder	Foreign	Akineton Retard	PS		ORAL	4 MG OD PO	
		Study	Haldol	SS		ORAL	5 MG DAILY PO	
		Health	Risperdal	SS		ORAL	2 MG DAILY PO	
		Professional Other						

Date:02/04/02ISR Number: 3863898-1Report Type:Expedited (15-DaCompany Report #EMADSS2002000529
Age:1 DY Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Congenital Anomaly	Congenital Foot Malformation Maternal Drugs Affecting	Foreign Health Professional	Risperdal (Unspecified) (Risperidone)	PS				
						INTRA-UTERINE	2 MG, 1 IN 1	

Foetus
DAY(S),

UTERINE

				Haldol (5 Mg Tablet) (Haloperidol)	SS		
INTRA-UTERINE	5 MG, 1 IN 1						

DAY(S),

UTERINE

				Largactil (Chlorpromazine Hydrochloride)	C		
				Rivotril (Clonazepam)	C		
				Atarax (Hydroxyzine Hydrochloride)	C		
				Kardegic (Acetylsalicylate Lysine)	C		

Date:02/04/02ISR Number: 3863906-8Report Type:Expedited (15-DaCompany Report #EMADSS2002000529
Age:1 DY Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Congenital Anomaly	Maternal Drugs Affecting Foetus	Foreign Health	Haldol (5 Mg Tablet) (Haloperidol)	PS		
INTRA-UTERINE	5 MG, 1 IN 1					
	Talipes	Professional				
DAY(S),						

UTERINE

			Risperdal (Unspecified) (Risperidone)	SS		
INTRA-UTERINE	2 MG, 1 IN 1 DAY(S),					
UTERINE			Largactil (Chlorpromazine Hydrochloride)	C		
			Rivotril (Clonazepam)	C		
			Atarax (Hydroxyzine Hydrochloride)	C		
			Kardegic (Acetylsalicylate Lysine)	C		

Date:02/05/02ISR Number: 3865311-7Report Type:Expedited (15-DaCompany Report #PHBS2001JP11159
Age:20 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Alanine Aminotransferase Increased	Foreign Literature	Tegretol (Carbamazepine)					
	Aspartate Aminotransferase Increased	Health Professional Other	Tablet	PS		ORAL	300 MG/DAY, ORAL	
	Hepatic Function Abnormal		Serenace (Haloperidol) Tablet	SS		ORAL	3 TO 6 MG/DAY, ORAL	
	Infectious Mononucleosis							
	Lymphadenopathy		Akineton (Biperiden Hydrochloride)					
	Lymphocyte Morphology Abnormal		Tablet	SS		ORAL	3 MG/DAY, ORAL	
	Pharyngolaryngeal Pain							
	Pyrexia		Solanax (Alprazolam)	SS		ORAL	1.2 MG/DAY,	

	Rash Generalised					
ORAL						
	Rash Pruritic					
	Skin Test Positive					

Date:02/05/02ISR Number: 3865581-5Report Type:Expedited (15-DaCompany Report #K200200170
Age:84 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Aggression	Foreign Health Professional	Altace Capsules(Ramipril) Capsule, 2.5 Mg	PS		ORAL	2.5 MG, QD,	
	Hallucination	Other				ORAL		
			Remeron (Mirtazapine) 1.5 Mg	SS		ORAL	1.5 MG, QD,	
						ORAL		
			Serenase(Haloperidol)	SS		ORAL	10 DROPS, QD,	
						ORAL		

Date:02/05/02ISR Number: 3865649-3Report Type:Expedited (15-DaCompany Report #EMADSS2002000263
Age:48 YR Gender:Female I/FU:F

Outcome	PT	Report Source
Hospitalization - Initial or Prolonged	Circulatory Collapse	Foreign Study Health

Professional

			Product	Role	Manufacturer	Route	Dose Duration
			Haldol (Unspecified) (Haloperidol)	PS		ORAL	ORAL
			Risperidone (Unspecified) (Risperidone)	SS		ORAL	ORAL
			Placebo (Unspecified) (Placebo)	SS		ORAL	ORAL

Date:02/05/02ISR Number: 3865650-XReport Type:Expedited (15-DaCompany Report #EMADSS2002000513
Age:21 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Life-Threatening Hospitalization - Initial or Prolonged Disability	Blood Creatine Phosphokinase Increased Stupor	Foreign Health Professional	Haldol (Unspecified) (Haloperidol)	PS		ORAL	3 MG, ORAL

Date:02/06/02ISR Number: 3866175-8Report Type:Expedited (15-DaCompany Report #EMADSS2002000513
Age:21 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Life-Threatening Hospitalization - Initial or Prolonged	Neuroleptic Malignant Syndrome Rhabdomyolysis	Foreign Health Professional	Haldol (Unspecified) (Haloperidol)	PS		ORAL	3 MG, ORAL

Date:02/06/02ISR Number: 3866290-9Report Type:Expedited (15-DaCompany Report #PHRM2002FR00518
Age:68 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain Acinetobacter Infection Acute Respiratory Distress Syndrome	Foreign Health Professional Other	Voltarene (Diclofenac Sodium) Enteric-Film-Coated Tablet	PS		ORAL		
	Alveolitis Pneumonia Pulmonary Hypertension Pyrexia		Di-Antalvic (Dextropropoxyphene Hydrochloride, Paracetamol) Capsule	SS		ORAL		
	Tumour Marker Increased Urinary Retention		Doliprane (Paracetamol)	SS		ORAL		
			Haldol (Haloperidol)	SS		ORAL		
			Modecate "Sanofi Winthrop" (Fluphenazine Decanoate) Solution For Injection	SS		INTRAMUSCULAR		INTRAMUSCULAR
			Seglor (Dihydroergotamine Mesilate)	SS		ORAL		
			Xanax (Alprazolam)	C				
			Parkinane (Trihexyphenidyl Hydrochloride)	C				
			Floxyfral (Fluvoxamine					

Maleate)	C
Hept-A-Myl (Heptaminol Hydrochloride)	C
Duphalac	C
Didronel "Procter And Gamble" (Etidronate Disodium)	C
Dedrogyl (Calciferol)	C
Ostram	C

Date:02/08/02ISR Number: 3867325-XReport Type:Expedited (15-DaCompany Report #APCDSS2001001332
Age:25 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Required	Circulatory Collapse Compartment Syndrome Infarction	Foreign Health Professional	Risperdal (Unspecified) (Risperidone)	PS				
Intervention to Prevent Permanent Impairment/Damage	Loss Of Consciousness Overdose Renal Impairment Rhabdomyolysis Thrombosis	Company Representative	Haldol (Unspecified) (Haloperidol)	SS				

OVERDOSE UP
TO 120 MG,
STABLE DOSE
3-4 MG/DAY

Date:02/08/02ISR Number: 3867394-7Report Type:Expedited (15-DaCompany Report #APCDSS2001001332
Age:25 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Required	Blood Calcium Decreased Body Temperature Increased Compartment Syndrome Infarction Loss Of Consciousness	Foreign Health Professional	Haldol (Unspecified) (Haloperidol) Risperdal (Unspecified) (Risperidone)	PS SS		ORAL		
Intervention to Prevent Permanent Impairment/Damage		Company Representative						

OVERDOSE UP

	Muscle Disorder					
TO 120 MG,						
	Overdose					
STABLE DOSE 3						
	Renal Impairment					
- 4 MG/DAY						
	Rhabdomyolysis					
	Swelling					
	Thrombosis					
	White Blood Cell Count Increased					

Date:02/11/02ISR Number: 3866760-3Report Type:Direct Company Report #CTU 161348
Age:28 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Electroencephalogram		Haldol	PS		ORAL	SEE IMAGE	
	Abnormal		Depokote	SS		ORAL	1000MG PO BID	

Date:02/11/02ISR Number: 3869085-5Report Type:Expedited (15-DaCompany Report #EMADSS2001007586
Age:43 YR Gender:Female I/FU:F

Outcome	PT	Report Source
Death	Cerebral Ischaemia	Foreign
Other		Health

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Professional

			Product	Role	Manufacturer	Route
Dose	Duration					
			Haldol (Haloperidol)	PS		ORAL
3 MG, 2 IN 1						
DAILY, ORAL						
			Lamotrigine	C		

Date:02/19/02ISR Number: 3870386-5Report Type:Expedited (15-DaCompany Report #US-BRISTOL-MYERS SQUIBB COMPANY-11716206
Age:54 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Death	Death		Quantalan-50 Powder			
Life-Threatening	Stevens-Johnson Syndrome		4 G Packet	PS	Apothecon	
			Dormicum	SS		
			Eunerpan	SS		
			Eugalac	SS		
			Polybion	SS		
Dose Value: 2						
amp						
			Albumin	SS		
			Tromcardin	SS		
Dose Value:						
1-2 tablets						
			Unat	SS		
Dose Value:						
5-10						
milligrams						
			Ornithine	SS		
Dose Value: 1						
Amp						
			Haldol	SS		
			Pantozol	SS		
			Aldactone	SS		
			Remestan	SS		
Dose Value: 1						

tbl

			Bifiteral	C		
			Ringers Solution	C		
			Tutofusin	C		

Date:02/19/02ISR Number: 3871281-8Report Type:Expedited (15-DaCompany Report #EMADSS2002000803
Age:44 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Deep Vein Thrombosis	Foreign	Haldol (Solution)					
Hospitalization -		Health	(Haloperidol)	PS		ORAL	SEE IMAGE	
Initial or Prolonged		Professional	Solian (Amisulpride)	C				

Date:02/19/02ISR Number: 3871359-9Report Type:Expedited (15-DaCompany Report #EMADSS2002000735
Age:39 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Flushing	Foreign	Haldol Decanoas (50					
Initial or Prolonged	Rash	Health	Mg/Ml Injection)					
		Professional	(Haloperidol					
			Decanoate)	PS		INTRAMUSCULAR	1 AMP, 1 IN	30 DAY(S), IM

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Freedom Of Information (FOI) Report

Date:02/19/02ISR Number: 3872516-8Report Type:Expedited (15-DaCompany Report #PHRM2002FR00550
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Atrioventricular Block Complete Bradycardia Hyperkalaemia Loss Of Consciousness Malaise	Foreign Health Professional Company Representative Other	Trileptal (Oxcarbazepine) Tablet Haldol (Haloperidol) Drops Urbanyl (Clobazam)	PS SS C		ORAL ORAL	SEE IMAGE 10 DROPS / DAY, ORAL	

Date:02/19/02ISR Number: 3872678-2Report Type:Expedited (15-DaCompany Report #EMADSS2002000263
Age:48 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Circulatory Collapse Loss Of Consciousness Orthostatic Hypotension	Foreign Study Health Professional	Haldol (Unspecified) (Haloperidol) Risperidone (Unspecified) (Risperidone) Placebo (Unspecified) (Placebo) Biperiden (Biperiden)	PS SS SS C		ORAL ORAL ORAL	ORAL ORAL ORAL	

Date:02/20/02ISR Number: 3870876-5Report Type:Expedited (15-DaCompany Report #307186
Age:26 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Syncope		Diazepam	PS	Roche			34 DAY

Initial or Prolonged			Ciatyl	SS		
22 DAY						
			Haldol	SS		
34 DAY						
			Akineton	C		
31 DAY						

Date:02/20/02ISR Number: 3873486-9Report Type:Expedited (15-DaCompany Report #FLUV00302000285
Age:70 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Alanine Aminotransferase Increased	Foreign Literature	Fluvoxamine (Fluvoxamine)	PS			100 MG DAILY	
	Anxiety	Other	Haloperidol					
	Aspartate		(Haloperidol)	SS				
INTRAMUSCULAR							5 MG DAILY IM	2 DAY
	Aminotransferase Increased		Chlorpromazine (Chlorpromazine)	SS			100 MG DAILY	
	Blood Creatine Phosphokinase Increased		Risperidone (Risperidone)	SS			2 MG DAILY	
	Diet Refusal							
	Excitability							
	Hyperhidrosis							
	Muscle Rigidity							
	Neuroleptic Malignant Syndrome							
	Pyrexia							
	Somnolence							
	Suicidal Ideation							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/20/02ISR Number: 3873818-1Report Type:Expedited (15-DaCompany Report #APCDSS2002000067
Age:21 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Electroencephalogram Abnormal	Foreign Health Professional	Risperdal (Unspecified) (Risperidone)	PS		ORAL	MG, DAILY,	
Other	Fracture						ORAL	
	Injury							
	Suicide Attempt		Haldol (Unspecified) (Haloperidol)	SS			MG, DAILY	
			Carbamazepine (Carbamazepine)	C				
			Zonisamide (Zonisamide)	C				
			Clonazepam (Clonazepam)	C				
			Biperiden Hydrochloride (Biperiden Hydrochloride)	C				
			Diazepam (Diazepam)	C				
			Magnesium Oxide (Magnesium Oxide)	C				
			Solitax-H (Nacl, Kcl)	C				

Date:02/21/02ISR Number: 3871336-8Report Type:Expedited (15-DaCompany Report #307186
Age:26 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Syncope		Diazepam	PS	Roche		34	DAY
			Ciatyl-Z	SS			22	DAY
			Haldol	SS			34	DAY
			Akineton	C			31	DAY

Date:02/22/02ISR Number: 3874528-7Report Type:Expedited (15-DaCompany Report #307186
Age:26 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Pressure Decreased	Foreign Study	Diazepam (Diazepam)	PS		ORAL	15 MG DAILY	
	Fall							
	Syncope	Health Professional	Ciatyl (Clopenthixol)	SS		ORAL	30 MG DAILY	
	Visual Disturbance							
			Haldol (Haloperidol)	SS		ORAL	20 MG DAILY	
			Akineton (Biperiden Hydrochloride)	C				

Date:02/22/02ISR Number: 3874920-0Report Type:Expedited (15-DaCompany Report #PHEH2002US01556
Age:74 YR Gender:Female I/FU:I

Outcome	PT
Other	Clonic Convulsion
	Convulsion
	Drug Interaction
	Drug Level Increased
	Fall
	Manganese Decreased

Muscle Twitching

Dose	Duration	Report Source	Product	Role	Manufacturer	Route
75 MG AM + 400 MG HS, ORAL		Health Professional	Clozaril (Clozapine) Tablet	PS		ORAL
			Haldol (Haloperidol)	SS		
			Albuterol	C		
			Atrovent (Ipratropium Bromide)	C		
			Colace	C		
			Valproic	C		
			Norvasc	C		
			Fosamax (Alendronate Sodium)	C		
			Simethicone (Simeticone)	C		
			Milk Of Magnesia	C		

Date:02/22/02ISR Number: 3879462-4Report Type:Periodic Company Report #HQ2442222JUN2001
Age:36 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Other	Drug Ineffective	Consumer	Effexor (Venlafaxine Hydrochloride, Unspec)	PS		ORAL
ORAL						
			Haldol (Haloperidol,)	SS		
			Remeron (Mirtazapine,)	SS		
			Wellbutrin (Amfebutamone Hydrochloride,)	SS		

Date:02/25/02ISR Number: 3874974-1Report Type:Expedited (15-DaCompany Report #307186
Age:26 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Pressure Decreased	Foreign Study	Diazepam (Diazepam)	PS		ORAL	15 MG; DAILY;	
	Fall							
	Syncope	Health Professional	Ciatyl-Z (Zuclopenthixol)	SS		ORAL	30 MG; DAILY;	
	Visual Disturbance							
			Haldol (Haloperidol)	SS		ORAL	20 MG DAILY;	
			Akineton (Biperiden Hydrochloride)	C		ORAL		

Date:02/26/02ISR Number: 3873659-5Report Type:Expedited (15-DaCompany Report #US-BRISTOL-MYERS SQUIBB COMPANY-11727773
Age:24 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hypokalaemia		Dapotum D	PS	Apothecon	INTRAMUSCULAR		
	Neuroleptic Malignant Syndrome		Haldol	SS		ORAL		
			Akineton	C		ORAL		
	Rhabdomyolysis		Diazepam	C		ORAL		

Date:02/26/02ISR Number: 3875840-8Report Type:Expedited (15-DaCompany Report #PHBS2001JP11159
Age:20 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Aspartate Aminotransferase Increased	Foreign Literature Health	Tegretol (Carbamazepine) Tablet	PS		ORAL	SEE IMAGE	
	Gamma-Glutamyltransferase Increased	Professional Other	Serenace (Haloperidol) Tablet	SS		ORAL	3 TO 6	MG/DAY, ORAL
	Lymphadenopathy							
	Lymphocyte Morphology Abnormal		Akineton (Biperiden Hydrochloride)					
	Mononucleosis Syndrome		Tablet	SS		ORAL	3 MG/DAY,	ORAL
	Pharyngolaryngeal Pain							
	Pyrexia		Solanax (Alprazolam)	SS		ORAL	1.2 MG/DAY,	ORAL
	Rash Generalised							
	Rash Pruritic							

Date:02/26/02ISR Number: 3875955-4Report Type:Expedited (15-DaCompany Report #EMADSS2002001024
Age:26 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Blood Pressure Decreased	Foreign	Haldol (Haloperidol)	PS			SEE IMAGE	
Initial or Prolonged	Fall	Health	Valium (Diazepam)	SS			SEE IMAGE	
	Syncope	Professional	Ciatyl Z (Zyclopenthixol Hydrochloride)	SS		ORAL	SEE IMAGE	
			Akineton (Biperiden Hydrochloride)	C				

Date:02/26/02ISR Number: 3875987-6Report Type:Expedited (15-DaCompany Report #2002AP00385
Age:39 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Agranulocytosis	Foreign	Seroquel	PS				
		Health	Seroquel	SS		ORAL	300 MG DAILY	
		Professional					PO	
		Other	Minomycin	SS		ORAL	100 MG DAILY	
							PO	
			Serenace	SS				
INTRAVENOUS							5 MG DAILY	IV
			Halcion	C				
			Lendormin	C				
			Alosenn	C				

Date:02/27/02ISR Number: 3874938-8Report Type:Direct Company Report #CTU 162346
Age:19 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Parkinsonism		Haloperidol	PS				
			Risperidone	SS				

Date:03/04/02ISR Number: 3879034-1Report Type:Expedited (15-DaCompany Report #2002AP00385
Age:39 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Agranulocytosis	Foreign	Seroquel	PS				
	Pyrexia	Health	Seroquel	SS		ORAL	300 MG DAILY	
		Professional					PO	

			Minomycin	SS		ORAL	100 MG DAILY
							PO
			Serenace	SS			
INTRAVENOUS	5 MG DAILY IV						
			Halcion	C			
			Lendormin	C			
			Alosenn	C			

Date:03/05/02ISR Number: 3879997-4Report Type:Expedited (15-DaCompany Report #002-0945-M0100118
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Neuroleptic Malignant Syndrome	Foreign Health Professional	Gabapentin (Gabapentin)	PS		ORAL	PER ORAL	
			(Haloperidol)	SS				
			(Unspecified Medications)	C				

Date:03/05/02ISR Number: 3880372-7Report Type:Expedited (15-DaCompany Report #EMADSS2002001319
Age:16 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Bundle Branch Block Right	Foreign Health Professional	Haldol (Unspecified) (Haloperidol)	PS			12 MG DAILY;	
	Catatonia							
	Condition Aggravated						10 MG DAILY	
	Dyskinesia							
	Extrapyramidal Disorder							
	Oral Intake Reduced							

Date:03/05/02ISR Number: 3880416-2Report Type:Expedited (15-DaCompany Report #EMADSS2002001246
Age:86 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Death	Dementia Alzheimer'S Type	Foreign	Haldol (Unspecified)			
	Disease Progression	Health	(Haloperidol)	PS		ORAL 5 DROP, PRN,
		Professional				ORAL
			Risperdal (Unspecified) (Risperidone)	C		
			Dipiperon (Pipamperone)	C		

Date:03/05/02ISR Number: 3880418-6Report Type:Expedited (15-DaCompany Report #EMADSS2001006957
Age:29 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Hospitalization - Initial or Prolonged	Purpura	Foreign	Haldol (20 Mg/Ml			
	Schizophrenia	Health	Solution)			
	Spinal Myelogram Abnormal	Professional	(Haloperidol)	PS		ORAL 175 DROP,
	Thrombocytopenia					DAILY, ORAL

Date:03/06/02ISR Number: 3879663-5Report Type:Expedited (15-DaCompany Report #A204692
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Hospitalization - Initial or Prolonged	Abnormal Behaviour	Consumer	Ziprasidone Po	PS		160.00 MG TOTAL; BID;
	Drug Hypersensitivity					

UNKNOWN

			Haldol (Haloperidol)	SS		
INTRAMUSCULAR	INTRAMUSCULAR					

Date:03/07/02ISR Number: 3880524-6Report Type:Direct Company Report #CTU 163035
Age:44 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Aggression Anxiety Heart Rate Decreased Neuroleptic Malignant Syndrome Respiratory Rate Increased		Haldol (5 Mg Iv/Im	PS				

Date:03/08/02ISR Number: 3881907-0Report Type:Expedited (15-DaCompany Report #HQ1082828FEB2002
Age:41 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Cheilitis Conjunctival Hyperaemia Dermatitis Exfoliative	Literature	Methotrexate (Methotrexate, Unspec)	PS		ORAL	SEE IMAGE	10 MON
	Drug Interaction Face Oedema		Haloperidol (Haloperidol,)	SS			1.5 MG TWICE DAILY	
	Lacrimation Increased Localised Oedema Oedema Peripheral Photophobia Photosensitivity Reaction Rash Scaly Recall Phenomenon Stomatitis							

Date:03/12/02ISR Number: 3883060-6Report Type:Expedited (15-DaCompany Report #B0253266A2001020347-1
Age:81 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Electrocardiogram Qt Corrected Interval Torsade De Pointes Ventricular Arrhythmia Ventricular Fibrillation Ventricular Tachycardia	Literature Health Professional Other	Thorazine (Formulation Unknown) (Chlorpromazine Hcl) Fluvoxamine (Formulation Unknown) (Fluvoxamine) Haloperidol (Formulation Unknown) (Haloperidol) Promethazine Lormetazepam Rilmazafone Hydrochloride Flunitrazepam Levofloxacin Biperiden Etizolam Diazepam Sulpiride	PS SS SS C C C C C C C C C				

Domperidone	C
Dipyridamole	C
Spironolactone	C
Warfarin Sodium	C
Amitriptyline	C
Methylphenidate	C
Trimipramine	C
Frusemide	C

Date:03/13/02ISR Number: 3883176-4Report Type:Expedited (15-DaCompany Report #EMADSS2001006957
Age:29 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hepatitis B Antibody Positive Hepatitis Infectious Mononucleosis Infection Purpura Schizophrenia Thrombocytopenia	Foreign Health Professional	Haldol (20 Mg/Ml Solution) (Haloperidol)	PS		ORAL	175 DROP, DAILY, ORAL	

Date:03/13/02ISR Number: 3883208-3Report Type:Expedited (15-DaCompany Report #EMADSS2002000218
Age:37 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Hospitalization - Initial or Prolonged	Anaphylactic Shock Angioneurotic Oedema Cardiac Arrest Laryngeal Oedema Respiratory Failure	Foreign Health Professional	Haldol (Injection) (Haloperidol) Seroxat (Paroxetine Hydrochloride)	PS SS		INTRAMUSCULAR ORAL	1 VIAL, IM 20 MG, DAILY, ORAL	

Date:03/13/02ISR Number: 3883210-1Report Type:Expedited (15-DaCompany Report #EMADSS2002001666
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Foreign Health Professional	Haldol (Injection) (Haloperidol)	PS		INTRAMUSCULAR	IM	

Date:03/13/02ISR Number: 3883329-5Report Type:Expedited (15-DaCompany Report #NSADSS2002006985
Age:37 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Withdrawal Syndrome Murder	Consumer	Haldol (Unspecified) (Haloperidol)	PS		ORAL	ORAL	

Date:03/14/02ISR Number: 3882501-8Report Type:Expedited (15-DaCompany Report #US-BRISTOL-MYERS SQUIBB COMPANY-11716206
Age:54 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death Life-Threatening	Acute Respiratory Distress Syndrome Dyspnoea Pneumonia Stevens-Johnson Syndrome		Quantalan-50 Powder 4 G Packet Dormicum Eunerpan Eugalac	PS SS SS SS	Apothecon			

			Polybion	SS		
Dose Value: 2 amp						
			Albumin	SS		
			Tromcardin	SS		
Dose Value: 1-2 tablets						
			Unat	SS		
Dose Value: 5-10 milligrams						
			Ornithine	SS		
Dose Value: 1 Amp						
			Haldol	SS		
			Pantozol	SS		
			Aldactone	SS		
			Remestan	SS		
Dose Value: 1 tbl						
			Bifiteral	C		
			Ringers Solution	C		
			Tutofusin	C		

Date:03/14/02ISR Number: 3883827-4Report Type:Expedited (15-DaCompany Report #01-1953 FOL#1
Age:83 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death Hospitalization - Initial or Prolonged	Grand Mal Convulsion Somnolence	Foreign Health Professional Company Representative	Loxitane (Loxapac) Capsules, Wyeth Ayerst Risperdal (Risperidone)	PS SS	Wyeth Ayerst	ORAL ORAL	15 MG 1 X PER 1 DAY, 500 UG 1 X	ORAL 305 DAY

PER 1 DAY,

ORAL 28 DAY

Serenase (Haloperidol) SS ORAL 2 MG 1 X PER 1 DAY, ORAL 305 DAY

Zyprexa (Olanzapine) SS ORAL 2.5 MG 1 X PER 1 DAY, ORAL 301 DAY

Date:03/15/02ISR Number: 3884368-0Report Type:Expedited (15-DaCompany Report #APCDSS2002000067
Age:20 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Blood Alkaline Phosphatase Increased	Foreign Health	Risperdal (Tablet) (Risperidone)	PS		ORAL	MG, DAILY,
Other	Condition Aggravated	Professional				ORAL	
	Delusion		Haldol (Unspecified) (Haloperidol)	SS			MG, DAILY,
	Abnormal Fall		Carbamazepine (Carbamazepine)	SS		ORAL	200-400 MG DAILY, PO
	Fracture						
	Hallucination, Auditory Inflammation		Zonisamide (Zonisamide)	SS		ORAL	1) MG, DAILY,
	Injury						ORAL; 2)
	Suicide Attempt					ORAL	
			Clonazepam (Clonazepam)	SS		ORAL	1) MG, DAILY,
							ORAL; 2)
							ORAL
			Biperiden				

				Hydrochlorie (Biperiden Hydrochloride)	SS		ORAL
2-3 MG DAILY, PO							
				Diazepam (Diazepam)	SS		ORAL
MG, DAILY, ORAL							
				Magnesium Oxide (Magnesium Oxide)	SS		ORAL
G, DAILY, ORAL							
				Solitax-H (Nacl, Kcl)	C		

Date:03/18/02ISR Number: 3885103-2Report Type:Expedited (15-DaCompany Report #NSADSS2002007651
Age:84 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardiac Failure	Consumer	Haldol (Injection) (Haloperidol)	PS		INTRAMUSCULAR	IM	8 DAY

Date:03/19/02ISR Number: 3885997-0Report Type:Expedited (15-DaCompany Report #A204692
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abnormal Behaviour	Consumer	Ziprasidone Po	PS			160.00 MG TOTAL:BID:	
	Movement Disorder							
	Muscle Twitching		Haldol (Haloperidol)	SS		INTRAMUSCULAR	INTRAMUSCULAR	
	Tongue Disorder							
	Weight Decreased							

Date:03/20/02ISR Number: 3884877-4Report Type:Expedited (15-DaCompany Report #EMADSS2002001803
Age:24 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Abortion Induced		Haldol	PS		ORAL	3	DAY
Initial or Prolonged	Catatonia		Risperdal	SS			UNKNOWN	
	Drug Exposure During		Lorazepam	C			3	DAY
	Pregnancy						UNKNOWN	

Date:03/21/02ISR Number: 3887008-XReport Type:Expedited (15-DaCompany Report #2002AP00508
Age:74 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Haemodialysis	Foreign	Tenormin	PS		ORAL	50 MG DAILY	
Hospitalization -	Hypokalaemia	Literature					PO	
Initial or Prolonged	Pyrexia	Health	Serenace	SS		ORAL	6 MG DAILY PO	
	Renal Failure	Professional	Levotomin	SS		ORAL	50 MG DAILY	
	Rhabdomyolysis	Other					PO	
	Tachycardia							

Date:03/21/02ISR Number: 3887050-9Report Type:Expedited (15-DaCompany Report # EMADSS2002001803
Age:24 YR Gender:Female I/FU:I

Outcome	PT
Hospitalization -	Abortion Induced
Initial or Prolonged	Catatonia
Other	Complications Of Maternal
	Exposure To Therapeutic

	Drugs Maternal Drugs Affecting Foetus Pregnancy		Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
			Foreign Health	Haladol (5mg Tablet) (Haloperidol)	PS		ORAL
5 MG, 3 IN 1							
			Professional				
DAY(S), ORAL							
				Risperdal (Tablet) (Risperidone)	SS		
3 MG, DAILY							
				Lorazepam (Lorazepam)	C		

Date:03/21/02ISR Number: 3887052-2Report Type:Expedited (15-DaCompany Report #EMADSS2002001803
Age:24 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization -	Abortion Induced	Foreign	Risperdal (Tablet)			
Initial or Prolonged	Catatonia	Health	(Risperidone)	PS		
3 MG, DAILY						
Other	Complications Of Maternal	Professional	Haldol (5mg Tablet)			
	Exposure To Therapeutic		(Haloperidol)	SS		ORAL
5MG, 3 IN 1						
	Drugs					
DAY, ORAL						
			Lorazepam (Lorazepam)	C		

Date:03/21/02ISR Number: 3887055-8Report Type:Expedited (15-DaCompany Report #2002AP00385
Age:39 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization -	Agranulocytosis	Foreign	Seroquel	PS		
Initial or Prolonged	Pyrexia	Health	Seroquel	SS		ORAL
300 MG DAILY						
Required		Professional				
PO						
Intervention to		Other	Minomycin	SS		ORAL
100 MG DAILY						

Prevent Permanent
PO
Impairment/Damage Serenace SS
INTRAVENOUS 5 MG DAILY IV

Halcion C
Lendormin C
Alosenn C

Date:03/21/02ISR Number: 3887060-1Report Type:Expedited (15-DaCompany Report #EMADSS2002001759
Age:47 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Coma	Foreign	Haldol (Injection)					
Required	Diarrhoea	Health	(Haloperidol)	PS				
MOST RECENT								
Intervention to	Hyponatraemia	Professional						
DOSE SEP-01.								
Prevent Permanent	Inappropriate		Picolax (Sodium					
Impairment/Damage	Antidiuretic Hormone		Picosulfate)	SS		ORAL		
ORAL								
	Secretion		Mirtazapine					
	White Blood Cell Count		(Mirtazapine)	C				
	Increased		Clonazepam					
			(Clonazepam)	C				
			Procyclidine					
			(Procyclidine)	C				
			Lansoprazole					
			(Lansoprazole)	C				
			Senna (Senna)	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/22/02ISR Number: 3887103-5Report Type:Expedited (15-DaCompany Report #HQ2442222JUN2001
Age:36 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Depression Drug Ineffective Murder	Literature	Effexor (Venlafaxine Hydrochloride, Unspec)	PS		ORAL	ORAL	
			Haldol (Haloperidol)	SS				
			Remeron (Mirtazapine)	SS				
			Wellbutrin (Amfebutamone Hydrochloride)	SS				

Date:03/25/02ISR Number: 3887765-2Report Type:Direct Company Report #CTU 163981
Age:53 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Dystonia		Haloperidol	PS		INTRAMUSCULAR	5MG, 5MG Q6H	, INTRAMUS
			Triamcinolone Acetonide	C				
			Multivitamin	C				
			Thiamine Hcl	C				
			Rabeprazole Na	C				
			Ferrous Sulfate	C				
			Absorbase Top Oint	C				

Date:03/27/02ISR Number: 3889345-1Report Type:Expedited (15-DaCompany Report #US-BRISTOL-MYERS SQUIBB COMPANY-11615622
Age:52 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anxiety Asthenia Epigastric Discomfort Eye Disorder Hepatitis		Haloperidol	PS		ORAL		

Date:03/27/02ISR Number: 3890856-3Report Type:Expedited (15-DaCompany Report #EMADSS2002001666
Age:39 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Foreign	Haldol (Injection) (Haloperidol)	PS		INTRAMUSCULAR	4 ML, 1 IN 21 DAY (S) IM; 3 ML, 1 IN 1 21 DAY (S), IM	

Date:03/28/02ISR Number: 3890226-8Report Type:Expedited (15-DaCompany Report #EMADSS2002001888
Age:80 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Chromaturia Parkinson'S Disease		Haldol	PS		ORAL		
			Durogesic	SS		TRANSDERMAL	UNKNOWN	
			Nozinan	SS		UNKNOWN		
			Lovenox	C		UNKNOWN		
			Sinemet	C		UNKNOWN		

			Dopergine	C			
UNKNOWN							
			Movicol	C			
UNKNOWN							
			Cetornan	C			
UNKNOWN							

Date:03/29/02ISR Number: 3892819-0Report Type:Expedited (15-DaCompany Report #A204692
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Akathisia	Consumer	Ziprasidone Po	PS			160.00 MG	
Initial or Prolonged	Drug Hypersensitivity						TOTAL:BID:UNK	
	Dyskinesia						NOWN	
	Muscle Twitching		Haldol (Haloperidol)	SS			INTRAMUSCULAR	INTRAMUSCULAR
	Refusal Of Treatment By Patient							
	Tongue Disorder							
	Tremor							
	Weight Decreased							

Date:04/01/02ISR Number: 3893280-2Report Type:Expedited (15-DaCompany Report #EMADSS2002001957
Age:20 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Dyskinesia	Foreign	Haldol (5 Mg Tablet)					
Initial or Prolonged	Hypertonia	Health	(Haloperidol)	PS		ORAL	5 MG, 2 IN 1	
	Nystagmus	Professional					DAY(S), ORAL	
	Oculogyration							

Date:04/01/02ISR Number: 3893338-8Report Type:Expedited (15-DaCompany Report #EMADSS2002001996
Age:83 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Pancytopenia	Foreign Health Professional	Haldol (Solution) (Haloperidol)	PS		ORAL	0.75 MG,	DAY(S), ORAL
			Epoetin Alfa (Injection) Epoetin Alfa	SS				
			Calciparine (Heparin Calcium)	SS				
						SUBCUTANEOUS	15000 IU,	DAILY, SUBCU
			Orelox (Cefpodoxime Proxetil)	SS		ORAL	100 MG,	DAY(S), ORAL
			Prozac (Fluoxetine Hydrochloride)	SS		ORAL	20 MG,	DAY(S), ORAL
			Equanil (Meprobamate)	C				
			Stilnox (Zolpidem)	C				
			Myolastan (Tetrazepam)	C				
			Bricanyl (Terbutaline Sulfate)	C				
			Duphalac (Lactulose)	C				
			Amlor (Amlodipine Besilate)	C				
			Eucalcic (Calcium					

			Carbonate)	C		

Date:04/01/02ISR Number: 3893393-5Report Type:Expedited (15-DaCompany Report #EMADSS2002001926
Age:77 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Medication Error	Foreign	Haldol Decanoate (50			
	Sedation	Health	Mg/Ml Injection)			
		Professional	(Haloperidol			
			Decanoate)	PS		
INTRAVENOUS 50 MG, IV						
			Tavor (Lorazepam)	C		
			Truxal			
			(Chlorprothixene			
			Hydrochloride)	C		

Date:04/02/02ISR Number: 3894086-0Report Type:Direct Company Report #CTU 164821
Age:36 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	No Adverse Drug Effect		Haldol	PS		ORAL
5MG PO						
			Cogentin	SS		ORAL
1MG PO						

Date:04/02/02ISR Number: 3898305-6Report Type:Expedited (15-DaCompany Report #EMADSS2002001996
Age:83 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Pancytopenia	Foreign	Epoetin			
Initial or Prolonged		Health	Alfa(Injection)			
		Professional	(Epoetin Alfa)	PS		
START DATE						
NOT PROVIDED						
			Haldol (Solution)			
			(Haloperidol)	SS		ORAL
0.75 MG,						

DAY(S), ORAL

	Calciparine (Heparin Calcium)	SS	

SUBCUTANEOUS 15000 IU,

DAILY,

SUBCUTANEOUS

	Orelox (Cefpodoxime Proxetil)	SS	ORAL

100 MG,

DAY(S), ORAL

	Prozac (Fluoxetine Hydrochloride)	SS	ORAL

20 MG,

DAY(S), ORAL

	Equanil (Meprobamate)	C
	Stilnox	C
	Myolastan	C
	Bricanyl	C
	Duphalac	C
	Amlor	C
	Eucalcic	C

Date:04/03/02ISR Number: 3894779-5Report Type:Expedited (15-DaCompany Report #NSADSS2002009152
Age:45 YR Gender:Male I/FU:I

Outcome
Death
Hospitalization -

Initial or Prolonged

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Blood Culture Positive	Health	Haldol (Injection)					
	Body Temperature Increased	Professional	(Haloperidol)	PS		INTRAVENOUS	SEE IMAGE	
	Fungaemia							
	Hepatorenal Syndrome							
	Renal Failure							
	Respiratory Arrest							
	Staphylococcal Infection							

Date:04/03/02ISR Number: 3894780-1Report Type:Expedited (15-DaCompany Report #NSADSS2001018709
Age:73 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Abnormal Behaviour	Consumer	Haldol (Injection)					
	Agitation	Health	(Haloperidol)	PS		INTRAMUSCULAR	0.5 MG, IM	
	Blindness	Professional	Zoloft (Sertraline					
	Catatonia		Hydrochloride)	C				
	Confusional State		Restoril (Temazepam)	C				
	Dysphagia							
	Neuroleptic Malignant							
	Syndrome							
	Paranoia							
	Starvation							
	Tardive Dyskinesia							

Date:04/03/02ISR Number: 3895040-5Report Type:Expedited (15-DaCompany Report #134511USA
Age:42 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Accidental Exposure	Health	Haloperidol Oral					
	Blood Pressure Increased	Professional	Solution	PS				
	Coma							
	Dyspnoea							
	Electrocardiogram Abnormal							

	Urticaria						

Date:04/03/02ISR Number: 3895319-7Report Type:Expedited (15-DaCompany Report #EMADSS2002001957
Age:20 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dyskinesia Eye Movement Disorder Hypertonia Movement Disorder Nystagmus	Foreign Health Professional	Haldol (5 Mg Tablet) (Haloperidol)	PS		ORAL	5 MG, DAILY, ORAL	

Date:04/03/02ISR Number: 3895415-4Report Type:Expedited (15-DaCompany Report #EMADSS2002001888
Age:80 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Chromaturia Parkinson'S Disease	Foreign Health Professional	Durogesic (25 Mcg/Hr Patch) (Fentanyl)	PS			START DATE NOT PROVIDED	

			Haldol (2 Mg/Ml Solution) (Haloperidol)	SS		
START DATE AND DOSE NOT PROVIDED						
			Nozinan (Levomepromazine)	SS		
START DATE AND DOSE NOT PROVIDED						
			Lovenox (Heparin-Fraction, Sodium Salt)	C		
			Sinemet (Sinemet)	C		
			Dopergine (Lisuride)	C		
			Movicol (Movicol)	C		
			Cetornan (Ornithine Oxoglurate)	C		

Date:04/03/02ISR Number: 3895419-1Report Type:Expedited (15-DaCompany Report #EMADSS2002001888
Age:80 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Chromaturia Parkinson'S Disease	Foreign Health Professional	Haldol (2mg/Ml Solution) (Haloperidol)	PS				
START DATE AND DOSE NOT PROVIDED								
			Durogesic (25 Mch/Hr Patch) (Fentanyl)	SS				
START DATE NOT PROVIDED								
			Nozinan (Levomepromazine)	SS				
START DATE								

AND DOSE NOT

PROVIDED

Lovenox (Heparin-F-Raction, Sodium Salt)	C
Sinemet (Sinemet)	C
Dopergine (Lisuride)	C
Movicol (Movicol)	C
Cetornan (Ornithine Oxoglurate)	C

Date:04/04/02ISR Number: 3895750-XReport Type:Expedited (15-DaCompany Report #EMADSS2002002004
Age:68 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abnormal Behaviour Akinesia	Foreign Health	Haldol (5 Mg Tablet) (Haloperidol)	PS		ORAL	5 MG, ORAL	
	Condition Aggravated Hypertonia Parkinson'S Disease Tachyarrhythmia Tremor	Professional	Gardenal (Phenobarbital)	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/04/02ISR Number: 3895753-5Report Type:Expedited (15-DaCompany Report #EMADSS2002002002
Age:25 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dyskinesia Tremor	Foreign Health Professional	Haldol (Tablet) (Haloperidol)	PS			50 MG ORAL : 100 MG ORAL : 50 MG ORAL	
			Nozinan (Levomepromazine)	SS		ORAL		
			Tranxene (Clorazepate Dipotassium)	C				
			Lexomil (Bromazepam)	C				
			Noctamide (Lormetazepam)	C				

Date:04/10/02ISR Number: 3898400-1Report Type:Expedited (15-DaCompany Report #EMADSS2002002189
Age:30 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abortion Spontaneous Complications Of Maternal	Foreign Health	Haldol (Solution) (Haloperidol)	PS		ORAL	0.25 MG; ORAL	
	Exposure To Therapeutic Drugs Maternal Drugs Affecting Foetus	Professional	Effexor (Venlafaxine Hydrochloride)	SS				

Date:04/10/02ISR Number: 3898402-5Report Type:Expedited (15-DaCompany Report #EMADSS2002002179
Age:45 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Arrhythmia Coronary Artery Disease Sudden Death	Foreign Health Professional	Haldol (20 Mg Tablet) (Haloperidol)	PS		ORAL	ORAL	

			Nozinan (Levomepromazine)	SS		
75 MG, DAILY;						

Date:04/10/02ISR Number: 3898571-7Report Type:Expedited (15-DaCompany Report #EMADSS2002002180
Age:63 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Thrombocytopenia	Foreign Health Professional	Haldol Decanoate (50 Mg/Ml Injection)(Haloperidol Decanoate)	PS		
INTRAMUSCULAR 50 MG, 2 IN 1 MONTH(S), IM						
			Artane(Trihexyphenidyl Hydrochloride)	SS		ORAL
1 CAP, DAILY, ORAL						

Date:04/10/02ISR Number: 3899553-1Report Type:Direct Company Report #CTU 165442
Age:36 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Electrocardiogram		Haldol	PS		ORAL
5MG PO						
	Abnormal		Cogentin	SS		ORAL
1MG PO						

Date:04/12/02ISR Number: 3899944-9Report Type:Expedited (15-DaCompany Report #01020405
Age:72 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cerebral Atrophy	Consumer	Enbrel 25 Mg	PS		SUBCUTANEOUS	25 MG, BIW,	
Hospitalization - Initial or Prolonged	Dialysis	Health Professional				SUBCUTANEOUS		
	Drug Hypersensitivity		Haloperidol	SS				
	Medication Error		Celecoxib	C				
	Oedema Peripheral		Omeprazole	C				
	Pyrexia		Paroxetine	C				
	Renal Failure		Prednisone	C				
	Renal Pain							

Date:04/12/02ISR Number: 3900491-6Report Type:Expedited (15-DaCompany Report #EMADSS2002002201
Age:24 HR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Caesarean Section	Foreign Health Professional	Haldol Decanoate (Injection) (Haloperidol Decanoate)	PS		MOTHER TOOK	150 MG, 1 IN	30 DAYS
	Complications Of Maternal Exposure To Therapeutic Drugs							
	Flatulence							
	Maternal Drugs Affecting Foetus							
	Menometrorrhagia							
	Somnolence Neonatal		Haldol (2 Mg/Ml Solution)(Haloperidol)	SS		MOTHER TOOK	100 DROPS BID	DURING HER PREGNANCY.
			Gyno-Pevaryl					

			(Unspecified)(Econaz ole Nitrate)	SS		

MOTHER TOOK

DURING HER

PREGNANCY.

			Largactil (Chlorpromazine Hydrochloride)	C		
			Clamoxyl (Amoxicillin Trihydrate)	C		
			Spasfon (Spasfon)	C		
			Debridat(Trimebutine Maleate)	C		

Date:04/12/02ISR Number: 3900634-4Report Type:Expedited (15-DaCompany Report #FR8952405APR2002
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Congenital Hydronephrosis	Health	Seresta (Oxazepam,			
	Maternal Drugs Affecting	Professional	Unspec, 0)	PS		

TRANSPLACENTAL TRANSPLACENTA

Foetus

L; DURING THE

Pregnancy

FIRST QUARTER

Renal Dysplasia

OF PREGNANCY

			Haldol (Haloperidol, , 0)	SS		

TRANSPLACENTAL TRANSPLANCENT

AL; DURING

THE FIRST

QUARTER OF

PREGNANCY

TRANSPLACENTA

L; DURING THE

FIRST QUARTER

OF PREGNANCY

Date:04/12/02ISR Number: 3900666-6Report Type:Expedited (15-DaCompany Report #EMADSS2002002197
Age:43 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain Aggression Anxiety Caesarean Section	Foreign Health Professional	Haldol Decanoate (Injection) (Haloperidol Decanoate)	PS		INTRAMUSCULAR	150 MG, 1 IN	1 MONTH (S),
	Candidiasis Complications Of Maternal Exposure To Therapeutic Drugs Fall		Haldol (2 Mg/Ml Solution) (Haloperidol)	SS		ORAL	100 DROP, 2	IN 1 DAY (S),
	Malaise Menometrorrhagia							
	Streptococcal Infection		Gyno-Pevaryl (Econazole Nitrate)	SS		VAGINAL	VAGINA	
			Largactil (Chlorpromazine Hydrochloride)	C				
			Spasfon (Spasfon)	C				
			Debridat (Trimebutine Maleate)	C				
			Clamoxyl					

			(Amoxicillin Trihydrate)	C		

Date:04/15/02ISR Number: 3901121-XReport Type:Expedited (15-DaCompany Report #EMADSS2001004198
Age:38 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Suicide Attempt	Foreign Health Professional	Haldol (2 Mg Tablet) (Haloperidol)	PS		ORAL	2 MG, 1 IN 1 DAILY, ORAL	Other
			Risperidone (2 Mg Tablet) (Risperidone)	SS		ORAL	2 MG, 1 IN 1 DAILY, ORAL	

Date:04/15/02ISR Number: 3901122-1Report Type:Expedited (15-DaCompany Report #EMADSS2002002229
Age:82 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Antisocial Behaviour Blood Creatinine Increased	Foreign Health Professional	Haldol (2 Mg/Ml Solution) (Haloperidol)	PS		ORAL	5.5 MG, DAILY, ORAL	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/17/02ISR Number: 3902899-1Report Type:Direct Company Report #CTU 165936
Age:67 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required	Blood Creatine		Haloperidol	PS				
INTRAVENOUS							5MG IV	Q 2H
Intervention to	Phosphokinase Increased							
PRN TOTAL								
Prevent Permanent								
DOSE 30MG IV								
Impairment/Damage								
ALSO GIVE								
35MG IM AND								
			Lorazepam	SS				
INTRAVENOUS							2MG IV	Q 2
HRS PRN TOTAL								
DOSE 24.5 MG								
			Clonazepam	C				
			Sertraline	C				
			Trazodone	C				
			Baclofen	C				
			Diclofenac Sodium	C				
			Furosemide	C				
			Lisinopril	C				
			Carafate	C				
			Gemfibrozil	C				
			Metoprolol	C				
			Insulin Nph	C				
			Regular Insulin	C				
			Albuterol	C				
			Supplemental Oxygen	C				

Date:04/18/02ISR Number: 3902840-1Report Type:Expedited (15-DaCompany Report #K200200544
Age:79 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Blood Glucose Decreased	Foreign	Altace Capsules					
Hospitalization -	Blood Pressure Decreased	Health	(Ramipril) Capsule,					
Initial or Prolonged	Bradycardia	Professional	1.25 Mg	PS		ORAL		
2.5 MG, QD,								

	Condition Aggravated	Other				
ORAL						
	Cyanosis		Hydrochlorothiazide	SS		ORAL
2.5 MG, QD,						
	Hyperglycaemia					
ORAL						
	Renal Impairment		Lithium-Duriles (Lithium Sulfate)	SS		ORAL
	Somnolence					
42 MG, ORAL						
			Nebilet (Nebivolol Hydrochloride)	SS		ORAL
5 MG, ORAL						
			Ass "Ct-Arzneimittel" (Acetylsalicylic Acid)	SS		ORAL
100 MG, ORAL						
			Haloperidol-Ratiopharm (Haloperidol)	SS	Ratiopharm	ORAL
5 MG, ORAL						
			Digitoxin "Awd" (Digitoxin)	SS		ORAL
0.07 MG, ORAL						
			Sarptem "Bayer Vital" (Amitriptyline Hydrochloride)	SS		ORAL
25 MG, ORAL						
			Allopurinol	SS		ORAL
100 MG, ORAL						
			Akatinol (Memantine Hydrochloride)	C		
			Venoruton Retard (Troxerutin)	C		
			Amaryl (Glimepiride)	C		
			Diastabol (Miglitol)	C		
			Espa-Lipon (Thioctic			

			Acid)	C		
			Nitrendipine	C		

Date:04/18/02ISR Number: 3902859-0Report Type:Direct Company Report #USP 54834
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Medication Error		Haloperidol	PS	Mylan			
			Haloperidol	SS	Mylan			
			Haloperidol	SS	Mylan			
			Haloperidol	SS	Mylan			

Date:04/18/02ISR Number: 3903101-7Report Type:Expedited (15-DaCompany Report #2002AP00508
Age:73 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Haemodialysis	Foreign	Tenormin	PS		ORAL	50 MG DAILY	
Hospitalization -	Renal Impairment	Literature					PO	
Initial or Prolonged	Rhabdomyolysis	Health	Serenace	SS		ORAL	6 MG DAILY PO	
		Professional	Levotomin	SS		ORAL	50 MG DAILY	
		Other					PO	

Date:04/19/02ISR Number: 3902307-0Report Type:Expedited (15-DaCompany Report #APCDSS2002000366
Age:27 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Condition Aggravated		Risperidone	PS		ORAL		
Initial or Prolonged	Dyskinesia		Haloperidol	SS				
UNKNOWN	maximum dose							
Other	Dystonia							
was 16 mg/day	6 YR							
	Fall							
	Mobility Decreased							
	Opisthotonus							

Psychiatric Symptom
Tardive Dyskinesia
Treatment Noncompliance

Date:04/19/02ISR Number: 3904264-XReport Type:Direct Company Report #CTU 166215
Age:81 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Acute Respiratory Failure		Haloperidol 7.5mg	PS			7.5MG	
	Cardio-Respiratory Arrest		Lorazepam 1mg	SS			1MG	
			Aspirin Ec	C				
			Carbidopa/Levodopa	C				
			Citalopram Hydrobromide	C				
			Donepezil Hcl	C				
			Levothyroxine Na-Synthroid	C				
			Methylcellulose	C				
			Multivitamin	C				
			Olanzapine	C				
			Ranitidine Hcl	C				
			Vitamin E	C				

Date:04/19/02ISR Number: 3904301-2Report Type:Expedited (15-DaCompany Report #FR8959415APR2002
Age:30 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abortion Spontaneous Maternal Drugs Affecting Foetus	Health Professional Other	Effexor (Venlafaxine Hydrochloride, Unspec, 0)	PS		ORAL	5 MG DAILY	
ORAL								15 DAY
ORAL			Haldol (Haloperidol, , 0)	SS		ORAL		

Date:04/22/02ISR Number: 3907314-XReport Type:Expedited (15-DaCompany Report #01020405
Age:72 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Hypersensitivity	Consumer	Enbrel 25 Mg	PS		SUBCUTANEOUS	25 MG, BIW,	
Hospitalization - Initial or Prolonged	Nervous System Disorder Oedema Peripheral Pain In Extremity Pyrexia Rash Scaly Renal Failure	Health Professional	Haloperidol Celecoxib Omeprazole Paroxetine Prednisone Calcium Risperidone Divalproex Sodium Furosemide Ranitidine	SS C C C C C C C C C		SUBCUTANEOUS		

Date:04/23/02ISR Number: 3905342-1Report Type:Expedited (15-DaCompany Report #APCDSS2002000366
Age:27 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Condition Aggravated Dystonia	Foreign Health	Risperidone (Risperidone0	PS		ORAL		
ORAL								

Required	Fall	Professional	Haloperidol				
Intervention to	Medication Error		(Haloperidol)	SS			
MAXIMUM DOSE							
Prevent Permanent	Mental Disorder						
WAS 16 MG/DAY 6 YR							
Impairment/Damage	Tardive Dyskinesia						

Date:04/23/02ISR Number: 3906244-7Report Type:Expedited (15-DaCompany Report #APCDSS2002000366
Age:27 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Condition Aggravated	Foreign	Haloperidol				
Initial or Prolonged	Difficulty In Walking	Health	(Haloperidol)	PS			
MAXIMUM DOSE							
Required	Dyskinesia	Professional					
WAS 16 MG/DAY 6 YR							
Intervention to	Dystonia		Risperidone				
Prevent Permanent	Fall		(Unspecified)				
Impairment/Damage	Mental Disorder		(Risperidone)	SS		ORAL	
ORAL							
	Opisthotonus						
	Treatment Noncompliance						

Date:04/24/02ISR Number: 3905744-3Report Type:Expedited (15-DaCompany Report #A0366463A
Age:16 YR Gender:Female I/FU:I

Outcome	PT
Other	Drug Interaction
	Dystonia

	Fatigue					
	Gaze Palsy					
	Headache	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
	Muscle Spasms		Wellbutrin	PS	Glaxo Wellcome	ORAL
150MG Per day						
	Musculoskeletal Stiffness		Haldol	SS		ORAL
1 DAY						
	Oculogyration		Zoloft	C		
UNKNOWN	100MG Per day 1 YR					
	Pruritus		Oral Contraceptives	C		ORAL
2 WK						
	Rash					
	Viral Infection					
	Vision Blurred					

Date:04/26/02ISR Number: 3908121-4Report Type:Expedited (15-DaCompany Report #EMADSS2002002595
Age:88 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Other	Eosinophilia	Foreign	Haldol (1 Mg Tablet)			
	Hepatitis	Health	(Haloperidol)	PS		ORAL
1MG, DAILY,						
	Pruritus	Professional				
ORAL	4 WK					
	Toxocariasis		Resonium (Sodium Polystyrene Sulfonate)	C		
			Liquemin (Heparin)	C		
			Tavegyl (Clemastine)	C		
			Temgesic (Buprenorphine)	C		
			Dafalgan (Paracetamol)	C		
			Insulatard (Insulin Human Injection, Isophane)	C		

Date:04/26/02ISR Number: 3908124-XReport Type:Expedited (15-DaCompany Report #EMADSS2002002557
Age:65 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Confusional State Dysphagia		Haldol(Unspecified) (Haloperidol)	PS		ORAL		
	Pneumonia Aspiration		Aricept (Donepezil Hydrochloride)	SS		ORAL	10MG, 1 IN 1	DAY(S), ORAL
			Tranxene (Clorazepate Dipotassium)	SS				

Date:04/26/02ISR Number: 3908845-9Report Type:Expedited (15-DaCompany Report #FR8959415APR2002
Age:30 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abortion Spontaneous Complications Of Maternal	Health Professional	Effexor (Venlafaxine Hydrochloride)	PS		ORAL		
ORAL							15	DAY
	Exposure To Therapeutic Drugs	Other	Haldol (Haloperidol, 0)	SS		ORAL	5 MG DAILY	
	Maternal Drugs Affecting							
ORAL							15	DAY
	Foetus Pregnancy							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/30/02ISR Number: 3910605-XReport Type:Expedited (15-DaCompany Report #NSADSS2002013121
Age:74 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Aphasia	Consumer	Haldol (Injection)					
Hospitalization -	Nasopharyngitis		(Haloperidol)	PS				
INTRAMUSCULAR							10 MG,	1 IN 1
Initial or Prolonged	Pain							
TIME (S), IM								
	Pneumonia							
	Post Procedural Complication							
	Sedation							
	Upper Limb Fracture							

Date:04/30/02ISR Number: 3910798-4Report Type:Expedited (15-DaCompany Report #APCDSS2002000366
Age:27 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Dystonia	Foreign	Risperidone					
Initial or Prolonged	Fall	Health	(Risperidone)	PS				
MAXIMUM DOSE								
Required	Tardive Dyskinesia	Professional						
WAS 12 MG/DAY								
Intervention to	Treatment Noncompliance		Haloperidol					
Prevent Permanent			(Haloperidol)	SS				
MAXIMUM DOSE								
Impairment/Damage								
WAS 16 MG/DAY							6	YR
			Quetiapine					
			(Quetiapine)	SS		ORAL		
MG, DAILY,								
ORAL								
			Diazepam (Diazepam)	C				
			Chlorpromazine (Chlorpromazine)	C				
			Clonazepam (Clonazepam)	C				
			Trihexyphenidyl Hydrochloride (Trihexyphenidyl Hydrochloride)	C				

Date:05/01/02ISR Number: 3910505-5Report Type:Direct Company Report #CTU 167084
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Attention Deficit/Hyperactivity Disorder		Haldol Deconate	PS		
			Zyprexa	C		
			Prozac	C		
			Cogentin	C		
			Haldol	C		

Date:05/01/02ISR Number: 3911512-9Report Type:Expedited (15-DaCompany Report #EMADSS2002000720
Age:28 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Orthostatic Proteinuria	Foreign Study Health Professional	Haldol Decanoas (50 Mg/Ml Injection) (Haloperidol Decanoate)	PS		
INTRAMUSCULAR 100 MG, 1 IN 21 DAY (S), IM						
			Risperidone (Microspheres) (Risperidone)	SS		
INTRAMUSCULAR IM						

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/02/02ISR Number: 3911589-0Report Type:Expedited (15-DaCompany Report #134511USA
Age:42 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Accidental Exposure Blood Pressure Increased Coma Dyspnoea Electrocardiogram Abnormal Eye Irritation Face Oedema Pharyngeal Oedema Urticaria	Health Professional	Haloperidol Oral Solution	PS				

Date:05/03/02ISR Number: 3912064-XReport Type:Expedited (15-DaCompany Report #NSADSS2002014364
Age:53 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Blood Ph Decreased Blood Pressure Systolic Increased Body Temperature Increased Cardiac Failure Congestive Cough Dyspnoea Haematocrit Increased Haemoglobin Abnormal Heart Rate Increased Lymphocyte Count Decreased Malaise Oedema Oxygen Saturation Decreased Pco2 Increased Pneumonia Aspiration Po2 Increased Proteinuria	Health Professional	Haldol (Haloperidol) Humulin (Insulin) Accolate (Zafirlukast) Norvasc (Amlodipine Besilate) Zestril (Lisinopril) Lasix (Furosemide) Theophylline (Theophylline) Combivent (Combivent)	PS C C C C C C			INTRAMUSCULAR	1 IN 1 MONTH(S), IM

	Respiratory Distress					
	Respiratory Rate Increased					
	Urine Analysis Abnormal					
	White Blood Cell Count Increased					

Date:05/03/02ISR Number: 3912192-9Report Type:Direct Company Report #CTU 167282
Age:54 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability Required	Anxiety Fear		Haldol , 5mg Tab , Ortho-Novum	PS	Ortho-Novum		1 TAB PRN	
Intervention to Prevent Permanent Impairment/Damage	Hallucination Memory Impairment Movement Disorder Muscle Rigidity Speech Disorder Tongue Disorder		Neurontin Gabitril	C C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/07/02ISR Number: 3913491-7Report Type:Expedited (15-DaCompany Report #EMADSS2002002836
Age:68 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Blood Pressure Increased Myocardial Infarction	Foreign Study Health Professional	Haldol ((Unspecified)(Haloperidol)	PS			1 CAPSULE +5 TABLETS	
			Risperidone (Unspecified)(Risperidone)	SS			1 CAPSULE + 5 TABLETS	
			Placebo (Unspecified)(Placebo)	SS			1 CAPSULE +5 TABLETS	

Date:05/08/02ISR Number: 3914076-9Report Type:Expedited (15-DaCompany Report #02P-056-0192148-00
Age:65 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Confusional State Dysphagia Lung Disorder	Foreign Health Professional Other	Tranxene (Clorazepate Dipotassium) (Clorazepate Dipotassium)	PS		ORAL	1 IN 1 D, PER ORAL	
			Haloperidol	SS		ORAL	PER ORAL	
			Donepezil Hydrochloride	SS		ORAL	10 MG, 1 IN 1 D, PER ORAL	
			Clomipramine					

			Hydrochloride	C			
			Pipamperone	C			

Date:05/09/02ISR Number: 3914742-5Report Type:Direct Company Report #CTU 167787
Age:37 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Death	Apallic Syndrome		Haldol	PS			
	Body Temperature Increased		Ritonavir	C			
			Saquinavir	C			
	Myocardial Infarction		Neverapine	C			
	Neuroleptic Malignant Syndrome		Gemfibrozole	C			
			Gliburide	C			

Date:05/10/02ISR Number: 3913582-0Report Type:Expedited (15-DaCompany Report #EMADSS2002002873
Age:17 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Benign Neoplasm		Risperdal	PS		ORAL	
Other	Extrapyramidal Disorder		Haldol	SS		ORAL	
	Hyperprolactinaemia		Laubeel	C		ORAL	
	Tremor						
	Urinary Incontinence						

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/10/02ISR Number: 3915560-4Report Type:Expedited (15-DaCompany Report #EMADSS2001005100
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Erectile Dysfunction	Foreign	Haldol (Tablet)					
	Tremor	Consumer	(Haloperidol)	PS		ORAL		
ORAL								
	Weight Increased		Haldol (Haloperidol Decanoate)	SS				
INTRAMUSCULAR	1 ML, 1 IN 3							
WEEK(S), IM								

Date:05/10/02ISR Number: 3915564-1Report Type:Expedited (15-DaCompany Report #EMADSS2001006043
Age:43 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Alanine Aminotransferase Increased	Foreign Health Professional	Vesadol (Tablet) (Haloperidol/ Buezepide Metiodide)	PS		ORAL	1 TABLE, 1 IN	
	Asthenia							
	Gamma-Glutamyltransferase Increased						1 DAY(S), ORAL	
	Haemochromatosis		Pentasa (Mesalazine)	C				
	Lipase Increased		Ventolin (Salbutamol)	C				
	Serum Ferritin Increased							

Date:05/13/02ISR Number: 3915672-5Report Type:Expedited (15-DaCompany Report #NSADSS2002014708
Age:59 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other Required Intervention to Prevent Permanent Impairment/Damage	Medication Error	Health Professional	Haldol Decanoate (Injection) (Haloperidol Decanoate)	PS		INTRAVENOUS	10 MG, 1 IN 1 DAY(S), IV	

Date:05/13/02ISR Number: 3916227-9Report Type:Expedited (15-DaCompany Report #EMADSS2002002836
Age:68 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Pressure Increased Myocardial Infarction	Foreign Study Health Professional	Haldol (Unspecified) (Haloperidol)	PS			1 CAPSULE + 5 Other TABLETS	
			Risperidone (Unspecified) (Risperidone)	SS			1 CAPSULES + 5 TABLETS	
			Placebo (Unspecified) (Placebo)	SS			1 CAPSULE + 5 TABLETS	

Date:05/14/02ISR Number: 3916228-0Report Type:Expedited (15-DaCompany Report #EMADSS2002002873
Age:17 YR Gender:Female I/FU:I

Outcome
Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent

Impairment/Damage

	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Extrapyramidal Disorder Fibrous Dysplasia Of Bone Hyperprolactinaemia Tremor Urinary Incontinence	Foreign Health Professional	Risperdal (4 Mg Tablet) (Risperidone) Haldol (Tablet) (Haloperidol) Laubeel (Lorazepam)	PS SS C		ORAL ORAL ORAL	4 MG, DAILY, 8 MG, DAILY,	

Date:05/22/02ISR Number: 3921876-8Report Type:Expedited (15-DaCompany Report #02P-087-0192829
Age:72 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Depressed Level Of Consciousness Dysarthria Muscle Rigidity Neuroleptic Malignant Syndrome Pneumonia Somnolence Tremor	Foreign Literature Health Professional Other	Akineton Injection (Biperiden) (Biperiden) Haloperidol Decanoate Fluphenazine Decanoate	PS SS SS		INTRAMUSCULAR INTRA-MUSCULAR INTRAMUSCULAR INTRAMUSCULAR	EVERY OTHER DAY, R 2 YR 6 MON	6 MON 6 MON

Date:05/22/02ISR Number: 3921878-1Report Type:Expedited (15-DaCompany Report #02P-062-0193121-00
Age:40 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Required Intervention to Prevent Permanent Impairment/Damage SEE IMAGE	Agranulocytosis Asthenia Night Sweats Pharyngolaryngeal Pain	Foreign Health Professional	Akineton (Biperiden) (Biperiden) Perazine Haloperidol Venlafaxine Hydrochloride	PS SS SS SS		ORAL ORAL ORAL	2 MG, 2 IN 1 D, PER ORAL 15 MG, 1 IN 1 D, PER ORAL 150 MG, 1 IN 1 D, PER ORAL

Date:05/22/02ISR Number: 3922163-4Report Type:Expedited (15-DaCompany Report #A210947
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Akathisia Depression Parkinsonian Gait Tremor	Health Professional	Ziprasidone Po Lithium Haldol Effexor	PS SS SS SS		ORAL ORAL ORAL	40.00 MG TOTAL: BID: ORAL 300.00 MG TOTAL 3.00 MG TOTAL: ORAL

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/24/02ISR Number: 3922462-6Report Type:Direct Company Report #CTU 168903
Age:14 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Confusional State		Haldol	PS				
INTRAMUSCULAR	5MG IM X 1							
Initial or Prolonged	Dysarthria							
DOSE								
	Dystonia							
	Tremor							

Date:05/28/02ISR Number: 3924416-2Report Type:Expedited (15-DaCompany Report #NSADSS2002016821
Age: Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Ventricular Tachycardia	Health Professional	Haldol (Injection) (Haloperidol)	PS				
INTRAVENOUS	MG, IV							

Date:05/28/02ISR Number: 3924432-0Report Type:Expedited (15-DaCompany Report #NSADSS2002016698
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Supraventricular Tachycardia	Health Professional	Haldol (Injection) (Haloperidol)	PS				
INTRAVENOUS	MG, IV							
	Ventricular Tachycardia							

Date:05/30/02ISR Number: 3926769-8Report Type:Expedited (15-DaCompany Report #02P-087-0192829-00
Age:72 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required	Delusion	Foreign	Akineton Injection					
Intervention to	Depressed Level Of	Literature	(Biperiden)	PS				
INTRAMUSCULAR	5 MG, EVERY							
Prevent Permanent	Consciousness	Health						
OTHER DAY,								

Impairment/Damage		Dysarthria	Professional				
INTRA-MUSCULA							
		Muscle Rigidity	Other				
R							
		Neuroleptic Malignant Syndrome		Haloperidol Decanoate	SS		
INTRAMUSCULAR	INTRAMUSCULAR						
		Pneumonia		Fluphenazine Decanoate	SS		
		Pyrexia					
INTRAMUSCULAR	25 MG, 1 IN 2 WK,						
		Somnolence					
		Staphylococcal Infection					
INTRA-MUSCULA							
		Tremor					
R							

Date:06/01/02ISR Number: 3941575-6Report Type:Direct Company Report #CTU 171255
Age:58 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Electrocardiogram Qt		Tequin 400mg Iv	PS				
INTRAVENOUS	400MG QD IV							
Required	Prolonged		Haldol Iv	SS				
INTRAVENOUS	2-5MG Q2H IV							
Intervention to	Torsade De Pointes							
PRN								
Prevent Permanent								
Impairment/Damage								

Date:06/03/02ISR Number: 3926730-3Report Type:Expedited (15-DaCompany Report #US-BRISTOL-MYERS SQUIBB COMPANY-11727773
Age:24 YR Gender:Male I/FU:F

Outcome	PT
Hospitalization -	Hypokalaemia
Initial or Prolonged	Neuroleptic Malignant

Syndrome
Rhabdomyolysis

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
		Health	Dapotum D	PS	Apothecon	INTRAMUSCULAR		
		Professional	Haldol	SS		ORAL		
			Akineton	C		ORAL		
			Diazepam	C		ORAL		

Date:06/03/02ISR Number: 3928186-3Report Type:Expedited (15-DaCompany Report #EMADSS2002003427
Age:29 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Parkinsonism Spinal Cord Neoplasm	Foreign Health	Haldol (Unspecified) (Haloperidol)	PS		ORAL	15 MG, DAILY,	ORAL
		Professional	Clopixol (Zuclopenthixol Deconoate)	SS		ORAL	20 MG, DAILY,	ORAL
			Prazine (Promazine Hydrochloride)	SS		INTERMITTENTL Y FROM RESERVE		
			Clopixol Acutard (Zuclopenthixol Acetate)	SS		INTRAMUSCULAR	200 MG, 1 IN	1 TOTAL IM
			Akineton (Biperiden Hydrochloride)	C				
			Convulex (Valproate Sodium)	C				
			Rivotril (Clonazepam)	C				

			Konsyl (Psyllium Hydrophilic Mucilloid)	C			

Date:06/03/02ISR Number: 3928189-9Report Type:Expedited (15-DaCompany Report #EMADSS2002003357
Age:82 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Life-Threatening	Appendicitis	Foreign	Haldol (2 Mg Tablet)				
Hospitalization -	Bladder Disorder	Health	(Haloperidol)	PS		ORAL	2 MG, 3 IN 1
Initial or Prolonged	Neuroleptic Malignant	Professional					DAILY, ORAL
Required	Syndrome		Dipiperon				
Intervention to			(Pipamperone)	SS		ORAL	20 MG, 1 IN 1
Prevent Permanent							DAY(S), ORAL
Impairment/Damage			Acesal (Acetylsalicylic Acid)	C			
			Arelix (Piretanide)	C			
			Bisoprolol (Bisoprolol)	C			
			Mictonorm (Propiverine Hydrochloride)	C			
			Nifedipin (Nifedipine)	C			
			Thyreotom (Thyrar)	C			

			Ximovan (Zopiclone)	C			

Date:06/03/02ISR Number: 3928190-5Report Type:Expedited (15-DaCompany Report #EMADSS2002003268
Age:48 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Cholangitis Hepatic Cirrhosis Hepatic Fibrosis Hepatic Steatosis	Foreign Health Professional	Haldol (5 Mg Tablet) (Haloperidol)	PS		ORAL	10 MG, DAILY, ORAL
			Tercian (Cyamemazine)	SS		ORAL	25 MG, DAILY, ORAL
			Retrovir (Zidovudine)	C			
			Viramune (Nevirapine)	C			
			Viracept (Nelfinavir Mesilate)	C			

Date:06/04/02ISR Number: 3928177-2Report Type:Expedited (15-DaCompany Report #02P-062-0193121-00
Age:40 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Required Intervention to Prevent Permanent Impairment/Damage SEE IMAGE	Agranulocytosis Asthenia Night Sweats Pharyngolaryngeal Pain	Foreign Health Professional	Akineton (Biperiden) (Biperiden)	PS		ORAL	2 MG, 2 IN 1 D, PER ORAL
			Perazine	SS		ORAL	15 MG, 1 IN 1 D, PER ORAL
			Haloperidol	SS		ORAL	
			Venlafaxine Hydrochloride	SS		ORAL	150 MG, 1 IN

1 D, PER ORAL

Date:06/05/02ISR Number: 3930240-7Report Type:Expedited (15-DaCompany Report #FR8994630MAY2002
Age:75 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	C-Reactive Protein Increased Confusional State Dehydration Extrapyramidal Disorder Hypertension	Health Professional Other	Parkinane (Trihexyphenidyl, Tablet, 0) Haldol (Haloperidol , , 0) Equanil (Meprobamate)	PS SS C		ORAL ORAL	5 MG 1X PER 1 DAY 0.5 ML 1X PER 1 DAY	

Date:06/05/02ISR Number: 3930491-1Report Type:Expedited (15-DaCompany Report #2002AP00385
Age:39 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Agranulocytosis Pyrexia	Foreign Health Professional Other	Seroquel Seroquel Minomycin	PS SS SS		ORAL ORAL	UNKNOWN DOSAGE 300 MG DAILY PO 100 MG DAILY PO	

			Serenace	SS		
INTRAVENOUS	5 MG DAILY IV					
			Halcion	C		
			Lendormin	C		
			Alosenn	C		

Date:06/12/02ISR Number: 3933282-0Report Type:Expedited (15-DaCompany Report #PHBS2001JP12995
Age:63 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Alanine Aminotransferase Increased Aspartate Aminotransferase Increased Blood Creatine Phosphokinase Increased Blood Pressure Increased Insomnia Liver Disorder Pyrexia	Foreign Health Professional Other	Symmetrel (Amantadine Hydrochloride)	PS		ORAL	50 MG, BID, ORAL
			Tegretol (Carbamazepine)	SS		ORAL	30 MG, TID, ORAL
			Serenace (Haloperidol)	SS		ORAL	0.75 MG, TID, ORAL; SEE IMAGE
			Amlodin (Amlodipine Besilate)	SS		ORAL	1 DF/DAY, ORAL
			Hirnamin (Levomepromazine)	SS		ORAL	5 MG/DAY, ORAL; SEE IMAGE
			Wypax (Lorazepam)	SS		ORAL	1 MG/DAY, ORAL

			Tetramide (Mianserin Hydrochloride)	SS		ORAL
10 MG, BID, ORAL						
			Rohypnol (Flunitrazepam)	C		
			Magnesium Oxide	C		
			Pursennid	C		

Date:06/12/02ISR Number: 3933357-6Report Type:Expedited (15-DaCompany Report #A212723
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Neuroleptic Malignant Syndrome	Health Professional	Ziprasidone Po Haldol Decanoate	PS SS		INTRAMUSCULAR INTRAMUSCULAR		

Date:06/12/02ISR Number: 3933649-0Report Type:Expedited (15-DaCompany Report #PHBS2002DK06593
Age:22 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Dialysis	Foreign	Leponex(Clozapine)					
Hospitalization - Initial or Prolonged	Diplegia	Health	Tablet	PS		ORAL		
	Intentional Misuse	Professional	Serenase(Haloperidol					
	Intestinal Hypomotility	Other	) Tablet	SS		ORAL		
	Liver Disorder		Oxapax(Oxazepam)					
	Loss Of Consciousness		Tablet	SS		ORAL		
	Renal Failure		Lithium (Lithium)					
	Suicide Attempt		Tablet	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/13/02ISR Number: 3933329-1Report Type:Direct Company Report #CTU 170163
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Akathisia		Haloperidol 250mg	PS		INTRAMUSCULAR	250MG IM Q	
Initial or Prolonged	Dystonia							MONTH
	Muscle Rigidity							

Date:06/13/02ISR Number: 3934395-XReport Type:Expedited (15-DaCompany Report #EMADSS2002003557
Age:35 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Thrombocythaemia	Foreign Health Professional	Haldol (Injection) (Haloperidol)	PS		INTRAMUSCULAR	100 MG 1 IN 2	WEEK(S) IM

Date:06/14/02ISR Number: 3934542-XReport Type:Expedited (15-DaCompany Report #NSADSS2002014364
Age:53 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Bacteriuria	Health Professional	Haldol (Unspecified) (Haloperidol)	PS		INTRAMUSCULAR	1 IN 1	MONTH(S), IM
Hospitalization -	Blood Ph Decreased							
Initial or Prolonged	Cardiac Failure							
Required	Congestive		Humulin (Insulin)	C				
Intervention to	Chronic Obstructive		Accolate					
Prevent Permanent	Airways Disease		(Zafirlukast)	C				
Impairment/Damage	Exacerbated		Norvasc (Amlodipine					
	Coma		Besilate)	C				
	Haematocrit Increased		Zestril (Lisinopril)	C				
	Lymphocyte Count Abnormal		Lasix (Furosemide)	C				
	Malaise		Theophylline					
	Monocyte Count Abnormal		(Theophylline)	C				
	Pneumonia Aspiration		Combivent					
	Proteinuria		(Combivent)	C				

	Respiratory Distress
	White Blood Cells Urine
	Positive

Date:06/17/02ISR Number: 3935593-1Report Type:Expedited (15-DaCompany Report #NSADSS2002019628
Age:17 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Neuroleptic Malignant Syndrome	Health Professional	Haldol (Unspecified) (Haloperidol)	PS				
			Risperdal (Unspecified) (Risperidone)	SS		ORAL		
			Zyprexa (Olanzapine)	SS		ORAL		

Date:06/17/02ISR Number: 3936062-5Report Type:Expedited (15-DaCompany Report #APCDSS2001001538
Age:63 YR Gender:Female I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Anxiety
	Condition Aggravated
Other	Hallucination, Visual
	Hepatocellular Damage
	Impulse-Control Disorder

		Insomnia Irritability Neuroleptic Malignant Syndrome Pyrexia	Report Source Foreign Health Professional	Product Haldol (Unspecified) (Haloperidol)	Role PS	Manufacturer	Route ORAL
Dose MG, DAILY, ORAL	Duration						
				Risperidone (Tablet) (Risperidone)	SS		ORAL
MG, DAILY, ORAL							
				Mianserin Hydrochloride (Mianserin Hydrochloride)	SS		ORAL
ORAL							
				Lorazepam (Lorazepam)	SS		
				Amantadine (Amantadine)	SS		ORAL
ORAL							
				Carbamazepine (Carbamazepine)	SS		
DAILY							
				Chlorpromazine Hydrochloride (Chlorpromazine Hydrochloride)	SS		ORAL
DAILY, ORAL							
				Magnesium Oxide (Magnesium Oxide)	C		
				Sennosides (Sennosides)	C		
				Levomepromazine (Levomepromazine)	C		
				Flunitrazepam (Flunitrazepam)	C		

Date:06/18/02ISR Number: 3934954-4Report Type:Expedited (15-DaCompany Report #EMADSS2001005194
Age:63 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Distension Change Of Bowel Habit Constipation	Foreign Health Professional	Haldol (5 Mg/Ml Injection) (Haloperidol)	PS			INTRAVENOUS	3 AMP, DAILY, IV
	Flatulence Respiratory Distress Shock		Sufenta (Injection) (Sufentanil Citrate)	SS			INTRAVENOUS	30 DROPS, DAILY, IV
			Dogmatil (Sulpiride)	SS		ORAL	ORAL	30, DAILY
			Nozinan (Levomepromazine)	SS				
			Anafranil (Clomipramine Hydrochloride)	C				
			Rohypnol (Flunitrazepam)	C				

Date:06/19/02ISR Number: 3936369-1Report Type:Expedited (15-DaCompany Report #PHBS2002DK06593
Age:22 YR Gender:Female I/FU:F

Outcome	PT
Life-Threatening	Dialysis
Hospitalization - Initial or Prolonged	Diplegia Intentional Misuse

	Intestinal Hypomotility Liver Disorder Loss Of Consciousness	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Renal Failure Rhabdomyolysis	Foreign Health	Leponex (Clozapine) Tablet	PS		ORAL	ORAL, 100
	Suicide Attempt	Professional					TABLETS/D,
		Other					ORAL
			Serenase (Haloperidol)	SS		ORAL	ORAL
			Oxapax (Oxazepam) Tablet	SS		ORAL	ORAL
			Lithium (Lithium)	C			

Date:06/20/02ISR Number: 3936178-3Report Type:Direct Company Report #CTU 170563
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Akathisia		Haloperidol 250mg	PS		INTRAMUSCULAR	250MG IM Q
Initial or Prolonged	Dystonia						MONTH
	Muscle Rigidity						

Date:06/24/02ISR Number: 3968228-2Report Type:Periodic Company Report #NSADSS2001012727
Age:87 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Pneumonia	Consumer	Haldol (Injection) (Haloperidol)	PS			
Initial or Prolonged	Tardive Dyskinesia		Risperdal (2 Mg Tablet) (Risperidone)	SS		ORAL	2 MG, DAILY,
							ORAL

Norvasc (Amlodipine Besilate)	C
Vasotec (Enalapril Maleate)	C
Paxil (Paroxetine Hydrochloride)	C
Detrol (Tolterodine L-Tartrate)	C
Synthroid (Levothyroxine Sodium)	C
Premarin (Estrogens Conjugated)	C

Date:06/25/02ISR Number: 3939514-7Report Type:Expedited (15-DaCompany Report #EMADSS2002003794
Age:33 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Interaction	Foreign	Haldol (Unspecified)					
	Hypertension	Health Professional	(Haloperidol)	PS				
			Clozapine (Clozapine)	SS				

LOW DOSE

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/25/02ISR Number: 3939529-9Report Type:Direct Company Report #CTU 170865
Age:19 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Heart Rate Increased		Haloperidol	PS				
	Parkinsonism		Risperidone	SS				

Date:06/26/02ISR Number: 3940069-1Report Type:Expedited (15-DaCompany Report #FLUV00302001487
Age:52 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Effect Decreased	Foreign	Fluvoxamine					
	Drug Ineffective	Literature	(Fluvoxamine)	PS			DAILY	
	Neuroleptic Malignant Syndrome	Other	Amitriptyline (Amitriptyline)	SS			DAILY	
			Haloperidol (Haloperidol)	SS			10 MG DAILY	

Date:06/26/02ISR Number: 3940453-6Report Type:Expedited (15-DaCompany Report #EMADSS2002003864
Age:88 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Diarrhoea	Foreign	Haldol (Inspecified)					
	Phlebothrombosis	Health Professional	(Haloperidol)	PS		ORAL	1 MG, DAILY, ORAL 4 MG, DAILY, ORAL 6 MG DAILY, ORAL	
			Eunerpan (Melperone Hydrochloride)	SS		ORAL	75 MG, DAILY,	

ORAL 100

MG, DAILY,

ORAL

Date:06/26/02ISR Number: 3940969-2Report Type:Direct Company Report #CTU 170991
Age:64 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Face Oedema		Zestril 10mg	PS		ORAL	10MG PO QD	
			Haloperidol Injection	SS		INTRAMUSCULAR	3MG IM X 1	DOSE
			Zyprexa	C				
			Neurontin	C				
			Bactrim Ds	C				
			Multivitamin	C				
			Albuterol	C				
			Levaquin	C				

Date:06/26/02ISR Number: 3940971-0Report Type:Direct Company Report #CTU 171035
Age:29 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Pruritus Rash		Haloperidol 5mg Tablet	PS		ORAL	5MG PO QHS	
			Haloperidol Injection	SS		INTRAMUSCULAR	5MG IM X 1	
			Cogentin	C				

			Vitamin C	C		
			Benadryl	C		

Date:06/28/02ISR Number: 3941849-9Report Type:Expedited (15-DaCompany Report #EMADSS2002003875
Age:71 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Acute Myocardial Infarction	Foreign Health	Haldol (Haloperidol)	PS		ORAL	SEE IMAGE	
Initial or Prolonged	Asthenia	Professional	Taxilan (Perazine)	SS		ORAL	SEE IMAGE	
	Condition Aggravated		Laubeel (Lorazepam)	SS		ORAL	1 MG, 1 IN 1	
	Cough						DAY (S), ORAL	
	Fall		Methizol (Thiamazol)	C				
	Pyrexia		Allopurinol (Allopurinol)	C				
	Restlessness		Delix (Ramipril)	C				
	Schizophrenia, Paranoid Type		Clexane (Heparin-Fraction, Sodium Salt)	C				
			Ass (Acetylsalicylic Acid)	C				

Date:06/28/02ISR Number: 3942262-0Report Type:Expedited (15-DaCompany Report #EMADSS2002003869
Age:80 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Cardiac Arrest	Foreign	Haldol(Haloperidol)	PS		ORAL	6 MG, DAILY,	
Hospitalization -	Dementia	Health					ORAL	
Initial or Prolonged	Hallucination, Visual	Professional	Risperdal (Tablet)(Risperidone)	SS		ORAL	2 MG, DAILY,	
	Hypotension						ORAL	
	Loss Of Consciousness							
	Restlessness							
	Syncope		Atosil					

			(Isopromethazine Hydrochloride)	SS		ORAL
75 MG, DAILY, ORAL						
			Saroten (Amitriptyline Hydrochloride)	SS		ORAL
50 MG, DAILY, ORAL						
			Eunerpan(Melperone Hydrochloride)	SS		ORAL
45 MG, DAILY, ORAL						
			Tavor (Lorazepam)	C		

Date:06/28/02ISR Number: 3942266-8Report Type:Expedited (15-DaCompany Report #EMADSS2002003876
Age:73 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Life-Threatening	Thrombocytopenia	Foreign Health Professional	Haldol (2 Mg Tablet) (Haloperidol)	PS		ORAL
SEE IMAGE						
			Cipramil (Citalopram)	SS		ORAL
40 MG, DAILY, ORAL, 60 MG, DAILY, ORAL						
			Stangyl (Trimipramine Maleate)	C		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/28/02ISR Number: 3942268-1Report Type:Expedited (15-DaCompany Report #EMADSS2002003878
Age:52 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Catatonia	Foreign	Haldol (Unspecified)					
	Neuroleptic Malignant	Health	(Haloperidol)	PS				
SEE IMAGE								
	Syndrome	Professional	Benperidol					
			(Benperidol)	SS			4 MG DAILY, 6	
							MG, DAILY	
			Pirenzepine					
			(Pirenzepine)	C				
			Tavor (Lorazepam)	C				
			Leponex (Clozapine)	C				

Date:06/28/02ISR Number: 3942274-7Report Type:Expedited (15-DaCompany Report #EMADSS2002003870
Age:72 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Bronchopneumonia	Foreign	Haldol (Tablet)					
	Delusion	Health	(Haloperidol)	PS		ORAL	8 MG, 1 IN 1	
	Depression	Professional					DAY(S), ORAL	
	Fall		Orap (Tablet)					
	Femoral Neck Fracture		(Pimozide)	SS		ORAL	2 MG, 1 IN 1	
							DAY(S), ORAL	
			Tavor (Lorazepam)	SS		ORAL	2 MG, 1 IN 1	
							DAY(S), ORAL	
			Ludiomil (Maprotiline Hydrochloride)	SS		ORAL	SEE IMAGE	
			Allopurinol (Allopurinol)	C				
			Alna (Tamsolosin Hydrochloride)	C				

Spasmex (Trospium Chloride)	C	
Dalmadorm (Flurazepam Hydrochloride)	C	
Remergil (Mirtazapine)	C	
Madopar (Madopar)	C	

Date:07/01/02ISR Number: 3942407-2Report Type:Direct Company Report #CTU 171364
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Blood Potassium Decreased		Haloperidol	PS		INTRAVENOUS	2MG/5MG IV	
Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Cardio-Respiratory Arrest Electrocardiogram Qt Corrected Interval Prolonged Electrocardiogram Qt Shortened Oxygen Saturation Decreased Ventricular Fibrillation Ventricular Tachycardia		Hctz Fentanyl Lorazepam Ceftriaxone Enalipril Morphine Ranitidine	PRN C C C C C C C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/01/02ISR Number: 3942897-5Report Type:Expedited (15-DaCompany Report #APCDSS2002000429
Age:37 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anorexia Blood Glucose Increased Blood Pressure Increased Condition Aggravated Delusion Hallucination Respiratory Distress	Foreign Health Professional	Haldol (Tablet) (Haloperidol)	PS		ORAL	MG, DAILY, ORAL	
			Risperdal (Tablet) (Risperidone)	SS		ORAL	SEE IMAGE	
			Quetiapine Fumarate (Quetiapine Fumarate)	SS		ORAL	MG, DAILY, ORAL	
			Hydroxyzine Pamoate (Hydroxyzine)	C				
			Estazolam (Estazolam)	C				
			Zopiclone (Zopiclone)	C				
			Biperiden Hydrochloride (Biperiden Hydrochloride)	C				

Date:07/01/02ISR Number: 3943121-XReport Type:Expedited (15-DaCompany Report #FR9081220JUN2002
Age:50 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Hepatitis	Foreign Health Professional	Seresta (Oxazepam, Tablet, 0)	PS		ORAL	1 DOSE 1X PER 1 DAY ORAL	
		Other	Depakote (Valproate Semisodium, ,0)	SS		ORAL	500 MG 3X PER 1 DAY ORAL	31 DAY

				Haldol (Haloperidol, ,0)	SS		ORAL	1 MG 2X PER 1 DAY ORAL
	3 DAY			Imovane (Zopiclone, ,0)	SS		ORAL	1 DOSE 1X PER 1 DAY ORAL
				Oromone (Estradiol, ,0)	SS		ORAL	1 DOSE 1X PER 1 DAY ORAL
	46 DAY			Teralithe (Lithium Carbonate)	C			

Date:07/01/02ISR Number: 3943468-7Report Type:Expedited (15-DaCompany Report #EMADSS2002003949
Age:66 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Stevens-Johnson Syndrome	Foreign Health Professional	Risperdal (Tablet) (Risperidone)	PS		ORAL	1, DAILY, ORAL	
			Haldol (Unspecified) (Haloperidol)	SS			2.5 MG, DAILY, UNKNOWN	
			Imap (2 Mg/Ml Injection) (Fluspirilene)	SS		INTRAMUSCULAR	12 MG, IM	

			Captohexal (Captopril)	C		
			Kliogest (Kliogest)	C		
			Doxepin (Doxepin)	C		
			Diazepam Tropfen (Diazepam)	C		
			Beloc-Zok Forte (Metoprolol)	C		
			Truxal (Chlorprothixene Hydrochloride)	C		
			Cotrim (Bactrim)	C		
			Dytide (Dytide)	C		
			Norvasc (Amlodipine Besilate)	C		
			Furorese (Furosemide)	C		
			Tavegil (Clemastine)	C		
			Dexa-Polyspectran (Dexa Polyspectran N)	C		

Date:07/01/02ISR Number: 3943469-9Report Type:Expedited (15-DaCompany Report #EMADSS2002003882
Age:31 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Condition Aggravated Hepatic Steatosis	Foreign Health	Haldol (Injection) (Haloperidol)	PS		INTRAMUSCULAR	SEE IMAGE	
	Hepatitis	Professional	Zyprexa (Olanzapine)	SS		ORAL	SEE IMAGE	
	Rhabdomyolysis Schizophrenia, Paranoid		Glianimon (Benperidol)	SS		ORAL	SEE IMAGE	
	Type		Dociton (Propranol-Ol Hydrochloride)	C				
			Akineton (Biperiden Hydrochloride)	C				
			Atropinsulfat (Trospium Chloride)	C				
			Quilonum (Lithium Acetate)	C				
			Orfiril (Valproate					

Sodium)	C
Tavor (Lorazepam)	C

Date:07/01/02ISR Number: 3943824-7Report Type:Expedited (15-DaCompany Report #APCDSS2002000429
Age:37 YR Gender:Male I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Anorexia
	Blood Creatine Phosphokinase Increased
	Blood Glucose Increased
	Blood Pressure Increased
	Condition Aggravated
	Delusion
	Glycosylated Haemoglobin
	Glycosylated Haemoglobin Increased
	Hallucination

Hypoventilation Insomnia Oxygen Saturation Decreased Respiratory Distress	Report Source Foreign Health Professional	Product Risperdal (Tablet) (Risperidone) Haldol (Tablet) (Haloperiodol) Quetiapine Fumarate (Quetiapine Fumarate) Hydroxyzine Pamoate (Hydroxyzine) Estazolam (Estazolam) Zopiclone (Zopiclone) Biperiden Hydrochloride (Biperiden Hydrochloride)	Role PS SS SS C C C C	Manufacturer	Route ORAL ORAL ORAL	Dose SEE IMAGE MG, DAILY, ORAL MG, DAILY, ORAL

Date:07/01/02ISR Number: 3944001-6Report Type:Expedited (15-DaCompany Report #EMADSS2002003949
Age:66 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Stevens-Johnson Syndrome	Foreign Health Professional	Haldol (Unspecified) (Haloperidol) Risperdal (Tablet) (Risperidone) Imap (2 Mg/Ml Injection)	PS SS		ORAL	2.5 MG, DAILY 1, DAILY,	 ORAL

INTRAMUSCULAR 12 MG, IM

(Flusprilene)	SS
Capthohexal (Captopril)	C
Kliogest (Kliogest)	C
Doxepin (Doxepin)	C
Diazepam Tropfen (Diazepam)	C
Beloc-Zok Forte (Metoprolol)	C
Truxal (Chlorprothixene Hydrochloride)	C
Cotrim (Bactrim)	C
Dytide (Dytide)	C
Norvasc (Amlodipine Besilate)	C
Furorese (Furosemide)	C
Tavegil (Clemastine)	C
Dexa-Polyspectran (Dexa Polyspectran N)	C

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/01/02ISR Number: 3944002-8Report Type:Expedited (15-DaCompany Report #EMADSS2002003688
Age:46 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Fatigue Medication Error Overdose	Foreign Health Professional	Haldol Decanoas (50 Mg/Ml Injection) (Haloperidol Decanoate)	PS			ONE VIAL	GIVEN IN ERROR
			Tiapridal (Tiapride)	C				
			Akineton (Biperiden Hydrochloride)	C				
			Equanil (Meprobamate)	C				
			Moditen (Fluphenazine Hydrochloride)	C				
			Modecate (Fluphenazine Decanoate)	C				
			Lepticur (Tropatepine Hydrochloride)	C				

Date:07/02/02ISR Number: 3942385-6Report Type:Direct Company Report #CTU 171394
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Convulsion Grand Mal Convulsion		Cyclosporine	PS		ORAL	150 MG 2 TIME	ORAL
	Tongue Biting		Haloperidol	SS		INTRAVENOUS	2 MG 1 TIME	INTRAVENOUS
						BOLUS		

BOLUS

	Valganciclovir	SS	ORAL

450 MG ORALLY

2 TIME A DAY

Prednisone	C
Cellcept	C
Nystatin	C
Pepcid	C
Regular Insulin	C
Alternagel	C
Aspirin	C
Flomax	C
Magnesium Oxide	C
Calcium Carbonate	C
Iron	C
Lasix	C
Colace	C

Date:07/03/02ISR Number: 3944268-4Report Type:Expedited (15-DaCompany Report #NSADSS2002021526
Age:83 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Apallic Syndrome	Consumer	Haldol (Injection) (Haloperidol)	PS		INTRAMUSCULAR	IM	
			Wellbutrin (Amfebutamone Hydrochloride)	C				

			Depakote (Valproate Semisodium)	C		

Date:07/03/02ISR Number: 3944275-1Report Type:Expedited (15-DaCompany Report #NSADSS2002021526
Age:83 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Apallic Syndrome	Consumer	Haldol (Injection) (Haloperidol)	PS		
INTRAMUSCULAR IM						
			Wellbutrin (Amfebutamone Hydrochloride)	C		
			Depakote (Valproate (Semisodium)	C		

Date:07/03/02ISR Number: 3944656-6Report Type:Expedited (15-DaCompany Report #PHNU2002DE02111
Age:72 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Arthralgia Asthenia Bronchopneumonia Dysphagia	Foreign Study Health Professional	Ludiomil (Maprotiline Hydrochloride) Film-Coated Tablet	PS		ORAL
SEE IMAGE						
	Extrapyramidal Disorder Fall	Other	Tavor (Lorazepam) Tablet	SS		
SEE IMAGE						
	Femoral Neck Fracture Pneumonia Aspiration		Haldol "Janssen-Cilag" (Haloperidol) Tablet	SS	"Janssen-Cilag"	ORAL
SEE IMAGE						
			Orap (Pimozide) Tablet	SS		ORAL
2MG/DAY; ORAL						
			Allopurinol	C		
			Alna (Tamsulosin Hydrochloride) Slow Release	C		
			...	C		
			Spasmex (Trospium			

			Chloride)	C		
			Dalmadorm "Icn" (Flurazepam Hydrochloride)	C		
			Remergil (Mirtazapine)	C		
			Madopar (Benserazide Hydrochloride, Levodopa)	C		

Date:07/03/02ISR Number: 3945075-9Report Type:Expedited (15-DaCompany Report #EMADSS2002003934
Age:57 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Neuroleptic Malignant Syndrome	Foreign Health Professional	Haldol Decanoate (100 Mg/Ml Injection) (Haloperidol Decanoate)	PS		INTRAMUSCULAR	200 MG/ML, IM	
			Cisordinol-Acutard (Zuclopenthixol Acetate)	SS			50 MG/ML,	

TOTAL, INJECT

			Heminevrin (Clomethiazole Edisilate)	C		
			Nozinan (Levomepromazine)	C		
			Oralovite (Parentrovite)	C		
			Disipal (Orphenadrine Hydrochloride)	C		

Date:07/03/02ISR Number: 3945077-2Report Type:Expedited (15-DaCompany Report #EMADSS2002003948
Age:81 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Erythema Oedema Peripheral Prurigo	Foreign Health Professional	Haldol Faible (0.5 Mg/Ml Solution) (Haloperidol)	PS		ORAL	DAILY, ORAL	
	Rash		Lamictal (Lamotrigine)	SS		ORAL	50 MG, DAILY,	ORAL
			Praxilene (Naftidrofuryl Oxalate)	SS				
			Doliprane (Paracetamol)	C				
			Josir (Tamsulosin Hydrochloride)	C				
			Equanil (Meprobamate)	C				
			Zestril (Lisinopril)	C				
			Lasilix (Furosemide)	C				
			Kardegic (Acetylsalicylate Lysine)	C				
			Lansoyl (Paraffin, Liquid)	C				
			Forlax (Macrogol)	C				
			Cordarone (Amiodarone					

			Hydrochloride)	C			

Date:07/05/02ISR Number: 3944489-0Report Type:Expedited (15-DaCompany Report #2002000488
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Delirium Depression	Foreign Health	Amlodipine (Amlodipine)	PS		ORAL	(DAILY), ORAL
Other	Hypertension	Professional	Cotrim (Bactrim)	SS		ORAL	20 MG (BID),
	Oedema	Other					ORAL
	Sleep Disorder Stevens-Johnson Syndrome Urinary Tract Infection		Truxal (Chlorprothixene Hydrochloride)	SS		ORAL	50 ML (BID),
							ORAL
			Diazepam (Diazepam)	SS		ORAL	15 MG (TID),
							ORAL
			Furorese (Furosemide)	SS		ORAL	ORAL
			Dytide H (Dyazide)	SS		ORAL	ORAL

			Tafil (Alprazolam)	SS		ORAL
ORAL						
			Saroten (Amitriptyline Hydrochloride)	SS		ORAL
ORAL						
			Captohexal (Captopril)	SS		ORAL
ORAL						
			Haldol (Haloperidol)	SS		ORAL
ORAL						
			Beloc-Zok Forte (Metoprolol Succinate)	SS		ORAL
ORAL						
			Risperdal (Risperidone)	SS		ORAL
ORAL						
			Planum (Temazepam)	SS		ORAL
ORAL						
			Prent 400 (Acebutolol Hydrochloride)	C		
			Kliogest (Kliogest "Novo Industri")	C		
			Doneurin (Doxepin Hydrochloride)	C		
			Captogamma 25 (Captopril)	C		

Date:07/05/02ISR Number: 3945747-6Report Type:Expedited (15-DaCompany Report #2002PK00632
Age:65 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Delirium Stevens-Johnson Syndrome	Foreign Health Professional Other	Beloc Zok	PS		ORAL	50 MG DAILY	
			Cotrim	SS		ORAL	20 ML DAILY	
			Saroten	SS		ORAL	70 MG DAILY	

PO			
	Prent	SS	
	Planum	SS	
	Captogamma	SS	ORAL
25 MG BID PO			
	Kliogest	SS	
	Imap	SS	
1 AMP BIMO SQ			
	Tafil	SS	ORAL
0.5 MG PRN PO			
	Doneurin	SS	ORAL
50 MG TID PO			
	Diazepam	SS	ORAL
15 MG DAILY			
PO			
	Diazepam	SS	ORAL
15 MG DAILY			
PO			
	Haldol	SS	
	Haldol	SS	ORAL
10 GTT DAILY			
PO			
	Truxal	SS	ORAL
50 ML DAILY			
PO			
	Dytide H	SS	ORAL
16 MG DAILY			
PO			
	Captohexal	SS	ORAL
75 MG DAILY			
PO			
	Risperdal	SS	ORAL
4 DF DAILY PO			
	Norvasc	SS	
	Furorese	SS	ORAL
20 MG DAILY			
PO			
	Tavegil	C	
	Dexa Polyspectran N	C	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/05/02ISR Number: 3945759-2Report Type:Expedited (15-DaCompany Report #EMADSS2002003949
Age:66 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Stevens-Johnson Syndrome	Foreign Health Professional	Risperdal (Tablet) (Risperidone)	PS		ORAL	1, DAILY, ORAL	
			Haldol (Unspecified) (Haloperidol)	SS			2.5 MG, DAILY,	
			Imap (2 Mg/Ml Injection) (Fluspirilene)	SS		INTRAMUSCULAR	12 MG, IM	
			Captohexal (Captopril)	C				
			Kliogest (Kliogest)	C				
			Doxepin (Doxepin)	C				
			Diazepam Tropfen (Diazepam)	C				
			Beloc-Zok Forte (Metoprolol)	C				
			Truxal (Chlorprothixene Hydrochloride)	C				
			Cotrim (Bactrim)	C				
			Dytide (Dytide)	C				
			Norvasc (Amlodipine Besilate)	C				
			Furorese (Furosemide)	C				
			Tavegil (Clemastine)	C				
			Dexa-Polyspectran (Dexa Polyspectran N)	C				

Date:07/05/02ISR Number: 3946661-2Report Type:Expedited (15-DaCompany Report #EMADSS2002003949
Age:66 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Stevens-Johnson Syndrome	Foreign Health Professional	Haldol (Unspecified) (Haloperidol)	PS			2.5 MG, DAILY	
			Risperdal (Tablet) (Risperidone)	SS		ORAL	1, DAILY,	
			Imap (2 Mg/Ml Injection) (Fluspirilene)	SS		INTRAMUSCULAR	12 MG, IM	
			Captohexal (Captopril)	C		ORAL		
			Kliogest	C				
			Doxepin	C				
			Diazepam Tropfen	C				
			Beloc-Zok Forte (Metoprolol)	C				
			Truxal (Chlorprothixene Hydrochloride)	C				
			Cotrim (Bactrim)	C				
			Dytide	C				
			Norvasc (Amlodipine Besilate)	C				

				Furorese (Furosemide)	C		
				Tavegil (Clemastine)	C		
				Dexa-Polyspectran (Dexa Polyspectran N)	C		

Date:07/09/02ISR Number: 3945135-2Report Type:Direct Company Report #CTU 171779
Age:53 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardio-Respiratory Arrest		Haloperidol 5 Mg/Ml					
	Heart Rate Increased		Bedford					
	Hypotension		Labs/Novaplus	PS	Bedford Labs/Novaplus	INTRAVENOUS		
	Joint Stiffness							
	Musculoskeletal Stiffness					BOLUS	2 MG Q4H PRN	
	Neuroleptic Malignant Syndrome					INTRAVENOUS BOLUS		
			Xigris	C				
			Vancomycin	C				
			Tobramycin	C				
			Merrem	C				

Date:07/09/02ISR Number: 3945459-9Report Type:Direct Company Report #CTU 171906
Age:60 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hypersensitivity		Haliperidol 150mg Decanoate (4 Months)+ Unknown					
	Medication Error		Oral	PS		ORAL	150MG + PO (OFF AND ON 20 YEARS)	
			Lithium	C				

Date:07/09/02ISR Number: 3945925-6Report Type:Direct Company Report #CTU 171926
Age:48 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Hyperventilation		Olanzapine (Zyprexa (R)) - Eli Lilly	PS	Eli Lilly		10 MG Q 6-8 HR PRN	
	Neuroleptic Malignant Syndrome							
	Screaming		Haloperidol	SS		INTRAMUSCULAR	TOTAL OF 15MG IM/IV - 1-2MG Q6 HR ON 3/22 & 3/24	
			Pseudoephedrine	C				
			Prazosin	C				
			Trazadone	C				
			Olanzapine	C				
			Mirtazipine	C				
			Clonazepam	C				
			Silenafil	C				
			Kava Kava Root	C				

Date:07/09/02ISR Number: 3946812-XReport Type:Expedited (15-DaCompany Report #NSADSS2002020969
Age:49 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Medication Error Pneumonia Psychotic Disorder	Study Health Professional	Haldol Decanoate (100 Mg/Ml Injection) (Haloperidol Decanoate)	PS		INTRAVENOUS	100 MG, IV	
			Metoprolol (Metoprolol)	C				
			Olanzapine (Olanzapine)	C				
			Fentanyl (Unspecified) (Fentanyl)	C				
			Lorazepam (Lorazepam)	C				
			Vancomycin (Vancomycin)	C				
			Acyclovir (Aciclovir)	C				
			Fluconazole (Fluconazole)	C				
			Prevacid (Lansoprazole)	C				
			Gcss	C				
			Maalox (Maalox)	C				
			Tpn Fat Emulsion (Solutions For Parenteral Nutrition)	C				

Date:07/10/02ISR Number: 3947692-9Report Type:Expedited (15-DaCompany Report #APCDSS2002000429
Age:37 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anorexia Blood Creatine Phosphokinase Increased	Foreign Health Professional	Haldol (Tablet) (Haloperidol)	PS		ORAL	MG, DAILY, ORAL	

	Blood Pressure Increased Diabetes Mellitus Hypoventilation Insomnia Oxygen Saturation Decreased Respiratory Distress Schizophrenia	Risperidal (Tablet) (Risperidone)	SS	ORAL MG, DAILY, ORAL
		Quetiapine Fumarate (Quetiapine Fumarate)	SS	ORAL MG, DAILY, ORAL
		Hydroxyzine Pamoate (Hydroxyzine)	C	
		Estazolam (Estazolam)	C	
		Zopiclone (Zopiclone)	C	
		Biperiden Hydrochloride (Biperiden Hydrochloride)	C	

Date:07/10/02ISR Number: 3947694-2Report Type:Expedited (15-DaCompany Report #APCDSS2002000429
Age:37 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anorexia Blood Creatine Phosphokinase Increased Blood Pressure Increased Diabetes Mellitus Hypoventilation Insomnia Oxygen Saturation Decreased Respiratory Distress Schizophrenia	Foreign Health Professional	Risperidal (Tablet) (Risperidone) Haldol (Tablet) (Haloperidol) Quetiapine Fumarate (Quetiapine Fumarate) Hydroxyzine Pamoate (Hydroxyzine) Estazolam (Estazolam) Zopiclone (Zopiclone) Biperiden Hydrochloride (Biperiden (Hydrochloride)	PS SS SS C C C		ORAL ORAL ORAL	MG, DAILY, MG, DAILY, MG, DAILY,	

Date:07/12/02ISR Number: 3948288-5Report Type:Expedited (15-DaCompany Report #2002112013JP
Age:38 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Confusional State Dyspnoea Haemodialysis Haemoptysis Hallucination	Foreign Literature Health Professional Other	Etoposide (Etoposide) Solution, Sterile	PS		INTRAVENOUS	300 MG/M2, DAYS 1-5,	CYCLIC, IV

		Pulmonary Haemorrhage Respiratory Failure Rhabdomyolysis		Ifosfamide (Ifosfamide)	SS			
INTRAVENOUS	1500 MG/M2, DAYS 1-5, CYCLIC, IV							
				Carboplatin (Carboplatin)	SS			
INTRAVENOUS	250 MG/M2, DAYS 1-5, CYCLIC, IV							
				Haloperidol (Haloperidol)	SS			
7.5 MG, QD	2 DAY							

Date:07/12/02ISR Number: 3948302-7Report Type:Expedited (15-DaCompany Report #EMADSS2002003608
Age:70 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardiac Arrest	Foreign	Haldol(Haloperidol)	PS		ORAL	SEE IMAGE	
	Fall General Physical Health Deterioration Laceration	Health Professional	Dipiperon (Pipamperone) Akineton(Biperiden Hydrochloride)	SS C		ORAL	SEE IMAGE	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/16/02ISR Number: 3949853-1Report Type:Expedited (15-DaCompany Report #2002AP01561
Age:41 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardio-Respiratory Arrest	Foreign	Seroquel	PS		ORAL	600 MG DAILY	
	Condition Aggravated	Health					PO	
	Psychiatric Symptom	Professional	Linton	SS		ORAL	6 MG DAILY PO	
		Other	Contomin	SS		ORAL	150 MG DAILY	
							PO	
			Tasmolin	SS		ORAL	6 MG DAILY PO	
			Depas	C				
			Risumic	C				
			Benzalin	C				
			Rohypnol	C				
			Levotomin	C				
			Hiberna	C				

Date:07/16/02ISR Number: 3950324-7Report Type:Expedited (15-DaCompany Report #S02-GER-01382-01
Age:73 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Thrombocytopenia	Foreign	Cipramil (Citalopram					
Hospitalization -		Health	Hydrobromide)	PS		ORAL	40 MG QD PO	
Initial or Prolonged		Professional	Cipramil (Citalopram					
		Other	Hydrobromide)	SS		ORAL	60 MG QD PO	
			Haldol (Haloperidol)	SS		ORAL	2 MG QD PO	
			Haldol (Haloperidol)	SS		ORAL	2 MG QD PO	
			Haldol (Haloperidol)	SS		ORAL	5 MG QD PO	
			Aponal (Doxepin Hydrochloride)	C				
			Edronax (Reboxetine)	C				
			Venlafaxin					

			(Venlafaxine)	C		
			Trimipramin (Trimipramine)	C		
			Sertraline	C		
			Levomepromazin (Levomepromazine)	C		
			Biperiden	C		

Date:07/18/02ISR Number: 3951218-3Report Type:Expedited (15-DaCompany Report #EMADSS2002004248
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Incontinence	Foreign	Haldol (Haloperidol)	PS		
	Parkinson'S Disease	Consumer	Risperdal (Tablet) (Risperidone)	SS		ORAL
6 MG, DAILY,						
ORAL						
			Zoloft (Sertraline Hydrochloride)	C		

Date:07/18/02ISR Number: 3951235-3Report Type:Expedited (15-DaCompany Report #EMADSS2002004281
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Haemochromatosis	Foreign	Haldol			
		Health	(Haloperidol)	PS		
INTRAMUSCULAR 1 ML, DAILY,						
		Professional				
IM						

Date:07/18/02ISR Number: 3951358-9Report Type:Expedited (15-DaCompany Report #EMADSS2002004248
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Parkinsonism	Foreign Consumer	Risperdal (Risperidone)	PS		ORAL	6 MG, DAILY,	ORAL
			Haldol (Haloperidol)	SS				
			Zoloft (Sertraline Hydrochloride)	C				

Date:07/19/02ISR Number: 3951650-8Report Type:Expedited (15-DaCompany Report #PHBS2002AU08140
Age:27 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Aspiration	Foreign	Clozaril (Clozapine)					
	Completed Suicide	Study	Tablet	PS		ORAL	400 MG/DAY,	
	Overdose	Health						ORAL
		Professional Other	Olanzapine (Olanzapine)	SS				
			Haloperidol (Haloperidol)	SS				
			Metazapine	SS				
			Clonidine Hydrochloride(Clonidine Hydrochloride)	SS				

Date:07/23/02ISR Number: 3952872-2Report Type:Expedited (15-DaCompany Report #EMADSS2002004315
Age:68 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Hospitalization -	Coagulation Factor V Level Decreased	Foreign Health	Haldol (5mg Tablet) (Haloperidol)	PS		ORAL	15 MG, DAILY,	

Initial or Prolonged	Coma	Professional				
ORAL						
Required	Condition Aggravated		Deroxat (Paroxetine			
Intervention to	Drug Interaction		Hydrochloride)	SS		ORAL
20 MG, DAILY,						
Prevent Permanent	Hepatocellular Damage					
ORAL						
Impairment/Damage	Prothrombin Time		Nozinan			
	Prolonged		(Levomepromazine)	SS		ORAL
8 MG, DAILY,						
	Respiratory Failure					
ORAL						
	Right Ventricular Failure		Tegretol			
			(Carbamazepine)	SS		ORAL
200, ORAL						
			Clopixol			
			(Zuclopenthixol			
			Decanoate)	C		

Date:07/23/02ISR Number: 3952965-XReport Type:Expedited (15-DaCompany Report #EMADSS2002004319
Age:60 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Dysphagia	Foreign	Risperdal			
Initial or Prolonged	Extrapyramidal Disorder	Health	(Unspecified)			
	Pneumonia Aspiration	Professional	(Risperidone)	PS		ORAL
ORAL						
	Respiratory Distress		Haldol Decanoate			
			(Injection)			
			(Haloperidol			
			Decanoate)	SS		
INTRAMUSCULAR 50 MG, 5 IN 3						

WEEK(S), IM

			Solian (Amisulpride)	C		

Date:07/23/02ISR Number: 3952973-9Report Type:Expedited (15-DaCompany Report #EMADSS2002004331
Age:28 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Medication Error Overdose	Foreign Health Professional	Haldol Decanoas (50 Mg/Ml Injection) (Haloperidol Decanoate)	PS		
INTRAMUSCULAR 1) 250 MG, 1						
IN 30 DAY(S),						
IM; 2) 250						
MG, DAILY, IM						
			Nozinan (Levomepromazine)	C		
			Depakote (Valproate Semisodium)	C		
			Lepticur (Tropatepine Hydrochloride)	C		

Date:07/23/02ISR Number: 3952974-0Report Type:Expedited (15-DaCompany Report #EMADSS2002004325
Age:70 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Blood Creatine Phosphokinase Increased C-Reactive Protein Increased Leukocytosis Renal Failure	Foreign Health Professional	Haldol Faible (0.5 Mg/Ml Solution) (Haloperidol)	PS		ORAL
25 DROPS, ORAL						
			Tercian (Cyamemazine)	SS		ORAL
25 MG, DAILY, ORAL						

			Hyperium (Rilmenidine)	C		
			Insuline (Insulin)	C		

Date:07/23/02ISR Number: 3953851-1Report Type:Expedited (15-DaCompany Report #1998-002044
Age:48 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Acute Psychosis Drug Interaction Incoherent Loose Associations Schizophrenia	Study Health Professional	Viracept (Nelfinavir Mesilate)	PS		ORAL	1000 MG (TID), ORAL 750 MG (BID) ORAL	
			Emivirine	SS		ORAL		
			Haloperidol	SS		INTRAMUSCULAR	100 MG (QOW), INTRAMUSCULAR	
			Valproate Semisodium	SS			120 MG (TID)	
			Stavudine	SS			40 MG (BID)	
			Didanosine	SS			200 MG (BID)	
			Furosemide	C				
			Verapamil Hydrochloride	C				
			Benzatropine Mesilate	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/24/02ISR Number: 3953504-XReport Type:Expedited (15-DaCompany Report #2002AP01561
Age:41 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardio-Respiratory Arrest	Foreign	Seroquel	PS		ORAL	600 MG DAILY	
	Psychotic Disorder	Health					PO	
	Sudden Death	Professional	Linton	SS		ORAL	6 MG DAILY PO	
		Other	Contomin	SS		ORAL	150 MG DAILY	
							PO	
			Tasmolin	SS		ORAL	6 MG DAILY PO	
			Depas	C				
			Risumic	C				
			Benzalin	C				
			Rohyonol	C				
			Levotomin	C				
			Hiberna	C				

Date:07/26/02ISR Number: 3955349-3Report Type:Expedited (15-DaCompany Report #EMADSS2002004427
Age:80 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Cardiac Failure	Foreign	Haldol (Solution)					
	Pleural Infection	Health	(Haloperidol)	PS		ORAL	5 DROP, 3 IN	
	Pneumonia	Professional					1 DAY(S),	
	Pulmonary Embolism						ORAL	
			Tavor (Lorazepam)	C				
			Lopirin (Captopril)	C				
			Valoron 50 (Tilidine)	C				
			Bifiteral (Lactulose)	C				
			Remergil (Mirtazapine)	C				
			Innohep					

			(Heparin-Fraction, Sodium Salt)	C		
			Locacorten (Flumetasone Pivalate)	C		

Date:07/26/02ISR Number: 3955352-3Report Type:Expedited (15-DaCompany Report #EMADSS2002004315
Age:68 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Cardiac Failure	Foreign	Haldol (5 Mg Tablet)					
Hospitalization - Initial or Prolonged	Coagulation Factor V Level Decreased	Health Professional	(Haloperidol)	PS		ORAL	15 MG, DAILY, ORAL	
Required Intervention to Prevent Permanent Impairment/Damage	Coma Condition Aggravated Drug Interaction Hepatocellular Damage Prothrombin Time Prolonged Respiratory Failure		Deroxat (Paroxetine Hydrochloride)	SS		ORAL	20 MG, DAILY, ORAL	
			Nozinan (Levomepromazine)	SS		ORAL	8 MG, DAILY, ORAL	
			Tegretol (Carbamazepine)	SS		ORAL	200, ORAL	
			Clopixol (Zuclopenthixol Decanoate)	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/26/02ISR Number: 3955355-9Report Type:Expedited (15-DaCompany Report #EMADSS2002004430
Age:31 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Bradycardia	Foreign	Risperdal (3 Mg Tablet) (Risperidone)	PS		ORAL	3 MG, DAILY,	ORAL
	Decreased Activity	Health Professional						
	Dizziness							
	Electrocardiogram Qt Prolonged		Haldol (Unspecified) (Haloperidol)	SS		ORAL	3 MG, DAILY,	ORAL
	Malaise							
			Biperiden (Biperiden)	C				

Date:07/26/02ISR Number: 3955356-0Report Type:Expedited (15-DaCompany Report #EMADSS2002004430
Age:31 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Bradycardia	Foreign	Haldol (Unspecified) (Haloperidol)	PS		ORAL	3 MG, DAILY,	ORAL
	Decreased Activity	Health Professional						
	Dizziness							
	Electrocardiogram Qt Prolonged		Risperdal (3 Mg Tablet) (Risperidone)	SS		ORAL	3 MG, DAILY,	ORAL
	Malaise							
			Biperiden (Biperiden)	C				

Date:07/29/02ISR Number: 3954594-0Report Type:Direct Company Report #CTU 173072
Age:34 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Hospitalization - Initial or Prolonged	Anxiety		Haldol 600mgm Prozac	PS		
EPIDURAL 2 TIME 2 EPIDURAL	Injury					
Disability	Memory Impairment		Zyprexa 100mgm Lilly	SS	Lilly	
DENTAL 2 TIMES 2 DENTAL	Performance Status					
Congenital Anomaly	Decreased					
Other Required Intervention to Prevent Permanent Impairment/Damage						

Date:07/31/02ISR Number: 3956999-0Report Type:Expedited (15-DaCompany Report #EMADSS2002004493
Age:57 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Angioneurotic Oedema Face Oedema Pyrexia	Foreign Health Professional	Vesadol (Haloperidol/Buzepide Metiodide)	PS		ORAL	ORAL	
			Inexium (Esomeprazole Magnesium)	SS		ORAL	1 CAP, DAILY,	ORAL
			Orbenine (Cloxacillin Sodium)	SS		ORAL	ORAL	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/31/02ISR Number: 3957288-0Report Type:Expedited (15-DaCompany Report #S02-GER-01382-01
Age:73 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Idiopathic	Foreign	Cipramil (Citalopram					
Hospitalization -	Thrombocytopenic Purpura	Health	Hydrobromide)	PS		ORAL	40 MG QD PO	
Initial or Prolonged		Professional	Cipramil (Citalopram					
		Other	Hydrobromide)	SS		ORAL	60 MG QD PO	
			Haldol (Haloperidol)	SS		ORAL	2 MG QD PO	
			Haldol (Haloperidol)	SS		ORAL	2 MG QD PO	
			Haldol (Haloperidol)	SS		ORAL	5 MG QD PO	
			Aponal (Doxepin Hydrochloride)	C				
			Edronax (Reboxetine)	C				
			Venlafaxin (Venlafaxine)	C				
			Trimipramin (Trimipramine)	C				
			Sertraline	C				
			Levomepromazin (Levomepromazine)	C				
			Biperiden	C				

Date:08/01/02ISR Number: 3957693-2Report Type:Expedited (15-DaCompany Report #APCDSS2002000668
Age:73 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Blood Creatine	Foreign	Haldol Decaonate					
Initial or Prolonged	Phosphokinase Increased	Health	(Injection)					
Required	Body Temperature	Professional	(Haloperidol					
Intervention to	Increased		Decanoate)	PS		INTRAMUSCULAR	MG, DAILY, IM	
Prevent Permanent	Condition Aggravated		Akineton (Biperiden					
Impairment/Damage	Dehydration		Hydrochloride)	C				
	Delusion		Pyrethia					
	Fall		(Promethazine					
	Haematuria		Hydrochloride)	C				
	Loss Of Consciousness							

Neuroleptic Malignant
Syndrome
Oliguria
Renal Failure Acute
Rhabdomyolysis
Treatment Noncompliance

Date:08/02/02ISR Number: 3959866-1Report Type:Periodic Company Report #2001AP05243
Age:49 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Literature	Amitriptyline	PS				
		Health Professional	Haloperidol	SS				

Date:08/02/02ISR Number: 3961103-9Report Type:Periodic Company Report #NSADSS2002015641
Age:16 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Extrapyramidal Disorder Hypotension	Health Professional	Risperdal (Unspecified) (Risperidone)	PS		ORAL	2 MG, 1 IN 1	

DAY(S), ORAL

			Haldol (Haloperidol)	SS		ORAL

ORAL

Date:08/05/02ISR Number: 3957832-3Report Type:Direct Company Report #CTU 173499
Age:37 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Hypotension		Haloperidol	PS		
	Sedation		Lorazepam	SS		
			Diphenhydramine	C		

Date:08/06/02ISR Number: 3958609-5Report Type:Direct Company Report #CTU 173587
Age:40 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Life-Threatening	Torsade De Pointes		Haloperidol	PS		

Date:08/06/02ISR Number: 3959466-3Report Type:Expedited (15-DaCompany Report #EMADSS2002004545
Age:67 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Coma	Foreign	Haldol Decanoate			
	Renal Failure Acute	Health	(Unspecified)			
	Respiratory Arrest	Professional	(Haloperidol Decanoate)	PS		

INTRAMUSCULAR 150 MG, 1 IN

1 MONTH(S),

IM	3 YR					
			Talofen (Promazine Hydrochloride)	C		
			Entumin (Clotiapine)	C		

Date:08/08/02ISR Number: 3959899-5Report Type:Direct Company Report #CTU 173808
Age:24 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Blood Pressure Increased Body Temperature Increased Heart Rate Increased Incontinence Lethargy Movement Disorder		Haldol 10mg Iv 6-17-02(0400) Seroquel 100am And 200mg Hs	PS SS		ORAL	INTRAVENOUS	IV, 10MG X 1 PO, 100AM 2 DAYS

Date:08/08/02ISR Number: 3960910-6Report Type:Expedited (15-DaCompany Report #EMADSS2002004621
Age:88 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Neutropenic Sepsis	Foreign Health Professional	Haldol (Unspecified) (Haloperidol) Lansoprazole (Lansoprazole) Amoxycillin (Amoxicillin)	PS C C		ORAL	1 MG 1 IN 1 DAY (S) ORAL	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/12/02ISR Number: 3961440-8Report Type:Expedited (15-DaCompany Report #EMADSS2002004498
Age:21 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Angioneurotic Oedema Respiratory Rate Increased	Foreign Health Professional	Haldol (2 Mg/Ml Solution) (Haloperidol)	PS		ORAL	4 MG, DAILY, ORAL

Date:08/12/02ISR Number: 3961612-2Report Type:Expedited (15-DaCompany Report #NSADSS2002026133
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Death	Abnormal Behaviour	Consumer	Haldol (Injection) (Haloperidol)	PS			

Date:08/13/02ISR Number: 3962804-9Report Type:Expedited (15-DaCompany Report #PHBS2001JP11159
Age:20 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Alanine Aminotransferase Increased Aspartate Aminotransferase Increased Drug Hypersensitivity Hepatic Function Abnormal Infectious Mononucleosis Lymphadenopathy Lymphocyte Morphology Abnormal	Foreign Literature Health Professional Other	Tegretol (Carbamazepine) Tablet Serenace(Haloperidol) Tablet Akineton(Biperiden Hydrochloride) Tablet	PS SS SS		ORAL	300 MG/DAY ORAL; 200 MG, TID, ORAL 3 TO 6 MG/DAY, ORAL 3 MG/DAY,

	Pharyngitis						
ORAL							
	Pruritus		Solanax (Alprazolam)	SS			ORAL
1.2 MG/DAY,							
	Pyrexia						
ORAL							
	Rash						
	Rash Generalised						

Date:08/14/02ISR Number: 3963294-2Report Type:Expedited (15-DaCompany Report #2002AP02135
Age:28 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardio-Respiratory Arrest	Foreign	Seroquel	PS		ORAL	700 MG DAILY	
	Delusion	Health					PO	
	Hallucination	Professional	Zyprexa	SS		ORAL	10 MG DAILY	
	Mydriasis	Other					PO	
			Serenace	SS		ORAL	15 MG DAILY	
							PO	
			Hirnamin	C				
			Contomin	C				
			Benzalin	C				
			Pyrethia	C				
			Artane	C				
			Barnetil	C				
			Tegretol	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/15/02ISR Number: 3962491-XReport Type:Direct Company Report #CTU 174190
Age:24 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Blood Pressure Systolic Increased		Haldol 10 Mg Iv 6-17-02 (0040)	PS		INTRAVENOUS	IV, 10 MG X 1	
	Body Temperature Increased		Seroquel 100 Am And 200 Mg Hs	SS		ORAL	PO, 100 AM , 200 MG HS	
	Heart Rate Increased							
	Incontinence							
	Lethargy							

Date:08/15/02ISR Number: 3962560-4Report Type:Direct Company Report #CTU 174196
Age:78 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Creatine Phosphokinase Increased		Quetiapine	PS				
			Haloperidal	SS				
			Olanzapine	SS				

Date:08/15/02ISR Number: 3963671-XReport Type:Expedited (15-DaCompany Report #PHNU2002DE01559
Age:36 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Coma	Foreign	Leponex (Clozapine) Tablet	PS		ORAL	300 MG, QD, ORAL	
	Intentional Misuse	Health Professional						
	Suicide Attempt	Other	Haldol Decanoate (Haloperidol Decanoate) Solution	SS		INTRAMUSCULAR	2 ML, BIW, INTRAMUSCULAR	

Date:08/15/02ISR Number: 3963985-3Report Type:Expedited (15-DaCompany Report #B0273338A
Age:28 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Abnormal Behaviour Aggression Condition Aggravated Prostration Sleep Apnoea Syndrome Tachycardia Torsade De Pointes	Foreign Health Professional	Paxil Tablet (Paroxetine Hydrochloride)	PS		ORAL	20 MG/PER DAY/ORAL	
			Amisulpride Tablet (Amisulpride)	SS		ORAL	200 MG/PER DAY/ORAL	
			Cyamemazine (Cyamemazine)	SS				
			Olanzapine (Olanzapine)	SS				
			Haloperidol (Haloperidol)	SS				

Date:08/15/02ISR Number: 3964105-1Report Type:Expedited (15-DaCompany Report #EMADSS2002004816
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Congestive Cardiomyopathy	Foreign Health Professional	Haldol (Tablet)(Haloperidol)	PS		ORAL	ORAL	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/15/02ISR Number: 3964106-3Report Type:Expedited (15-DaCompany Report #EMADSS2002004545
Age:67 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Agitation	Foreign	Haldol Decanoate (Unspecified)(Haloperidol Decanoate)	PS		INTRAMUSCULAR	50 MG, 1 IN 1	MONTH(S), IM
	Coma	Health						
	Dehydration	Professional						
	Renal Failure Acute							
	Respiratory Arrest		Talofen (Promazine Hydrochloride)	C				
			Entumin (Clotiapine)	C				

Date:08/15/02ISR Number: 3964320-7Report Type:Expedited (15-DaCompany Report #PHBS2001JP11159
Age:20 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Alanine Aminotransferase Increased	Foreign	Tegretol (Carbamazepine)					
	Aspartate Aminotransferase Increased	Literature						
		Health	Tablet	PS		ORAL	300 MG/DAY;	
		Professional					200 MG, TID	
		Other					ORAL	
	Drug Hypersensitivity Mononucleosis Syndrome		Serenace (Haloperidol) Tablet	SS		ORAL	3 TO 6	MG/DAY, ORAL
	Pruritus Generalised							
			Akineton (Biperiden Hydrochloride) Tablet	SS		ORAL	3 MG/DAY,	ORAL
			Solanax (Alprazolam)	SS		ORAL	1.2 MG/DAY,	ORAL

Date:08/16/02ISR Number: 3962998-5Report Type:Direct Company Report #CTU 174354
Age:20 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Cardio-Respiratory Arrest Neuroleptic Malignant Syndrome		Haloperidol	PS		INTRAVENOUS BOLUS	5MG QI-2HOURS	IV BOLUS
			Metoclopramide	SS		INTRAVENOUS BOLUS	10MG Q6HOURS	PRN IV BOLUS
			Metronidazole	C				
			Morphine	C				
			Kcl	C				
			Ranitidine	C				
			Acetaminophen	C				

Date:08/16/02ISR Number: 3962999-7Report Type:Direct Company Report #CTU 174355
Age:73 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Neuroleptic Malignant Syndrome		Haloperidol	PS		INTRAVENOUS BOLUS	1MG Q4HPRN IV	BOLUS
			Seroquel 25mg	SS		ORAL	25MG BID AND	PRN ORAL
			Wellbutrin	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/16/02ISR Number: 3963681-2Report Type:Expedited (15-DaCompany Report #02P-087-0197518-00
Age:28 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Gases Abnormal Dyspnoea Exacerbated Eosinophilic Pneumonia Acute	Foreign Other	Akineton (Biperiden) (Biperiden) Haloperidol Flunitrazepam	 PS SS SS				

Date:08/16/02ISR Number: 3964527-9Report Type:Expedited (15-DaCompany Report #EMADSS2002004823
Age:78 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hyponatraemia Neuropathy Peripheral	Foreign Health Professional	Haldol (2 Mg/Ml Solution) (Haloperidol)	 PS		ORAL	2 MG, DAILY,	ORAL
			Cordarone (Amiodarone Hydrochloride)	SS		ORAL	200 MG,	DAILY, ORAL
			Di-Antalvic (Aporex)	SS		ORAL	2400 MG,	DAILY, ORAL
			Levothyrox (Levothyroxine Sodium)	SS		ORAL	100 MCG,	DAILY, ORAL
			Deroxat (Paroxetine Hydrochloride)	SS		ORAL	20 MG, DAILY,	ORAL

Date:08/19/02ISR Number: 3964753-9Report Type:Expedited (15-DaCompany Report #2002003203
Age:24 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abnormal Behaviour Confusional State	Foreign Consumer	Sertraline (Sertraline)	PS		ORAL	400 MG	
Disability	Convulsion							(DAILY), ORAL
Other	Fall Loss Of Consciousness Memory Impairment Social Avoidant Behaviour		Haloperidol Clozapine (Clozapine)	SS SS				

Date:08/21/02ISR Number: 3965858-9Report Type:Expedited (15-DaCompany Report #2002003203
Age:24 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abnormal Behaviour Confusional State	Foreign Consumer	Sertraline (Sertraline)	PS		ORAL	200 MG	
Disability	Convulsion							(DAILY), ORAL
Other	Fall Loss Of Consciousness Memory Impairment Palpitations Social Avoidant Behaviour		Haloperidol (Haloperidol) Clozapine (Clozapine) Deptran (Doxepin Hydrochloride) Oxycodone (Oxycodone)	SS SS SS C			75 MG (DAILY)	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/21/02ISR Number: 3965876-0Report Type:Expedited (15-DaCompany Report #EMADSS2002004325
Age:70 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Creatine Phosphokinase Increased	Foreign Health Professional	Haldol Faible (0.5 Mg/Ml Solution) (Haloperidol)	PS		ORAL	25 DROPS,	
	Leukocytosis							
	Pyrexia						ORAL	
	Renal Failure		Tercian (Cyamemazine)	SS		ORAL	25 MG, DAILY,	
							ORAL	
			Hyperium (Rilmenidine)	C				
			Insuline (Insulin)	C				

Date:08/23/02ISR Number: 3967196-7Report Type:Expedited (15-DaCompany Report #EMADSS2002003557
Age:35 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Thrombocythaemia	Foreign Health Professional	Haldol(Injection) (Haloperidol)	PS		INTRAMUSCULAR	100 MG, 1 IN	2 WEEK (S),
						IM		

Date:08/27/02ISR Number: 3967601-6Report Type:Direct Company Report #CTU 175190
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Agitation		Haloperidol 5mg Geneva	PS	Geneva	ORAL	5MG QAM PO/IM	
	Extrapyramidal Disorder						10MG QHS	

Date:08/27/02ISR Number: 3967664-8Report Type:Direct Company Report #CTU 175183
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Extrapyramidal Disorder		Haldol 5mg	PS		ORAL	5MG Q 1 HR	PRN PO
AGGITATION								
			Haloperidol 5mg Geneva	SS	Geneva			

Date:08/27/02ISR Number: 3967669-7Report Type:Direct Company Report #CTU 175185
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Agitation		Haldol 5mg And 10mg	PS	Geneva		CHANGES FROM	
	Extrapyramidal Disorder						5 BID TO 10MG	
BID								
			Haloperidol 5mg And 10mg Geneva	SS				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/27/02ISR Number: 3968313-5Report Type:Expedited (15-DaCompany Report #EMADSS2002004997
Age:46 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Agitation	Foreign	Haldol (Unspecified)					
	Blood Creatine Phosphokinase Increased	Health Professional	(Haloperidol)	PS			5 MG,	
	Dystonia		Lithium Carbonate (Lithium Carbonate)	SS				
	Overdose		Risperidone (Risperidone)	C				
			Fluoxetine (Fluoxetine)	C				
			Depot Provera (Medroxyprogesterone Acetate)	C				
			Clonazepam (Clonazepam)	C				

Date:09/03/02ISR Number: 3971160-1Report Type:Expedited (15-DaCompany Report #02P-087-0197518-00
Age:27 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Gases Abnormal	Foreign	Akineton (Biperiden)					
	Eosinophilic Pneumonia	Other	(Biperiden)	PS		ORAL	2 MG, 1 IN 1 D, PER ORAL	
	Respiratory Failure							
	Respiratory Rate Increased		Haloperidol	SS		ORAL	6 MG, 1 IN 1 D, PER ORAL	
	Schizophreniform Disorder		Flunitrazepam	SS		ORAL	2 MG, 1 IN 1 D, PER ORAL	
			Akinetron (Biperiden) (Biperiden)	SS				
INTRAMUSCULAR	INTRAMUSCULAR							
			Haloperidol	SS				
INTRAMUSCULAR	INTRAMUSCULAR							

			Flunitrazepam	SS		
INTRAMUSCULAR	INTRAMUSCULAR					

Date:09/03/02ISR Number: 3971633-1Report Type:Expedited (15-DaCompany Report #EMADSS2002004248
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Condition Aggravated	Foreign	Haldol	PS				
	Pain	Consumer	Risperdal (Tablet)					
Other	Parkinson'S Disease		(Risperidone)	SS		ORAL	6 MG DAILY	
	Restlessness					ORAL		
			Zoloft (Sertraline Hydrochloride)	C				

Date:09/03/02ISR Number: 3971634-3Report Type:Expedited (15-DaCompany Report #JACGER2000000222
Age:18 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Neutropenia	Foreign	Haldol	PS		ORAL	MG, DAILY	
		Health Professional	Leponex (Clozapine)	SS		ORAL	MG, DAILY,	
			Ciatyl-Z (Zuclopenthixol Hydrochloride)	C				
			Taxilan (Perazine)	C				
			Tavor (Lorazepam)	C				

			Sulp (Sulpiride)	C		
			Risperdal (Tablet) (Risperidone)	C		
			Akineton (Biperiden Hydrochloride)	C		

Date:09/05/02ISR Number: 3973439-6Report Type:Expedited (15-DaCompany Report #B0277719A
Age:68 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Cholestasis	Foreign	Paxil (Formulation Unkown) (Paroxetine Hydrochloride)	PS		ORAL	1 UNIT /PER DAY/ORAL	
Hospitalization - Initial or Prolonged	Coagulation Factor V Level Decreased							
	Coma							
	Condition Aggravated		Methotrimeprazine Tablet (Methotrimeprazine)	SS		ORAL	4 UNIT/ORAL	
	Dyspnoea							
	Hepatic Function Abnormal		Carbamazepine Talbet (Carbamazepine0	SS		ORAL	PER DAY/ORAL	
	Hepatocellular Damage							
	Prothrombin Level Decreased		Haloperidol Tablet (Haloperidol)	SS		ORAL	THREE TIMES PER DAY /ORAL	
	Respiratory Failure							
	Right Ventricular Failure							
			Zuclopenthixol Hcl (Formulation Unknown) (Zuclopenthixol Hcl)	SS		INTRAMUSCULAR	1 UNIT CYCLIC/INTRAM USCULAR	

Date:09/06/02ISR Number: 3972688-0Report Type:Direct Company Report #CTU 175848
Age:82 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Ventricular Tachycardia		Haloperidol 5mg/Ml	PS				
			Amiodarone	C				
			Hyperlimentation	C				
			Aspirin	C				
			Potassium Chloride	C				
			Calcium Chloride	C				
			Morphine	C				
			Lidocaine	C				
			Cholorthiazide	C				
			Midazolam	C				
			Atropine	C				
			Levofloxacin	C				
			Furosemide	C				
			Docusate Sodium	C				
			Cefazolin	C				
			Famotidine	C				
			Heparin	C				

Date:09/06/02ISR Number: 3972807-6Report Type:Expedited (15-DaCompany Report #NSADSS2001024190
Age:59 YR Gender:Female I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Asthenia
	Atrophy
	Catatonia

	Cognitive Disorder Dissociation Dyskinesia	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Flat Affect Flat Feet Limb Deformity	Consumer	Haldol Decanoate (Injection)(Haloperidol Decanoate)	PS			100 - 150 MG
	Pain						EVERY 3-4
	Paraesthesia						WEEKS
	Respiratory Tract Infection Thrombosis Weight Increased		Coumadin (Warfarin Sodium) Artane(Trihexyphenidyl Hydrochloride)	C C			

Date:09/06/02ISR Number: 3973161-6Report Type:Expedited (15-DaCompany Report #EMADSS2002005201
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Death Hospitalization - Initial or Prolonged	Blood Creatine Phosphokinase Increased Chills Condition Aggravated Delirium Extrapyramidal Disorder Neuroleptic Malignant Syndrome Pneumonia Rhabdomyolysis	Foreign Health Professional	Haldol (Unspecified) (Haloperidol) Leponex (Clozapine) Eunerpan (Melperone Hydrochloride)	PS SS C			

Date:09/09/02ISR Number: 3973947-8Report Type:Expedited (15-DaCompany Report #PHRM2002FR02138
Age:68 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Life-Threatening Hospitalization - Initial or Prolonged	Cholestasis Coagulation Factor V Level Decreased	Foreign Health Professional	Tegretol(Carbamazdepine)Extended Release Tablet	PS		ORAL	ORAL
	Coma	Other	Deroxat(Paroxetine)T				

	Condition Aggravated	ablet	SS	ORAL
20 MG, QD,				
	Drug Interaction			
ORAL				
	Hepatocellular Damage	Nozinan Tablet		
	Prothrombin Level	(Levomepromazine)Tab		
	Decreased	let	SS	ORAL
8 MG/DAY,				
	Respiratory Failure			
ORAL				
	Right Ventricular Failure	Haldol		
		"Janssen-Cilag"(Halo		
		peridol)Tablet	SS	ORAL
5MG, TID,				
ORAL				
		Clopixol (Decanoate)		
		(Zuclopenthixol		
		Decanoate)	C	

Date:09/09/02ISR Number: 3974007-2Report Type:Expedited (15-DaCompany Report #FR9163303SEP2002
Age: Gender:Female I/FU:I

Outcome	PT
Other	Agitation Neonatal
	Congenital Anomaly
	Feeding Problem In
	Newborn

		Maternal Drugs Affecting Foetus Small For Dates Baby	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
			Health Professional	Effexor (Venlafaxine Hydrochloride, Tablet, 0)	PS		ORAL
3 FIRST MONTHS OF PREGNANCY							
				Anafranil (Clomipramine Hydrochloride, , 0)	SS		
SINCE THE 6TH MONTH OF GESTATION							
				Haldol (Haloperidol, , 0)	SS		
SINCE THE 6TH MONTH OF GESTATION							

Date:09/11/02ISR Number: 3974338-6Report Type:Expedited (15-DaCompany Report #FR9163303SEP2002
Age: Gender:Female I/FU:F

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Other		Agitation Neonatal Congenital Anomaly Feeding Problem In Newborn Maternal Drugs Affecting Foetus Small For Dates Baby	Health Professional	Effexor (Venlafaxine Hydrochloride, Tablet, 0)	PS		ORAL
3 FIRST MONTHS OF PRENANCY							
				Anafranil (Clomipramine Hydrochloride, , 0)	SS		
SINCE THE 6TH							

MONTH OF

GESTATION

			Haldol (Haloperidol, , 0)	SS		

SINCE THE 6TH

MONTH OF

GESTATION

Date:09/11/02ISR Number: 3974542-7Report Type:Expedited (15-DaCompany Report #USA-2002-0001747
Age:71 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agitation Anxiety Blood Pressure Systolic Increased Depressed Level Of Consciousness Drug Interaction Hyperventilation Muscle Spasms Respiratory Arrest Respiratory Rate Increased	Health Professional	Oxycontin Tablets (Oxycodone Hydrochloride) Cr Tablet	PS		ORAL	SEE TEXT, ORAL	
			Morphine Sulfate (Similar To Nda 19-516) (Morphine Sulfate) Other	SS		INTRAVENOUS	5 MG, SINGLE, INTRAVENOUS	
			Ativan (Lorazepam) Tablet	SS		PARENTERAL	MG, SEE TEXT, PARENTERAL	
			Xanax (Alprazolem) Tablet	SS		ORAL	MG, ORAL	235 DAY
			Haldol (Haloperidon) Injectable	SS		INTRAMUSCULAR	10 MG, SINGLE,	

INTRAMUSCULAR							
				Cogentin(Benzatropine Mesilate) Injectable	SS		
INTRAMUSCULAR	1 MG, SINGLE,						
INTRAMUSCULAR							
				Soma (Carisoprodol) Tablet	C		
				Amoxicillin (Amoxicillin)	C		
				Percocet Tablet	C		
				Pepcid (Famotidine)	C		
				Flonase (Fluticasone)	C		
				Trazodone (Trazodone)	C		
				Allegra (Fexofenadine Hydrochloride) Tablet	C		
				Premarin (Estrogens Conjugated)	C		
				Lasix (Furosemide)	C		
				Pyridium (Phenazopyridine) Tablet	C		
				Paxil (Paroxetine Hydrochloride)	C		
				Aspirin Bayer Tablet	C		

Date:09/11/02ISR Number: 3974747-5Report Type:Expedited (15-DaCompany Report #EMADSS2002005282
Age:22 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Extrapyramidal Disorder	Foreign Health Professional	Haldol (2 Mg/Ml Drops) Haloperidol)	PS		ORAL	30 DROP, DAILY, ORAL	
			Largactil (Chlorpromazine Hydrochloride)	C				

				Disipal (Orphenadrine Hydrochloride)	C		

Date:09/11/02ISR Number: 3974866-3Report Type:Expedited (15-DaCompany Report #EMADSS2002004281
Age:59 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Haemochromatosis	Foreign Health Professional	Haldol (Injection) (Haloperidol)	PS		INTRAMUSCULAR	25 MG, 1 IN 5	WEEK(S), IM
			Levothyroxine (Levothyroxine)	C				
			Lepticur (Tropatepine Hydrochloride)	C				

Date:09/11/02ISR Number: 3974871-7Report Type:Expedited (15-DaCompany Report #EMADSS2002004997
Age:46 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blood Creatine Phosphokinase Increased	Foreign Health	Haldol(Unspecified)(Haloperidol)	PS			5 MG	
	Dystonia	Professional	Risperidone (Risperidone)	C				
			Lithium Carbonate (Lithium Carbonate)	C				
			Fluoxetine (Fluoxetine)	C				
			Depot Provera (Medroxyprogesterone Acetate)	C				
			Clonazepam(Clonazepa m)	C				

Date:09/12/02ISR Number: 3975281-9Report Type:Expedited (15-DaCompany Report #APCDSS2002000634
Age:21 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blood Glucose Increased	Foreign	Haladol (Unspecified)					
	Obesity	Health	Haloperidol)	PS		ORAL	MG, DAILY,	
	Polydipsia	Professional						
	Thirst						ORAL	
	Tonic Convulsion		Risperdal (Tablet) (Risperidone)	SS		ORAL	MG, DAILY,	
							ORAL	
			Levomepromazine Maleate (Levopromazine Maleate)	SS		ORAL	NG, DAILY,	
							ORAL	
			Promethazine Hydrochloride					

				(Promethaizine Hydrochloride)	SS		
				Biperiden Hydrochloride(Biperiden Hydrochloride)	C		
				Flunitrazepam (Flunitrazepam)	C		
				Sennosides(Sennosides)	C		

Date:09/13/02ISR Number: 3976174-3Report Type:Expedited (15-DaCompany Report #HQ4140010SEP2002
Age:57 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agitation Dysarthria Dysuria	Health Professional Other	Artane (Trihexyphenidyl, Tablet)	PS			10 MG 1X PER 1 DAY	
	Hyperhidrosis Muscle Rigidity Psychomotor Hyperactivity Restlessness		Citalopram (Citalopram)	SS			80 MG 1X PER 1 DAY	6 DAY
	Tremor		Cogentin (Benzatropine Mesilate)	SS			2 MG 1X PER 1	

DAY

Haloperidol (Haloperidol) SS

7.5 MG 1X PER

1 DAY

Pravachol (Pravastatin Sodium) SS

10 MG 1X PER

1 DAY 6 DAY

Temaze (Temazepam) SS

10 MG 1X PER

1 DAY

Antenex (Diazepam) C

Date:09/13/02ISR Number: 3976201-3Report Type:Expedited (15-DaCompany Report #PHNU2002DE03041
Age:67 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Aggression	Foreign	Leponex/Clozaril (Clozapine)(Clozapine) Tablet	PS		ORAL		
Life-Threatening	Akathisia	Consumer						
Other	Blood Creatine Phosphokinase Increased	Other						
	Cerebral Atrophy		Haldol "Janssen"(Haloperidol)	SS				
	Colitis Ischaemic		Distraneurin(Clomethiazole Edisilate)Unknown	SS				
	Coma		Eunerpan (Melperone Hydrochloride)	C				
	Computerised Tomogram Abnormal		Elobact (Cefuroxime Axetil)	C				
	Decubitus Ulcer							
	Delirium							
	Dementia							
	Electroencephalogram Abnormal							
	General Physical Health Deterioration							
	Hypertonia							
	Muscle Rigidity							
	Muscle Spasms							
	Neuroleptic Malignant Syndrome							
	Oedema							

	Oliguria					
	Pain In Extremity					
	Pleural Effusion					
	Pneumonia					
	Pyrexia					
	Rhabdomyolysis					
	Urosepsis					

Date:09/16/02ISR Number: 3976682-5Report Type:Expedited (15-DaCompany Report #2002090011
Age:71 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Creatine Phosphokinase Increased	Foreign Health	Doral (Quazepam) Tablets	PS		ORAL	20 MG/D, PO	
	Difficulty In Walking	Professional	Haloperidol	SS		ORAL	SEE IMAGE	
	Dysuria		Olanzapine	SS		ORAL	10 MG/D, PO	
	Neuroleptic Malignant Syndrome		Bromocriptine Mesilate	C				
			Dantrolene Sodium	C				
			Trihexyphenidyl Hcl	C				
			Biperiden Hcl	C				
			Brotizolam	C				
			Sennosides	C				

				Valsartan	C		

Date:09/19/02ISR Number: 3978192-8Report Type:Expedited (15-DaCompany Report #B0279390A
Age:41 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide Intentional Misuse	Literature Health Professional	Lithium Salt (Formulation Unknown) (Lithium Salt)	PS		ORAL	ORAL	
			Haloperidol (Formulation Unknown) (Haloperidol)	SS		ORAL	ORAL	

Date:09/19/02ISR Number: 3978228-4Report Type:Expedited (15-DaCompany Report #EMADSS2002005402
Age:70 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Medication Error Somnolence	Foreign Health Professional	Haldol Decanoate (Injection) (Haloperidol Decanoate)	PS		ORAL	50 MG, 5 IN 1 NIGHT(S), ORAL	

Date:09/19/02ISR Number: 3978251-XReport Type:Expedited (15-DaCompany Report #EMADSS2002005441
Age:87 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Confusional State Opisthotonus	Foreign Health	Haldol (1.5 Mg Tablet)					

	Professional	(Haloperidol)	PS	ORAL
1.5 MG, DAILY, ORAL				
		Ciproxine (Ciprofloxacin)	SS	ORAL
500 MG, 2 IN 1 DAY(S), ORAL				
		Sinemet (Sinemet)	SS	ORAL
3 CAP, DAILY, ORAL				
		Antra (Omeprazole)	SS	ORAL
20 MG, DAILY, ORAL				
		Prednisone (Prednisone)	C	ORAL
20 MG, 2 IN 1 DAY(S), ORAL				
		Leukeran (Chlorambucil)	C	

Date:09/20/02ISR Number: 3979396-0Report Type:Expedited (15-DaCompany Report #APCDSS2002000429
Age:37 YR Gender:Male I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Anorexia
	Blood Creatine Phosphokinase Increased
	Blood Pressure Increased
	Delusion

	Diabetes Mellitus Hallucination Hypoventilation	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Insomnia Respiratory Distress	Foreign Health	Haldol(Tablet)(Haloperidol)	PS		ORAL	MG, DAILY,
	Schizophrenia	Professional					ORAL;SEE
							IMAGE
			Risperdal (Tablet) (Risperidone)	SS		ORAL	MG, DAILY,
							AORAL
			Hydroxyzine Pamoate	C			
			Estazolam (Estazolam)	C			
			Zopiclone (Zopiclone	C			
			Biperiden Hydrochloride(Biperiden Hydrochloride)	C			

Date:09/20/02ISR Number: 3979398-4Report Type:Expedited (15-DaCompany Report #EMADSS2002005247
Age:78 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Bacteria Urine Identified Cerebral Atrophy	Foreign Health	Haldol (2 Mg/Ml Drops)(Haloperidol)	PS		ORAL	20 DROPS,
	Coma	Professional					DAILY, ORAL
	Convulsion Dysphagia Enterobacter Infection Lung Infection Neuroleptic Malignant Syndrome Rhabdomyolysis		Equanil (Meprobamate)	C			
			Tanaakan (Ginkgo Tree Leaves Extract)	C			
			Moduretic (Moduretic)	C			
			Diffu K (Potassium Chloride)	C			
			Lopressor (Metoprolol Tartrate)	C			

Ogast (Lansoprazole)	C	
Lipanthyl (Fenofibrate)	C	

Date:09/20/02ISR Number: 3979400-XReport Type:Expedited (15-DaCompany Report #NSADSS2002032303
Age:21 MON Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Accidental Exposure Somnolence	Foreign Consumer	Haldol(Concentrate) (Haloperidol)	PS		ORAL	ORAL	

Date:09/20/02ISR Number: 3979403-5Report Type:Expedited (15-DaCompany Report #EMADSS20020054042
Age:70 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Medication Error Somnolence	Foreign Health Professional	Haldol Decanoate (Injection)(Haloperidol Decanoate)	PS		ORAL	50 MG, 5 IN NIGHT(S), ORAL	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/22/02ISR Number: 4013043-7Report Type:Periodic Company Report #A119959
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Leukopenia	Health Professional	Thiothixene (Tiotixene)	PS		ORAL		
			Zyprexa (Olanzapine)	SS				
			Haldol (Haloperidol)	SS				
			Seroquel (Quetiapine Fumarate)	SS				

Date:09/23/02ISR Number: 3979495-3Report Type:Expedited (15-DaCompany Report #EMADSS2002005441
Age:87 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Confusional State Disorientation Memory Impairment Opisthotonus	Foreign Health Professional	Haldol (1.5 Mg Tablet) (Haloperidol)	PS		ORAL	0.5 MG, 3 IN 1 DAILY,	ORAL
			Ciproxine (Ciprofloxacin)	SS		ORAL	500 MG, 2 IN 1 DAY(S),	ORAL
			Prednisone (Prednisone)	SS		ORAL	20 MG, 2 IN 1 DAY(S),	ORAL
			Sinemet (Sinemet)	SS			DOSE DECREASED ON 10-MAR-02	
			Antra (Omeprazole)	SS		ORAL	20 MG, DAILY,	

ORAL						
			Leukeran (Chlorambucil)	SS		ORAL
2 MG, 3 IN 1 DAY(S), ORAL						

Date:09/23/02ISR Number: 3979580-6Report Type:Expedited (15-DaCompany Report #APCDSS2002000429
Age:37 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anorexia Blood Creatine Phosphokinase Increased Blood Pressure Increased Diabetes Mellitus Hypoventilation Insomnia Respiratory Distress Schizophrenia	Foreign Health Professional	Risperdal (Tablet) (Risperidone)	PS		ORAL	MG, DAILY, ORAL	
			Haldol (Tablet) (Haloperidol)	SS		ORAL	MG, DAILY, ORAL	
			Quetiapine Fumarate (Quetiapine Fumarate)	SS		ORAL	MG, DAILY, ORAL	
			Hydroxyzine Pamoate (Hydroxyzine)	C				
			Estazolam (Estazolam)	C				
			Zopiclone (Zopiclone)	C				
			Biperiden Hydrochloride (Biperiden Hydrochloride)	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/24/02ISR Number: 3981278-5Report Type:Expedited (15-DaCompany Report #NSADSS2002032586
Age:41 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Literature	Haldol (Injection)					
	Drug Abuser	Health	(Haloperidol)	PS		PARENT		
		Professional	Diazepam (Diazepam)	SS		PARENT		
			Diphenhydramine (Diphenhydramine)	C				

Date:09/24/02ISR Number: 3981831-9Report Type:Expedited (15-DaCompany Report #NSADSS2002032584
Age:43 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Intentional Misuse	Literature	Haldol (Unspecified)					
		Health	(Haloperidol)	PS		ORAL		
		Professional	Trazodone (Trazodone)	SS		ORAL		

Date:09/24/02ISR Number: 3981832-0Report Type:Expedited (15-DaCompany Report #NSADSS2002032591
Age:58 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Death	Literature	Haldol (Unspecified)					
		Health	(Haloperidol)	PS		ORAL		
		Professional	Propranolol (Propranolol)	SS		ORAL		

Date:09/24/02ISR Number: 3981833-2Report Type:Expedited (15-DaCompany Report #NSADSS2002032593
Age:22 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Death	Completed Suicide	Literature	Haldol (Unspecified)			
		Health	(Haloperidol)	PS		ORAL
ORAL						
		Professional	Fluoxetine			
			(Fluoxetine)	SS		ORAL
ORAL						

Date:09/25/02ISR Number: 3981328-6Report Type:Direct Company Report #CTU 177109
Age:61 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Akathisia		Haloperidol	PS				
	Extrapyramidal Disorder		Haloperidol Tab	SS		ORAL	2MGPO	
Required Intervention to Prevent Permanent Impairment/Damage			Chlorpromazine	C				

Date:09/25/02ISR Number: 3981632-1Report Type:Expedited (15-DaCompany Report #PHBS2002JP10378
Age:46 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Impaired Healing	Foreign	Carbamazepine(Carbam					
	Suicide Attempt	Literature	azepine) Unknown	PS		ORAL		
ORAL								
	Thermal Burn	Health	Haloperidol(Haloperi					
	Transplant Rejection	Professional	dol)	SS				
		Other	Levomepromazine(Levo					

			mepromazine)	SS			

Date:09/25/02ISR Number: 3982009-5Report Type:Expedited (15-DaCompany Report #EMADSS2002004498
Age:21 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Angioneurotic Oedema Dystonia	Foreign Health Professional	Haldol (2 Mg/Ml Solution) (Haloperidol)	PS		ORAL	4MG, DAILY, ORAL

Date:09/26/02ISR Number: 3982377-4Report Type:Expedited (15-DaCompany Report #FLUV00302002187
Age:20 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Life-Threatening Hospitalization - Initial or Prolonged	Convulsion Depressed Level Of Consciousness	Foreign Health Professional	Depromel 25 (Fluvoxamine Maleate)	PS		ORAL	25 MG BID PO
	Hyperammonaemia Inadequate Diet	Other	Haloperidol (Haloperidol)	SS		ORAL	5 MG DAILY
	Laboratory Test Abnormal						IM, 2.25 MG
	Muscle Twitching						DAILY PO
	Ornithine Transcarbamoylase Deficiency Status Epilepticus		Levomepromazine Maleate (Levomepromazine Maleate)	SS		ORAL	5 MG DAILY PO
			Diazepam (Diazepam)	C			
			Paroxetine Hydrochloride (Paroxetine Hydrochloride)	C			
			Bromazepam (Bromazepam)	C			
			Chlorpromazine And Preparations				

				(Chlorpromazine)	C		
				Etizolam (Etizolam)	C		
				Alprazolam (Alprazolam)	C		
				Biperiden Hydrochloride (Biperiden Hydrochloride)	C		

Date:09/27/02ISR Number: 3982526-8Report Type:Direct Company Report #CTU 177434
Age:25 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Speech Disorder Tongue Disorder Torticollis		Haloperidol	PS				

Date:09/27/02ISR Number: 3982959-XReport Type:Direct Company Report #CTU 177501
Age:73 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Neuroleptic Malignant Syndrome		Haloperidol	PS		INTRAVENOUS BOLUS	1MG Q4H PRN	

INTRAVENOUS

BO

			Bupropion Sr 100 Mg	SS		ORAL

100 MG QD

ORAL

			Seroquel	C		

Date:09/27/02ISR Number: 3983624-5Report Type:Expedited (15-DaCompany Report #EMADSS2002005441
Age:87 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Disability	Agitation	Foreign	Haldol (1.5 Mg			
	Confusional State	Health	Tablet)			
	Disorientation	Professional	(Haloperidol)	PS		ORAL

0.5 MG, 3 IN

	Memory Impairment					

1 DAILY, ORAL

	Opisthotonus		Ciproxine			
			(Ciprofloxacin)	SS		ORAL

500 MG, 2 IN

1 DAY(S),

ORAL

			Prednisone			
			(Prednisone)	SS		ORAL

20 MG, 2 IN 1

DAY(S), ORAL

			Sinemet (Sinemet)	SS		

DOSES

DECREASED ON

10-MAR-02

			Antra (Omeprazole)	SS		ORAL

20 MG, DAILY,

ORAL

			Leukeran			
			(Chlorambucil)	SS		ORAL

2 MG, 3 IN 1

DAY(S), ORAL

Date:09/27/02ISR Number: 3983650-6Report Type:Expedited (15-DaCompany Report #02P-087-0192829-00
Age:72 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Neuroleptic Malignant Syndrome Pneumonia Refusal Of Treatment By Patient Renal Impairment Staphylococcal Infection Tremor	Foreign Literature Health Professional Other	Akineton Injection (Biperiden) (Biperiden) Haloperidol Decanoate Fluphenazine Decanoate	PS SS SS		INTRAMUSCULAR INTRAMUSCULAR INTRAMUSCULAR INTRAMUSCULAR	5 MG, EVERY OTHER DAY, INTRAMUSCULAR 25 MG, 1 IN 2 WK, INTRAMUSCULAR	

Date:10/01/02ISR Number: 3985775-8Report Type:Expedited (15-DaCompany Report #2002002294
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Cardiac Failure Congestive Cardiomyopathy Condition Aggravated Ejection Fraction Decreased Ventricular Hypertrophy	Health Professional Company Representative	Geodon (Ziprasidone Hydrochloride) Haldol (Haloperidol) Cogentin (Benzatropine Mesilate)	PS SS C		INTRAMUSCULAR	160 MG (BID) 150 MG (EVERY FOUR WEEKS) ,	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/01/02ISR Number: 4027317-7Report Type:Periodic Company Report #2001UW07551
Age:24 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Required	Drooling	Health	Seroquel "Zeneca"	PS		ORAL	400 MG QAM PO
Intervention to	Neuroleptic Malignant	Professional	Seroquel "Zeneca"	SS		ORAL	1600 MG HS PO
Prevent Permanent	Syndrome		Haldol	SS		ORAL	5 MG BID PO
Impairment/Damage			Lithium	SS		ORAL	600 MG QAM PO
			Lithium	SS		ORAL	300 MG HS PO
			Propranolol	C			

Date:10/01/02ISR Number: 4027351-7Report Type:Periodic Company Report #2001UW11613
Age:80 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Neuroleptic Malignant	Health	Seroquel "Zeneca"	PS	Zeneca	ORAL	800 MG DAILY
Initial or Prolonged	Syndrome	Professional					PO
			Haldol	SS		ORAL	0.5 MG BID PO

Date:10/02/02ISR Number: 3984326-1Report Type:Expedited (15-DaCompany Report #2002SE05170
Age:87 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Required	Confusional State	Foreign	Antra	PS		ORAL	40 MG DAILY
Intervention to	Opisthotonus	Health					PO
Prevent Permanent		Professional	Ciproxine	SS		ORAL	1000 MG DAILY
Impairment/Damage		Other					PO

			Prednisone	SS		ORAL	40 MG DAILY
							PO
			Sinemet	SS		ORAL	3*25/250
							MG/PO
			Haldol	SS		ORAL	1.5 MG DAILY
							PO
			Leukeran	C			

Date:10/02/02ISR Number: 3984370-4Report Type:Direct Company Report #CTU 177797
Age:43 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Insomnia		Propranolol	PS			15MG/D	
Hospitalization - Initial or Prolonged	Mental Disorder		Haldolial X 2	SS			10 MG	
			Benztropine	SS				
Disability			Zyprexa	SS			5 MG/D	
Other			Diabetes Meds	C				
Required Intervention to Prevent Permanent Impairment/Damage								

Date:10/02/02ISR Number: 3985467-5Report Type:Direct Company Report #CTU 177744
Age:61 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Salivary Hypersecretion		Haloperidol Tab	PS		ORAL	15MG, 15MG	
							QHS, PO	
			Trazodone	C				
			Acetaminophen	C				
			Divalproex Ec					

			(Delayed Release)	C		
			Olanapine	C		
			Clonazepam	C		
			Multivitamin	C		
			Felodipine	C		

Date:10/03/02ISR Number: 3987372-7Report Type:Expedited (15-DaCompany Report #02P-008-0200591-00
Age:50 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Life-Threatening	Coma	Foreign	Epilim Tablets				
Hospitalization -	Condition Aggravated	Health	(Sodium Valproate)				
Initial or Prolonged	Delirium	Professional	(Sodium Valproate)				
	Hallucination, Auditory	Other	(Sodium Valproate)	PS		ORAL	10 GM, ONCE,
	Intentional Misuse						ORAL
			Olanzapine	SS		ORAL	2.5 GM, ONCE,
							ORAL
			Haloperidol	SS		ORAL	100 MG, ONCE,
							ORAL
			Trifeme	C			
			Bekunis	C			

Date:10/03/02ISR Number: 3988019-6Report Type:Expedited (15-DaCompany Report #2002003203
Age:24 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Abnormal Behaviour	Foreign	Sertraline				
Initial or Prolonged	Confusional State	Consumer	(Sertraline)	PS		ORAL	200 MG
Disability	Convulsion						(DAILY), ORAL
Other	Fall		Haloperidol				
	Loss Of Consciousness		(Haloperidol)	SS			
	Memory Impairment		Clozapine				
	Palpitations		(Clozapine)	SS			
	Social Avoidant Behaviour		Deptran (Doxepin				

			Hydrochloride0	SS		
75 MG DAILY						
			Oxycodone (Oxycodone)	C		

Date:10/04/02ISR Number: 3988319-XReport Type:Expedited (15-DaCompany Report #NSADSS2002033980
Age:1 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Hyperthermia Malignant	Foreign Health Professional	Haldol (Unspecified) (Haloperidol)	PS		
			Clomipramine (Clomipramine)	C		

Date:10/04/02ISR Number: 3988336-XReport Type:Expedited (15-DaCompany Report #APCDSS2002001111
Age:53 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Leukopenia Restlessness	Foreign Health Professional	Risperdal (Tablet) (Risperidone)	PS		ORAL
ORAL						
			Haloperidol (Haloperidol)	SS		
			Biperiden Hydrochloride (Biperiden			

				Hydrochloride)	SS		
INTRAMUSCULAR	IM						
				Antiepileptics (Antiepileptics)	C		

Date:10/08/02ISR Number: 3989592-4Report Type:Expedited (15-DaCompany Report #2002002294
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Cardiac Failure	Health	Geodon (Ziprasidone)	PS			160 MG (BID)
Initial or Prolonged	Congestive	Professional	Haldol (Haloperidol)	SS			INTRAMUSCULAR 150 MG (Q4W),
Other	Cardiomyopathy						INTRAMUSCULAR
	Ventricular Hypertrophy		Klonopin (Clonazepam)	SS			4 MG (DAILY)
			Cogentin (Benzatropine Mesilate)	C			

Date:10/08/02ISR Number: 3989743-1Report Type:Direct Company Report #CTU 178236
Age:76 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Neuroleptic Malignant		Quitiapine 25 Mg	PS		ORAL	25 MG BID &
Initial or Prolonged	Syndrome						50 MG ORAL
	Renal Failure Acute		Haloperidol 5mg/Ml Inj	SS			
			Sertraline	C			
			Furosemide	C			
			Docusate	C			
			Enalapril	C			
			Pantoprazole	C			
			Ipratropium	C			

Date:10/09/02ISR Number: 3991000-4Report Type:Expedited (15-DaCompany Report #NSADSS2002035141
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Death	Health Professional	Haldol (Injection) (Haloperidol)	PS		INTRAVENOUS	60 MG,	24 HOUR(S), IV

Date:10/10/02ISR Number: 3992166-2Report Type:Expedited (15-DaCompany Report #PHBS2002AU08140
Age:27 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Aspiration	Foreign	Clozaril (Clozapine)					
	Completed Suicide	Study	Tablet	PS		ORAL	400 MG/DAY,	
	Overdose	Health Professional Other	ORAL Olanzapine (Olanzapine)	SS				
			Haloperidol (Haloperidol)	SS				
			Metazapine ()	SS				
			Clonidine Hydrochloride (Clonidine Hyrdochloride)	SS				

Date:10/15/02ISR Number: 3993448-0Report Type:Expedited (15-DaCompany Report #APCDSS2002001072
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anorexia Blood Cholinesterase Decreased Pyrexia	Foreign Health Professional	Risperdal (Risperidone) Haldol (Haloperidol)	PS SS		ORAL ORAL		

Date:10/15/02ISR Number: 3993449-2Report Type:Expedited (15-DaCompany Report #APCDSS2002001111
Age:50 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Leukopenia Restlessness	Foreign Health Professional	Risperdal (Tablet) (Risperidone) Haloperidol (Haloperidol) Biperiden Hydrochloride (Biperiden Hydrochloride) Antiepileptics (Antiepileptics)	PS SS SS C		ORAL INTRAMUSCULAR	IM	

Date:10/15/02ISR Number: 3993457-1Report Type:Expedited (15-DaCompany Report #EMADSS2002006037
Age:15 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Accidental Exposure Akathisia Anxiety Euphoric Mood Eye Movement Disorder Hallucination	Foreign Consumer	Haldol (5 Mg Tablet) (Haloperidol)	PS		ORAL	5 MG, 3 IN 1	DAY(S), ORAL 4 DAY

Headache
Insomnia
Medication Error
Muscle Spasms
Nervousness
Pharyngolaryngeal Pain
Pyrexia
Tachycardia
Vision Blurred

Date:10/15/02ISR Number: 3993458-3Report Type:Expedited (15-DaCompany Report #APCDSS2002001072
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anorexia Blood Cholinesterase Decreased Pyrexia	Foreign Health Professional	Haldol (Haloperidol) Risperdal (Risperidone)	PS SS		ORAL ORAL	ORAL ORAL	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/15/02ISR Number: 3993459-5Report Type:Expedited (15-DaCompany Report #EMADSS2002006058
Age:32 MON Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Aphasia Depressed Level Of Consciousness Extrapyramidal Disorder Hypertonia Overdose Urinary Retention	Foreign Health Professional	Haldol Faible (0.5 Mg/Ml Solution) (Haloperidol)	PS		ORAL	8 MG, DAILY, ORAL	

Date:10/16/02ISR Number: 3992999-2Report Type:Direct Company Report #CTU 178839
Age:61 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Extrapyramidal Disorder		Haloperidol Haloperidol Tab Chlorpromazine Tab	PS SS C		ORAL	MGPO	

Date:10/16/02ISR Number: 3993158-XReport Type:Expedited (15-DaCompany Report #PHEH2002US08129
Age:61 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Aggression Drug Interaction Face Oedema Oedema Rash Tongue Oedema	Study Health Professional	Exelon (Rivastigmine) Haloperidol (Haloperidol) Wellbutrin (Bupropion Hydrochloride) Artane (Trihexyphenidyl	PS SS C		ORAL	SEE IMAGE	

			Hydrochloride)	C		
			Celexa	C		

Date:10/16/02ISR Number: 3995495-1Report Type:Expedited (15-DaCompany Report #EMADSS2002006126
Age:26 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Activated Partial Thromboplastin Time	Foreign Health	Haldol (Unspecified) (Haloperidol)	PS		ORAL	DAILY, ORAL	
	Prolonged	Professional	Implanon					
	Antinuclear Antibody		(Progesterone)	SS		SUBCUTANEOUS	SUBCU	
	Positive		Birodogyl					
	Dna Antibody Positive		(Spiramycin)	C				
			Mepronizine (Mepronizine)	C				

Date:10/16/02ISR Number: 3995859-6Report Type:Expedited (15-DaCompany Report #2002AP02947
Age:44 YR Gender:Female I/FU:F

Outcome
Life-Threatening
Hospitalization -

Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Anger	Foreign	Seroquel	PS		ORAL	100 MG DAILY	
	Cerebrovascular Disorder	Health					PO	
	Coma	Professional	Tegretol	SS		ORAL	1 G DAILY PO	
	Condition Aggravated	Other	Tasmolin	SS		ORAL	0.3 G DAILY	
	Crying						PO	
	Dehydration		Gramalil	SS		ORAL	0.6 G DAILY	
	Disseminated						PO	
	Intravascular Coagulation		Serenace	SS				
	Euphoric Mood		Fludecasin	SS			250 MG ONCE	
	Glycosylated Haemoglobin						IM	
	Increased		Solon	C				
	Haemodialysis		Linton	C				
	Hyperglycaemia		Magnesium Oxide	C				
	Hypernatraemia		Cercine	C				
	Insomnia							
	Ischaemia							
	Malnutrition							
	Neuroleptic Malignant Syndrome							
	Renal Failure Acute							
	Shock							
	White Blood Cell Count Increased							

Date:10/17/02ISR Number: 3995910-3Report Type:Expedited (15-DaCompany Report #NSADSS2002032586
Age:41 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Aggression	Literature	Haldol (Injection)					
Required	Agitation	Health	(Haloperidol)	PS		INTRAMUSCULAR	IM	

Intervention to	Electromechanical	Professional	Diazepam (Diazepam)	SS			
INTRAMUSCULAR IM							
Prevent Permanent	Dissociation		Cogentin				
Impairment/Damage	Respiratory Arrest		(Benzatropine Mesilate)	SS			
INTRAMUSCULAR IM							
			Diphenhydramine (Diphenhydramine)	SS			
INTRAMUSCULAR IM							

Date:10/17/02ISR Number: 3995911-5Report Type:Expedited (15-DaCompany Report #NSADSS2002032584
Age:43 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardiac Arrest	Literature	Haldol (Haloperidol)	PS		ORAL	ORAL	
	Medication Error	Health Professional	Trazodone (Trazodone)	SS		ORAL	ORAL	

Date:10/17/02ISR Number: 3995913-9Report Type:Expedited (15-DaCompany Report #NSADSS2002032593
Age:22 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Body Temperature	Literature	Haldol (Haloperidol)	PS		ORAL	ORAL	
Required Intervention to Prevent Permanent Impairment/Damage	Increased Cardiac Arrest Coma Completed Suicide Overdose	Health Professional	Fluoxetine (Fluoxetine)	SS		ORAL	ORAL	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/17/02ISR Number: 3995914-0Report Type:Expedited (15-DaCompany Report #NSADSS2002032591
Age:58 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Circulatory Collapse	Literature	Haldol (Haloperidol)	PS		ORAL		
	Coma	Health Professional	Propranolol (Propranolol)	SS		ORAL		
	Electromechanical Dissociation		Olanzapine (Olanzapine)	C				
			Clonazepam (Clonazepam)	C				
			Lorazepam (Lorazepam)	C				
			Prednisone (Prednisone)	C				

Date:10/17/02ISR Number: 3997315-8Report Type:Expedited (15-DaCompany Report #002#2#2002-00109
Age:43 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Arthralgia	Consumer	Reglan (Metoclopramide Hcl)	PS		ORAL	10 MG, 4 IN 1	
Disability	Blepharospasm						D, ORAL	
	Blood Pressure Increased							
	Bruxism		Prochlorperazine - Edisylate	SS				
	Conversion Disorder		Haloperidol	SS				
	Dizziness		Gabapentin	SS				
	Dystonia		Olanzapine	SS				
	Eye Disorder		Lisinopril	C				
	Feeling Abnormal		Diazepam	C				
	Grimacing		Mylanta	C				
	Haemangioma		Metoprolol	C				
	Halo Vision		Heparin	C				
	Movement Disorder		Clopidogrel	C				
	Muscle Spasms							
	Nausea							
	Nervousness							
	Nightmare							
	Pain							
	Paraesthesia							

	Photopsia					
	Photosensitivity Reaction					
	Restlessness					
	Strabismus					
	Tardive Dyskinesia					

Date:10/18/02ISR Number: 3995748-7Report Type:Expedited (15-DaCompany Report #FLUV00302002187
Age:20 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Life-Threatening Hospitalization - Initial or Prolonged	Depressed Level Of Consciousness Hyperammonaemia	Foreign Health Professional	Depromel 25 (Fluvoxamine Maleate)	PS		ORAL	25 MG BID PO
	Laboratory Test Abnormal Pneumonia Status Epilepticus	Other	Haloperidol (Haloperidol)	SS		ORAL	5 MG DAILY IM, 2.25 MG DAILY PO
			Levomepromazine Maleate (Levomepromazine Maleate)	SS		ORAL	5 MG DAILY PO

Diazepam (Diazepam)	C
Paroxetine Hydrochloride (Paroxetine Hydrochloride)	C
Bromazepam (Bromazepam)	C
Chlorpromazine And Preparations (Chlorpromazine)	C
Etizolam (Etizolam)	C
Alprazolam (Alprazolam)	C
Biperiden Hydrochloride (Biperiden Hydrochloride)	C

Date:10/18/02ISR Number: 3996752-5Report Type:Expedited (15-DaCompany Report #APCDSS2002001072
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anorexia	Foreign	Haldol (Unspecified)					
	Blood Cholinesterase Decreased	Health Professional	(Haloperidol)	PS		ORAL	ORAL	
	Pyrexia		Risperdal (Unspecified) (Risperidone)	SS		ORAL	ORAL	

Date:10/18/02ISR Number: 3997789-2Report Type:Expedited (15-DaCompany Report #APCDSS2002001072
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anorexia	Foreign	Risperdal					
	Blood Cholinesterase Decreased	Health Professional	(Unspecified) (Risperidone)	PS		ORAL	ORAL	
	Chemical Poisoning		Haladol					
	Pyrexia		(Unspecified)					

			(Haloperidol)	SS		ORAL

ORAL

Date:10/21/02ISR Number: 3998829-7Report Type:Expedited (15-DaCompany Report #EMADSS2002005148
Age:1 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Accidental Exposure Asthenia	Foreign Health	Haldol (5 Mg Tablet) (Haloperidol)	PS		ORAL	DAILY	ORAL
	Confusional State Cyanosis Depressed Level Of Consciousness Extrapyramidal Disorder Hypertonia Screaming Somnolence	Professional	Acidum Acetylsalicylicum (Acetylsalicylic Acid) Paracetamol (Paracetamol)	C C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/21/02ISR Number: 3998832-7Report Type:Expedited (15-DaCompany Report #EMADSS2002006159
Age:77 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Abdominal Pain Upper	Foreign	Haldol (Haloperidol)	PS		ORAL	0.5 MG NIGHT	
Initial or Prolonged	Alanine Aminotransferase Increased	Health Professional	Warfarin (Warfarin)	C			(S) ORAL	
	Blood Alkaline Phosphatase Increased		Lisinopril (Lisinopril)	C				
	Blood Bilirubin Increased		Co-Tenidone (Tenoretic)	C				
	Gamma-Glutamyltransferase Increased							
	Hepatic Function Abnormal							

Date:10/22/02ISR Number: 3997820-4Report Type:Expedited (15-DaCompany Report #2002061792
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Coma	Foreign	Sinequan (Doxepin)	PS		ORAL	ORAL	
Initial or Prolonged	Pneumonia	Health	Haloperidol	SS				
Other	Status Epilepticus	Professional						

Date:10/25/02ISR Number: 3999262-4Report Type:Direct Company Report #CTU 179557
Age:47 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hypotension		Haloperidol Decanoate 100mg/Ml	PS				

Date:10/28/02ISR Number: 3999417-9Report Type:Direct Company Report #CTU 179712
Age:68 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Joint Stiffness		Haldol	PS				

Date:10/29/02ISR Number: 4001346-1Report Type:Expedited (15-DaCompany Report #APCDSS2002001248
Age:35 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardiac Failure	Foreign Health Professional	Risperidone (Tablet) (Risperidone)	PS		ORAL		
			Haloperidol (Haloperidol)	SS		ORAL		
			Sodium Valproate (Valproate Sodium)	SS		ORAL		
			Paroxetine Hydrochloride Hydrate (Paroxetine Hydrochloride)	C				
			Paroxetine Hydrochloride	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/29/02ISR Number: 4003129-5Report Type:Expedited (15-DaCompany Report #APCDSS2002001248
Age:35 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardiac Failure	Foreign Health Professional	Haloperidol (Haloperidol)	PS		ORAL		
			Riseperidone (Tablet) (Risperidone)	SS		ORAL		
			Sodium Valproate (Valproate Sodium)	SS		ORAL		
			Paroxetine Hydrochloride Hydrate (Paroxetine Hydrochloride)	C				

Date:10/30/02ISR Number: 4003562-1Report Type:Expedited (15-DaCompany Report #PHBS2001BR07808
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dermatosis Inguinal Hernia Laboratory Test Abnormal Pruritus Rash Serum Serotonin Decreased	Foreign Consumer Other	Anafranil (Clomipramine Hydrochloride)	PS				
			Mellaril (Thioridazine Hcl) (Thioridazine Hydrochloride, Thioridazine	SS				
			Orap (Pimozide)	SS				
			Piportil (Pipotiazine)	SS				
			Artane (Trihexyphenidyl Hydrochloride)	SS				
			Haldol "Janssen" (Haloperidol)	SS	Janssen			
			Anatensol (Fluphenazine Hydrochloride)	SS				
			Fenergan					

			(Promethazine)	SS		
			Dipyrone (Metamizole Sodium)	SS		
			Neozine (Levomepromazine)	C		

Date:10/31/02ISR Number: 4004286-7Report Type:Expedited (15-DaCompany Report #EMADSS2002006449
Age:41 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Rhabdomyolysis	Foreign Health Professional	Haldol Decanoas (50 Mg/Ml Injection) (Haloperidol Decanoate)	PS		
INTRAMUSCULAR 300 MG, 1 IN 30 DAY(S), IM						
			Haldol (Unspecified) (Haloperidol)	SS		ORAL
30 MG, DAILY, ORAL						
			Depamide (Valpromide)	SS		ORAL
600 MG,						

DAILY, ORAL

			Tercian (Cyamemazine)	SS		ORAL

300 MG,

DAILY, ORAL

Date:11/01/02ISR Number: 4005268-1Report Type:Expedited (15-DaCompany Report #APCDSS2002001273
Age:36 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Completed Suicide	Foreign Health Professional	Haldol (Unspecified) (Haloperidol)	PS		

MG, DAILY

			Risperidone (Unspecified) (Risperidone)	SS		ORAL

MG, DAILY;

ORAL

Date:11/04/02ISR Number: 4005963-4Report Type:Expedited (15-DaCompany Report #HQ4951730OCT2002
Age:41 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Death	Literature	Diazepam (Diazepam, Unspec)	PS		
			Diphenhydramine Hcl (Diphenhydramine Hydrochloride, Unspec)	SS		
			Haloperidol (Haloperidol,)	SS		

Date:11/04/02ISR Number: 4006070-7Report Type:Expedited (15-DaCompany Report #EMADSS2002006529
Age:40 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						

Hospitalization - Initial or Prolonged	Asthenia Confusional State Disturbance In Attention Epilepsy Headache Hyperhidrosis Medication Error Memory Impairment Weight Increased	Foreign Health Professional	Haldol (2mg/Ml Solution) (Haloperidol)	PS		ORAL 7 MG, DAILY, ORAL

Date:11/04/02ISR Number: 4006217-2Report Type:Expedited (15-DaCompany Report #PHBS2001BR07808
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Other	Blood Pressure Increased Dermatosis Inguinal Hernia Laboratory Test Abnormal Malaise Metabolic Function Test Abnormal Pruritus Rash Generalised Serum Serotonin Decreased	Foreign Consumer Other	Anafranil (Clomipramine Hydrochloride) Mellaril (Thioridazine Hcl)(Thioridazine Hydrochloride, Thioridazine Orap (Pimozide) Piportil (Pipotizaine)	PS SS SS SS		

				Fenergan (Promethazine)	SS		
				Artane (Trihexyphenidyl Hydrochloride)	SS		
				Anatensol (Fluphenazine Hydrochloride)	SS		
				Akineton (Biperiden Hydrochloride)	SS		
				Dipyrone	SS		
				Neozine	SS		
				Haldol	SS		

Date:11/05/02ISR Number: 4006181-6Report Type:Expedited (15-DaCompany Report #135898USA
Age:79 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accident	Health	Haloperidol	PS				
	Agitation	Professional						
	Mouth Haemorrhage							
	Mouth Injury							

Date:11/05/02ISR Number: 4006731-XReport Type:Expedited (15-DaCompany Report #HQ4976031OCT2002
Age:43 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Death	Literature	Diphenhydramine Hcl (Diphenhydramine Hydrochloride, Injection)	PS				
			Diazepam (Diazepam, Vial Injection, 5 Mg/Ml)	SS				
			Haloperidol (Haloperidol)	SS				

Date:11/06/02ISR Number: 4007664-5Report Type:Expedited (15-DaCompany Report #HQ5017101NOV2002
Age:58 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Unevaluable Event	Literature	Inderal (Propranolol Hydrochloride, Unspec)	PS		ORAL		
			Haloperidol (Haloperidol,)	SS		ORAL		

Date:11/06/02ISR Number: 4008485-XReport Type:Expedited (15-DaCompany Report #APCDSS2002001273
Age:36 YR Gender:Female I/FU:F

Outcome	PT
Death	Completed Suicide
	Disturbance In Attention
	Fatigue
	Hallucination, Auditory
	Malaise

		Muscle Rigidity Somnolence Treatment Noncompliance	Report Source	Product	Role	Manufacturer	Route	Dose Duration
			Foreign Health Professional	Haldol (Unspecified) (Haloperidol)	PS		ORAL	MG, DAILY, ORAL
				Risperidone (Unspecified) (Risperidone)	SS		ORAL	MG, DAILY, ORAL
				Trihexyphenidyl Hydrochloride (Trihexyphenidyl Hydrochloride)	C			
				Biperiden Hydrochloride (Biperiden Hydrochloride)	C			
				Chlorpromazine Hydrochloride (Chlorpromazine Hydrochloride)	C			

Date:11/07/02ISR Number: 4005475-8Report Type:Direct Company Report #CTU 180509
Age:32 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Required Intervention to Prevent Permanent Impairment/Damage	Neuroleptic Malignant Syndrome		Haldol	PS		INTRAVENOUS	10-20 MG IV Q 4-6 HOURS

Date:11/07/02ISR Number: 4008607-0Report Type:Expedited (15-DaCompany Report #EMADSS2002005148
Age:1 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Asthenia Depressed Level Of Consciousness Extrapyramidal Disorder Hypertonia Skin Discolouration Somnolence	Foreign Health Professional	Haldol (Haloperidol) Acidum Acetylsalicylicum (Acetylsalicylic Acid) Paracetamol (Paracetamol)	PS C C		ORAL	DAILY, ORAL	

Date:11/07/02ISR Number: 4009511-4Report Type:Expedited (15-DaCompany Report #2002CG01642
Age:80 YR Gender:Male I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Aspartate Aminotransferase Increased Gamma-Glutamyltransferase Increased Hepatomegaly Lymphadenopathy Rash

Rash Maculo-Papular

Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Foreign	Nexium	PS		ORAL	20 MG DAILY	PO
Health Professional	Kardegic	SS		ORAL	75 MG DAILY	PO
Other	Paracetamol	SS		ORAL	500 MG DAILY	PO
	Trivastal	SS		ORAL	50 MG DAILY	PO
	Haldol "Janssen"	SS	"Janssen"	ORAL	5 DF DAILY	PO
	Nootropyl	SS		ORAL	3 DF DAILY	PO

Date:11/08/02ISR Number: 4009346-2Report Type:Expedited (15-DaCompany Report #NSADSS2002039470
Age:47 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Ageusia Anhedonia Feeling Abnormal Posture Abnormal	Consumer	Haldol (Injection) (Haloperidol) Xanax (Alprazolam) Restoril (Temazepam)	PS C C				, 1

Date:11/12/02ISR Number: 4008401-0Report Type:Direct Company Report #CTU 180781
Age:61 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Akathisia		Haloperidol	PS				

Initial or Prolonged	Extrapyramidal Disorder		Haloperidol Tab	SS		ORAL
2 MG PO						
Required			Chlorpromazine	C		
Intervention to						
Prevent Permanent						
Impairment/Damage						

Date:11/18/02ISR Number: 4013494-0Report Type:Expedited (15-DaCompany Report #EMADSS2002006908
Age:55 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Acromegaly	Foreign	Haldol (Unspecified)			
	Adenoma Benign	Consumer	(Haloperidol)	PS		
	Blood Prolactin Increased					

Date:11/18/02ISR Number: 4013495-2Report Type:Expedited (15-DaCompany Report #EMADSS2002006792
Age:90 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Cardio-Respiratory	Foreign	Haldol (5 Mg/Ml			
Life-Threatening	Distress	Health	Injection)			
	Coma	Professional	(Haloperidol)	PS		
SUBCUTANEOUS 8 MG, DAILY,						
	Medication Error					
SUBCU						
	Nervous System Disorder		Morphine (Morphine)	SS		
SUBCUTANEOUS 24, SUBCU						
	Overdose		Hydromorphine(Morphi			
			ne Hydrochloride)	SS		
			Antra (Omeprazole)	C		
			Robinul			
			(Glycopyronium			
			Bromide)	C		

			Sandostatine (Octreotide Acetate)	C			

Date:11/19/02ISR Number: 4014409-1Report Type:Expedited (15-DaCompany Report #200211-0770 (0)
Age:51 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Heat Stroke Rhabdomyolysis	Literature Health Professional	Benadryl - Formulation Unspecified (Diphenhydramine)	PS		ORAL	PER ORAL	
			Haloperidol (Haloperidol)	SS		ORAL	PER ORAL	

Date:11/20/02ISR Number: 4015975-2Report Type:Expedited (15-DaCompany Report #EMADSS2002006938
Age:93 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Hospitalization - Initial or Prolonged Disability Other Required Intervention to Prevent Permanent Impairment/Damage	Atrioventricular Block Complete Bronchopneumonia Electrocardiogram Qt Prolonged Insomnia Staphylococcal Infection Torsade De Pointes	Foreign Health Professional	Haldol (Solution) (Haloperidol)	PS		ORAL	0.6 MG, DAILY, ORAL	
			Zyprexa (Olanzapine)	SS		ORAL	2.5 MG, DAILY, ORAL	
			Madopar (Madopar)	C				
			Symmetrel (Amantadine Hydrochloride)	C				
			Sinemet-Cr (Sinemet)	C				
			Aspirine Cardio (Acetylsalicylic Acid)	C				
			Concor Cor (Bisoprolol Fumarate)	C				
			Dafalgan					

				(Paracetamol)	C		
				Imovane (Zopiclone)	C		
				Nitroderm Tts (Glyceryl Trinitrate)	C		

Date:11/22/02ISR Number: 4016117-XReport Type:Expedited (15-DaCompany Report #DEU-2002-0000194
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Coma	Foreign	Morphine Sulfate					
Life-Threatening	Drug Interaction	Health	Injectable(Morphine					
	Medication Error	Professional	Sulfate) Injectable	PS				
SUBCUTANEOUS							24 MG,	DAILY,
	Overdose	Other						
SUBCUTANEOUS								
			Hydromorphone Hcl(Hydromorphone Hydrochloride) Other	SS				
SUBCUTANEOUS							6 MG,	DAILY,
SUBCUTANEOUS								
			Haldol(Haloperidol)	SS				
SUBCUTANEOUS							8 MG,	DAILY,
SUBCUTANEOUS								
			Antra (Omeprazole) Ampoule Robinul	C				

			(Glycopyrronium Bromide) Ampoule	C		
			Sandostatine (Octreotide) Ampoule	C		

Date:11/22/02ISR Number: 4016428-8Report Type:Expedited (15-DaCompany Report #K200201908
Age:22 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide Intentional Misuse	Literature Health Professional	Haloperidol Decanoate (Haloperidol Decanoate) Injection, 50 Mg/Ml	PS		ORAL	ORAL	
			Fluoxetine (Fluoxetione)	SS		ORAL	ORAL	

Date:11/22/02ISR Number: 4016431-8Report Type:Expedited (15-DaCompany Report #K200201905
Age:41 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide Intentional Misuse	Literature Health Professional	Haloperidol Decanoate (Haloperidol Decanoate) Injection, 50 Mg/Ml	PS		ORAL	ORAL	
			Trazodone (Trazodone)	SS		ORAL	ORAL	

Date:11/22/02ISR Number: 4016433-1Report Type:Expedited (15-DaCompany Report #K200201907
Age:58 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Death	Literature Health	Haloperidol Decanoate					

		Professional	(Haloperidol Decanoate) Injection, 50 Mg/Ml	PS		ORAL
ORAL						
			Propanolol (Propanolol)	SS		ORAL
ORAL						

Date:11/22/02ISR Number: 4016438-0Report Type:Expedited (15-DaCompany Report #K200201906
Age:41 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Death	Death	Literature	Haloperidol			
		Health Professional	Decanoate (Haloperidol Decanoate) Injection, 50 Mg/Ml	PS		
PARENTERAL	PARENTERAL					
			Diphenhydramine (Diphenhydramine)	SS		
PARENTERAL	PARENTERAL					
			Diazepam (Diazepam)	SS		
PARENTERAL	PARENTERAL					

Date:11/25/02ISR Number: 4017414-4Report Type:Expedited (15-DaCompany Report #EMADSS2002006938
Age:93 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Life-Threatening	Atrioventricular Block Complete	Foreign Health Professional	Haldol (Solution) (Haloperidol)	PS		ORAL	0.6 MG, DAILY, ORAL
Hospitalization - Initial or Prolonged	Bronchopneumonia		Zyprexa (Olanzapine)	SS		ORAL	2.5 MG, DAILY, ORAL
Disability	Electrocardiogram Qt Prolonged		Madopar (Madopar)	C			
Required Intervention to Prevent Permanent Impairment/Damage	Electrocardiogram T Wave Abnormal		Symmetrical (Amantadine Hydrochloride)	C			
	Staphylococcal Infection		Sinemet-Cr (Sinemet)	C			
	Torsade De Pointes		Aspirine Cardio (Acetylsalicylic Acid)	C			
			Concor Cor (Bisoprolol Fumarate)	C			
			Dafalgan (Paracetamol)	C			
			Imovane (Zopiclone)	C			
			Nitroderm Tts (Glyceryl Trinitrate)	C			

Date:11/25/02ISR Number: 4017417-XReport Type:Expedited (15-DaCompany Report #EMADSS2002005214
Age:49 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Atrial Fibrillation	Foreign	Vesadol (Tablet)				
Required Intervention to Prevent Permanent	Atrial Flutter	Health Professional	(Haloperidol/Buzepide Metiodide)	PS		ORAL	1 TABLET, 2 IN 1 DAILY, ORAL
	Cardio-Respiratory Arrest						
	Circulatory Collapse						
	Congestive Cardiomyopathy						

Impairment/Damage	Electrocardiogram Qt Prolonged	Cordarone (Amiodarone Hydrochloride)	SS
	Malaise	Burinex (Bumetanide)	C
	Torsade De Pointes	Inexium (Esomeprazole Magnesium)	C
	Ventricular Fibrillation	Dicetel (Pnaverium Bromide)	C
		Avlocardyl (Propranolol)	C
		Hemigoxine (Digoxin)	C
		Vitamin K Antagonist (Vit K Antagonists)	C

Date:11/26/02ISR Number: 4017949-4Report Type:Expedited (15-DaCompany Report #EMADSS2002006995
Age:30 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardiomegaly	Foreign	Haldol (Haloperidol)	PS		ORAL	SEE IMAGE	
Life-Threatening	Deep Vein Thrombosis	Health	Diazepam (Diazepam)	SS		ORAL	SEE IMAGE	
	Depression	Professional	Taxilan (Perazine)	SS		ORAL	100 MG,	
	Pulmonary Embolism						DAILY, ORAL	
	Sedation		Akineton (Biperiden					

			Hydrochloride)	C		

Date:11/26/02ISR Number: 4018043-9Report Type:Expedited (15-DaCompany Report #NSADSS2002041880
Age:51 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Heat Stroke	Health Professional	Haldol (Unspecified) (Haloperidol)	PS				
	Rhabdomyolysis		Diphenhydramine (Diphenhydramine)	C				

Date:11/26/02ISR Number: 4018654-0Report Type:Expedited (15-DaCompany Report #325793
Age:30 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Decreased Activity	Foreign	Diazepam (Diazepam)	PS		ORAL	2.5 MG DAILY	
	Deep Vein Thrombosis	Study				ORAL		
	Depression	Health	Haldol (Haloperidol)	SS		ORAL	5 MG DAILY	
	Pulmonary Embolism	Professional				ORAL		
	Sedation		Taxilan (Perazine)	SS		ORAL	400 MG DAILY	
			Akineton (Biperiden Hydrochloride)	C				

Date:11/27/02ISR Number: 4019305-1Report Type:Expedited (15-DaCompany Report #STA-AE-02-MTX-217
Age:41 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Cheilitis	Foreign	Methotrexate	PS		ORAL	15MG, 1 X A WEEK, ORAL	10 MON
	Conjunctival Hyperaemia	Literature						

	Lacrimation Increased		Haloperidol	SS		
1.5 MG, BID						
	Nicotinic Acid Deficiency					
	Photophobia					
	Photosensitivity Reaction					
	Stomatitis					
	Vitamin B Complex Deficiency					
	Vitamin B2 Deficiency					

Date:11/29/02ISR Number: 4019146-5Report Type:Expedited (15-DaCompany Report #EMADSS2002007164
Age:17 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Arrhythmia	Foreign	Haldol (2 Mg/Ml Liquid)			
	Atrial Fibrillation	Health				
	Rhabdomyolysis	Professional	(Haloperidol)	PS		ORAL
12 MG, DAILY, ORAL						
			Depakine (Valproate Sodium)	SS		ORAL
400 MG, DAILY, ORAL						
			Zyprexa (Olanzapine)	SS		ORAL
10 MG, DAILY, ORAL						
			Tercian (Cyamemazine)	SS		ORAL
200 MG, DAILY, ORAL						

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/29/02ISR Number: 4019154-4Report Type:Expedited (15-DaCompany Report #EMADSS2002006215
Age:87 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Depressed Level Of Consciousness Dizziness Hallucination Inappropriate Antidiuretic Hormone Secretion	Foreign Health Professional	Durogesic (100 Mcg/Hr Patch) (Fentanyl)	PS			TEMPORARILY STOPPED	
			Haldol (Unspecified) (Haloperidol)	SS			20 MG, 1 IN 1	DAY(S),
			Godamed (Paynocil)	C				
			Madopar (Madopar)	C				

Date:11/29/02ISR Number: 4019446-9Report Type:Expedited (15-DaCompany Report #EMADSS2002006215
Age:87 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dizziness Hyponatraemia	Foreign Health Professional	Haldol (Unspecified) (Haloperidol)	PS			20 MG, 1 IN 1	DAY (S)
			Durogesic (100 Mcg/Hr Patch) (Fentanyl)	SS			TEMPORARILY STOPPED	
			Godamed (Paynocil)	C				
			Madopar (Madopar)	C				

Date:11/29/02ISR Number: 4019598-0Report Type:Expedited (15-DaCompany Report #NSADSS2002043378
Age:48 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Other	Blood Magnesium Decreased	Literature	Haldol (Unspecified)			
	Blood Potassium Decreased	Health	(Haloperidol)	PS		ORAL
210 MG, ORAL						
	Disease Recurrence	Professional	Orphenadrine			
	Electrocardiogram Qt		(Orphenadrine)	SS		ORAL
1400 MG, ORAL						
	Corrected Interval					
	Prolonged					
	Suicide Attempt					
	Torsade De Pointes					
	Ventricular Tachycardia					

Date:11/29/02ISR Number: 4019704-8Report Type:Expedited (15-DaCompany Report #135898USA
Age:79 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Laceration	Health	Haloperidol	PS		
	Mouth Haemorrhage	Professional	Roxanol	C		

Date:12/02/02ISR Number: 4017511-3Report Type:Expedited (15-DaCompany Report #B0284466A
Age:28 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Injury Asphyxiation	Consumer	Seroxat	PS	Glaxo Wellcome	ORAL
	Suicide Attempt		Dolmatil	SS		
200MG per day						
			Serenace	SS		
			Melleril	C		
			Zimovane	C		

			Faverin	C			
			Cogentin	C			

Date:12/03/02ISR Number: 4021473-2Report Type:Expedited (15-DaCompany Report #EMADSS2002003794
Age:33 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Interaction	Foreign	Haldol (Unspecified)					
	Hypertension	Health	(Haloperidol)	PS			5 MG, DAILY	
		Professional	Clozaril (Clozapine)	SS		ORAL	300 MG , DAILY ORAL	
			Epilim Chrono (Valproate Sodium)	C				

Date:12/05/02ISR Number: 4021653-6Report Type:Expedited (15-DaCompany Report #EMADSS2002007360
Age:48 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Creatinine Abnormal	Foreign	Haldol (Tablet)(Haloperidol)	PS		ORAL	6 TABLE, DAILY, ORAL	
	Haemoglobin Decreased	Health						
	Neutrophil Count Increased	Professional						
	Platelet Count Decreased		Nozinan (Levomepromazine)	SS		ORAL	50 DROP, DAILY, ORAL	
	Pyrexia		Loxapac(Loxapine Succinate)	SS		ORAL	ORAL	
			Depakote(Valproate Semisodium)	SS		ORAL	1000 MG, DAILY, ORAL	
			Combivir(Zidovudine					

			W/Lamivudine)	C		
			Viread(Tenofovir)	C		

Date:12/05/02ISR Number: 4024065-4Report Type:Expedited (15-DaCompany Report #EMADSS2002007369
Age:3 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agitation Confusional State Hallucination Mydriasis Sinus Tachycardia	Foreign Health Professional	Haldol (2 Mg/Ml Solution) (Haloperidol) Artane (Trihexyphenidyl Hydrochloride)	PS SS		ORAL ORAL	0.5 MG, 8 MG, DAILY,	DAILY, ORAL

Date:12/09/02ISR Number: 4020964-8Report Type:Direct Company Report #CTU 182411
Age:47 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Convulsion Epilepsy Fall Neuroleptic Malignant Syndrome Rhabdomyolysis		Clozaril 150 Mg Po Tid Haldol Decanoate 75 Mg Q Month Cogentin	PS SS C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/09/02ISR Number: 4023681-3Report Type:Expedited (15-DaCompany Report #PHBS2002NL14119
Age:40 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Condition Aggravated	Foreign	Carbamazepine(Carbamazepine) Unknown	PS			600 MG/DAY	
	Drug Interaction	Literature						
	Schizoaffective Disorder	Health Professional Other	Haloperidol(Haloperidol)	SS				

Date:12/10/02ISR Number: 4024902-3Report Type:Expedited (15-DaCompany Report #NSADSS2002044709
Age:34 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Bundle Branch Block Right	Literature	Haldol (Unspecified)					
Hospitalization -	Cardiac Arrest	Health	(Haloperidol)	PS		ORAL	5 MG, 2 IN 1	
Initial or Prolonged	Catatonia	Professional						DAY(S), ORAL
	Circulatory Collapse		Risperdal					
	Coma		(Unspecified)					
	Electrocardiogram Qt		(Risperidone)	SS		ORAL	SEE IMAGE	
	Corrected Interval		Amantadine					
	Prolonged		(Amantadine)	C				
	Electromechanical		Lorazepam					
	Dissociation		(Lorazepam)	C				
	Grand Mal Convulsion		Clozapine					
	Loss Of Consciousness		(Clozapine)	C				
	Orthostatic Hypotension							
	Supraventricular Extrasystoles							
	Tonic Clonic Movements							

Date:12/10/02ISR Number: 4025020-0Report Type:Expedited (15-DaCompany Report #NSADSS2002044709
Age:34 YR Gender:Female I/FU:I

Outcome	PT
Death	Aphasia
Hospitalization -	Back Pain

Initial or Prolonged	Blood Pressure Systolic Decreased
	Bundle Branch Block Right
	Cardiac Arrest
	Chest Wall Pain
	Convulsion
	Electrocardiogram Qrs Complex Abnormal
	Electrocardiogram Qrs Complex Prolonged
	Electromechanical Dissociation
	Flat Affect
	Loss Of Consciousness
	Orthostatic Hypotension
	Pain In Extremity
	Pharyngolaryngeal Pain
	Pyrexia
	Schizophrenia, Paranoid Type
	Supraventricular Extrasystoles
	Ventricular Extrasystoles

	White Blood Cell Count Increased						
		Report Source	Product	Role	Manufacturer	Route	Dose Duration
		Literature	Risperdal				
		Health	(Risperidone)	PS		ORAL	SEE IMAGE
		Professional	Haldol (Haloperidol)	SS		ORAL	5 MG, 2 IN 1 DAY(S), ORAL
			Amantadine (Amantadine)	C			
			Lorazepam (Lorazepam)	C			
			Clozapine (Clozapine)	C			

Date:12/10/02ISR Number: 4025032-7Report Type:Expedited (15-DaCompany Report #NSADSS2002043378
Age:48 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Other	Blood Glucose Increased	Literature	Haldol (Unspecified)				
	Blood Magnesium Decreased	Health	(Haloperidol)	PS		ORAL	210 MG, ORAL
	Cardiac Pacemaker Insertion	Professional	Orphenadrine (Orphenadrine)	SS		ORAL	1400 MG, ORAL
	Hypokalaemia						
	Hypotension						
	Overdose						
	Pulse Absent						
	Somnolence						
	Suicide Attempt						
	Torsade De Pointes						
	Ventricular Extrasystoles						
	Ventricular Tachycardia						

Date:12/10/02ISR Number: 4025415-5Report Type:Expedited (15-DaCompany Report #PHBS2002JP14142
Age:65 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blood Creatine Phosphokinase Increased	Foreign Health Professional Other	Tegretol (Carbamazepine) Tablet	PS		ORAL	100 MG, TID, ORAL	
			Serenace (Haloperidol)	SS				
			Hydantol (Phenytoin)	SS				

Date:12/11/02ISR Number: 4021751-7Report Type:Direct Company Report #CTU 182533
Age:22 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Extrapyramidal Disorder		Haldol	PS		ORAL	5MG PO QHS	

Date:12/11/02ISR Number: 4021753-0Report Type:Direct Company Report #CTU 182534
Age:53 YR Gender:Male I/FU:I

Outcome	PT
	Extrapyramidal Disorder
	Fatigue

	Gait Disturbance Tremor						
		Report Source	Product	Role	Manufacturer	Route	Dose Duration
			Ativan	PS			
			Haldol	SS			
			Mvi	C			
			Folic Acid	C			
			Thiamine	C			
			Geodon	C			
			Trileptal	C			
			Zyprexa	C			

Date:12/16/02ISR Number: 4026139-0Report Type:Direct Company Report #CTU 182739
Age:82 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Death	Ventricular Extrasystoles		Haldol 0.5mg Iv X 1	PS			
INTRAVENOUS	0.5MG IV X 1						
	Ventricular Tachycardia		Ativan	C			
			Haldol	C			

Date:12/16/02ISR Number: 4026880-XReport Type:Periodic Company Report #EMADSS2002007591
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Hemianopia Hyperprolactinaemia	Foreign Health	Serenase (Injection) (Haloperidol)	PS			INTRAMUSCULAR 200 M,
Disability	Pituitary Tumour	Professional					WEEKLY, IM ; Required 600 MG , Intervention to DAILY, IM
			Leponex (Clozapine)	SS			Prevent Permanent 600 MG, Impairment/Damage DAILY,
			Rivotril (Clonazepam)	C			

				Truxal (Chlorprothixene Hydrochloride)	C		
				Novaluzid (Novaluzide)	C		

Date:12/16/02ISR Number: 4026881-1Report Type:Expedited (15-DaCompany Report #EMADSS2002007590
Age:16 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Convulsions Local	Foreign	Haldol (Solution)					
	Dysphagia	Health	(Haloperidol)	PS		ORAL	ORAL	
	Medication Error	Professional						

Date:12/16/02ISR Number: 4026954-3Report Type:Expedited (15-DaCompany Report #NSADSS2002045324
Age:82 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cerebrovascular Accident	Consumer	Haldol (Injection)					
			(Haloperidol)	PS		INTRAVENOUS	IV	
			Ativan(Lorazepam)	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/16/02ISR Number: 4027031-8Report Type:Expedited (15-DaCompany Report #PHBS2002NL14119
Age:40 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Agitation	Foreign	Carbamazepine(Carbamazepine)	PS			600 MG/DAY	
	Condition Aggravated	Literature						
	Drug Interaction	Health Professional	Haloperidol (Haloperidol)	SS			INTRAMUSCULAR	SEE IMAGE
	Drug Level Decreased							
	Restlessness	Other	Haloperidol (Haloperidol)	SS		ORAL	15 MG/DAY, ORAL	
	Schizoaffective Disorder							
			Diazepam	C				
			Levomepromazine	C				

Date:12/16/02ISR Number: 4027135-XReport Type:Expedited (15-DaCompany Report #02P-056-0205684-00
Age:17 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Arrhythmia	Foreign	Depakine Tablets (Sodium Valproate)	PS		ORAL	400 MG, 1 IN 1 D, ORAL	
	Atrial Fibrillation	Health Professional						
	Rhabdomyolysis		(Sodium Valproate)					
	Tachycardia		(Sodium Valproate)					
			Olanzapine	SS		ORAL	10 MG, 1 IN 1 D, ORAL	
			Haloperidol	SS		ORAL	12 MG, 1 IN 1 D, ORAL	
			Cyamemazine	SS			200 MG, 1 IN 1 D	

Date:12/16/02ISR Number: 4030285-5Report Type:Expedited (15-DaCompany Report #PHBS2002DK14873
Age:38 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Disability	Hemianopia Homonymous Hyperprolactinaemia Pituitary Tumour Benign Visual Disturbance	Foreign Health Professional Other	Leponex(Clozapine)Tablet Serenase Dekanoat(Haloperidol Decanoate)Injection Rivotril Truxal (Chlorprothixene Hydrochloride)Tablet Norvalusid Tablet	PS SS C C C		ORAL INTRAMUSCULAR	600 MG/DL, 200 MG, QW, INTRAMUSCULAR	ORAL

Date:12/17/02ISR Number: 4027367-0Report Type:Periodic Company Report #M2002.0326
Age:85 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hallucination	Consumer Other	Haloperidol 1 Mg Tablet, Geneva Manufacturer Zestril Clonidine Nitro Levoxyl	PS C C C C	Geneva		3 TABLETS DAILY	

			Lasix	C		

Date:12/17/02ISR Number: 4028522-6Report Type:Expedited (15-DaCompany Report #EMADSS2002007648
Age:75 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Brain Scan Abnormal Cerebral Atrophy Gait Disturbance Hallucination Hypoacusis Miosis Vertigo	Foreign Health Professional	Haldol Faible (0.5 Mg/Ml Solution) (Haloperidol)	PS		ORAL	2 DROP, 3 IN	1 DAY (S), ORAL
			Seloken 100 (Metoprolol Tartrate)	SS		ORAL	50 MG, 2 IN 1	DAY (S), ORAL
			Sintron (Acenocoumarol)	SS			2 MG, 1 IN 1	DAY (S)

Date:12/17/02ISR Number: 4028525-1Report Type:Expedited (15-DaCompany Report #APCDSS2002000429
Age:37 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anorexia Blood Creatine Phosphokinase Increased Blood Pressure Increased Condition Aggravated Delusion Diabetes Mellitus	Foreign Health Professional	Risperdal (Tablet) (Risperidone)	PS		ORAL	MG, DAILY,	ORAL
			Haldol (Tablet) (Haloperidol)	SS		ORAL	MG, DAILY,	ORAL
			Quetiapine Fumarate					

	Hallucination		(Quetiapine				
	Hypoventilation		Fumarate)	SS			ORAL
MG, DAILY,							
	Insomnia						
ORAL							
	Respiratory Distress		Hydroxyzine Pamoate				
	Schizophrenia		(Hydroxyzine)	C			
			Estazolam				
			(Estazolam)	C			
			Zopiclone				
			(Zopiclone)	C			
			Biperiden				
			Hydrochloride				
			(Biperiden				
			Hydrochloride)	C			

Date:12/17/02ISR Number: 4029067-XReport Type:Expedited (15-DaCompany Report #APCDSS2002000429
Age:37 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Anorexia	Foreign	Haldol (Tablet)			
Initial or Prolonged	Blood Creatine	Health	(Haloperidol)	PS		ORAL
MG, DAILY,						
	Phosphokinase Increased	Professional				
ORAL						
	Blood Pressure Increased		Risperdal (Tablet)			
	Condition Aggravated		(Risperidone)	SS		ORAL
MG, DAILY,						
	Delusion					
ORAL						
	Diabetes Mellitus		Quetiapine Fumarate			
	Hallucination		(Quetiapine			
	Insomnia		Fumarate)	SS		ORAL
MG, DAILY,						
	Respiratory Distress					
ORAL						

				Hydroxyzine Pamoate (Hydroxyzine)	C		
				Estazolam (Estazolam)	C		
				Zopiclone (Zopiclone)	C		
				Biperiden Hydrochloride (Biperiden Hydrochloride)	C		

Date:12/18/02ISR Number: 4029104-2Report Type:Expedited (15-DaCompany Report #02H-163-0206057-00
Age:41 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardio-Respiratory Arrest	Literature Health Professional	Diphenhydramine Hcl Injection, Usp, 50mg/Ml (Diphenhydramine Hcl Injection	PS		PARENTERAL	PARENTERAL	
			Haloperidol	SS				
			Diazepam Injection, Usp, 5mg/Ml, 10 Ml Vials (Diazepam) (Diazepam)	SS				

Date:12/19/02ISR Number: 4031235-8Report Type:Expedited (15-DaCompany Report #02P-056-0206013-00
Age:48 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agranulocytosis Pancytopenia Pyrexia	Foreign Health Professional	Depakote Tablets (Depakote) (Divalproex Sodium) (Divalproex Sodium)	PS		ORAL	1000 MG, 1 IN 1 D, PER ORAL	
			Haloperidol	SS		ORAL	2MG, 1 IN 1	

D, PER ORAL

Levomepromazine	SS	ORAL

50 MG, 1 IN 1

D, PER ORAL

Loxapine Succinate	SS	ORAL

PER ORAL

Zidovudine W/Lamivudine	C
Viread	C
Peginterferon Alfa-2b	C

Date:12/23/02ISR Number: 4029203-5Report Type:Direct Company Report #CTU 183299
Age:61 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Neuroleptic Malignant Syndrome		Haldol	PS				

Date:12/23/02ISR Number: 4032199-3Report Type:Expedited (15-DaCompany Report #2002071040
Age:52 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Dystonia Fall Gait Disturbance Salivary Hypersecretion	Foreign Health Professional	Zoloft (Sertraline) Haldol (Haloperidol) Risperdal (Risperidone) Trimipramine Maleate Amlodipine Besilate Diazepam	PS SS SS C C C		ORAL	200 MG, ORAL 6 MG (DAILY) 4 MG, ORAL	

Date:12/23/02ISR Number: 4032369-4Report Type:Expedited (15-DaCompany Report #EMADSS2002004325
Age:70 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Creatine Phosphokinase Increased Blood Growth Hormone Decreased Blood Thyroid Stimulating Hormone Decreased C-Reactive Protein Increased Gonadotrophin Deficiency Leukocytosis Pyrexia Renal Failure	Foreign Health Professional	Haldol Faible (0.5 Mg/Ml Solution) (Haloperidol) Tercian (Cyamemazine) Hyperium (Rilmenidine) Insuline (Insulin)	PS SS C C		ORAL ORAL	25 DROPS, ORAL 25 MG, DAILY, ORAL	

Date:12/23/02ISR Number: 4032371-2Report Type:Expedited (15-DaCompany Report #EMADSS2002007830
Age:30 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Hospitalization - Initial or Prolonged	Convulsion Rhabdomyolysis	Foreign Health Professional	Haldol (Unspecified) (Haloperidol)	PS		
INTRAMUSCULAR	5 MG, DAILY, IM					
			Lepticur (Tropatepine Hydrochloride)	SS		
INTRAMUSCULAR	10 MG, DAILY, IM					
			Moditen (Fluphenazine Hydrochloride)	SS		ORAL
300 MG, DAILY, ORAL						
			Nozinan (Levomepromazine)	SS		
INTRAMUSCULAR	25 MG, DAILY, IM					
			Tegretol (Carbamazepine)	SS		ORAL
800 MG, DAILY, ORAL						
			Loxapac (Loxapine Succinate)	SS		
INTRAMUSCULAR	200 MG, DAILY, IM					
			Parkinane (Trihexyphenidyl Hydrochloride)	C		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/23/02ISR Number: 4032374-8Report Type:Expedited (15-DaCompany Report #EMADSS2002006058
Age:32 MON Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Accidental Exposure Aphasia Depressed Level Of Consciousness Extrapyramidal Disorder Hypertonia Overdose Urinary Retention	Foreign Health Professional	Haldol Faible (0.5 Mg/Ml Solution) (Haloperidol)	PS		ORAL	8 MG, DAILY, ORAL	

Date:12/24/02ISR Number: 4028428-2Report Type:Expedited (15-DaCompany Report #US-BRISTOL-MYERS SQUIBB COMPANY-12140752
Age:30 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Convulsion Rhabdomyolysis		Moditen Tabs 100 Mg Haldol	PS SS	Apothecon	ORAL	INTRAMUSCULAR INTRAMUSCULAR	SOLUTION 2 DAY SOLUTION 1 DAY
			Lepticur Nozinan Tegretol Loxapac Parkinane	SS SS SS SS SS		ORAL	INTRAMUSCULAR INTRAMUSCULAR capsule	2 DAY 2 DAY

Date:12/24/02ISR Number: 4033563-9Report Type:Expedited (15-DaCompany Report #S00-GER-01905-01
Age:68 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Disability	Tardive Dyskinesia	Foreign Health Professional	Cipramil (Citalopram) Cipramil	PS		ORAL	20 MG QD PO	

	Other	(Citalopram)	SS		ORAL
30 MG QD PO					
		Cipramil (Citalopram)	SS		ORAL
40 MG QD PO					
		Cipramil (Citalopram)	SS		ORAL
20 MG QD PO					
		Cipramil (Citalopram)	SS		ORAL
40 MG QD PO					
		Cipramil (Citalopram)	SS		ORAL
60 MG QD PO					
		Fluanxol "Lundbeck" (Flupentixol Dihydrochloride)	SS		ORAL
20 MG QD PO					
		Fluanxol "Lundbeck"(Flupentixol Dihydrochloride)	SS		ORAL
30 MG QD PO					
		Fluanzol "Lundbeck" (Flupentixol Dihydrochloride)	SS		ORAL
25 MG QD PO					
		Risperdal (Risperidone)	SS		
2 MG QD					
		Risperdal (Risperidone)	SS		
4 MG QD					
		Risperdal (Risperidone)	SS		
6 MG QD					
		Risperdal (Risperidone)	SS		
4 MG QD					
		Risperdal(Risperidone)	SS		
3 MG QD					

				Risperdal (Risperidone)	SS		
2 MG QD							
				Haldol(Haloperidol)	SS		
5 MG QD							
				Haldol(Haloperidol)	SS		
10 MG QD							
				Haldol(Haloperidol)	SS		
5 MG QD							
				Haldol(Haloperidol)	SS		
3 MG QD							
				Haldol(Haloperidol)	SS		
10 MG QD							
				Haldol(Haloperidol)	SS		
12.5 MG QD							
				Haldol(Haloperidol)	SS		
10 MG QD							
				Haldol (Haloperidol)	SS		
5 MG QD							
				Akineton(Biperiden Hydrochloride)	C		
				Trevilor(Venlafaxine Hydrochloride)	C		

Date:12/24/02ISR Number: 4033882-6Report Type:Expedited (15-DaCompany Report #NSADSS2002046689
Age:80 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Medication Error Sedation	Consumer	Haldol (Injection) (Haloperidol)	PS		INTRAMUSCULAR	10 MG,	IM

Date:12/26/02ISR Number: 4036488-8Report Type:Periodic Company Report #02-08-0762
Age:45 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other Required	Neuroleptic Malignant Syndrome	Health Professional Other	Clozapine - Ivax Pharmaceuticals, Inc. Tablets	PS	Ivax Pharmaceuticals, Inc	ORAL	12.5 -250MG	

Intervention to
QD; ORAL
Prevent Permanent
Impairment/Damage
INTRAMUSCULAR 150-200MG;

INTRAMUSCULAR

Haldol Decanoate
Injectable Solution SS

Cogentin C
Depakote C

Date:12/27/02ISR Number: 4035649-1Report Type:Expedited (15-DaCompany Report #APCDSS2002001248
Age:35 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardiac Failure	Foreign Health Professional	Risperidone (Tablet) (Risperidone)	PS		ORAL	ORAL	
			Haloperidol (Haloperidol)	SS		ORAL	ORAL	
			Sodium Valproate (Valproate Sodium)	SS		ORAL	ORAL	
			Paroxetine Hydrochloride Hydrate (Paroxetine Hydrochloride)	C				
			Lithium Carbonate (Lithium Carbonate)	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/27/02ISR Number: 4035729-0Report Type:Expedited (15-DaCompany Report #APCDSS2002001248
Age:35 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardiac Failure	Foreign Health Professional	Haloperidol (Haloperidol)	PS		ORAL		
			Risperidone	SS		ORAL		
			Sodium Valproate (Valproate Sodium)	SS		ORAL		
			Paroxetine Hydrochloride Hydrate	C				
			Lithium Carbonate	C				

Date:12/31/02ISR Number: 4036795-9Report Type:Expedited (15-DaCompany Report #EMADSS2002007917
Age:79 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agitation Drug Interaction	Foreign Health	Haldol (Unspecified) (Haloperidol)	PS			25 MG, DAILY	
	Epilepsy	Professional	Nozinan (Levomepromazine)	SS			25 MG, DAILY	
			Seropram (Citalopram Hydrobromide)	SS		ORAL	30 MG, DAILY,	ORAL
			Maxipime (Cefepime)	SS			INTRAVENOUS	1 G, IV
			Seroquel (Seroquel)	SS		ORAL	25 MG, DAILY,	ORAL
			Akineton (Biperiden Hydrochloride)	SS			INTRAVENOUS	2 G, DAILY, IV

Dafalgan (Paracetamol)	C	
Nitroderm (Glyceryl Trinitrate)	C	
Antra (Omeprazole)	C	
Morfina (Morphine)	C	
Atrovent (Ipratropium Bromide)	C	
Ventolin (Salbutamol)	C	
Dobutrex (Dobutamine Hydrochloride)	C	
Heparin (Heparin)	C	
Flagyl (Metronidazole)	C	

Date:12/31/02ISR Number: 4037873-0Report Type:Expedited (15-DaCompany Report #APCDSS2002001590
Age: Gender: I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death Hospitalization - Initial or Prolonged	Alcohol Withdrawal Syndrome Condition Aggravated Delirium	Foreign Health Professional	Haldol Decanoate (Unspecified) (Haloperidol Decanoate)	PS		INJECT		
			Haldol (Unspecified) (Haloperidol)	SS		ORAL		ORAL

Date:01/02/03ISR Number: 4038563-0Report Type:Expedited (15-DaCompany Report #EMADSS2002007954
Age:40 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Rhabdomyolysis	Foreign Health Professional	Haldol Decanoate (Injection) (Haloperidol Decanoate)	PS		INTRAVENOUS	25 MG, 1 IN	30 DAY(S), IM
			Oflocet (Ofloxacin)	SS		ORAL	200 MG,	DAILY, ORAL

Date:01/06/03ISR Number: 4037026-6Report Type:Direct Company Report #CTU 183951
Age:84 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Catatonia Insomnia Restlessness		Haldol	PS				
			Amitriptyline	C				

Date:01/07/03ISR Number: 4039309-2Report Type:Expedited (15-DaCompany Report #NSADSS2003000130
Age:31 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Convulsion Injury Asphyxiation Psychotic Disorder Screaming	Health Professional	Haldol Decanoate (Injection) (Haloperidol Decanoate)	PS			62.5 MG, 1 IN	2 WEEK(S), IM

Date:01/10/03ISR Number: 4040147-5Report Type:Direct Company Report #CTU 184199
Age:40 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Parkinson'S Disease		Haloperidol	PS		ORAL	65 MG	ORAL

Date:01/10/03ISR Number: 4041039-8Report Type:Expedited (15-DaCompany Report #NSADSS2003000763
Age:59 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Asthenia Confusional State	Health Professional	Haldol (Unspecified) (Haloperidol)	PS			10 MG, PRN	
	Gait Disturbance Medication Error		Clozapine (Clozapine)	SS		ORAL	250 MG,	
	Treatment Noncompliance						DAILY,	ORAL
			Congentin (Benzatropine Mesilate)	C				
			Clonidine (Clonidine)	C				
			Fluoxetine (Fluoxetine)	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/10/03ISR Number: 4041186-0Report Type:Expedited (15-DaCompany Report #2002068780
Age:26 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Asthenia	Foreign	Geodon (Ziprasidone)	PS		ORAL	200 MG, ORAL	
	Chest Pain	Health	Haloperidol	SS		ORAL	60 MG, ORAL	
	Dizziness	Professional	Valproic Acid	C				
	Dyspepsia	Company	Levomepromazine	C				
	Electrocardiogram St Segment Depression	Representative	Amantadine	C				

Date:01/13/03ISR Number: 4041745-5Report Type:Expedited (15-DaCompany Report #NSADSS2003000496
Age:40 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Rhabdomyolysis	Foreign	Haldol (Injection)					
		Health	(Haloperidol)	PS			INTRAMUSCULAR	0.5 MG, IM
		Professional	Ofloxacin (Tablet) (Ofloxacin)	SS		ORAL	400 MG, ORAL	

Date:01/14/03ISR Number: 4041862-XReport Type:Direct Company Report #CTU 184427
Age:21 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Feeling Abnormal		Ativan	PS			UNKNOWN	
Hospitalization - Initial or Prolonged	Hallucination		Haldol	SS				
Congenital Anomaly	Intentional Self-Injury							
Other	Paranoia							
Required Intervention to Prevent Permanent Impairment/Damage	Physical Assault							

Date:01/15/03ISR Number: 4042621-4Report Type:Direct Company Report #CTU 184579
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	General Physical Health Deterioration		Atenolol 50mg Tablet / Mylan	PS	Mylan		ONCE A DAY	
			Dicyclomine Hcl 20mg Tablet Mylan	SS	Mylan		AS NEEDED	
			Haloperidol Tablets 0.5 Mg	SS			1/2 TAB	INCLINE X 1/2 X 3 DAYS
			Fluphenazine Hcl Tablets 1mg	SS			1/2 TAB	INCLINE X 1/2 X 3 DAYS

Date:01/15/03ISR Number: 4043500-9Report Type:Expedited (15-DaCompany Report #EMADSS2003000152
Age: Gender:Male I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Abnormal Palmar/Plantar Creases
Congenital Anomaly	Apgar Score Low

	Complications Of Maternal Exposure To Therapeutic Drugs	Report Source	Product	Role	Manufacturer	Route Dose Duration
	Congenital Foot Malformation	Foreign Health Professional	Haldol (5 Mg Tablet) (Haloperidol)	PS		PARENTERAL TAKEN BY MOTHER DURING PREGNANCY
	Cryptorchism					
	Hypertonia Neonatal					
	Induced Labour		Nozinan (Levomepromazine)	SS		PARENTERAL TAKEN BY MOTHER DURING PREGNANCY
	Joint Stiffness					
	Maternal Drugs Affecting Foetus					

Date:01/17/03ISR Number: 4044194-9Report Type:Expedited (15-DaCompany Report #EMADSS2003000162
Age:54 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Hospitalization - Initial or Prolonged	Abnormal Behaviour	Foreign	Haladol (Unspecified)(Haloperidol)	PS		ORAL 20 DROP, DAILY, ORAL
	Anorexia	Health				
	Anticholinergic Syndrome	Professional				
	Condition Aggravated					
	Delirium		Laroxyl (Amitriptyline Hydrochloride)	SS		ORAL ORAL
	Disorientation					
	Drug Withdrawal Syndrome					
	Dry Mouth		Artane (Trihexyphenidyl Hydrochloride)	SS		ORAL 15 MG, DAILY, ORAL
	Dysphasia					
	Dysphonia					
	Fatigue					
	Logorrhoea		Equanil (Meprobamate)	C		
	Medication Error					
	Mydriasis		Lexomil (Bromazepam)	C		
	Speech Disorder					

Date:01/23/03ISR Number: 4046531-8Report Type:Expedited (15-DaCompany Report #EMADSS2003000309
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Congenital Foot Malformation	Foreign Health	Haldol (5 Mg Tablet) (Haloperidol)	PS				
OTHER Congenital Anomaly Other	Congenital Hand Malformation Facial Dysmorphism Foetal Growth Retardation Hypertonia Neonatal Hypothermia Neonatal Hypotonia Neonatal Maternal Drugs Affecting Foetus Neonatal Hypoxia	Professional	Tercian (Cyamemazine)	C				

Date:01/23/03ISR Number: 4046769-XReport Type:Expedited (15-DaCompany Report #EMADSS2003000478
Age:69 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dysarthria Tremor	Foreign Health	Haldol (Haloperidol)	PS		ORAL	5 MG, DAILY, ORAL	
		Professional	Eunerpan (Melperone Hydrochloride)	SS			40 MG, DAILY	
			Hypnorex (Lithium					

			Carbonate)	C			

Date:01/23/03ISR Number: 4047234-6Report Type:Expedited (15-DaCompany Report #L03-USA-00139-03
Age:58 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Death	Literature	Propranolol	PS				
		Health Professional	Haloperidol	SS				

Date:01/27/03ISR Number: 4047091-8Report Type:Expedited (15-DaCompany Report #US-BRISTOL-MYERS SQUIBB COMPANY-12162152
Age:52 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Aggression Fall Other Product		Fludecasin Inj	PS	Apothecon	INTRAMUSCULAR	Started "a year ago".	
	Treatment Noncompliance							
reintroduced, but date not								
			Lodopin	SS		ORAL	2	DAY
			Serenace	SS		ORAL	2	DAY
			Akineton	SS		ORAL	2	DAY
			Benzalin	SS		ORAL	2	DAY
			Hirnamin	SS		ORAL	2	DAY
			Pantosin	C				

Date:01/27/03ISR Number: 4048099-9Report Type:Expedited (15-DaCompany Report #EMADSS2003000345
Age:43 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Diabetes Mellitus Extrapyramidal Disorder Speech Disorder	Foreign Health Professional	Haldol Decanoate (Injection) (Haloperidol Decanoate)	PS		INTRAMUSCULAR	250 MG, 1 IN	28 DAY(S), IM
			Risperidone (Risperidone)	SS		ORAL	8 MG, DAILY,	ORAL / SEE IMAGE
			Zyprexa (Olanzapine)	C				

Date:01/27/03ISR Number: 4048100-2Report Type:Expedited (15-DaCompany Report #APCDSS2002001273
Age:36 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide Disturbance In Attention Fatigue Hallucination, Auditory Malaise Muscle Rigidity Somnolence Treatment Noncompliance	Foreign Health Professional	Haldol (Haloperidol)	PS		ORAL	18 M,G DIALY,	ORAL / SEE IMAGE
			Risperidone (Risperidone)	SS		ORAL	4 MG, DAILY,	ORAL
			Trihexyphenidyl Hydrochloride(Trihexyphenidyl Hydrochloride) Biperiden Hydrochloride (Biperiden	C				

			Hydrochloride)	C		
			Chlorpromazine Hydrochloride (Chlorpromane Hydrochloride)	C		

Date:01/27/03ISR Number: 4048584-XReport Type:Expedited (15-DaCompany Report #EMADSS2003000484
Age:33 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anxiety Overdose	Foreign Health Professional	Haldol (Unspecified) (Haloperidol)	PS		ORAL	8 MG, DAILY, ORAL; 20 TABLE 1 IN 1 TIME(S)	Required
Intervention to Prevent Permanent Impairment/Damage			Risperdal (Unspecified) (Risperidone)	SS		ORAL	SEE IMAGE, ORAL	
			Akineton (Biperiden Hydrochloride)	SS		ORAL	4 MG, DAILY, ORAL; 80 TABLE, 1 IN 1 TIME(S),	
			Tavor (Lorazepam)	SS			10 MG, 1 IN 1 TIME(S), UNKNOWN	

Date:01/27/03ISR Number: 4048622-4Report Type:Expedited (15-DaCompany Report #EMADSS2003000484
Age:33 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Required	Anxiety Overdose	Foreign Health Professional	Risperdal (Unspecified) (Risperidone)	PS		ORAL	8 & 20 MG, Intervention to DAILY, ORAL	
Prevent Permanent Impairment/Damage			Haldol (Unspecified) (Haloperidol)	SS		ORAL	8 MG, DAILY, ORAL; 20 TABLE, 1 IN 1 TIME(S)	
			Akineton (Biperiden Hydrochloride)	SS		ORAL	4 MG, DAILY, ORAL; 80 TABLE, 1 IN 1 TIME(S)	
			Tavor (Lorazepam)	SS			10 MG, 1 IN 1 TIME(S), UNKNOWN	

Date:01/27/03ISR Number: 4048702-3Report Type:Expedited (15-DaCompany Report #PHRM2003FR00497
Age:30 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Alanine Aminotransferase Increased Convulsion	Foreign Health Professional	Tegretol (Carbamazepine) Tablet	PS			800 MG, DAY	
	Rhabdomyolysis	Other	Haldol "Jassen-Cilag"					

				(Haloperidol) Solution	SS			
INTRAMUSCULAR	5 MG, QD,							
INTRAMUSCULAR								
				Lepticur (Tropatepine Hydrochloride) Solution	SS			
INTRAMUSCULAR	10 MG, QD,							
INTRAMUSCULAR								
				Moditen (Fluphenazine Hydrochloride) Tablet	SS			ORAL
100 MG, TID,								
ORAL								
				Nozinan (Levomepromazine) Solution	SS			
25 MG, QD								
				Loxapac (Loxapine Succinate) Solution	SS			
INTRAMUSCULAR	100 MG/DAY,							
INTRAMUSCULAR								
				Parkinane (Trihexyphenidyl Hydrochloride) Capsule	SS			ORAL
ORAL								

Date:01/28/03ISR Number: 4048797-7Report Type:Expedited (15-DaCompany Report #EMADSS2003000582
Age:46 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Asthenia Cholestasis Hepatic Failure Hepatocellular Damage	Foreign Health Professional	Haldol (Tablet) (Haloperidol)	PS		ORAL	0.5 TABLET, 1 IN 1 NIGHT(S),	

	Weight Decreased						
ORAL							
				Artane (Trihexyphenidyl Hydrochloride)	C		

Date:01/30/03ISR Number: 4049504-4Report Type:Direct Company Report #CTU 185669
Age:30 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Back Pain		Haldol Deck Shot And					
Hospitalization -	Dysuria		20 Mg Pill	PS				
20 MGS								
Initial or Prolonged	Pain		Seroquel 100 And 200					
Disability			Mg Pills	SS				
100 MGS								
Required								
MORNING 200								
Intervention to								
MGS NIGHTLY								
Prevent Permanent								
Impairment/Damage								

Date:01/31/03ISR Number: 4051110-2Report Type:Expedited (15-DaCompany Report #PHBS2003JP00643
Age:74 YR Gender:Male I/FU:F

Outcome	PT
Other	Bronchitis
	Drug Level Increased
	Mental Impairment
	Oral Intake Reduced
	Pneumonia

	Sedation						
		Report Source	Product	Role	Manufacturer	Route	Dose Duration
		Foreign Health Professional	Melleril(Thioridazine Hydrochloride) Tablet	PS		ORAL	90 MG/D, ORAL; 50 MG/D, ORAL
		Other	Serenace (Haloperidol)	SS		ORAL	3 MG/D, ORAL
			Norvasc	C			
			Tanatril "Algol" (Imidapril Hydrochloride)	C			

Date:02/03/03ISR Number: 4051552-5Report Type:Expedited (15-DaCompany Report #APCDSS2003000108
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Death	Death	Foreign Health Professional	Haldol (Unspecified) (Haloperidol)	PS			

Date:02/03/03ISR Number: 4051553-7Report Type:Expedited (15-DaCompany Report #EMADSS2003000749
Age:80 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Abdominal Distension Constipation Decubitus Ulcer Diarrhoea Intestinal Dilatation Ischaemia Megacolon	Foreign Health Professional	Haldol (Unspecified) (Haloperidol)	PS		ORAL	20 MG, DAILY, ORAL
			Equanil (Meprobamate)	C			
			Tranxene (Clorazepate				

			Dipotassium)	C		
			Deroxat (Paroxetine Hydrochloride)	C		
			Forlax (Macrogol)	C		

Date:02/03/03ISR Number: 4051554-9Report Type:Expedited (15-DaCompany Report #EMADSS2003000725
Age:73 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Obstruction	Foreign Health Professional	Haldol (Unspecified) (Haloperidol)	PS				
			Terican (Cyamemazine)	SS		ORAL	75 MG, DAILY, ORAL	
			Atarax (Hydroxyzine Hydrochloride)	SS		ORAL	25 MG, DAILY, ORAL	
			Lepticur (Tropatepine Hydrochloride)	SS		ORAL	5 MG, DAILY, ORAL	
			Zopliclone (Zopiclone)	C				
			Kardegic					

			(Acetylsalicylate Lysine)	C		

Date:02/03/03ISR Number: 4051555-0Report Type:Expedited (15-DaCompany Report #EMADSS2003000700
Age:37 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Decreased Activity	Foreign	Haldol (5 Mg Tablet)					
	Deep Vein Thrombosis	Health	(Haloperidol)	PS		ORAL	20 MG, DAILY,	
	Weight Increased	Professional				ORAL		
			Zyprexa (Olanzapine)	SS		ORAL	20 MG, ORAL	
			Akineton (Biperiden Hydrochloride)	C				
			Lormetazepam (Lormetazepam)	C				

Date:02/03/03ISR Number: 4051569-0Report Type:Expedited (15-DaCompany Report #EMADSS2003000582
Age:46 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Cholestasis	Foreign	Haldol (Tablet)					
	Hepatic Failure	Health	(Haloperidol)	PS		ORAL	0.5 TABLE, 1	
	Hepatocellular Damage	Professional					IN 1 NIGHT	
							(S), ORAL	
			Artane (Trihexyphenidyl Hydrochloride)	C				

Date:02/03/03ISR Number: 4051570-7Report Type:Expedited (15-DaCompany Report #EMADSS2003000741
Age:27 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Neutropenia	Foreign	Haldol (Unspecified)					

Initial or Prolonged		Health	(Haloperidol)	PS		ORAL
60 MG, DAILY,						
		Professional				
ORAL						
			Tercian (Cyamemazine)	SS		ORAL
300 MG,						
DAILY, ORAL						
			Depakote (Valproate Semisodium)	C		
			Rivotril (Clonazepam)	C		

Date:02/04/03ISR Number: 4051058-3Report Type:Expedited (15-DaCompany Report #WAES 0301GRC00010
Age:71 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - 2 YR	Polyuria	Health	Proscar	PS	Merck & Co., Inc	ORAL
Initial or Prolonged	Rhabdomyolysis	Professional	Biperiden Hydrochloride	SS		
PARENTERAL 3 YR						
			Haloperidol	SS		ORAL
2 YR						
			Ipratropium Bromide	C		
			Fluticasone Propionate And Salmeterol Xinafoate	C		ORAL
			Gliclazide	C		ORAL
			Isosorbide Mononitrate	C		ORAL

			Aspirin	C		ORAL

Date:02/04/03ISR Number: 4052334-0Report Type:Direct Company Report #CTU 185937
Age:19 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Binocular Eye Movement		Haloperidol	PS			2MG Q A, 3MG	
	Disorder						Q 2PM, 4MG Q	
	Extrapyramidal Disorder						HS	
	Eye Disorder		Benztropine	C				
	Gaze Palsy		Calcium Carbonate	C				
	Vision Blurred		Clonidine	C				
			Citalopram	C				
			Clonazepam	C				
			Docusate Soduim	C				
			Multivit W/Minerals	C				
			Lactulose	C				
			Ranitidine	C				
			Topiramate	C				
			Saline Nasal Spray	C				

Date:02/06/03ISR Number: 4053293-7Report Type:Direct Company Report #CTU 186158
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Delusion		Haloperidol Dec					
	Pharmaceutical Product		100mg/Ml	PS				
INTRAMUSCULAR	2ML IM Q3WKS	3	MON					
	Complaint		Paxil	C				
			Cogentin	C				

Date:02/06/03ISR Number: 4055456-3Report Type:Expedited (15-DaCompany Report #NSADSS2002039470
Age:47 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Hospitalization - Initial or Prolonged , 1	Ageusia Anhedonia Confusional State Drug Hypersensitivity Medication Error Movement Disorder Tongue Oedema	Consumer	Haldol (Injection) (Haloperidol) Xanax (Alprazolam) Restoril (Temazepam)	PS C C				

Date:02/07/03ISR Number: 4054181-2Report Type:Expedited (15-DaCompany Report #EMADSS2003000966
Age:85 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Circulatory Collapse Parkinsonism	Foreign Health Professional	Haldol(Unspecified) (Haloperidol) Aspirin (Acetylsalicylic Acid) Amiodarone (Amiodarone) Digoxin (Digoxin) Risperidone (Risperidone) Calcichew (Calcium	PS C C C C		ORAL ORAL		

				Carbonate)	C		

Date:02/07/03ISR Number: 4054255-6Report Type:Expedited (15-DaCompany Report #APCDSS2003000110
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Loss Of Consciousness Stupor	Foreign Health Professional	Risperidone (Unspecified) Risperidone)	PS		ORAL	2 MG, DAILY, ORAL	
			Haldol (Unspecified) (Haloperidol)	SS				

Date:02/07/03ISR Number: 4054392-6Report Type:Expedited (15-DaCompany Report #03-00278
Age:22 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide Intentional Misuse	Literature Health Professional Other	Fluoxetine Haloperidol	PS SS				

Date:02/07/03ISR Number: 4054574-3Report Type:Expedited (15-DaCompany Report #FLUV00303000293
Age:39 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Neuroleptic Malignant Syndrome	Foreign Health Professional Other	Depromel 25 (Fluvoxamine Maleate) Linton (Haloperidol)	PS SS		ORAL ORAL	50 MG DAILY, PO 2.4 G DAILY	
			Hirnamin					

(Levomepromazine)	SS	ORAL	3 G; 5 DF DAILY PO
Hyserenin (Valproate Sodium)	SS	ORAL	1.5 G DAILY PO
Rivotril (Clonazepam)	SS	ORAL	3 DF DAILY PO
Akineton (Biperiden Hydrochloride)	SS	ORAL	3 DF DAILY PO
Excegran (Zonisamide)	SS	ORAL	2 DF DAILY PO
Magnesium Oxide (Magnesium Oxide)	SS	ORAL	2 G DAILY PO
Lullan (Perospirone Hydrochloride Hydrate)	SS	ORAL	16 MG DAILY PO
Vegetamin A ()	SS	ORAL	2 DF DAILY PO
Rophynol (Flunitrazepam)	SS	ORAL	2 DF DAILY PO

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/10/03ISR Number: 4054442-7Report Type:Direct Company Report #CTU 186302
Age:19 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Emotional Disorder		Haldol Decanoate	PS				MONTHLY SHOTS
Hospitalization -	Grand Mal Convulsion		Lithium	SS		ORAL		DAILY ORALLY
Initial or Prolonged	Malaise							
Disability	Mental Disorder							
Required	Nervous System Disorder							
Intervention to								
Prevent Permanent								
Impairment/Damage								

Date:02/10/03ISR Number: 4055099-1Report Type:Expedited (15-DaCompany Report #2003003803
Age:48 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Anxiety	Consumer	Benadryl					
Initial or Prolonged	Condition Aggravated		Injection(Diphenhydr					
Other	Medication Error		amine)	PS				
INTRAVENOUS							25 MG,	
	Paraesthesia							
INTRAVENOUS								
	Post-Traumatic Stress		Haloperidol	SS				
INTRAVENOUS							5 MG,	
	Disorder							
INTRAVENOUS								
	Tinnitus		Ethanol	SS		ORAL		
ORAL								
	Vision Blurred							

Date:02/11/03ISR Number: 4056578-3Report Type:Expedited (15-DaCompany Report #2003004280
Age:73 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Anticholinergic Syndrome	Foreign	Atarax (Tablet)					
Initial or Prolonged	Intestinal Obstruction	Health	(Hydroxyzine					

			Professional	Hydrochloride)	PS		ORAL
25 MG, ORAL							
				Haloperidol	SS		ORAL
ORAL							
				Cyamemazine	SS		ORAL
75 MG, ORAL							
				Tropatepine Hydrochloride	SS		ORAL
5 MG, ORAL							
				Zopiclone	C		
				Acetylsalicylate Lysine	C		

Date:02/11/03ISR Number: 4056614-4Report Type:Expedited (15-DaCompany Report #APCDSS2002001248
Age:35 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Cardiac Failure	Foreign	Risperidone (Tablet)			
	Neuroleptic Malignant	Health	(Risperidone)	PS		ORAL
ORAL						
	Syndrome	Professional	Haloperidol(Haloperidol)	SS		
ORAL						
			Sodium Valproate(Valproate Sodium)	SS		ORAL
ORAL						
			Paroxetine Hydrochloride Hydrate (Paroxetine Hydrochloride)	C		
			Lithium Carbonate(Lithium Carbonate)	C		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/11/03ISR Number: 4056624-7Report Type:Expedited (15-DaCompany Report #APCDSS2002001248
Age:35 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardiac Failure	Foreign	Haloperidol					
	Neuroleptic Malignant	Health	(Haloperidol)	PS		ORAL		
	Syndrome	Professional	Risperidone(Tablet)Risperidone	SS		ORAL		
			Sodium Valproate(Valproate Sodium)	SS		ORAL		
			Paroxetine Hydrochloride Hydrate(Paroxetine Hydrochloride)	C				
			Lithium Carbonate(Lithium Carbonate)	C				

Date:02/13/03ISR Number: 4057190-2Report Type:Expedited (15-DaCompany Report #EMADSS20030001148
Age:74 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dizziness	Foreign	Haldol (Unspecified)					
	Immobile	Health	(Haloperidol)	PS			2 MG, 1 IN 1	DAY (S),
	Lung Infection	Professional						UNKNOWN
	Lymphopenia							
	Neutrophil Count Increased		Risperdal (Tablet) (Risperidone)	SS		ORAL	4 MG, 2 IN 1	DAILY, ORAL
	Psychotic Disorder							
	Tremor		Carbimazole (Carbimazole)	C				
			Delix (Ramipril)	C				

Date:02/13/03ISR Number: 4057558-4Report Type:Expedited (15-DaCompany Report #PHBS2003JP00643
Age:74 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Bronchitis	Foreign	Melleril					
	Dialysis	Health	(Thioridazine					
	Dysphagia	Professional	Hydrochloride)					
	Mental Impairment	Other	Tablet	PS		ORAL	90 MG/D,	
	Oral Intake Reduced						ORAL; 50	
	Pneumonia						MG/D, ORAL	
	Renal Failure Chronic		Serenace					
	Sedation		(Haloperidol)	SS		ORAL	3 MG/D, ORAL	
			Norvasc	C				
			Tanatril "Algol"					
			*Imidapril					
			Hydrochloride)	C				
			Panaldine					
			(Ticlopidine					
			Hydrochloride)	C				
			Alfacalcidol	C				
			Dialysis	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/13/03ISR Number: 4057932-6Report Type:Expedited (15-DaCompany Report #NSADSS2003006105
Age:52 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Convulsion Dyspnoea Fatigue Polyuria Tardive Dyskinesia Treatment Noncompliance	Consumer	Haldol (Haloperidol) Haldol Decanoate (Haloperidol Decanoate) Doxepin (Doxepin)	PS SS C		ORAL INTRAMUSCULAR	20 YR IM	

Date:02/14/03ISR Number: 4060215-1Report Type:Expedited (15-DaCompany Report #2003003045
Age:41 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death Other	Cardio-Respiratory Arrest	Literature Health Professional	Diphenhydramine (Diphenhydramine) Haloperidol	PS SS		PARENTERAL	PARENTERAL	

Date:02/19/03ISR Number: 4059469-7Report Type:Expedited (15-DaCompany Report #EMADSS2003000162
Age:54 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abnormal Behaviour Agitation Anticholinergic Syndrome Clonic Convulsion Condition Aggravated Confusional State Delirium Disorientation Drug Withdrawal Syndrome Dry Mouth	Foreign Health Professional	Haldol (Haloperidol) Laroxyl (Amitriptyline Hydrochloride) Artane (Trihexyphenidyl Hydrochloride) Equanil	PS SS SS		ORAL ORAL ORAL	SEE IMAGE ORAL 15 MG, DAILY, ORAL	

		Insomnia		(Meprobamate)	C		
		Joint Stiffness		Lexomil (Bromazepam)	C		
		Logorrhoea					
		Mydriasis					
		Speech Disorder					
		Tremor					

Date:02/19/03ISR Number: 4059628-3Report Type:Expedited (15-DaCompany Report #2003004277
Age:57 YR Gender:Female I/FU:F

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Other		Blood Gases Abnormal	Foreign	Atarax-P (Iv/Im)			
		Chest X-Ray Abnormal	Literature	(Hydroxyzine			
		Condition Aggravated	Health	Hydrochloride)	PS		
INTRAVENOUS	50 MG						
		Pneumonia Aspiration	Professional				
(SINGLE),							
		Rales					
INTRAVENOUS							
		Respiratory Failure		Pentazocine	SS		
INTRAVENOUS	15 MG						
		Restlessness					
(SINGLE)							
INTRAVENOUS							
				Haloperidol	SS		
INTRAVENOUS	5 MG (SINGLE)						
INTRAVENOUS							
				Roxatidine	C		
				Atropine	C		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/19/03ISR Number: 4059823-3Report Type:Expedited (15-DaCompany Report #EMADSS2003001171
Age:30 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Arrhythmia Atrial Fibrillation	Foreign Health Professional	Haldol Decanoate (Injection) (Haloperidol Decanoate)	PS		INTRAMUSCULAR	75 MG, 1 IN 4	WEEK (S), IM
			Leponex (Clozapine)	SS		ORAL	SEE IMAGE	
			Glianimon (Benperidol)	SS		ORAL	SEE IMAGE	
			Zeldox	SS		ORAL	SEE IMAGE	
			Ximovan (Zopiclone)	C				
			Pantozol (Pantoprazole Sodium)	C				

Date:02/19/03ISR Number: 4059825-7Report Type:Expedited (15-DaCompany Report #EMADSS2003000309
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Apgar Score Low Areflexia	Foreign Health Professional	Haldol (5 Mg Tablet) (Haloperidol)	PS		OTHER	5 MG, 4 IN 1	
Congenital Anomaly	Congenital Anomaly							DAY (S),
Other	Deformity Of Orbit							
OTHER								
	Facial Dysmorphism		Tercian (Cyamemazine)	C				
	Foetal Growth Retardation							
	Hypertonia Neonatal							
	Hypothermia Neonatal							
	Hypotonia Neonatal							
	Ligament Laxity							
	Limb Malformation							
	Maternal Drugs Affecting Foetus							

Neonatal Hypoxia
Retrognathia
Small For Dates Baby

Date:02/19/03ISR Number: 4060034-6Report Type:Expedited (15-DaCompany Report #2003AP00738
Age:72 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Creatine Phosphokinase Increased	Foreign Health	Seroquel	PS		ORAL	100 MG DAILY	
	Drug Ineffective	Professional	Seroquel	SS		ORAL	200 MG DAILY, PO	
	Schizophrenia	Other						
			Serenace	SS		ORAL	4 MG DAILY PO	
			Serenace	SS		ORAL	2 MG DAILY PO	
			Clofekton	SS			40 MG DAILY	
			Tasmolin	C				
			Pantosin	C				
			Etilefrine Hydrochloride	C				
			Dihydergot	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/20/03ISR Number: 4058353-2Report Type:Direct Company Report #CTU 186934
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Depressed Level Of Consciousness		Haloperidol 2mg 2MG TID ORAL	PS		ORAL		
			Risperidone 0.5mg 0.5MG TID ORAL	SS		ORAL		
			Levofloxacin	C				
			Allopurinol	C				
			Gabapentin	C				
			Naproxen	C				
			Trazodone	C				
			Levothyroxine	C				

Date:02/21/03ISR Number: 4062224-5Report Type:Expedited (15-DaCompany Report #EMADSS2003001348
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Death Neonatal Drug Exposure During Pregnancy	Foreign Health Professional	Risperdal (1 Mg Tablet) (Risperidone) TAKEN BY MOTHER	PS				
			Haldol (1 Mg Tablet) (Haloperidol) TAKEN BY MOTHER	SS				

Date:02/21/03ISR Number: 4062225-7Report Type:Expedited (15-DaCompany Report #EMADSS2003000741
Age:27 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Neutrophil Count	Foreign	Haldol (Unspecified)					

Initial or Prolonged	Increased	Health	(Haloperidol)	PS			ORAL
60 MG, DAILY,							
		Professional					
ORAL							
			Tercian				
			(Cyamemazine)	SS			ORAL
300 MG,							
DAILY, ORAL							
			Depakote (Valproate				
			Semisodium)	C			
			Rivotril				
			(Clonazepam)	C			

Date:02/21/03ISR Number: 4062226-9Report Type:Expedited (15-DaCompany Report #EMADSS2003001254
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Disability	Hypospadias	Foreign	Haldol (Unspecified)			
Congenital Anomaly	Maternal Drugs Affecting	Health	(Haloperidol)	PS		
TAKEN BY						
	Foetus	Professional				
MOTHER DURING						
PREGNANCY						
			Largactil			
			(Chlorpromazine			
			Hydrochloride)	SS		
TAKEN BY						
MOTHER DURING						
PREGNANCY						
			Parkinane			
			(Trihexyphenidyl			
			Hydrochloride)	SS		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/21/03ISR Number: 4062227-0Report Type:Expedited (15-DaCompany Report #EMADSS2003001348
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Death Neonatal Drug Exposure During Pregnancy	Foreign Health Professional	Haldol (1 Mg Tablet) (Haloperidol) TAKEN BY MOTHER	PS				
			Risperdal (1 Mg Tablet) (Risperidone) TAKEN BY MOTHER	SS				

Date:02/24/03ISR Number: 4065046-4Report Type:Expedited (15-DaCompany Report #EMADSS2002006537
Age:80 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Aspartate Aminotransferase Increased Gamma-Glutamyltransferase Increased Hepatomegaly Lymphadenopathy Rash Generalised Rash Maculo-Papular Toxic Skin Eruption	Foreign Health Professional	Haldol Faible (0.5 Mg/Ml Solution) (Haloperidol)	PS		ORAL	5 DROP,	DAILY, ORAL
			Kardegic (Acetysalicyate Lysine)	SS		ORAL	75 MG,	DAILY, ORAL
			Paracetamol (Paracetamol)	SS		ORAL	3000 MG,	DAILY, ORAL
			Nootropyl(Piracetam)	SS		ORAL	2400 MG,	DAILY, ORAL
			Trivastal					

			(Piribedil)	SS		ORAL
50 MG, DAILY,						
ORAL						
			Inexium (Esomeprazole Magnesium)	C		ORAL
20 MG, DAILY,						
ORAL						

Date:02/25/03ISR Number: 4066580-3Report Type:Expedited (15-DaCompany Report #EMADSS2003001491
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Electrocardiogram Qt Prolonged	Foreign Health	Haldol Decanoate (Haloperidol			
	Medication Error	Professional	Decanoate)	PS		
50 MG, 1 IN 1						
TIMES(S),						
INFUSI						

Date:02/27/03ISR Number: 4066739-5Report Type:Expedited (15-DaCompany Report #FLUV00303000293
Age:39 YR Gender:Male I/FU:F

Outcome	PT
Other	Alanine Aminotransferase Increased
	Aspartate Aminotransferase Increased
	Blood Creatine Phosphokinase Increased
	Blood Urea Increased

		C-Reactive Protein Increased Neuroleptic Malignant Syndrome	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
			Foreign Health Professional	Depromel 25 (Fluvoxamine Maleate)	PS		ORAL
SEE IMAGE							
			Other	Linton (Haloperidol)	SS		ORAL
2.4 G DAILY							
PO							
				Hirnamin (Levomepromazine)	SS		ORAL
SEE IMAGE							
				Hyserenin (Valproate Sodium)	SS		ORAL
1.5 G DAILY							
PO							
				Rivotril (Clonazepam)	SS		ORAL
3 MG DAILY PO							
				Excegran (Zonisamide)	SS		ORAL
200 MG DAILY							
PO							
				Vegetamin A ()	SS		ORAL
2 DF DAILY PO							
				Rohypnol (Flunitrazepam)	SS		ORAL
4 MG DAILY PO							
				Akineton (Biperiden Hydrochloride)	C		
				Magnesium Oxide (Magnesium Oxide)	C		
				Lullan (Perospirone Hydrochloride Hydrate)	C		

Date:02/27/03ISR Number: 4066963-1Report Type:Expedited (15-DaCompany Report #NSADSS2002033980
Age:8 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Hyperthermia Malignant	Foreign Health Professional	Haldol (Unspecified) (Haloperidol)	PS				
			Clomipramine (Clomipramine)	C				

Date:02/28/03ISR Number: 4065707-7Report Type:Direct Company Report #CTU 187672
Age:72 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Catatonia Hemiplegia Tardive Dyskinesia		Haldol	PS				

Date:02/28/03ISR Number: 4067554-9Report Type:Expedited (15-DaCompany Report #APCDSS2003000110
Age:55 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Loss Of Consciousness Sedation	Foreign Health	Haldol (Unspecified) (Haloperidol)	PS			1.5 MG, DAILY	
	Stupor	Professional	Risperidone (Risperidone)	SS		ORAL	2 MG, DAILY,	ORAL
			Lorazepam (Lorazepam)	SS			1.5 MG, DAILY	
			Flunitrazepam					

(Flunitrazepam) SS

Date:02/28/03ISR Number: 4067555-0Report Type:Expedited (15-DaCompany Report #EMADSS2003001581
Age:52 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agitation Brain Oedema Dehydration Depressed Level Of Consciousness Drug Interaction Miosis Nephrogenic Diabetes Insipidus Oedema Peripheral Pitting Oedema Pneumonia Somnolence Therapeutic Agent Toxicity	Foreign Health Professional	Haldol (10 Mg Tablet) (Haloperidol) Priadel (Lithium Carbonate) Depakine Chrono (Ergenyl Chrono) Moduretic (Moduretic) Augmentin (Clavulin) Risperdal (Risperidone) Nozinan (Levomepromazine) Sirdalud (Tizanidine Hydrochloride) Venoruton (Troxerutin) Urispas(Flavoxate Hydrochloride)	PS SS SS SS SS C C C C		ORAL ORAL ORAL ORAL ORAL	10 MG, DAILY, 800 MG, DAILY, ORAL SEE IMAGE 2 TABLE, WEEK (S), ORAL ORAL	

Date:02/28/03ISR Number: 4068058-XReport Type:Expedited (15-DaCompany Report #EMADSS2003001486
Age:45 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Colitis Rectal Haemorrhage		Foreign Health Professional	Haldol Decanoate (Injection) (Haloperidol Decanoate)	PS		
INTRAMUSCULAR	150 MG, 1 IN 21 DAY(S), IM						
				Artane (Trihexyphenidyl Hydrochloride)	C		

Date:02/28/03ISR Number: 4068661-7Report Type:Expedited (15-DaCompany Report #2003002640
Age:41 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardio-Respiratory Arrest	Literature Health Professional	Benadryl Injection (Diphenhydramine)	PS		PARENTERAL	PARENTERAL	
			Haloperidol (Haloperidol)	SS		PARENTERAL	PARENTERAL	
			Diazepam	SS		PARENTERAL	PARENTERAL	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/03/03ISR Number: 4069425-0Report Type:Expedited (15-DaCompany Report #2003000836
Age:64 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Anxiety	Foreign	Sertraline					
Hospitalization -	Blood Creatine	Health	(Sertraline)	PS		ORAL	50 MG (HS),	
Initial or Prolonged	Phosphokinase Increased	Professional				ORAL		
Other	Encephalopathy		Clomipramine	SS		ORAL	100 MG (QID),	
	Hypoxia					ORAL		
	Liver Function Test		Haloperidol	SS		ORAL	11 MG, ORAL	
	Abnormal		Flurazepam	C				
	Metabolic Acidosis		Procyclidine	C				
	Muscle Rigidity		Alprazolam	C				
	Respiratory Arrest							
	Shock							

Date:03/04/03ISR Number: 4069899-5Report Type:Expedited (15-DaCompany Report #PHBS2002JP14011
Age: Gender: I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Caesarean Section	Foreign	Tegretol					
	Cephalo-Pelvic	Literature	(Carbamazepine)	PS		TRANSPLACENTAL	TRANSPLACENTA	
	Disproportion	Health				L		
	Maternal Drugs Affecting	Professional	Etizolam	SS		TRANSPLACENTAL	TRANSPLACENTA	
	Foetus					L		
	Neonatal Asphyxia		Haloperidol	SS		TRANSPLACENTAL	TRANSPLACENTA	
	Somnolence Neonatal					L		
			Trihexyphenidyl Hydrochloride	SS		TRANSPLACENTAL	TRANSPLACENTA	
						L		

Date:03/05/03ISR Number: 4068176-6Report Type:Direct Company Report #USP 55479
Age:40 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Hypersensitivity		Haldol	PS	Purepac			
	Medication Error		Clonazepam	SS				
	Somnolence							

Date:03/06/03ISR Number: 4068609-5Report Type:Direct Company Report #CTU 188092
Age:66 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dystonia		Haloperidol	PS		ORAL	1.5 MG, BID,	
	Extrapyramidal Disorder					ORAL		
	Tremor		Divalproex Ec (Delayed Release)	C				
			Simvastatin	C				
			Benztropine Mesylate	C				
			Ipratropium Bromide	C				
			Albuterol	C				

Date:03/06/03ISR Number: 4069266-4Report Type:Direct Company Report #CTU 188041
Age:56 YR Gender:Female I/FU:I

Outcome
Required
Intervention to

Prevent Permanent
Impairment/Damage

	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Dystonia		Haldol	PS		ORAL	5MG BID	
	Jaw Disorder							

Date:03/07/03ISR Number: 4072523-9Report Type:Expedited (15-DaCompany Report #APCDSS2002001273
Age:36 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Foreign	Haldol (Tablet)					
	Condition Aggravated	Health	(Haloperidol)	PS		ORAL	18 MG, DAILY,	
	Delusion	Professional					ORAL; 9 MG,	
	Disturbance In Attention						DAILY, ORAL	
	Fatigue		Risperidone (Tablet)					
	Hallucination		(Risperidone)	SS		ORAL	4 MG, DAILY,	
	Malaise						ORAL	
	Muscle Rigidity		Trihexyphenidyl Hydrochloride					
	Somnolence		(Trihexyphenidyl Hydrochloride)	C				
	Treatment Noncompliance		Bipiriden Hydrochloride (Biperiden Hydrochloride)	C				
			Chlorpromazine Hydrochloride (Chlorpromazine Hydrochloride)	C				
			Bromazepam (Bromazepam)	C				
			Brotizolam (Brotizolam)	C				

Date:03/10/03ISR Number: 4068868-9Report Type:Expedited (15-DaCompany Report #US-BRISTOL-MYERS SQUIBB COMPANY-12199022
Age:64 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Bipolar I Disorder Depression Psychotic Disorder	Health Professional	Blinded: Efavirenz Caps	PS	Bristol-Myers Squibb Company	ORAL		
			Blinded: Ziagen	SS		ORAL		
			Blinded: Epivir	SS		ORAL		
			Haloperidol	SS		ORAL		

Date:03/10/03ISR Number: 4070126-3Report Type:Direct Company Report #CTU 188252
Age:75 YR Gender:Male I/FU:I

Outcome
Death
Life-Threatening
Hospitalization -
Initial or Prolonged
Disability
Other
Required
Intervention to
Prevent Permanent

Impairment/Damage

	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Basal Ganglion		Haldol	PS		ORAL	2.5MG 3 TID	
	Degeneration						ORAL	
	Dyskinesia		Haldol	SS		ORAL	5MG 3 TID	
	Hemiplegia						ORAL	

Date:03/11/03ISR Number: 4074048-3Report Type:Expedited (15-DaCompany Report #333051
Age:39 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Alanine Aminotransferase Increased	Foreign Health	Rivotril (Clonazepam)	PS		ORAL	3 MG DAILY	
	Aspartate Aminotransferase Increased	Professional Other	Rohypnol (Flunitrazepam)	SS		ORAL	ORAL 4 MG DAILY	
	C-Reactive Protein Increased		Depromel (Fluvoxamine)	SS		ORAL	ORAL 100 MG DAILY	
	Gamma-Glutamyltransferase Increased		Linton (Haloperidol)	SS		ORAL	ORAL 2.4 GRAM	
	Neuroleptic Malignant Syndrome		Hirnamin (Methotrimeprazine)	SS		ORAL	DAILY ORAL 280 MG DAILY	
	White Blood Cell Count Increased		Hyserenin (Valproate Sodium)	SS		ORAL	ORAL 1.5 GRAM	

DAILY ORAL

Excegran (Zonisamide)	SS	ORAL

200 MG DAILY

ORAL

Vegetamin A (Chlorpromazine Hydrochloride/Phenobarbital/Promethazine Hydrochloride)	SS	ORAL

2 DOSE FORM

DAILY ORAL

Akineton (Biperiden Hydrochloride)	C
Magnesium Oxide (Magnesium Oxide)	C
Lullan (Perospirone Hydrochloride Hydrate)	C

Date:03/11/03ISR Number: 4074694-7Report Type:Expedited (15-DaCompany Report #03P-151-0212144-00
Age:52 YR Gender:Female I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Agitation
	Brain Oedema
	Dehydration
	Depressed Level Of Consciousness
	Drug Interaction
	Drug Level Increased
	Miosis
	Nephrogenic Diabetes

		Insipidus Pneumonia Renal Failure Acute Schizophrenia	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
		Somnolence Tachypnoea	Foreign Health Professional Other	Depakine Chrono Tablets (Depakene) (Sodium Valproate/Valproic Acid) (Sodium	PS		ORAL
SEE IMAGE							
				Lithium Carbonate	SS		ORAL
400 MG, 2 IN 1 D, ORAL							
				Haloperidol	SS		ORAL
5 MG, 2 IN 1 D, PER ORAL							
				Moduretic	SS		ORAL
1 TABLET, 2 IN 1 WK, ORAL							
				Clavulin	SS		ORAL
ORAL							
				Levomepromazine	C		
				Risperidone	C		
				Tizanidine Hydrochloride	C		
				Flavoxate Hydrochloride	C		
				Troxerutin	C		

Date:03/12/03ISR Number: 4075228-3Report Type:Expedited (15-DaCompany Report #EMADSS2003001560
Age:17 YR Gender:Male I/FU:F

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Other		Body Temperature Decreased	Foreign Health	Haldol (Solution) (Haloperidol)	PS		ORAL
4 MG, 3 IN 1 DAY(S), ORAL							
		Extrapyramidal Disorder Psychotic Disorder	Professional				
				Dominal Forte (Prothipendyl Hydrochloride)	C		

			Zyprexa (Olanzapine)	C			

Date:03/12/03ISR Number: 4075232-5Report Type:Expedited (15-DaCompany Report #EMADSS2003001486
Age:45 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Colitis Oedema Mucosal Pseudopolyposis Rectal Haemorrhage	Foreign Health Professional	Haldol Decanoate (Injection) (Haloperidol Decanoate)	PS		INTRAMUSCULAR	150 MG, 1 IN 21 DAY(S), IM
			Artane (Trihexyphenidyl Hydrochloride)	SS		ORAL	ORAL

Date:03/12/03ISR Number: 4075233-7Report Type:Expedited (15-DaCompany Report #APCDSS2003000341
Age:76 YR Gender:Male I/FU:I

Outcome	PT
Life-Threatening	Agitation Anal Fistula Delusion Depression Gastrointestinal Injury Intentional Self-Injury

Laceration Malaise Suicidal Ideation		Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
		Foreign Health Professional	Haldol (Tablet) (Haloperidol)	PS		ORAL
6.75 MG, DAILY, ORAL						
			Haldol (Injection) (Haloperidol)	SS		
INTRAMUSCULAR IM	5 MG, DAILY,					
			Risperdal (Tablet) (Risperidone)	SS		ORAL
3 MG, DAILY, ORAL						
			Milnacipran Hydrochloride (Milnacipran)	SS		ORAL
45 MG, DAILY, ORAL						
			Etizolam (Etizolam)	C		
			Estazolam (Estalozam)	C		
			Flunitrazepam (Flunitrazepam)	C		
			Triazolam (Triazolam)	C		
			Amoxapine (Amoxapine)	C		
			Thioridazine Hydrochloride (Thioridazine Hydrochloride)	C		
			Biperiden Hydrochloride (Biperiden Hydrochloride)	C		

Date:03/13/03ISR Number: 4076279-5Report Type:Expedited (15-DaCompany Report #2003002640
Age:41 YR Gender: I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardio-Respiratory Arrest	Literature	Benadryl Injection					
		Health	(Diphenhydramine)	PS				
							PARENTERAL	PARENTERAL
		Professional	Haloperidol (Haloperidol)	SS				
			Diazepam	SS				
			All Other Therapeutic Products	SS				

Date:03/14/03ISR Number: 4074282-2Report Type:Direct Company Report #CTU 188790
Age:45 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Hyponatraemia		Haloperidol	PS				
	Polydipsia		Benztropine	C				
			Hydrocortisone	C				
			Ketoconazole	C				
			Sertraline	C				
			Rabeprazole	C				

Date:03/14/03ISR Number: 4076593-3Report Type:Expedited (15-DaCompany Report #B0294377A
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Endometrial Cancer Hyperprolactinaemia Oligomenorrhoea	Foreign Study Literature Health Professional	Chlorpromazine Hydrochloride (Formulation Unknown) (Chlorpromazine Hcl)	PS				140 MON
			Haloperidol (Formulation Unknown) (Haloperidol)	SS				140 MON

Date:03/14/03ISR Number: 4076697-5Report Type:Expedited (15-DaCompany Report #EMADSS2002007830
Age:30 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Akinesia Clonic Convulsion Convulsion Cyanosis Extensor Plantar Response Extrapyramidal Disorder Haemodialysis Hepatocellular Damage Hyperkalaemia Hyperpyrexia Hypertonia Hypotension Leukocytosis Mutism Pallor	Foreign Health Professional	Haldol (Unspecified) (Haloperidol) Lepticur (Tropatepine Hydrochloride) Moditen (Fluphenazine Hydrochloride) Nozinan (Levomepromazine) Tegretol	PS SS SS SS		ORAL	5 MG, DAILY, IM 20 MG, IM; 10, IM 300 MG, DAILY, ORAL 25 MG, DAILY, IM	

	Renal Failure		(Carbamazepine)	SS		ORAL	800 MG,
	Rhabdomyolysis						DAILY, ORAL
	Sinus Tachycardia Tremor		Loxapac (Loxapine Succinate)	SS			200 MG, IM; 100 MG, IM
			Parkinane (Trihexyphenidyl Hydrochloride)	C			

Date:03/17/03ISR Number: 4077601-6Report Type:Expedited (15-DaCompany Report #EMADSS2003002091
Age:75 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Death	Bronchopneumonia	Foreign	Haldol (Haloperidol)	PS		ORAL	0.5 MG, 3 IN
Hospitalization -	Dementia	Health					1 DAY(S),
Initial or Prolonged	Dry Mouth	Professional					ORAL
	Muscle Spasms		Dothiepin (Dosulepin)	SS		ORAL	75 MG, DAILY,
			Paroxetine (Paroxetine)	C			ORAL
			Ibuprofen(Ibuprofen)	C			
			Aspirin (Acetylsalicylic Acid)	C			
			Gaviscon (Gaviscon				

			/Old Form/)	C		
			Hydroxocobalamin (Hydroxocobalamin)	C		

Date:03/17/03ISR Number: 4077602-8Report Type:Expedited (15-DaCompany Report #EMADSS2003002064
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Death	Foreign Health Professional	Haldol (5 Mg Tablet) (Haloperidol)	PS		ORAL	5 MG, 2 IN 1	DAY(S),
			Haldol Decanoate (Injection) (Haloperidol Decanoate)	SS		INTRAMUSCULAR	110 MG, 1 IN	2 WEEK(S), IM
			Kemadrin (Procyclidine Hydrochloride)	C				

Date:03/17/03ISR Number: 4077603-XReport Type:Expedited (15-DaCompany Report #APCDSS2003000341
Age:76 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Anal Fistula Delirium Delusion Depression Drug Ineffective Indifference Intentional Self-Injury Laceration	Foreign Health Professional	Haldol (Tablet) (Haloperidol)	PS		ORAL	6.75 MG ,	DAILY,
			Haldol (Injection) (Haloperidol)	SS		INTRAMUSCULAR	5 MG, DAILY,	IM
			Risperdal (Tablet) (Risperidone)	SS		ORAL	3 MG, DAILY,	

Suicidal Ideation

ORAL

Milnacipran Hydrochloride (Milnacipran)	SS		ORAL

45 MG, DAILY,

ORAL

Etizolam(Etizolam)	C	
Estazolam(Estazolam)	C	
Flunitrazepam(Flunitrazepam)	C	
Triazolam(Triazolam)	C	
Amoxapine (Amoxapine)	C	
Thioridazine Hydrochloride (Thioridazine Hydrochloride)	C	
Biperiden Hydrochloride (Biperiden Hydrochloride)	C	

Date:03/18/03ISR Number: 4078097-0Report Type:Expedited (15-DaCompany Report #NSADSS2003011453
Age:80 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardio-Respiratory Arrest Death	Consumer	Haldol					

				(Haloperidol)	PS		ORAL
0.5 MG, 1 NIGHT (S), ORAL							
				Darvocet (Darvocet)	C		
				Reminyl (Galantamine)	C		

Date:03/19/03ISR Number: 4078124-0Report Type:Direct Company Report #USP 55670
Age:54 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Medication Error		Fluphenazine Decanoate	PS	Gensia Sicor			
			Haloperidol Decanoate	SS	Gensia Sicor			

Date:03/19/03ISR Number: 4078709-1Report Type:Expedited (15-DaCompany Report #EMADSS2003002149
Age:42 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Contusion Convulsion	Foreign Health	Haldol (Unspecified) (Haloperidol)	PS		ORAL	SEE IMAGE	
	Drug Dependence Drug Interaction Drug Level Increased	Professional	Stangyl (Trimipramine Maleate)	SS		ORAL	100 MG, DAILY, ORAL	
	Electrocardiogram Qt Prolonged		Taxilan (Perazine)	SS		ORAL	300 MG, DAILY, ORAL	
	Haematoma		Dominal (Prothipendyl Hydrochloride)	SS		ORAL	80 MG, DAILY,	

ORAL

			Fevarin (Fluvoxamine Maleate)	SS		ORAL
SEE IMAGE						
			Nexium (Esomeprazole Magnesium)	C		
			Vitamin B1 (Thimaine Hydrochloride)	C		
			Carbamezapine (Carbamezapine)	C		

Date:03/19/03ISR Number: 4078710-8Report Type:Expedited (15-DaCompany Report #EMADSS2003002175
Age:83 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Erythema Feeling Hot Oedema Peripheral	Foreign Health Professional	Haldol (Unspecified) (Haloperidol)	PS		ORAL	0.5 MG, 3 IN 1 DAY (S),	
						ORAL		6 WK
			Serlain (Sertraline)	C				
			Tenormin (Atenolol)	C				
			Fraxis (Heparin-Fraction, Calcium Salt)	C				
			Temesta (Lorazepam)	C				
			Aldactone (Spironolactone)	C				
			Dafalgan					

(Paracetamol) C

Date:03/20/03ISR Number: 4079581-6Report Type:Expedited (15-DaCompany Report #PHRM2003FR00497
Age:30 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agitation Coma Convulsion	Foreign Health Professional	Tegretol (Carbamazepine) Tablet	PS			400 MG, BID	
	Cyanosis Extrapyramidal Disorder Haemodialysis Hepatic Failure Hyperkalaemia	Other	Haldol "Janssen-Cilag" (Haloperidol) Solution For Injection	SS	"Janssen-Cilag"	INTRAMUSCULAR	5 MG, QD,	
	Hyperpyrexia					INTRAMUSCULAR		
	Hypertonia Hypotension Leukocytosis Mutism		Lepticur (Tropatepine Hydrochloride) Solution	SS		INTRAMUSCULAR	10 MG, BID,	
	Pallor					INTRAMUSCULAR		
	Renal Failure						; 10 MG, QD,	
	Rhabdomyolysis					INTRAMUSCULAR		
	Tachycardia		Moditen (Fluphenazine Hydrochloride) Tablet	SS		ORAL	100 MG, TID,	
						ORAL		
			Nozinan (Levomepromazine) Solution For Injection	SS			25 MG, QD	
			Loxapac (Loxapine Succinate) S	SS		INTRAMUSCULAR	100 MG, BID,	

INTRAMUSCULAR

; 100 MG,

QD,

INTRAMUSCULAR

			Parkinane (Trihexyphenidyl Hydrochloride) Capsule	SS		ORAL	ORAL
			Tercian (Cyamemazine)	C			
			Dipiperon (Pipamperone)	C			
			Depakote (Valproate Semisodium)	C			

Date:03/20/03ISR Number: 4079583-XReport Type:Expedited (15-DaCompany Report #EMADSS2003002224
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Depressed Level Of Consciousness	Foreign Health	Haldol (Unspecified) (Haloperidol)	PS			20 MG, DAILY,	
Disability								
Other	Drug Interaction	Professional	Valium (Diazepam)	SS			40 MG, DAILY,	
	Lower Respiratory Tract Infection		Orfiril (Valproate Sodium)	SS			2400 MG, DAILY,	
	Respiratory Depression							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/20/03ISR Number: 4079626-3Report Type:Expedited (15-DaCompany Report #L03-USA-00139-03
Age:58 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Bradycardia	Literature	Propranolol	PS				
Hospitalization - Initial or Prolonged	Circulatory Collapse	Health Professional	Haloperidol	SS				
	Coma		Olanzapine	C				
	Pulse Absent		Clonazepam	C				
			Lorazepam	C				
			Prednisone	C				

Date:03/20/03ISR Number: 4080141-1Report Type:Expedited (15-DaCompany Report #EMADSS2003002219
Age:30 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Optic Neuritis	Foreign Health Professional	Haldol (Unspecified) (Haloperidol)	PS		ORAL	SEE IMAGE	
			Haldol Decanoate (Injection) (Haloperidol Decanoate)	SS		INTRAMUSCULAR	4 AMP, 1 IN 3	DAY (S), IM

Date:03/20/03ISR Number: 4080660-8Report Type:Expedited (15-DaCompany Report #A114402
Age:49 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Abdominal Distension	Foreign	Hydroxyzine					
Other	Anxiety	Literature	(Hydroxyzine)	PS		INTRAVENOUS	100 MG,	
	Medication Error	Health				INTRAVENOUS		
	Peritoneal Carcinoma	Professional	Ketamine (Ketamine)	SS		INTRAVENOUS	100 MG,	
	Pleura Carcinoma					INTRAVENOUS		
			Haloperidol					

			(Haloperidol)	SS			
INTRAVENOUS	10 MG,						
INTRAVENOUS							
			Morphine (Morphine)	SS			
INTRAVENOUS	240 MG,						
INTRAVENOUS							

Date:03/21/03ISR Number: 4082136-0Report Type:Expedited (15-DaCompany Report #PHBS2003JP00643
Age:74 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Bronchitis	Foreign	Melleril(Thioridazin					
	Dysphagia	Health	e Hydrochloride)					
	Mental Impairment	Professional	Tablet	PS		ORAL	90 MG/D,	
	Muscle Rigidity	Other					ORAL; 50	
	Oral Intake Reduced						MG/D, ORAL	
	Pneumonia		Serenace					
	Pyrexia		(Haloperidol)	SS		ORAL	3 MG/D, ORAL	
	Sedation		Norvasc	C				
	Tremor		Tanatril "Algol" (Imidapril Hydrochloride)	C				
			Panaldine (Ticlopidine Hydrochloride)	C				
			Alfacalcidol (Alfacalcidol)	C				
			Dialysis	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/21/03ISR Number: 4082157-8Report Type:Expedited (15-DaCompany Report #APCDSS2003000341
Age:76 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Anorectal Disorder	Foreign	Haldol (Tablet)					
	Depression	Health	(Haloperidol)	PS		ORAL	6.75 MG,	
	Drug Ineffective	Professional					DAILY,	ORAL
	Insomnia		Haldol (Injection)					
	Intentional Self-Injury		(Haloperidol)	SS		INTRAMUSCULAR	5 MG, DAILY,	
	Laceration							IM
	Suicidal Ideation		Risperdal (Tablet)					
			(Risperidone)	SS		ORAL	3 MG, DAILY,	
								ORAL
			Milnacipran Hydrochloride					
			(Milnacipran)	SS		ORAL	45 MG, DAILY,	
								ORAL
			Etizolam (Etizolam)	C				
			Estazolam (Estazolam)	C				
			Flunitrazepam (Flunitrazepam)	C				
			Triazolam (Triazolam)	C				
			Amoxapine (Amoxapine)	C				
			Thioridzine Hydrochloride (Thioridazine Hydrochloride)	C				
			Biperiden Hydrochloride (Biperiden Hydrochloride)	C				

Date:03/24/03ISR Number: 4082357-7Report Type:Expedited (15-DaCompany Report #2003010593
Age:50 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Amnesia	Foreign	Zoloft (Sertraline)	PS		ORAL	50 MG	(DAILY), ORAL
	Blood Creatine Phosphokinase Increased	Health Professional	Haloperidol Decanoate	SS		INTRAMUSCULAR	200 MG,	INTRAMUSCULAR
	Drug Dependence							
	Drug Interaction							
	Drug Level Increased							
	Grand Mal Convulsion							

Date:03/24/03ISR Number: 4082707-1Report Type:Expedited (15-DaCompany Report #03P-163-0213077-00
Age:39 YR Gender:Male I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Alanine Aminotransferase Increased
	Aspartate Aminotransferase Increased
	Blood Urea Decreased
	Gamma-Glutamyltransferase Increased
	Neuroleptic Malignant

Dose	Duration		Report Source	Product	Role	Manufacturer	Route
		Syndrome Obsessive-Compulsive Disorder	Health Professional Other	Hyserenin (Depakene Tablets) (Valproate Sodium)	PS		ORAL
1.5 MG, 1 IN 1 D, PER ORAL; 100 MG, 1 IN 1 D, PER ORAL							
				Fluvoxamine	SS		ORAL
50 MG, 1 IN 1 D, PER ORAL; 100 MG, 1 IN 1 D , PER ORAL							
				Haloperidol	SS		ORAL
2.4 GM, 1 IN 1 D, PER ORAL							
				Levomepromazine	SS		ORAL
3 GM, 1 IN 1 D, PER ORAL; 250 MG, 1 IN 1 D, PER ORAL							
				Clonazepam	SS		ORAL
3 MG, 1 IN 1 D, PER ORAL							
				Zonisamide	SS		ORAL
200 MG, 1 IN 1 D, PER ORAL							

			Vegetamin A	SS		ORAL

2 DOSAGE

FORMS, 1 IN 1

D, PER ORAL

			Flunitrazepam	SS		ORAL

4 MG, 1 IN 1

D, PER ORAL

			Biperiden Hydrochloride	C		
			Magnesium Oxide	C		

Date:03/25/03ISR Number: 4083387-1Report Type:Expedited (15-DaCompany Report #EMADSS2003002309
Age:42 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Psychotic Disorder	Foreign Health Professional	Haldol (1mg Tablet) (Haloperidol)	PS		ORAL

1MG, DAILY,

ORAL

		Other	Nozinan (Levomepromazine)	SS		ORAL

100 MG,

DAILY, ORAL

			Solian (Amisulpride)	SS		ORAL

200 MG,

DAILY, ORAL

			Loxapac (Loxapine Succinate)	SS		

INTRAMUSCULAR 100 MG,

DAILY, IM

Date:03/25/03ISR Number: 4083597-3Report Type:Expedited (15-DaCompany Report #NSADSS2003013469
Age: Gender:Female I/FU:I

Outcome
Hospitalization -
Initial or Prolonged
Required
Intervention to
Prevent Permanent

Impairment/Damage

	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Endometrial Cancer	Foreign	Haldol (Haloperidol)	PS			6 MG, DAILY	
		Literature	Chlorpromazine					
		Health	(Chlorpromazine)	SS			100 MG, DAILY	11 YR
		Professional						

Date:03/25/03ISR Number: 4084465-3Report Type:Direct Company Report #CTU 189474
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required	Tardive Dyskinesia		Haloperidol	PS			5MG TID	
Intervention to			Risperidone	SS			2-6 MG /DAY	
Prevent Permanent			Benztropine	C				
Impairment/Damage			L-Thyroxine	C				
			Quetiapine	C				
			Ziprasidone	C				
			Olanzapine	C				

Date:03/26/03ISR Number: 4083862-XReport Type:Expedited (15-DaCompany Report #2003011623
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Anger	Consumer	Navane (Capsule)					
Initial or Prolonged	Anorexia		(Tiotixene)	PS			6 MG (TID)	
Other	Arthritis		Geodon (Ziprasidone)	SS			20 MG	
	Asthenia						(WEEKLY)	
	Bladder Disorder		Lithane (Lithium)	SS				
	Blood Cholesterol		Valdecoxib	SS				
	Blood Pressure		Celecoxib	SS				
	Blood Pressure Systolic		Haloperidol	SS				
	Cough		Calcium Ascorbate	C				

Dizziness	Cyanocobalamin	C
Dyspepsia	Pyridoxine	
Fatigue	Hydrochloride	C
Feeling Abnormal	Zinc Picolinate	C
Frequent Bowel Movements	Fluphenazine	
Gait Disturbance	Hydrochloride	C
Headache	Methylphenidate	
Heart Rate Increased	Hydrochloride	C
Incontinence	Ketoconazole	C
Increased Appetite	Levothyroxine Sodium	C
Mental Disorder	Estrogens Conjugated	C
Muscle Spasms	Clobetasol	
Pain In Extremity	Propionate	C
Paranasal Sinus	Rofecoxib	C
Hypersecretion	Tocopherol	C
Physical Examination	Clarithromycin	C
Abnormal	Entex	C
Pollakiuria	Mesoridazine	C
Pyrexia	Risperidone	C
Schizoaffective Disorder	Olanzapine	C
Screaming	Valproate Semisodium	C
Sleep Disorder	Omeprazole	C
Stress	Nizatidine	C
Suicidal Ideation	Thiamine	
Urinary Retention	Hydrochloride	C
Weight Fluctuation		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/28/03ISR Number: 4083147-1Report Type:Expedited (15-DaCompany Report #EMADSS2003002412
Age:87 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	International Normalised Ratio Increased	Foreign Health Professional	Haldol (Unspecified) (Haloperidol)	PS		ORAL	5 MG, DAILY, ORAL	
	Subdural Haematoma		Warfarin (Warfarin)	SS		ORAL	ORAL	

Date:03/28/03ISR Number: 4086768-5Report Type:Expedited (15-DaCompany Report #EMADSS2003002224
Age:52 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Aspiration	Foreign	Haldol (Unspecified)					
Disability	Depressed Level Of Consciousness	Health Professional	(Haloperidol)	PS			20 MG, DAILY	
Other			Valium (Diazepam	SS			40 MG	
	Drug Interaction		Orfiril (Valproate Sodium)	SS			2400 MG, DAILY	
	Hypoxia							
	Leukocytosis							
	Lower Respiratory Tract Infection							
	Respiratory Depression							
	Rhonchi							
	Sedation							

Date:03/28/03ISR Number: 4086770-3Report Type:Expedited (15-DaCompany Report #EMADSS2003002175
Age:83 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dyspepsia	Foreign	Haldol (Unspecified)					
	Erythema	Health	(Haloperidol)	PS		ORAL	0.5MG, 3 IN	

	Face Oedema	Professional					
1, DAY(S),							
	Localised Oedema						
ORAL 6 WK							
	Oedema Peripheral		Serlain (Sertraline)	SS			ORAL
25 MG, 1 IN 1							
	Skin Warm						
NIGHT(S),							
	Vomiting						
ORAL							
			Tenormin (Atenolol)	C			
			Fraxis (Heparin-Fraction, Calcium Slat)	C			
			Temesta (Lorazepam)	C			
			Aldactone (Spironolactone)	C			
			Dafalgan (Paracetamol)	C			
			Lasix (Furosemide)	C			

Date:03/31/03ISR Number: 4084030-8Report Type:Direct Company Report #CTU 189794
Age:51 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required	Platelet Count Decreased		Haloperidol Dec.	PS				
INTRAMUSCULAR							100MG Q 4	
Intervention to								
WEEKS IM								
Prevent Permanent								
Impairment/Damage								

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/01/03ISR Number: 4084535-XReport Type:Direct Company Report #CTU 189836
Age:58 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Oculogyration		Haldol 2mg/Ml	PS		ORAL	5MG/10MG	5MG BID /10 ORAL

Date:04/01/03ISR Number: 4084920-6Report Type:Direct Company Report #CTU 189927
Age:43 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Coma		Haldol Haloloperidol					
Hospitalization - Initial or Prolonged	Diaphragmatic Paralysis		5 Mg, 1.5 Mg, 4 Mg,					
Disability	Extrapyramidal Disorder		6 Mg, 7 Mg, 2 Mg,					
Other	Jaw Disorder		Injection 50 Mg, 175					
PILLSEE IMAGE	Malaise		Mg	PS				
Required Intervention to Prevent Permanent Impairment/Damage	Neuroleptic Malignant Syndrome		Felbamate	C				
	Pain		Depakote	C				
	Pharyngeal Oedema		Tegretol	C				
	Respiratory Arrest		Gabritil	C				
	Shock		Synthroid	C				
	Tongue Oedema		Keppra	C				
			Ativan	C				

Date:04/01/03ISR Number: 4085458-2Report Type:Expedited (15-DaCompany Report #EMADSS2003001560
Age:17 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Body Temperature Decreased	Foreign Health	Haldol (Solution) (Haloperidol)	PS		ORAL	4 MG, 3 IN 1	
	Extrapyramidal Disorder	Professional					DAY(S); ORAL	
	Psychotic Disorder		Dominal Forte					
	Restlessness		(Prothipendyl					

			Hydrochloride)	C		
			Ztprexa (Olanzapine)	C		

Date:04/01/03ISR Number: 4085462-4Report Type:Expedited (15-DaCompany Report #EMADSS2002006908
Age:55 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Acromegaly	Foreign	Haldol (Unspecified)			
	Endocrine Neoplasm	Consumer	(Haloperidol)	PS		
UNKNOWN 2 MG, 3 IN 1	Pituitary Tumour Benign					
DAY(S),	Schizophrenia					
UNKNOWN						
			Akineton Retard (Biperiden Hydrochloride)	C		
			Norprolac (Quinagolide Hydrochloride)	C		
			Tegretol Retard (Carbamazepine)	C		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/03/03ISR Number: 4087148-9Report Type:Direct Company Report #USP 55479
Age:40 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Hypersensitivity		Haldol Haloperidol	PS	Purepac			
	Medication Error		Clonazepam	SS	N/I			
	Somnolence							

Date:04/03/03ISR Number: 4087168-4Report Type:Direct Company Report #CTU 190042
Age:49 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Neuroleptic Malignant Syndrome		Haloperidol	PS		INTRAVENOUS	5MG/ML Q4H PRN IV	
			Promethazine	SS		INTRAVENOUS	25MG /1ML Q4H PRN IV	

Date:04/03/03ISR Number: 4089783-0Report Type:Expedited (15-DaCompany Report #EMADSS2003002583
Age:80 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Confusional State Fall	Foreign Health Professional	Haldol (Unspecified) (Haloperidol)	PS		ORAL	1.5 MG , 1 IN 1 NIGHT(S),	
			Calcichew (Calcium Carbonate)	C		ORAL	3	MON
			Digoxin (Digoxin)	C				
			Warfarin(Warfarin)	C				

Date:04/04/03ISR Number: 4088033-9Report Type:Direct Company Report #CTU 190271
Age:74 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Cardiac Arrest		Haloperidol	PS		INTRAVENOUS	25MG-20MG IV	
							5MG IM	

Date:04/04/03ISR Number: 4090344-8Report Type:Expedited (15-DaCompany Report #EMADSS2003002633
Age:23 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Tachyarrhythmia	Foreign	Haldol (Unspecified)					
	Ventricular Extrasystoles	Health	(Haloperidol)	PS		ORAL	10 MG, 3 IN 1	
		Professional					DAY(S), ORAL	
							: 30 MG , 3	
							IN 1 DAY(S),	
							ORAL	
			Haldol Decanoate (100 Mg/Ml Injection) (Haloperidol Decanoate)	SS		INTRAMUSCULAR	100 MG, 1 IN	
							1 TIME(S), IM	
			Quetiapine (Quetiapine)	C				
			Diazepam (Diazepam)	C				
			Procyclidine (Procyclidine)	C				

			Depakote (Valproate Semisodium)	C			

Date:04/08/03ISR Number: 4086499-1Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0296379A
Age:88 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Pruritus		Augmentin	PS	Glaxosmithkline	INTRAVENOUS		4 DAY
Initial or Prolonged	Rash Erythematous		Oflocet 200 Mg	SS		ORAL	2	DAY
	Rash Maculo-Papular		Equanil	SS		ORAL	8	DAY
			Mopral 20 Mg	SS		ORAL	4	DAY
			Haldol	SS		ORAL	7	DAY
			Taketiam	SS		ORAL	2	DAY
			Doliprane	C	Glaxosmithkline		4	DAY

Date:04/08/03ISR Number: 4091958-1Report Type:Expedited (15-DaCompany Report #2003CG00511
Age:78 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Anaemia	Foreign	Mopral	PS		20 MG DAILY		
Initial or Prolonged	Leukopenia	Health				PO		
		Professional	Atarax	SS		100 MG DAILY		
		Other				PO		
			Haldol	SS				
			Sermion	SS				
			Navelbine "Glaxo Wellcome"	SS				
			Cortancyl	SS				

Date:04/09/03ISR Number: 4092516-5Report Type:Expedited (15-DaCompany Report #EMADSS2003002836
Age:43 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Complications Of Maternal Exposure To Therapeutic Drugs Foetal Heart Rate Abnormal Maternal Drugs Affecting Foetus Uterine Dilation And Curettage	Foreign Health Professional	Haldol(Unspecified)(Haloperidol)	PS		ORAL	7 MG, DAILY, ORAL	

Date:04/10/03ISR Number: 4091455-3Report Type:Direct Company Report #CTU 190640
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Constipation Rectal Tenesmus		Haldol Decanoate	PS		INTRAMUSCULAR	150MG IM Q4 WEEKS	
			Clozapine	SS		ORAL	300MG PO BIID	
			Glucophage	SS		ORAL	500MG PO BID	
			Haldol	C				
			Zocor	C				
			Colace	C				
			Clozapine	C				
			Glucophage	C				
			Depakote	C				

			Lactulose	C			

Date:04/10/03ISR Number: 4093598-7Report Type:Expedited (15-DaCompany Report #APCDSS2002001273
Age:36 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Anxiety	Foreign	Haldol (Tablet)(Haloperidol)	PS		ORAL	18 MG, DAILY, ORAL; 9 MG, DAILY, ORAL	
	Completed Suicide	Health Professional						
	Delusion							
	Disturbance In Attention							
	Fatigue							
	Hallucination, Auditory		Risperidone(Tablet)(Risperidone)	SS		ORAL	4 MG, DAILY, ORAL	
	Malaise							
	Muscle Rigidity							
	Somnolence		Trihexyphenidyl Hydrochloride(Trihexyphenidyl Hydrochloride)	C				
	Suicide Attempt							
	Treatment Noncompliance		Biperiden Hydrochloride(Biperiden Hydrochloride)	C				
			Chlorpromazine Hydrochloride(Chlorpromazine Hydrochloride)	C				
			Bromazepam(Bromazepam)	C				
			Estazolam(Estazolam)	C				
			Brotizolam(Brotizolam)	C				

Date:04/10/03ISR Number: 4094167-5Report Type:Expedited (15-DaCompany Report #NSADSS2002033980
Age:8 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Neuroleptic Malignant	Foreign	Haldol (Unspecified)					

	Syndrome	Health Professional	(Haloperidol)	PS			
			Clomipramine(Clomipramine)	C			

Date:04/11/03ISR Number: 4094354-6Report Type:Expedited (15-DaCompany Report #EMADSS2003002833
Age:88 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Erythema Pruritus Rash Maculo-Papular	Foreign Health Professional	Haldol (1 Mg Tablet) (Haloperidol)	PS		ORAL	1MG, DAILY, ORAL	
			Oflocet (Ofloxacin)	SS		ORAL	ORAL	
			Equanil (Meprobamte)	SS		ORAL	ORAL	
			Mopral (Omeprazole)	SS		ORAL	20 MG, DAILY, ORAL	
			Augmentin (Clavulin)	SS		INTRAVENOUS	IV	
			Taketiam (Cefotiam Hexetill Hydrochloride)	SS		ORAL	ORAL	
			Doliprane(Paracetamol)	C				

Date:04/11/03ISR Number: 4094355-8Report Type:Expedited (15-DaCompany Report #EMADSS2003002908
Age: Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Complications Of Maternal Exposure To Therapeutic Drugs Excoriation Foetal Cardiac Disorder Heart Sounds Abnormal Maternal Drugs Affecting Foetus	Foreign Health Professional	Haldol (Unspecified) (Haloperidol)	PS			TAKEN BY MOTHER DURING PREGANCY	

Date:04/16/03ISR Number: 4095900-9Report Type:Expedited (15-DaCompany Report #5000
Age:35 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Joint Stiffness		Midazolam	PS		INTRAVENOUS	8 MG ONCE, IV	
			Haloperidol	SS		INTRAVENOUS	15 MG ONCE IV	1 DAY
			Timolol Maleate	C				

Date:04/18/03ISR Number: 4098747-2Report Type:Expedited (15-DaCompany Report #EMADSS2003003149
Age:41 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Gingival Hyperplasia Mastication Disorder	Foreign Health Professional	Haldol (Haloperidol)	PS		ORAL	10 MG, DAILY, ORAL	
			Semap (Penfluridol)	SS		ORAL	30 MG, WEEKLY, ORAL	
			Biperiden					

			(Biperiden)	SS		ORAL
4 MG, DAILY,						
ORAL						
			Temesta (Lorazepam)	C		

Date:04/21/03ISR Number: 4099248-8Report Type:Expedited (15-DaCompany Report #2003015212
Age:70 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Anaemia Leukopenia	Foreign Health Professional	Atarax (Tablet) (Hydroxyzine Hydrochloride)	PS		ORAL
ORAL						
			Omeprazole (Omeprazole)	SS		ORAL
ORAL						
			Haloperidol (Haloperidol)	SS		ORAL
ORAL						
			Nicergoline (Nicergoline)	SS		ORAL
ORAL						
			Vinorelbine Ditartrate (Vinorelbine Ditartrate)	SS		ORAL
ORAL						
			Prednisone (Prednisone)	SS		ORAL
ORAL						

Date:04/22/03ISR Number: 4099957-0Report Type:Expedited (15-DaCompany Report #APCDSS2003000541
Age:26 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Diabetes Mellitus	Foreign	Haldol (Tablet)					
	Extrapyramidal Disorder	Health	(Haloperidol)	PS		ORAL	SEE IMAGE	
	Weight Increased	Professional	Risperidone (Tablet)					
			(Risperidone)	SS		ORAL	SEE IMAGE	
			Cardiovascular Agents	C				
			Brotizolam (Brotizolam)	C				
			Triazolam (Triazolam)	C				
			Flunitrazepam (Flunitrazepam)	C				

Date:04/22/03ISR Number: 4100869-4Report Type:Expedited (15-DaCompany Report #NSDADSS2003018184
Age:47 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Anaphylactic Reaction	Health	Haldol (Haloperidol)	PS			5 MG	
	Respiratory Failure	Professional	Valium (Diazepam)	C				
	Sleep Disorder		Ativan (Lorazepam)	C				

Date:04/23/03ISR Number: 4101873-2Report Type:Expedited (15-DaCompany Report #03P-151-0216605-00
Age:41 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Gingival Hypertrophy	Foreign	Akineton (Biperiden)					
Required		Health	(Biperiden)	PS		ORAL	4 MG, 1 IN 1	
Intervention to		Professional					D, PER ORAL	
Prevent Permanent			Penfluridol	SS		ORAL	30 MG, 1 IN 1	

Impairment/Damage
WK, PER ORAL

		Haloperidol	SS	ORAL

10 MG, 1 IN 1

D, PER ORAL

		Lorazepam	C	

Date:04/24/03ISR Number: 4102881-8Report Type:Expedited (15-DaCompany Report #2003011333
Age:83 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hypersensitivity	Foreign Health Professional	Sertraline (Sertraline)	PS		ORAL	25 MG, ORAL	
			Haloperidol (Haloperidol)	SS		ORAL	ORAL	
			Atenolol (Atenolol)	C				
			Heparin-Fraction, Calcium Salt (Heparin-Fraction, Calcium Salt)	C				
			Furosemide (Furosemide)	C				
			Lorazepam (Lorazepam)	C				
			Spironolactone (Spironolactone)	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/25/03ISR Number: 4097922-0Report Type:Direct Company Report #USP 51462
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Medication Error		Haloperidol	PS				
TABLET 5 MG								
			Haloperidol (Haloperidol)	SS				
TABLET 0.5 MG								

Date:04/25/03ISR Number: 4097972-4Report Type:Direct Company Report #USP 51416
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Medication Error		Haldol(Haloperidol)	PS	Orth-Mcneil			
	Overdose		Haldol (Haloperidol)	SS	Ortho-Mcneil			

Date:04/25/03ISR Number: 4101039-6Report Type:Expedited (15-DaCompany Report #APCDSS2003000556
Age:30 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Renal Failure Acute	Foreign	Risperidone (Tablet)					
	Suicide Attempt	Health	(Risperidone)	PS				
1-2 MG DAILY								
		Professional	Haldol (Injection) (Haloperidol)	SS				
INTRAVENOUS	5 MG, DAILY,							
IV								
			Mianserin Hydrochloride (Mianserin Hydrochloride)	SS		ORAL		
10 MG, DAILY,								
ORAL								
			Brotizolam (Brotizolam)	C				
			Bromvalerylurea (Bromisoval)	C				

			Lormetazepam (Lormetazepam)	C		
			Zolpidem Tartrate (Zolpidem Tartrate)	C		

Date:04/25/03ISR Number: 4102933-2Report Type:Expedited (15-DaCompany Report #APCDSS2003000556
Age:30 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Renal Failure Acute	Foreign	Haldol (Injection)			
	Suicide Attempt	Health	(Haloperidol)	PS		
INTRAVENOUS 5 MG, DAILY,						
		Professional				
IV						
			Risperidone (Tablet) (Risperidone)	SS		
1-2 MG DAILY						
			Mianserin Hydrochoride (Mianserin Hydrochloride)	SS		ORAL
10 MG, DAILY,						
ORAL						
			Brotizolam (Brotizolam)	C		
			Bromvalerylurea (Bromisoval)	C		
			Lormetazepam (Lormetazepam)	C		
			Zolpidem Tartrate			

Date:04/25/03ISR Number: 4102935-6Report Type:Expedited (15-DaCompany Report #NSADSS2003019190
Age:77 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Coma Convulsion Fatigue Gait Disturbance Speech Disorder Tachycardia	Foreign Consumer	Haldol (Injection) (Haloperidol) Fenergan (Promethazine) Furosemide Digoxin	PS C C C		INTRAMUSCULAR IM	5 MG,	DAILY,

Date:04/25/03ISR Number: 4103106-XReport Type:Expedited (15-DaCompany Report #2003016415
Age:21 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Literature Health Professional	Gabapentin (Gabapentin) Haoperidol (Haloperidol) Benzatropine Mesilate (Benzatropine Mesilate)	PS SS SS		ORAL ORAL		

ILL-DEFINED

DISORDER NOS

Date:04/25/03ISR Number: 4103235-0Report Type:Expedited (15-DaCompany Report #NSADSS2003018698
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Brain Herniation	Health	Haldol (Injection)					

		Professional	(Haloperidol)	PS		
INTRAVENOUS	15 MG, IV					

Date:04/28/03ISR Number: 4101320-0Report Type:Direct Company Report #CTU 191775
Age:50 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Neuroleptic Malignant Syndrome		Haldol 5mg #2	PS		

Date:04/28/03ISR Number: 4104079-6Report Type:Expedited (15-DaCompany Report #NSADSS2003019453
Age:12 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Dyspnoea Dystonia	Consumer Health	Haldol (Injection) (Haloperidol)	PS		
INTRAMUSCULAR 2.5 , IM						
		Professional	Risperdal (Unspecified) (Risperidone)	SS		ORAL
1 IN 1						
TIME(S) ,						
ORAL 1 WK						

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/28/03ISR Number: 4104109-1Report Type:Expedited (15-DaCompany Report #2003016546
Age:41 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Literature	Lithane (Lithium)	PS				
		Health Professional	Haloperidol (Haloperidol)	SS				

Date:04/29/03ISR Number: 4099809-6Report Type:Expedited (15-DaCompany Report #JP-ROCHE-333746
Age:55 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Blood Pressure Decreased	Consumer	Dormicum	PS	Roche	INTRAVENOUS DRIP	6	DAY
	Cardiac Failure							
	Cardio-Respiratory Arrest		Serenace	SS		INTRAMUSCULAR	1	DAY
	Depressed Level Of Consciousness		Serenace	SS		INTRAVENOUS DRIP	7	DAY
	Inflammation		Dopamine Hydrochloride	C		INTRAVENOUS DRIP		
	Multi-Organ Failure							
	Muscle Rigidity					REPORTED		
	Myoglobinuria					DURATION: 1		
	Neuroleptic Malignant Syndrome		Dobutamine	C		WEEK, 5 DAYS. INTRAVENOUS	12	DAY
	Renal Failure					REPORTED		
	Restlessness					DURATION: 1		
	Sedation					WEEK, 5 DAYS.	12	DAY
	Ventricular Tachycardia		Heparin-Fraction, Sodium Salt	C		INTRAVENOUS		

DRIP

REPORTED

DURATION: 1

WEEK, 5 DAYS. 12 DAY

INTRAVENOUS

INDICATION:

CORONARY

VASODILATION

REPORTED

DURATION: 1 12 DAY

INTRAVENOUS

6 DAY

INTRAVENOUS 1 DAY

INTRAVENOUS

3 DAY

INTRAVENOUS

7 DAY

INTRAVENOUS

12 DAY

INTRAVENOUS

6 DAY

INTRAVENOUS

REPORTED

DURATION: 1

WEEK, 5 DAYS. 12 DAY

INTRAVENOUS

Nitorol C

DRIP

Buprenorphine Hydrochloride C

DRIP

Levomepromazine Maleate C

Cefotiam C

DRIP

Tienam C

DRIP

Furosemide C

DRIP

Mexiletine Hydrochloride C

DRIP

Famotidine C

DRIP

Dexpanthenol C

DRIP

4 DAY

Human Insulin C

INTRAVENOUS

DRIP

4 DAY

Clindamycin C

INTRAVENOUS

DRIP

4 DAY

			Saline	C		
INTRAVENOUS						
						DRIP

Date:05/01/03ISR Number: 4101605-8Report Type:Expedited (15-DaCompany Report #JP-ROCHE-333746
Age:55 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Blood Pressure Decreased	Consumer	Dormicum	PS	Roche	
INTRAVENOUS						
	Multi-Organ Failure					DRIP
6 DAY						
	Neuroleptic Malignant		Serenace	SS		
INTRAMUSCULAR	1 DAY					
	Syndrome		Serenace	SS		
INTRAVENOUS						
	Renal Failure					DRIP
7 DAY						
			Dopamine Hydrochloride	C		
INTRAVENOUS						
						DRIP
REPORTED						
DURATION: 1						
WEEK, 5 DAYS. 12 DAY						
			Dobutamine	C		
INTRAVENOUS						
						DRIP
REPORTED						
DURATION: 1						
WEEK, 5 DAYS. 12 DAY						
			Heparin-Fraction, Sodium Salt	C		
INTRAVENOUS						
						DRIP
REPORTED						
DURATION: 1						
WEEK, 5 DAYS. 12 DAY						

INTRAVENOUS

INDICATION:

CORONARY

VASODILATION

REPORTED

DURATION: 1 12 DAY

INTRAVENOUS

6 DAY

INTRAVENOUS 1 DAY

INTRAVENOUS

3 DAY

INTRAVENOUS

7 DAY

INTRAVENOUS

12 DAY

INTRAVENOUS

6 DAY

INTRAVENOUS

REPORTED

DURATION: 1

WEEK, 5 DAYS. 12 DAY

INTRAVENOUS

4 DAY

INTRAVENOUS

4 DAY

Nitorol	C
	DRIP
Buprenorphine Hydrochloride	C
	DRIP
Levomepromazine Maleate	C
Cefotiam	C
	DRIP
Tienam	C
	DRIP
Furosemide	C
	DRIP
Mexiletine Hydrochloride	C
	DRIP
Famotidine	C
	DRIP
Dexpanthenol	C
	DRIP
Human Insulin	C
	DRIP

Clindamycin C
INTRAVENOUS
DRIP
4 DAY

Saline C
INTRAVENOUS
DRIP

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/01/03ISR Number: 4106483-9Report Type:Expedited (15-DaCompany Report #03P-028-0217147-00
Age:40 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Drug Interaction Neutropenia White Blood Cell Count Decreased	Foreign Literature Health Professional	Valproic Acid (Depakene) (Valproic Acid) (Valproic Acid)	PS			1500 MG, 1 IN 1 D	
			Divalproex Sodium (Depakote) (Divalproex Sodium) (Divalproex Sodium)	SS			1500 MG, 1 IN 1 D	APPROXIMATELY 1999
			Haloperidol	SS			SEE IMAGE	
			Clozapine	SS			SEE IMAGE	
			Risperidone	SS			2 MG, 1 IN 1 D,	
			Levomepromazine	C				
			Procyclidine	C				

Date:05/02/03ISR Number: 4106248-8Report Type:Expedited (15-DaCompany Report #C2003-0933.01
Age:21 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Drug Interaction Sudden Death	Health Professional Other	Clozapine Tablets 100 Mg Mylan	PS	Mylan	ORAL	150MG QD, ORAL	
			Haloperidol					

			Decanoate Injection	SS			
INTRAMUSCULAR 250MG Q 3 WEEKS, INTRAMUSCULAR INJECTION							
			Benztropine Mesylate	C			

Date:05/05/03ISR Number: 4107976-0Report Type:Expedited (15-DaCompany Report #APCDSS2003000556
Age:30 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Atrioventricular Block	Foreign	Risperidone (Tablet)					
Hospitalization -	Complete	Health	(Risperidone)	PS			1-2 MG DAILY	
Initial or Prolonged	Blood Potassium Decreased	Professional					THEN 2 MG	
Required	Blood Pressure Decreased						DAILY	
Intervention to	Cardio-Respiratory Arrest		Haldol (Injection)					
Prevent Permanent	Delirium		(Haloperidol)	SS			INTRAVENOUS	5 MG, DAILY,
Impairment/Damage	Dialysis						IV	
	Gamma-Glutamyltransferase Increased		Mianserin Hydrochloride (Mianserin					
	Insomnia							
	Kidney Enlargement		Hydrochloride)	SS		ORAL	10 MG, DAILY,	
	Myopathy						ORAL	
	Renal Failure Acute		Brotizolam					
	Therapeutic Response Decreased		(Brotizolam)	C				
			Bromvalerylurea (Bromisoval)	C				
			Lormetazepam (Lormetazepam)	C				
			Zolpidem Tartrate					

(Zolpidem Tartrate)	C
Hydrocortisone (Hydrocortisone)	C
Levothyroxine Sodium (Levothyroxine Sodium)	C
Desmopressin Acetate (Desmopressin Acetate)	C
Theophylline (Theophylline)	C
Rinderon 0 Vg (Valisone-G)	C
Clobetasone Butyrate (Clobetasone Butyrate)	C
Trazodone Hydrochloride (Trazodone Hydrochloride)	C
Dydrogesterone (Dydrogesterone)	C
Pravastatin Sodium (Pravastatin Sodium)	C
Hydrocortisone Sodium Succinate (Hydrocortisone Sodium)	C

Date:05/05/03ISR Number: 4108178-4Report Type:Expedited (15-DaCompany Report #APCDSS2003000541
Age:26 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Diabetes Mellitus	Foreign	Haldol (Tablet)					
	Extrapyramidal Disorder	Health	(Haloperidol)	PS			0.5 MG,	
	General Physical Health	Professional					DAILY; 3 MG,	
	Deterioration						DAILY, ORAL	
	Weight Increased		Risperidone (Tablet) (Risperidone)	SS			2 MG, DAILY; 6 MG, DAILY,	

ORAL

Cardiovascular Agents	C	
Brotizolam (Brotizolam)	C	
Triazolam (Triazolam)	C	
Flunitrazepam (Flunitrazepam)	C	

Date:05/05/03ISR Number: 4108179-6Report Type:Expedited (15-DaCompany Report #EMADSS2003003509
Age:86 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Herpes Virus Infection Linear Iga Disease	Foreign Health Professional	Haldol (2 Mg/Ml Solution) (Haloperidol)	PS		ORAL	0.9 MG, DAILY,	
			Efferalgan (Paracetamol)	SS		ORAL	PRN,	

			Mopral (Omeprazole)	SS		ORAL
1 TABLE, DAILY, ORAL						
			Forlax (Macrogol)	SS		ORAL
1 SACHE, DAILY, ORAL						
			Zyrtec (Cetirizine Hydrochloride)	SS		ORAL
10 MG, DAILY, ORAL						
			Medrol (Methylprednisolone)	SS		ORAL
8 MG, DAILY, ORAL						
			Pulmicort (Budesonide)	SS		
INHALA						
			Bricanyl (Terbutaline Sulfate)	SS		
INHALA						

Date:05/05/03ISR Number: 4108181-4Report Type:Expedited (15-DaCompany Report #APCDSS2003000556
Age:30 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Atrioventricular Block	Foreign	Haldol (Injection)					
Hospitalization -	Complete	Health	(Haloperidol0	PS				
INTRAVENOUS							5 MG,	DAILY,
Initial or Prolonged IV	Blood Creatine	Professional						
	Phosphokinase Increased		Risperidone (Tablet)					
	Blood Potassium Abnormal		(Risperidone)	SS				
1-2 MG DAILY								
	Blood Pressure Decreased							
THEN 2 MG DAILY								
	Cardio-Respiratory Arrest							
	Delirium		Miaserin Hydrochloride					
	Drug Effect Decreased							

	Drug Ineffective Insomnia	(Mianserin Hydrochloride)	SS	ORAL 10 MG, DAILY,
	Kidney Enlargement			ORAL
	Renal Failure Acute Suicide Attempt	Brotizolam (Brotizolam)	C	
		Bromvalerylurea (Bromisoval)	C	
		Lormetazepam (Lormetazepam)	C	
		Zolpidem Tartrate (Zolpidem Tartrate)	C	
		Hydrocortisone (Hydrocortisone)	C	
		Levothyroxine Sodium (Levothyroxine Sodium)	C	
		Desmopressin Acetate (Desmopressin Acetate)	C	
		Theophylline (Theophylline)	C	
		Ridneron-Vg (Valisone-G)	C	
		Clobetasone Butyrate (Clobetasone Butyrate)	C	
		Trazodone Hydrochloride (Trazodone Hydrochloride)	C	
		Dydrogesterone		

			(Dydrogesterone)	C		
			Pravastatin Sodium (Pravastatin Sodium)	C		
			Hydrocortisone Sodium Succinate (Hydrocortisone Sodium Succinate)	C		

Date:05/05/03ISR Number: 4108372-2Report Type:Expedited (15-DaCompany Report #2003157660FR
Age:86 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Condition Aggravated Dermatitis Bullous Face Oedema	Foreign Health Professional	Medrol (Methylprednisolone) Tablet	PS		ORAL	8 MG, QD, ORAL	
	Herpes Simplex Linear Iga Disease Rash Erythematous	Other	Efferalgan (Paracetamol)	SS		ORAL	ORAL	
	Skin Disorder		Mopral (Omeprazole)	SS		ORAL	1 DF, QD, ORAL	
	Skin Ulcer		Forlax (Macrogol)	SS		ORAL	1 DF, QD, ORAL	
			Zyrtec (Cetirizine Hydrochloride)	SS		ORAL	10 MG, QD, ORAL	
			Haldol (Haloperidol)	SS			SEE IMAGE	
			Budesonide	C				
			Terbutaline (Terbutaline)	C				

Date:05/06/03ISR Number: 4106635-8Report Type:Direct Company Report #CTU 192333
Age:14 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dysarthria Dystonia Tremor		Abilify Otsuka	15 Mg PS	Otsuka	ORAL	15 MG	Q DAY
Required								
ORAL								
Intervention to Prevent Permanent Impairment/Damage			Haldol Mylan	5 Mg/1 Ml SS	Mylan		INTRAMUSCULAR	2.5 MG / 5/2
IM / INTRAMUSCULAR								
			Buspar	C				
			Miralax	C				
			Zoloft	C				
			Mvi	C				

Date:05/06/03ISR Number: 4108455-7Report Type:Expedited (15-DaCompany Report #EMADSS2003003606
Age:96 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Hospitalization - Initial or Prolonged	Cerebrovascular Accident Hemiplegia	Foreign Health Professional	Haldol (Unspecified) (Haloperidol)	PS		ORAL	3 IN 1	DAY(S), ORAL
			Triatec (Ramipril)	SS		ORAL	1.25 MG, 1 IN	1 DAY(S), ORAL
			Stilnox (Zolpidem)	SS		ORAL	10 MG, 1 IN 1	DAY(S), ORAL
			Furosemide					

			(Furosemide)	SS			ORAL
1, DAILY,							
ORAL							
			Potassium (Potassium)	SS			
2 IN 1							
DAY(S),							
			Hemigoxine Nativelle (Digoxin)	SS			ORAL
0.125 MG, 1							
IN 1 DAY(S),							
ORAL							

Date:05/07/03ISR Number: 4109403-6Report Type:Expedited (15-DaCompany Report #PHBS2003JP04386
Age:47 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Thirst Water Intoxication	Foreign Literature Health Professional Other	Carbamazepine (Carbamazepine) Unknown	PS		ORAL	400 MG/DAY,	ORAL
			Phenytoin (Phenytoin)	SS		ORAL	150 MG/DAY,	ORAL
			Phenobarbital (Phenobarbital)	SS		ORAL	150 MG/DAY,	ORAL
			Zonisamide (Zonisamide)	SS		ORAL	100 MG/DAY,	ORAL
			Haloperidol (Haloperidol)	SS			3 MG/DAY,	

ORAL

Date:05/08/03ISR Number: 4109870-8Report Type:Direct Company Report #USP 081069
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Medication Error		Haldol	PS	Mcneil Pharm			
			Halcion(Triazolam)	SS	Pharmacia/Upjohn			

Date:05/08/03ISR Number: 4110090-1Report Type:Expedited (15-DaCompany Report #EMADSS2003003716
Age:36 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Intentional Misuse Suicide Attempt	Foreign Health Professional	Haldol (Tablet) (Haloperidol)	PS		ORAL	10 TABLE,	TOTAL, ORAL
			Lisinopril (Lisinopril)	SS		ORAL	20 TABLE,	TOTAL, ORAL
			Insulin Human (Insulin Human)	SS			40 IU,	TOTAL,
			Levomeprazole (Levomepromazine)	C				
			Risperidone (Risperidone)	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/08/03ISR Number: 4110091-3Report Type:Expedited (15-DaCompany Report #EMADSS2003003606
Age:96 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Hospitalization -	Cerebrovascular Accident	Foreign Health	Haldol (Unspecified) (Haloperidol)	PS		ORAL	3 IN 1	Initial or Prolonged
		Professional					DAY(S), ORAL	
			Triatec (Ramipril)	SS		ORAL	1.25 MG, 1 IN	1 DAY(S),
							ORAL	
			Stilnox (Zolpidem)	SS		ORAL	10 MG, 1 IN 1	DAY(S), ORAL
			Furosemide (Furosemide)	SS		ORAL	1, DAILY,	
							ORAL	
			Potassium (Potassium)	SS			2 IN 1	DAY(S),
			Hemigoxine Nativelle (Digoxin)	SS		ORAL	0.125 MG, 1	IN 1 DAY(S),
							ORAL	

Date:05/08/03ISR Number: 4110141-4Report Type:Expedited (15-DaCompany Report #NSADSS2003020918
Age:21 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Death Disease Recurrence	Health Professional	Haldol Decanoate (Injection)					

	Drug Interaction Hallucination	Company Representative	(Haloperidol Decanoate)	PS			
INTRAMUSCULAR 250 MG, 1 IN 3 WEEK(S), IM	Hypotension						
	Pulmonary Embolism		Clozapine (Clozapine)	SS			ORAL
150 MG, DAILY, ORAL							
			Benztropine Mesylate (Benzatropine Mesilate)	C			

Date:05/12/03ISR Number: 4110835-0Report Type:Expedited (15-DaCompany Report #200311860FR
Age:88 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Life-Threatening Hospitalization - Initial or Prolonged	Bronchopneumopathy Dehydration Haematoma Renal Failure	Foreign Other	Zopiclone (Imovane) Tablets	PS		ORAL	7.5 MG/DAY PO
			Furosemide (Lasilix) Solution For Injection	SS			INTRAVENOUS 20 MG/DAY IV
			Haloperidol	SS		ORAL	15 U/DAY PO
			Clarithromycin (Zeclar) Tablets	SS		ORAL	PO 4 DAY

Date:05/12/03ISR Number: 4111237-3Report Type:Expedited (15-DaCompany Report #EMADSS2003003740
Age:47 YR Gender:Female I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Blood Calcium Decreased Bradycardia Electrocardiogram Qt

	Corrected Interval Prolonged Electrocardiogram Qt Prolonged	Report Source	Product	Role	Manufacturer	Route	Dose Duration
		Foreign Health Professional	Haldol (5mg/Ml Injection) (Haloperidol)	PS		INTRAVENOUS	60 MG, DAILY, IV

Date:05/14/03ISR Number: 4112371-4Report Type:Expedited (15-DaCompany Report #200311865FR
Age:96 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Life-Threatening Hospitalization - Initial or Prolonged	Arrhythmia Atrial Fibrillation Cerebrovascular Accident	Foreign Other	Ramipril (Triatec Faible 1.25 Mg) Capsules	PS		ORAL	1.25 MG QD PO
	Condition Aggravated		Furosemide	SS		ORAL	1 U/DAY PO
	Dementia		Haloperidol	SS		ORAL	3 U/DAY PO
	Hypertension Malnutrition		Zolpidem (Stilnox) Tablets	SS		ORAL	10 MG QD PO
			Potassium	SS		ORAL	2 U/DAY PO
			Digoxin (Hemigoxine Nativelle) Tablets	SS		ORAL	0.125 MG QD PO

Date:05/14/03ISR Number: 4112569-5Report Type:Expedited (15-DaCompany Report #HQWYE052405MAY03
Age:29 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Agitation Leukopenia	Health Professional	Temesta (Lorazepam, Tablet)	PS		ORAL	SEE IMAGE 69 DAY

Other	Neutropenia	Other	Clopixol (Zuclopenthixol Decanoate)	SS			ORAL
SEE IMAGE	16 DAY						
			Haldol (Haloperidol)	SS			ORAL
SEE IMAGE	5 DAY						
			Seroquel (Quetiapine)	SS			ORAL
SEE IMAGE	1 DAY						
			Risperdal (Risperdone)	C			
			Konakion (Phytomenadione)	C			
			Zyprexa (Olanzapine)	C			

Date:05/14/03ISR Number: 4113891-9Report Type:Direct Company Report #CTU 193097
Age:34 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Insomnia		Haloperidol Decanoate	PS			4 INECTIONS	
							100 MG	
			Benztropine Mesylate	SS			1 MG TABLETS	

Date:05/15/03ISR Number: 4112964-4Report Type:Expedited (15-DaCompany Report #EMADSS2003003847
Age: Gender:Female I/FU:I

Outcome	PT
Other	Abortion Spontaneous
	Complications Of Maternal

		Exposure To Therapeutic Drugs Maternal Drugs Affecting Foetus Pregnancy	Report Source Foreign Health Professional	Product Haldol (0.5 Mg Tablet) (Haloperidol)	Role PS	Manufacturer	Route ORAL
Dose 0.5 MG, DAILY, ORAL	Duration						

Date:05/15/03ISR Number: 4113161-9Report Type:Expedited (15-DaCompany Report #DEWYE127612MAY03
Age:56 YR Gender:Female I/FU:I

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Death		Abdominal Pain Upper Breast Pain Nausea Pain In Extremity	Study	Tavor(Lorazepam, Tablet, 0)	PS		ORAL
3,4,5,4,6,1 MG 1X PER 1 DAY	14 DAY						
		Vomiting		Haldol (Haloperidol, , 0)	SS		ORAL
10,5,10 MG 1X PER 1 DAY	1 DAY						
				Leponex(Clozapine, , 0)	SS		ORAL
12.5,25,12.5 MG 1X PER 1 DAY	2 DAY						
				Paspertin (Metoclopramide Hydrochloride)	C		
				Trevilor (Venlafaxine Hydrochloride)	C		
				Tamoxifen(Tamoxifen)	C		

Date:05/16/03ISR Number: 4113807-5Report Type:Expedited (15-DaCompany Report #03H-167-0218318-00
Age:70 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Condition Aggravated Drug Ineffective Pneumonia Sedation	Foreign Literature Health Professional	Midazolam Hydrochloride Injection 1mg/Ml Ftv (Midazolam Hydrochloride	PS		SUBCUTANEOUS	60 MG, SUBCUTANEOUS INFUSION, SUBCUTANEOUS	
			Phenobarbital Sodium Injection (Phenobarbital Sodium0 Phenobarbital	SS		SUBCUTANEOUS	200 MG, ONCE SUBCUTANEOUS	
			Haloperidol	SS			12 MG, DAILY	
			Levomepromazine	SS		SUBCUTANEOUS	SEE IMAGE	

Date:05/19/03ISR Number: 4111057-XReport Type:Expedited (15-DaCompany Report #DE-ROCHE-316897
Age:17 YR Gender:Male I/FU:F

Outcome
Hospitalization - Initial or Prolonged

Disability

	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Abnormal Behaviour		Roaccutan	PS	Roche	ORAL	5	MON
	Acute Psychosis		Haloperidol	SS	Roche		UNKNOWN	
	Aggression Apathy Bradyphrenia Convulsion Depressed Level Of Consciousness Depression Dysphonia Fatigue Infection Influenza Like Illness Lethargy Movement Disorder Psychotic Disorder Schizoaffective Disorder Somnolence Suicidal Ideation							

Date:05/19/03ISR Number: 4115125-8Report Type:Expedited (15-DaCompany Report #A02200301130
Age:96 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Hospitalization - Initial or Prolonged	Cerebrovascular Accident	Health Professional	Stilnox - (Zolpidem) - Tablet - 10 Mg	PS		ORAL		
			Haldol - (Haloperidol) - Unknown - Unit Dose: Unknown	SS		ORAL	1.25 MG OD,	
			Triatec - (Ramipril) - Capsule - 1.25 Mg	SS		ORAL		
			(Furosemide) - Unknown - Unit Dose - Unknown	SS		ORAL		
			(Potassium) -Unknown - Unit Dose :					

			Unknown	SS			
			Hemigoxine Nativelle - (Digoxin) - Tablet - 0.125 Mg	SS			ORAL
0.125 MG OD							

Date:05/19/03ISR Number: 4115229-XReport Type:Expedited (15-DaCompany Report #PHBS2003JP04386
Age:47 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Clonic Convulsion Convulsion Hypochloraemia Hyponatraemia Loss Of Consciousness Polydipsia Water Intoxication	Foreign Literature Health Professional Other	Carbamazepine (Carbamazepine) Unknown	PS		ORAL	400 MG/DAY, ORAL
			Phenytoin (Phenytoin)	SS		ORAL	150 MG/DAY, ORAL
			Phenobarbital (Phenobarbital)	SS		ORAL	150 MG/DAY, ORAL

			Zonisamide (Zonisamide)	SS		ORAL
100 MG/DAY, ORAL						
			Haloperidol (Haloperidol)	SS		ORAL
3 MG/DAY, ORAL						

Date:05/20/03ISR Number: 4114283-9Report Type:Expedited (15-DaCompany Report #K200300802
Age:96 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Life-Threatening	Atrial Fibrillation	Foreign	Altace Capsules			
Hospitalization -	Cerebral Artery Occlusion	Health	(Ramipril) Capsule,			
Initial or Prolonged	Cerebrovascular Accident	Professional	1.25 Mg	PS		ORAL
1.25 MG QD ORAL	Condition Aggravated	Other				
	Dementia		Furosemide			
	Hypertension		(Furosemide) Iu	SS		ORAL
I U, QD, ORAL	Malnutrition		Haldol (Haloperidol)			
			3u	SS		ORAL
3 U, QD, ORAL			Stilnox (Zolpidem)			
			Tablet, 10mg	SS		ORAL
10 MG, QD, ORAL						
			Potassium			
			(Potassium) 2u	SS		ORAL
2 U, QD, ORAL			Hemigoxine Nativelle			
			(Digoxin) 0.125 Mg	SS		ORAL
0.125 MG QD ORAL						

Date:05/20/03ISR Number: 4114796-XReport Type:Direct Company Report #CTU 193489
Age:76 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Cardio-Respiratory Arrest		Haldol (Haloperidol)					
Hospitalization -	Convulsion		Generic	PS				
INTRAVENOUS							4 MG/O	IV
Initial or Prolonged								
			Lovenox	C				
			Protonix	C				
			Synthroid	C				
			Zosyn	C				
			Nitro Bid	C				
			Fentanyl	C				
			Solumedrol	C				

Date:05/20/03ISR Number: 4114857-5Report Type:Direct Company Report #CTU 193516
Age:44 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Chorea		Haloperidol 5 Mg					
	Dyskinesia		Tablets	PS		ORAL		
2.5 MG PO BID								
			Phenytoin	C				
			Valproic Acid	C				
			Benztropine	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/21/03ISR Number: 4114224-4Report Type:Expedited (15-DaCompany Report #C2003-0933.01
Age:21 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Disease Recurrence	Health	Clozapine Tablets					
	Hallucination	Professional	100 Mg Mylan	PS		ORAL	150MG QD,	
	Hypotension	Other					ORAL	
	Pulmonary Embolism		Haloperidol Decanoate Injection	SS		INTRAMUSCULAR	250MG Q 3	WEEKS,
							INTRAMUSCULAR	
							INJECTION	
			Benztropine Mesylate	C				
			Citalopram	C				

Date:05/21/03ISR Number: 4116148-5Report Type:Direct Company Report #CTU 193683
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Dystonia		Divalproex Na (Ec)	PS		ORAL	250MG PO TID	
			Haldol	SS			2MG INJ PRN	
							AGITATION	

Date:05/22/03ISR Number: 4117326-1Report Type:Direct Company Report #USP 51004
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Medication Error		Haldol	PS	Geneva		TABLET	

Date:05/23/03ISR Number: 4116922-5Report Type:Expedited (15-DaCompany Report #APCDSS2003000556
Age:30 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Atrioventricular Block	Foreign	Risperidone(Tablet)Risperidone)	PS		ORAL	1 MG, DAILY,	
Hospitalization - Initial or Prolonged	Blood Creatine Phosphokinase Increased	Health Professional					ORAL; 2 MG,	
Required Intervention to Prevent Permanent Impairment/Damage	Blood Pressure Decreased Cardio-Respiratory Arrest Delirium		Haldol(Injection)(Haloperidol)	SS		IV	5 MG, DAILY,	
	Depressed Level Of Consciousness Dialysis Hepatic Steatosis		Mianserin Hydrochloride(Mianserin Hydrochloride)	SS		ORAL	10 MG, DAILY,	
	Insomnia Kidney Enlargement Muscle Disorder Renal Failure Acute Respiratory Disorder Sleep Phase Rhythm Disturbance Soliloquy Suicidal Ideation Suicide Attempt		Brotizolam(Brotizolam) Bromvalerylurea(Bromisoval) Lormetazepam(Lormetazepam) Zolpidem Tartrate(Zolpidem Tartrate) Hydrocortisone(Hydrocortisone) Levothyroxyne Sodium(Levothyroxine Sodium)	C C C C C C		ORAL		

Desmopressin Acetate(Desmopressin Acetate)	C
Theophylline(Theophylline)	C
Rinderon-Vg(Valisone-G)	C
Clobetasone Butyrate(Clobetasone Butyrate)	C
Trazodone Hydrochloride(Trazodone Hydrochloride)	C
Dydrogesterone (Dydrogesterone)	C
Pravastatin Sodium(Pravastatin Sodium)	C
Hydrocortisone Sodium Succinate(Hydrocortisone Sodium Succinate)	C

Date:05/27/03ISR Number: 4119174-5Report Type:Direct Company Report #CTU 193946
Age:64 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required	Dystonia		Haldol	PS				
INTRAVENOUS							5 MG IV X 1	
Intervention to Prevent Permanent Impairment/Damage	Muscle Spasms		Paxil	C				
			Trazadone	C				

Date:05/27/03ISR Number: 4119178-2Report Type:Direct Company Report #CTU 193932
Age:41 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Emotional Disorder		Haldol	PS				
INTRAMUSCULAR							10 MG	

Disability	Feeling Abnormal					
INTRAMUSCULAR						
Other			Haldol	SS		
5 MG						
			Depakote	SS		
250MG 3X A						
DAY						
			Cogentin	SS		
1MG 3X A DAY						
			Ativan	SS		
2 MG EVERY						
6HR						
			Desyrel	SS		
			Tranxene	SS		

Date:05/28/03ISR Number: 4117831-8Report Type:Direct Company Report #CTU 194107
Age:60 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Blood Creatine		Halperidol(Haldol)	PS		
INTRAMUSCULAR 5.0MG X1 IM						
Initial or Prolonged	Phosphokinase Increased		Quetiapine			
	Muscle Rigidity		(Seroquel)	SS		ORAL
50MG TID PO						
	Neuroleptic Malignant Syndrome					
	Pyrexia					

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/28/03ISR Number: 4118682-0Report Type:Expedited (15-DaCompany Report #2003-105038-NL
Age:92 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Dementia	Consumer	Remeron	PS			7.5 MG DAILY	
	Emotional Distress		Zyprexa	SS			DF DAILY	
	Hallucination		Haldol	SS			0.5 MG DAILY	
			Plafix	C				

Date:05/29/03ISR Number: 4119396-3Report Type:Direct Company Report #CTU 194261
Age:19 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Blood Prolactin Increased		Haloperidol	PS			2 MG 8AM, 3 MG Q 2PM	
			Citalopram	C				
			Clonidine	C				
			Topiramate	C				
			Benztropine	C				
			Miralax	C				
			Trazodone	C				
			Clindamycin Topical	C				
			Calcium	C				
			Clonazepam	C				
			Ranitidine	C				
			Multivit	C				

Date:06/02/03ISR Number: 4120614-6Report Type:Direct Company Report #CTU 194469
Age:44 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Asthenia Parkinsonism		Haloperidol	PS				

Date:06/03/03ISR Number: 4122285-1Report Type:Direct Company Report #CTU 194685
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Cerebral Atrophy		Haldol	PS				
FORCED ON Hospitalization - Initial or Prolonged Disability Other Required Intervention to Prevent Permanent Impairment/Damage	Nervous System Disorder		Resperidol	SS				

Date:06/04/03ISR Number: 4123004-5Report Type:Direct Company Report #USP 51266
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Medication Error		Haldol	PS	Ortho-Mcneil			
			Haldol	SS	Ortho-Mcneil			

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/04/03ISR Number: 4123307-4Report Type:Direct Company Report #CTU 194851
Age:60 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dizziness		Haloperidol	PS			2MG BID	
	Syncope		Baclofen	SS			10MG TID	
			Guaifenesin	C				
			Atenolol	C				
			Lorazepam	C				
			Meclizine	C				
			Venlafaxine	C				
			Fosinopril	C				
			Hctz	C				
			Fosinopril	C				

Date:06/04/03ISR Number: 4124143-5Report Type:Expedited (15-DaCompany Report #PHBS2003JP05441
Age:77 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Alkaline Phosphatase Increased	Foreign Health	Diovan (Valsartan)	PS		ORAL	40 MG/DAY, ORAL	
	Cholestasis Gamma-Glutamyltransferase Increased	Professional Other	Akineton (Biperiden Hydrochloride)	SS		ORAL	1 DF/DAY, ORAL	
	Hepatic Function Abnormal		Contomin (Chlorpromaine Hydrochloride)	SS		ORAL	2 DF/DAY, ORAL	
			Halosten (Haloperidol)	SS		ORAL	1 DF/DAY, ORAL	

Date:06/04/03ISR Number: 4124215-5Report Type:Expedited (15-DaCompany Report #B0300205A
Age:47 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Death	Literature Health Professional	Parnate (Formulation Unknown) (Tranylcypromine Sulphate) Haloperidol (Formulation Unknown) (Haloperidol)	 PS SS				

Date:06/04/03ISR Number: 4124674-8Report Type:Expedited (15-DaCompany Report #B0300211A
Age:30 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Adverse Drug Reaction	Literature Health Professional	Lithium Salt (Lithium Salt) Fluoxetine (Formulation Unknown) (Fluoxetine) Haloperidol (Formulation Unknown) (Haloperidol)	 PS SS SS				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/04/03ISR Number: 4124720-1Report Type:Expedited (15-DaCompany Report #B0300294A
Age:32 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Literature	Wellbutrin					
		Health	(Bupropion					
		Professional	Hydrochloride)	PS				
			Amitriptyline					
			(Amitriptyline)	SS				
			Haloperidol					
			(Formulation					
			Unknown)					
			(Haloperidol)	SS				

Date:06/09/03ISR Number: 4126041-XReport Type:Expedited (15-DaCompany Report #APCDSS2003000714
Age:1 DY Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Maternal Drugs Affecting	Foreign	Risperdal					
	Foetus	Health	(Risperidone)	PS				
SEE IMAGE								
	Pregnancy	Professional	Haldol (Haloperidol)	SS				
5 MG, DAILY,								
	Respiratory Rate							
UTERINE								
	Decreased							

Date:06/09/03ISR Number: 4126182-7Report Type:Expedited (15-DaCompany Report #NSADSS2003018184
Age:47 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Akathisia	Health	Haldol (Unspecified)					
Initial or Prolonged	Anaphylactic Reaction	Professional	(Haloperidol)	PS				
5 MG								
Other	Asthma		Valium (Diazepam)	C				
Required	Depression		Ativan (Lorazepam)	C				
Intervention to	Mental Status Changes							
Prevent Permanent	Post-Traumatic Stress							
Impairment/Damage	Disorder							

		Respiratory Failure					

Date:06/09/03ISR Number: 4126280-8Report Type:Expedited (15-DaCompany Report #EMADSS2003003740
Age:47 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Calcium Decreased Blood Creatinine Bradycardia Electrocardiogram Qt Corrected Interval Prolonged Electrocardiogram Qt Prolonged	Foreign Health Professional	Haldol (5 Mg/Ml Injection) (Haloperidol)	PS		IV	INTRAVENOUS 60 MG, DAILY,	

Date:06/09/03ISR Number: 4126282-1Report Type:Expedited (15-DaCompany Report #APCDSS2003000714
Age:1 DY Gender:Male I/FU:I

Outcome	PT
Other	Anxiety Complications Of Maternal Exposure To Therapeutic

		Drugs Maternal Drugs Affecting Foetus Neonatal Disorder Pregnancy Respiratory Rate	Report Source Foreign Health Professional	Product Haldol (Unspecified) (Haloperidol)	Role PS	Manufacturer	Route
INTRA-UTERINE	5 MG, DAILY,	Decreased					UTERINE
				Risperdal (Unspecified) (Risperidone)	SS		
INTRA-UTERINE	SEE IMAGE						

Date:06/09/03ISR Number: 4126375-9Report Type:Expedited (15-DaCompany Report #APCDSS2003000770
Age:78 YR Gender:Male I/FU:I

Outcome	Dose	PT	Report Source	Product	Role	Manufacturer	Route
Other	Duration	Blood Creatine Phosphokinase Increased Fall Nausea Somnolence	Foreign Health Professional	Duragesic (Patch) (Fentanyl)	PS		
TRANSDERMAL	5 MG, 1 IN 72 HOUR (S), TRANSD, 2.5 MG, 1 IN 72 HOUR (S),						
				Haldol (Unspecified) (Haloperidol)	SS		
	3 MG, DAILY, UNKNOWN; 2 MG, DAILY, UNKNOWN						

Date:06/10/03ISR Number: 4127825-4Report Type:Expedited (15-DaCompany Report #HQWYE395229MAY03
Age:5 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Hospitalization - Initial or Prolonged Other	Disseminated Intravascular Coagulation Hepatic Function Abnormal Neuroleptic Malignant Syndrome Rhabdomyolysis	Health Professional Other	Benzhexol (Trihexyphenidyl, Tablet)	PS		ORAL	10-15 MG TWICE DAILY ORAL	
			Haloperidol (Haloperidol)	SS		ORAL	0.75 MG 1X PER 1 DAY ORAL	6 DAY
			Tetrabenazine (Tetrabenazine)	SS		ORAL	12.5 MG EACH NIGHT ORAL	5 DAY

Date:06/13/03ISR Number: 4128858-4Report Type:Direct Company Report #CTU 195760
Age:64 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Cardio-Respiratory Arrest Pulse Absent Torsade De Pointes		Haloperidol Risperidone 1mg Janssen	PS SS	Jassen		5MG Q 6H 1MG BID ONLY GIVEN 1 DOSE	
			Fluconazole 400mg Pfizer	SS	Pfizer		INTRAVENOUS	400MG IV BID
			Metronidazole 500mg	SS		ORAL	500MG Q 8H ORAL	
			Albuterol Nebs Ceftrizidine Metoprolol	C C C				

			Lansoprazone	C			
			Calcium Acetate	C			

Date:06/16/03ISR Number: 4130332-6Report Type:Expedited (15-DaCompany Report #002#2#2002-00109 (0)
Age:43 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Akathisia Arthropathy	Consumer	Reglan-10mg-Tablet (Metoclopramide Hcl)	PS		ORAL	10MG, 4 IN 1	
Disability	Blepharospasm						D, ORAL	
	Blood Pressure Increased		Prochlorperazine-Edisylate	SS				
	Chest Discomfort		Haloperidol	SS				
	Condition Aggravated		Gabapentin	SS				
	Conversion Disorder		Olanzapine	SS				
	Depression		Lisinopril	C				
	Diarrhoea		Diazepam	C				
	Disturbance In Attention		Mylanta	C				
	Drug Withdrawal Syndrome		Metoprolol	C				
	Dry Mouth		Heparin	C				
	Dysphagia		Clopidogrel	C				
	Dysphemia							
	Dyspnoea							
	Dystonia							
	Eye Pain							
	Feeling Abnormal							
	Halo Vision							
	Headache							
	Hyperhidrosis							
	Impaired Driving Ability							
	Malaise							
	Migraine							
	Muscle Spasms							
	Nausea							
	Nervousness							
	Nightmare							
	Obsessive-Compulsive Disorder							
	Palpitations							
	Paraesthesia							
	Photosensitivity Reaction							
	Posture Abnormal							
	Restlessness							

Sleep Apnoea Syndrome
Speech Disorder
Strabismus
Syncope
Tardive Dyskinesia
Tic
Tremor
Visual Acuity Reduced

Date:06/16/03ISR Number: 4130413-7Report Type:Expedited (15-DaCompany Report #03P-087-0220637-00
Age:45 YR Gender:Male I/FU:I

Outcome	PT
Required	Akathisia
Intervention to	Cachexia
Prevent Permanent	Decreased Appetite
Impairment/Damage	Formication

		Hyperkinesia Oral Intake Reduced Weight Decreased	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
			Foreign Health Professional Other	Akineton (Biperiden) (Biperiden)	PS		ORAL
6 MG, 1 IN 1 D, PER ORAL; 3 MG, PER ORAL							
				Haloperidol	SS		ORAL
6 MG, 1 IN 1 D, PER ORAL; 3 MG, 1 IN 1 D, PER ORAL							
				Clonazepam	C		
				Cloxazolam	C		

Date:06/16/03ISR Number: 4130491-5Report Type:Expedited (15-DaCompany Report #03P-163-0221111-00
Age:40 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Death	Cardio-Respiratory Arrest Completed Suicide	Literature Health Professional	Valproic Acid (Depakene) (Valproic Acid)	PS		
			Phenobarbital	SS		
			Haloperidol	SS		

Date:06/16/03ISR Number: 4130498-8Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20030600544
Age:92 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Death	Death	Consumer	Haldol (Haloperidol)	PS		
0.5 MG						

Date:06/17/03ISR Number: 4130651-3Report Type:Direct Company Report #CTU 196045
Age:49 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Arrhythmia		Haloperidol	PS				
Hospitalization - Initial or Prolonged	Blood Pressure Decreased		Lorazepam	SS				
	Bradycardia							
	Coma							
	Electrocardiogram Qt Corrected Interval Prolonged							
	Hypothermia							

Date:06/17/03ISR Number: 4130979-7Report Type:Expedited (15-DaCompany Report #FR-JNJFOC-20030600601
Age:49 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain Upper	Foreign	Haldol (Haloperidol) Solution	PS		ORAL	8 MG, 1 IN 1	DAY, ORAL
	Arthralgia	Consumer						
	Asthenia							
	Erectile Dysfunction		Vasobral () Vasobral	C				
	Hyperglycaemia		Floxyfral ()					
	Tremor		Fluvoxamine Maleate	C				
	Vertigo		Lexomil ()					
	Weight Decreased		Bromazepam	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/18/03ISR Number: 4132158-6Report Type:Expedited (15-DaCompany Report #APCDSS2003000770
Age:78 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blood Creatine Phosphokinase Increased	Foreign Health Professional	Duragesic (Fentanyl) Patch	PS		TRANSDERMAL	2.5 MG, 1 IN 72 HOUR; 5 MG, 1 IN 72 HOUR; 2.5 MG, 1 IN 72 HOUR; 3 MG, 1 IN 1 DAY, ORAL; 1 MG, 1 IN 1 DAY, ORAL	
	Fall							
	Mucous Membrane Disorder							
	Nausea							
	Neoplasm							
	Neuroleptic Malignant Syndrome		Haldol (Haloperidol) Unspecified	SS		ORAL		
	Restlessness							
	Sedation							
	Somnolence							
	Urinary Incontinence							

Date:06/18/03ISR Number: 4132293-2Report Type:Expedited (15-DaCompany Report #2003CG00674
Age:86 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Linear Iga Disease	Foreign Health Professional Other	Mopral	PS		ORAL	1 DF DAILY PO	
			Efferalgan	SS				
			Forlax	SS		ORAL	1 DF DAILY PO	
			Zyrtec	SS		ORAL	10 MG DAILY PO	
			Haldol "Janssen"	SS	Janssen			
			Medrol	SS		ORAL	8 MG DAILY PO	
			Pulmicort	C				

			Bricanyl	C		

Date:06/20/03ISR Number: 4133649-4Report Type:Expedited (15-DaCompany Report #S03-USA-02531-02
Age:88 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Petit Mal Epilepsy	Health Professional	Lexapro (Escitalopram)	PS		ORAL	10 MG QD PO	
			Haldol	SS			SEE IMAGE	
			Ativan (Lorazepam)	C				
			Risperdal (Risperidone)	C				
			Vasotec (Enalapril Maleate)	C				
			Lopressor (Metoprolol Tartrate)	C				
			Nitro Patch (Glyceryl Trinitrate)	C				
			Hydrodiuril (Hydrochlorothiazide)	C				
			Potassium	C				
			Slow-Mag (Magnesium Chloride Anhydrous)	C				
			Premarin (Estrogens Conjugated)	C				
			Synthroid (Levothyroxine Sodium)	C				

Alphagan (Brimonidine Tartrate)	C
Levaquin (Levofloxacin)	C
Lidex (Fluocinonide)	C
Aspirin	C
Tylenol (Paracetamol)	C
Vicodin Es	C
Protonix "Pharmacia" (Pantoprazole)	C
Prilosec (Omeprazole)	C
Gaviscon	C
Maalox	C
Milk Of Magnesia	C
Theragram Vitamins	C
Vitamin E	C
Ensure	C

Date:06/20/03ISR Number: 4134226-1Report Type:Expedited (15-DaCompany Report #2003157660FR
Age:86 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Face Oedema Herpetic Stomatitis Linear Iga Disease	Foreign Health Professional Other	Medrol (Methylprednisolone) Tablet	PS		ORAL	8 MG, QD, ORAL	
			Efferalgan (Paracetamol)	SS		ORAL	ORAL	
			Mopral (Omeprazole)	SS		ORAL	10 MG, QD, ORAL	
			Forlax (Macrogol)	SS		ORAL	1 DF, QD, ORAL	
			Zyrtec (Cetirizine					

			Hydrochloride)	SS		ORAL
10 MG, QD,						
ORAL						
			Haldol (Haloperidol)	SS		
SEE IMAGE						
			Budesonide (Budesonide)	SS		
RESPIRATORY						
(INHALATION)	RESPIRATORY					
			Terbutaline (Terbutaline)	SS		
RESPIRATORY						
(INHALATION)	RESPIRATORY					

Date:06/23/03ISR Number: 4133314-3Report Type:Expedited (15-DaCompany Report #JP-BRISTOL-MYERS SQUIBB COMPANY-12301743
Age:25 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anxiety		Gatiflo	PS	Bristol-Myers Squibb Company	ORAL	2	DAY
	Confusional State							
	Dissociative Disorder		Serenace	SS		ORAL	12	MON
	Extrapyramidal Disorder		Serenace	SS		INTRAVENOUS DRIP	1	DAY
			Singulair	C		ORAL		
			Chinese Herbs	C		ORAL		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/24/03ISR Number: 4134642-8Report Type:Direct Company Report #CTU 196508
Age:72 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Abasia		Haldol	PS			2.5MG TID	5MG
	Brain Damage							3D
	Dysphagia		Trazodone Hcl	C				
	Hemiplegia		Seroquel	C				
	Tardive Dyskinesia		Aricept	C				
	Tongue Paralysis		Multi Vit With Iron	C				
	Tremor		Zyprexa	C				
			Coloace	C				

Date:06/24/03ISR Number: 4135672-2Report Type:Expedited (15-DaCompany Report #USA030537629
Age:92 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Dementia	Consumer	Zyprexa-Oral	PS			2.5 MG/DAY	2 DAY
	Hallucination		Remeron	SS				
	Restlessness		Haldol	SS				
	Speech Disorder							

Date:06/24/03ISR Number: 4137692-0Report Type:Periodic Company Report #NSADSS2002041257
Age:48 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anxiety	Consumer	Haldol (Injection) (Haloperidol)	PS			INTRAVENOUS	5 MG, IV
	Erectile Dysfunction							
	Hypoaesthesia							
	Tinnitus							

Date:06/24/03ISR Number: 4137694-4Report Type:Periodic Company Report #NSADSS2002037002
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Condition Aggravated Extrapyramidal Disorder Headache Insomnia Pain	Consumer	Haldol (Unspecified) (Haloperidol) Risperdal (1 Mg Tablet) (Risperidone) Seroquel (Seroquel)	PS SS C		ORAL	1 MG, 1 IN DAILY, ORAL	

Date:06/24/03ISR Number: 4137698-1Report Type:Periodic Company Report #NSADSS2002036878
Age:84 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Psychotic Disorder	Consumer	Haldol (Injection) (Haloperidol)	PS		INTRAMUSCULAR	IM	

Date:06/24/03ISR Number: 4137710-XReport Type:Periodic Company Report #NSADSS2002026490
Age:24 YR Gender:Male I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Amnesia Anorexia Arthralgia

		Hyperhidrosis Hypertension Pneumonia	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
		Pruritus Psychotic Disorder	Consumer	Haldol (Injection) (Haloperidol)	PS		
INTRAVENOUS	IV						
		Rash Tachycardia					

Date:06/24/03ISR Number: 4137716-0Report Type:Periodic Company Report #NSADSS2002013908
Age:69 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Convulsion	Health Professional	Haldol (Tablet) (Haloperidol)	PS		ORAL
SEE IMAGE						
Other			Nifedipine (Nifedipine)	C		
			Lipitor (Atorvastatin)	C		

Date:06/24/03ISR Number: 4137719-6Report Type:Periodic Company Report #NSADSS2002015246
Age:54 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Disability	Extrapyramidal Disorder	Consumer	Haldol (Tablet)			
Other	Psychotic Disorder	Health	(Haloperidol)	PS		ORAL
5 MG, 1 PRN,						
Required		Professional				
ORAL						
Intervention to Prevent Permanent Impairment/Damage			Ortho-Novum (Tablet) (Norethindrone-Mestranol)	C		
			Neurontin (Gabapentin)	C		
			Gabitril (Tiagabine Hydrochloride)	C		

Date:06/25/03ISR Number: 4135697-7Report Type:Direct Company Report #CTU 196639
Age:41 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Asthenia		Haldol-10mg					
Disability	Back Pain		Intramuiclar	PS				
FORCE TO TAKE								
Other	Dizziness							
COULDN'T								
Required	Dyspnoea							
REFUSE								
Intervention to	Emotional Disorder		Desyrel-100mg -At					
Prevent Permanent	Feeling Abnormal		Bedtime	SS				
Impairment/Damage	Hearing Impaired		Depakote	SS				
	Muscle Injury		Cogentin	SS				
	Palpitations		Tranxene 3.75mg					
	Syncope		Twice Daily Then 4 X					
	Victim Of Abuse		Wkly	SS				
	Victim Of Sexual Abuse							
	Visual Disturbance							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/26/03ISR Number: 4136968-0Report Type:Expedited (15-DaCompany Report #EMADSS2003003509
Age:86 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Face Oedema Herpes Virus Infection Linear Iga Disease Oral Soft Tissue Disorder	Foreign Health Professional	Haldol (Haloperidol) Solution	PS		ORAL	0.9 MG, 1 IN 1 DAY, ORAL	
			Efferalgan (Paracetamol)	SS		ORAL	, IN 1 AS NECESSARY, ORAL	
			Mopral (Omeprazole) Tablets	SS		ORAL	1 DOSE(S), 1 IN 1 DAY, ORAL	
			Forlax (Macrogol)	SS		ORAL	1 DOSE(S), 1 IN 1 DAY, ORAL	
			Zyrtec (Cetirizine Hydrochloride)	SS		ORAL	10 MG, 1 IN 1 DAY, ORAL	
			Medrol (Methylprednisolone)	SS		ORAL	8 MG, 1 IN 1 DAY, ORAL	
			Pulmicort (Budesonide)	SS		RESPIRATORY (INHALATION)	RESPIRATORY (INHALATION)	

				Bricanyl (Terbutaline Sulfate)	SS		

RESPIRATORY

(INHALATION) RESPIRATORY

(INHALATION)

Date:06/30/03ISR Number: 4138349-2Report Type:Direct Company Report #CTU 112792
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Life-Threatening	Medication Error		Haldol	PS	Mcneil	
			Halenol Liquid	SS	Blue Cross	

Date:06/30/03ISR Number: 4138352-2Report Type:Direct Company Report #CTU 112846
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Medication Error		Haldol Concentrate 2 Mg/Ml Mcneil	PS	Mcneil	
			Thiothixene Concentrate 5mg/Ml Goldline	SS	Goldline	

Date:06/30/03ISR Number: 4138355-8Report Type:Direct Company Report #CTU 112847
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Medication Error		Haldol Concentrate 2mg/Ml Mcneil	PS	Mcneil	
			Thiothixene Concentrate 5mg/Ml			

Goldline SS

Date:06/30/03ISR Number: 4139467-5Report Type:Expedited (15-DaCompany Report #APCDSS2002000429
Age:37 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Anorexia Blood Creatine Phosphokinase Increased Blood Pressure Increased Condition Aggravated Delusion Diabetes Mellitus Hallucination Hypoventilation Insomnia Respiratory Distress Schizophrenia	Foreign Health Professional	Haldol (Haloperidol Decanoate) Unspecified Risperdal (Risperidone) Tablets Quetiapine Fumarate (Quetiapine Fumarate) Tablets Hydroxyzine Pamoate (Hydroxyzine Embonate) Estazolam (Estazolam) Zopiclone (Zopiclone) Biperiden Hydrochloride (Biperiden Hydrochloride)	PS SS SS C C C		ORAL ORAL ORAL	10.5 MG, 1 IN 1 DAY, ORAL SEE IMAGE 600 MG, 1 IN 1 DAY, ORAL

Date:06/30/03ISR Number: 4139475-4Report Type:Expedited (15-DaCompany Report #APCDSS2002000429
Age:37 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Anorexia Blood Creatine	Foreign Health	Haldol (Haloperidol Decanoate)	PS		ORAL	10.5 MG, 1 IN

	Phosphokinase Increased	Professional			
1 DAY, ORAL					
	Blood Pressure Increased Condition Aggravated Delusion		Risperidal (Risperidone) Tablets	SS	ORAL
SEE IMAGE,					
	Diabetes Mellitus				
ORAL					
	Hallucination Hypoventilation Insomnia		Quetiapine Fumarate (Quetiapine Fumarate) Tablets	SS	ORAL
600 MG, 1 IN					
	Oxygen Saturation				
1 DAY, ORAL					
	Decreased Respiratory Distress Schizophrenia		Hydroxyzine Pamoate (Hydroxyzine Embonate)	C	
			Estazolam (Estazolam)	C	
			Zopiclone (Zopiclone)	C	
			Biperiden Hydrochloride (Biperiden Hydrochloride)	C	

Date:06/30/03ISR Number: 4139497-3Report Type:Expedited (15-DaCompany Report #APCDSS2003000614
Age:25 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Compartment Syndrome	Foreign	Risperdal					
Hospitalization -	Hyperreflexia	Health	(Risperidone)					
Initial or Prolonged	Hyporeflexia	Professional	Unspecified	PS			4 MG, 1 IN 1	
	Neuroleptic Malignant						DAY; 120 MG	
	Syndrome		Haloperidol					
	Overdose		(Haloperidol)					
	Rash Maculo-Papular		Unspecified	SS			6 MG, 1 IN 1	
	Rhabdomyolysis						DAY; 45 MG	
	Skin Graft							
	Vasculitic Rash							

Date:06/30/03ISR Number: 4139556-5Report Type:Expedited (15-DaCompany Report #APCDSS2003000614
Age:25 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Blood Creatinine	Foreign	Risperdal					
Hospitalization -	Compartment Syndrome	Health	(Risperidone)					
Initial or Prolonged	Hyperreflexia	Professional	Unspecified	PS			SEE IMAGE	
	Hyporeflexia		Haloperidol					
	Muscle Spasms		(Haloperidol)					
	Neuroleptic Malignant		Unspecified	SS			SEE IMAGE	
	Syndrome							
	Overdose							
	Rash Maculo-Papular							
	Rhabdomyolysis							
	Skin Graft							
	Vasculitic Rash							

Date:06/30/03ISR Number: 4139834-XReport Type:Expedited (15-DaCompany Report #2003026321
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Convulsion Drug Hypersensitivity	Consumer	Dilantin (Phenytoin Sodium)	PS			SEE IMAGE	
Other	Drug Level Increased Dyspnoea Lethargy Urinary Tract Infection Urticaria		Bactrim (Sulfamethoxazole, Trimethoprim)	SS		ORAL	2 MG (ONCE)	
			Norfloxacin (Norfloxacin)	SS		ORAL	5 MG (ONCE)	
			Lorazepam (Lorazepam)	SS			50 MG (ONCE)	
			Haloperidol (Haloperidol)	SS				
			Chlorpromazine (Chlorpromazine)	SS				
			Ferrous Sulfate (Ferrous Sulfate)	C				
			Doxazosin Mesilate (Doxazosin Mesilate)	C				
			Metoprolol Tartrate (Metoprolol Tartrate)	C				
			Digoxin (Digoxin)	C				
			Ascorbic Acid (Ascorbic Acid)	C				
			Ferrous Gluconate					

(Ferrous Gluconate)	C
Glyceryl Trinitrate (Glyceryl Trinitrate)	C
Donepezil Hydrochloride (Donepezil Hydrochloride)	C
Amlodipine Besilate (Amlodipine Besilate)	C

Date:07/01/03ISR Number: 4138847-1Report Type:Expedited (15-DaCompany Report #US-BRISTOL-MYERS SQUIBB COMPANY-12279857
Age:1 DY Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Congenital Anomaly	Atrial Septal Defect	Health Professional	Videx Ec Caps 400 Mg	PS	Bristol-Myers Squibb Company			
Other	Maternal Drugs Affecting Foetus							
TRANSPLACENTAL	Received from week 16 of gestation until delivery.							
	Maternal Use Of Illicit Drugs							
			Viracept	SS				
TRANSPLACENTAL	Received from week 16 of gestation until delivery.							
			Retrovir	SS				
TRANSPLACENTAL			Haldol	SS				
TRANSPLACENTAL			Zyprexa	SS				
TRANSPLACENTAL	during the 1st trimester							

Date:07/01/03ISR Number: 4140499-1Report Type:Expedited (15-DaCompany Report #2003026108
Age:88 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Anuria	Foreign	Zyrtec (Tablets)					
Hospitalization - Initial or Prolonged	Calculus Bladder	Health	(Cetirizine)	PS		ORAL	10 MG	ORAL
Other	Leukocytosis	Professional	Haloperidol					
	Pancreatitis Acute		(Haloperidol)	SS		ORAL		ORAL
	Renal Failure		Propranolol					
			(Propranolol)	SS		ORAL		ORAL
			Paracetamol					
			(Paracetamol)	SS		ORAL		ORAL
			Olanzapine					
			(Olanzapine)	SS		ORAL	5 MG	ORAL
			Troxerutin					
			(Troxerutin)	SS		ORAL	1000 MG	ORAL

Date:07/01/03ISR Number: 4140846-0Report Type:Expedited (15-DaCompany Report #2003018681
Age:86 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Face Oedema	Foreign	Zyrtec (Tablets)					
	Herpes Virus Infection	Health	(Cetirizine)	PS		ORAL	10 MG	
	Linear Iga Disease	Professional					(DAILY),	ORAL
	Oral Mucosal Disorder		Paracetamol					
			(Paracetamol)	SS		ORAL	UNKNOWN	
							(PRN),	ORAL

			Omeprazole (Omeprazole)	SS		ORAL
10 MG, (DAILY), ORAL						
			Macrogol (Macrogol)	SS		ORAL
10 GRAM (DAILY), ORAL						
			Haloperidol (Haloperidol)	SS		ORAL
ORAL						
			Methylprednisoloe (Methylprednisolone)	SS		ORAL
8 MG (DAILY), ORAL						
			Budesonide (Budesonide)	C		
			Terbutaline Sulfate (Terbutaline Sulfate)	C		

Date:07/01/03ISR Number: 4140943-XReport Type:Expedited (15-DaCompany Report #FR-JNJFOC-20030602182
Age:29 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Medication Error	Foreign Health Professional	Haldol Decanoate (Haloperidol Decanoate) Injection	PS		ORAL	50 MG, 1 IN 1 TOTAL, ORAL	
			Lepticur (Tropatepine Hydrochloride)	C				
			Haldol (Haloperidol)	C				

Date:07/01/03ISR Number: 4140961-1Report Type:Expedited (15-DaCompany Report #FR-JNJFOC-20030602181
Age:60 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Cardiomyopathy Pulmonary Embolism Respiratory Failure	Foreign Health Professional	Haldol Decanoas (Haloperidol Decanoate) Injection	PS			INTRAMUSCULAR	1 DOSE (S), 1
			Moditen (Fluphenazine Hydrochloride)	C				
			Largarctil (Chlorpromazine Hydrochloride)	C				
			Nozinan (Levomepromazine)	C				
			Neuleptil (Periciazine)	C				
			Terfluzine (Trifluoperazine Hydrochloride)	C				
			Piportil (Pipotiazine)	C				
			Solian (Amisulpride)	C				
			Tercian (Cyamemazine)	C				

IN 4 WEEK,

INTRA-MUSCULA

R

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/02/03ISR Number: 4139722-9Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0414060A
Age:39 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Abortion Spontaneous	Consumer	Paxil	PS	Glaxosmithkline	ORAL	20MG Per day	3 YR
	Bedridden		Haldol	SS				
	Complications Of Maternal Exposure To Therapeutic Drugs		Vitamins	C				
	Emotional Disorder							
	Maternal Drugs Affecting Foetus							
	Movement Disorder							
	Pregnancy							
	Treatment Noncompliance							

Date:07/02/03ISR Number: 4181724-0Report Type:Periodic Company Report #EMADSS2002006215
Age:87 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dizziness	Foreign	Haldol (Unspecified) (Haloperidol)	PS			20 MG, 1 IN 1 DAY	
	Hyponatraemia	Health Professional						
	Stupor		Durogesic (100 Mcg/Hr Patch) (Fentanyl)	SS			TEMPORARILY STOPPED	
			Godamed (Paynocil)	C				
			Madopar (Madopar)	C				

Date:07/03/03ISR Number: 4142104-7Report Type:Expedited (15-DaCompany Report #APCDSS2003000770
Age:78 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blood Creatine	Foreign	Duragesic (Fentanyl)					

	Phosphokinase Increased	Health	Patch	PS		
TRANSDERMAL 2.5 MG, 1 IN						
	Blood Creatine	Professional				
72 HOUR,						
	Phosphokinase Mm					
TRANSDERMAL;						
	Increased					
SEE IMAGE						
	Fall		Haldol (Haloperidol)			
	Nausea		Unspecified	SS		ORAL
3 MG, 1 IN 1						
	Neuroleptic Malignant					
DAY, ORAL;						
	Syndrome					
SEE IMAGE						
	Restlessness					
	Sedation					
	Somnolence					
	Urinary Incontinence					

Date:07/07/03ISR Number: 4142154-0Report Type:Expedited (15-DaCompany Report #DE-GLAXOSMITHKLINE-D0041254A
Age:56 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Drug Interaction	Health	Quilonum Retard	PS	Glaxosmithkline	ORAL	9	DAY
Initial or Prolonged	Enuresis	Professional	Anafranil	SS		ORAL	44	DAY
	Fall		Haldol	SS		ORAL	63	DAY
	Grand Mal Convulsion		Taxilan	SS		ORAL	50MG per day	5 DAY
	Myoclonus		Leponex	SS		ORAL	2	DAY
	Nervous System Disorder		Akineton	C			UNKNOWN	
	Tongue Biting							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/07/03ISR Number: 4142748-2Report Type:Direct Company Report #CTU 197340
Age:43 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Hyperreflexia		Haldol	PS				
INTRAVENOUS							35MG	ONCE IV
	Neuroleptic Malignant Syndrome							

Date:07/07/03ISR Number: 4142958-4Report Type:Direct Company Report #CTU 197308
Age:25 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drooling		Haldol	PS				
	Jaw Disorder		Cogentin	C				
	Joint Lock							
	Speech Disorder							

Date:07/07/03ISR Number: 4144378-5Report Type:Expedited (15-DaCompany Report #03P-009-0222841-00
Age:38 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Diarrhoea	Foreign	Akineton (Biperiden)	PS		ORAL	4 MG, 1 IN 1	D, PER ORAL
	Grand Mal Convulsion	Health Professional	Clozapine	SS		ORAL	SEE IMAGE	
			Haloperidol	SS		ORAL	SEE IMAGE	
			Cipralex	SS		ORAL	SEE IMAGE	
			Buspirone Hydrochloride	C				
			Metoprolol Tartrate	C				
			Enalapril Maleate	C				
			Simvastatin	C				
			Omeprazole	C				

Date:07/07/03ISR Number: 4144669-8Report Type:Expedited (15-DaCompany Report #2003027467
Age:16 YR Gender:Male I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Alanine Aminotransferase Increased
	Apathy
	Aspartate Aminotransferase Increased
	Blood Creatine Phosphokinase Increased
	Blood Sodium Decreased
	Blood Urea Increased
	Catatonia
	Echolalia
	Echopraxia
	Extensor Plantar Response
	Haemoglobin Decreased
	Hyperreflexia
	Monocyte Count Decreased
	Movement Disorder
	Muscle Rigidity
	Myalgia
	Negativism
	Neuroleptic Malignant

	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Syndrome Neutrophil Count Increased							
	Pyrexia	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Red Blood Cell Count	Foreign	Lithium (Lithium)	PS			900 MG	
	Decreased	Literature	Haloperidol					
	Somnolence	Health	(Haloperidol)	SS			4.5 MG	
	Tachycardia	Professional	Olanzapine					
	Urinary Retention		(Olanzapine)	SS				
	White Blood Cell Count Increased		Valproate Semisodium (Valproate Semisodium)	C				
			Clonazepam (Clonazepam)	C				
			Carbamazepine (Carbamazepine)	C				
			Thioridazine (Thioridazine)	C				

Date:07/07/03ISR Number: 4144729-1Report Type:Expedited (15-DaCompany Report #03P-062-0222823-00
Age:46 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Grand Mal Convulsion	Foreign Health Professional	Akineton Retard (Akineton) (Biperiden) (Biperiden)	PS		ORAL	4 MG, 1 IN 1 D, PER ORAL	
			Clozapine	SS		ORAL	SEE IMAGE	
			Haloperidol	SS			INTRAVENOUS	SEE IMAGE
			Citalopram Hydrobromide	SS		ORAL	SEE IMAGE	
			Diazepam	C				

Date:07/08/03ISR Number: 4144800-4Report Type:Expedited (15-DaCompany Report #2003PK01112
Age:68 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Bradycardia	Foreign	Seroquel	PS		ORAL	50 MG DAILY	
	Cerebellar Atrophy	Health Professional					PO	
	Cerebral Atrophy		Seroquel	SS		ORAL	100 MG DAILY	
	Drug Interaction	Other					PO	
	Gamma-Glutamyltransferase Increased		Seroquel	SS		ORAL	150 MG DAILY	
	Hemiparesis		Seroquel	SS		ORAL	200 MG DAILY	
	Pleurothotonus						PO	
	Supraventricular Extrasystoles		Seroquel	SS		ORAL	300 MG DAILY	
	Ventricular Extrasystoles		Seroquel	SS		ORAL	400 MG DAILY	
							PO	
			Seroguel	SS		ORAL	500 MG DAILY	
							PO	
			Seroquel	SS		ORAL	600 MG DAILY	
							PO	
			Seroquel	SS		ORAL	650 MG DAILY	
							PO	
			Seroquel	SS		ORAL	300 MG DAILY	
							PO	
			Haldol	SS		ORAL	10 MG DAILY	
							PO	

	Haldol	SS	ORAL
5 MG DAILY PO			
	Haldol	SS	ORAL
30 MG DAILY			
PO			
	Haldol	SS	ORAL
32.5 MG DAILY			
PO			
	Haldol	SS	ORAL
22.5 MG DAILY			
PO			
	Haldol	SS	ORAL
20 MG DAILY			
PO			
	Haldol	SS	ORAL
15 MG DAILY			
PO			
	Haldol	SS	ORAL
17.5 MG DAILY			
PO			
	Haldol	SS	ORAL
15 MG DAILY			
PO			
	Haldol	SS	ORAL
20 MG DAILY			
PO			
	Haldol	SS	ORAL
22.5 MG DAILY			
PO			
	Haldol	SS	ORAL
5 MG DAILY PO			
	Valiquid	C	
	Akineton Retard	C	
	Bifiteral	C	

Date:07/08/03ISR Number: 4145007-7Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20030604066
Age:81 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Amnestic Disorder Cognitive Deterioration Drug Interaction Hallucination, Auditory Hallucination, Visual Psychomotor Retardation Somnolence Sopor	Foreign Health Professional	Haldol-Janssen (Haloperidol) Unspecified	PS		ORAL	5 MG, 1 IN 1 DAY, ORAL	
			Risperdal (Risperidone) Unspecified	SS		ORAL	4 MG, 1 IN 1 DAY, ORAL	
			Eunerpan (Melperone Hydrochloride)	SS		ORAL	25 MG, 1 IN 1 DAY, ORAL	
			Lasix (Furosemide)	C				

Date:07/08/03ISR Number: 4145008-9Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20030604070
Age:37 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Compulsions Restlessness	Foreign Health Professional	Haldol-Janssen (Haloperidol) Unspecified	PS	Janssen	ORAL	SEE IMAGE	
			Zyprexa (Olanzapine)	C				
			Stilnox (Zolpidem)	C				
			Celebrex (Celecoxib)	C				
			Diclofenac (Diclofenac)	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/08/03ISR Number: 4145009-0Report Type:Expedited (15-DaCompany Report #EMADSS2003000484
Age:33 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Required	Anxiety Overdose	Foreign Study Health Professional	Risperdal (Risperidone) Tablets	PS		ORAL	SEE IMAGE	
Intervention to Prevent Permanent Impairment/Damage			Haldol (Haloperidol) Unspecified	SS			SEE IMAGE	
			Akineton (Biperiden Hydrochloride) Tablets	SS		ORAL	10 MG, 1 IN 1	AS NECESSARY
			Tavor (Lorazepam) Unspecified	SS				

Date:07/08/03ISR Number: 4145145-9Report Type:Expedited (15-DaCompany Report #EMADSS2003000484
Age:33 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Required	Anxiety Intentional Misuse	Foreign Study Health Professional	Risperdal (Risperidone) Tablets	PS		ORAL	SEE IMAGE	
Intervention to Prevent Permanent Impairment/Damage			Haldol (Haloperidol) Unspecified	SS			8 MG, 1 IN 1 DAY; 20 DOSE	(S), 1 IN 1 AS NECESSARY;
			Akineton (Biperiden Hydrochloride)				8 MG, 1 IN 1	

			Tablets	SS		ORAL
4 MG, 1 IN 1 DAY, ORAL; 80 DOSE (S), 1 IN 1 AS NECESSARY,						
			Tavor (Lorazepam) Unspecified	SS		
10 MG, 1 IN 1 AS NECESSARY						

Date:07/08/03ISR Number: 4145150-2Report Type:Expedited (15-DaCompany Report #S03-AUT-02739-01
Age:38 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Electroencephalogram Abnormal	Foreign Health	Cipralex (Escitalopram)	PS		ORAL	10 MG QD PO	
	Grand Mal Convulsion Tongue Biting	Professional Other	Haldol "Janssen" (Haloperidol)	SS	Janssen	ORAL	20 MG QD PO	
			Haldol "Janssen" (Haloperidol)	SS	Janssen	ORAL	10 MG QD PO	
			Biperiden (Biperiden)	SS		ORAL	4 MG QD PO	
			Leponex "Novartis" (Clozapine)	SS	Novartis	ORAL	100 MG QD PO	
			Leponex "Novartis" (Clozapine)	SS	Novartis	ORAL	250 MG QD PO	
			Leponex "Novartis" (Clozapine)	SS	Novartis	ORAL	400 MG QD PO	
			Leponex "Novartis" (Clozapine)	SS	Novartis	ORAL	500 MG QD PO	

			Leponex "Novartis" (Clozapine)	SS	Novartis	ORAL 400 MG QD PO
			Leponex "Novartis" (Clozapine)	SS	Novartis	ORAL 300 MG QD PO
			Bespar (Buspirone Hydrochloride)	C		
			Seloken (Metoprolol Tartrate)	C		
			Mepril (Enalapril Maleate)	C		
			Losec (Omeprazole)	C		
			Tannalbin (Albumin Tannate)	C		
			Zocord (Simvastatin)	C		

Date:07/09/03ISR Number: 4146913-XReport Type:Expedited (15-DaCompany Report #FR- JNJFOC-20030601299
Age:88 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Death	Anuria	Foreign	Haldol (Haloperidol)			
Life-Threatening	Drug Interaction	Health	Unspecified	PS		ORAL ORAL
Hospitalization - Initial or Prolonged	Neoplasm Of Appendix	Professional	Avlocardyl (Propranolol)	SS		ORAL 40 MG, ORAL
	Pancreatitis Acute					
	Renal Failure		Paracetamol (Paracetamol)	SS		ORAL ORAL
			Zyprexa (Olanzapine)	SS		ORAL 5 MG, 1 IN 1 DAY, ORAL
			Zyrtec (Cetirizine Hydrochloride)	SS		ORAL 10 MG, ORAL
			Veinamitol (Troxerutin)	SS		ORAL 1000 MG, 1 IN 1 DAY, ORAL

Date:07/09/03ISR Number: 4147665-XReport Type:Expedited (15-DaCompany Report #HQWYE801530JUN03
Age:88 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death Life-Threatening Hospitalization - Initial or Prolonged	Anuria Mass Pancreatitis Acute Renal Failure	Health Professional Other	Avlocardyl (Propranolol Hydrochloride, Tablet)	PS		ORAL	1 DF DAILY,	ORAL
			Haldol (Haloperidol)	SS		ORAL		ORAL
			Paracetamol (Paracetamol)	SS		ORAL		ORAL
			Veinamitol (Troxerutin)	SS				
			Zyprexa (Olanzapine)	SS		ORAL	5 MG 1 X PER	1 DAY, ORAL 10 DAY
			Zyrtec (Cetirizine Hydrochloride)	SS				

Date:07/10/03ISR Number: 4146396-XReport Type:Expedited (15-DaCompany Report #US-JNJFOC-20030700204
Age:52 YR Gender:Male I/FU:I

Outcome	PT
Death	Blood Test Abnormal Drug Abuser

	Hyperhidrosis Hyperpyrexia Muscle Rigidity	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Respiratory Arrest Urine Analysis Abnormal	Health Professional	Haldol (Haloperidol) Injection	PS			5 MG, 1 IN 1 TOTAL
			Ativan (Lorazepam) ..	C C			

Date:07/11/03ISR Number: 4147966-5Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20030604685
Age:54 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Other	Drug Interaction Increased Appetite	Foreign Health	Haldol (Haloperidol) Unspecified	PS			SEE IMAGE
	Weight Increased	Professional	Haldol Decanoat (Haloperidol Decanoate) Injection	SS		INTRAMUSCULAR	100 MG, 1 IN 3 WEEK, INTRA-MUSCULAR
			Neurocil (Levomepromazine Maleate)	SS		ORAL	SEE IMAGE
			Lyogen (Fluphenazine)	SS		ORAL	SEE IMAGE
			Bifiteral () Probucol	C			

Date:07/14/03ISR Number: 4148540-7Report Type:Expedited (15-DaCompany Report #APCDSS2002000429
Age:36 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anorexia Blood Creatine Phosphokinase Increased	Foreign Health Professional	Haloperidol (Haloperidol) Tablets	PS		ORAL	SEE IMAGE	
	Blood Pressure Increased Condition Aggravated Delusion		Risperdal (Risperidone) Tablets	SS		ORAL	SEE IMAGE	
	Diabetes Mellitus Hallucination Hypoventilation		Quetiapine Fumarate (Quetiapine Fumarate) Tablets	SS		ORAL	600 MG, 1 IN	1 DAY, ORAL
	Hypoxia Insomnia Respiratory Distress Schizophrenia		Hydroxyzine Pamoate (Hydroyzine Embonate)	C				
			Estazolam (Estazolam)	C				
			Zopiclone (Zopiclone)	C				
			Biperiden Hydrochloride (Biperiden Hydrochloride)	C				
			Sennoside (All Other Therapeutic Products)	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/14/03ISR Number: 4148735-2Report Type:Expedited (15-DaCompany Report #APCDSS2002000429
Age:36 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anorexia Blood Creatine Phosphokinase Increased Blood Glucose Increased Blood Pressure Increased Condition Aggravated Delusion Diabetes Mellitus Glycosylated Haemoglobin Increased Hallucination Hypoventilation Hypoxia Insomnia Po2 Increased Respiratory Distress Schizophrenia	Foreign Health Professional	Haloperidol (Haloperidol) Tablets Risperdal (Risperidone) Tablets Quetiapine Fumarate (Quetiapine Fumarate) Tablets Hydroxyzine Pamoate (Hydroxyzine Embonate) Estazolam (Estazolam) Zopiclone (Zopiclone) Biperiden Hydrochloride (Biperiden Hydrochloride) Sennoside (All Other Therapeutic Products)	PS SS SS C C C C C		ORAL ORAL ORAL	SEE IMAGE SEE IMAGE 600 MG, 1 IN 1 DAY, ORAL	

Date:07/14/03ISR Number: 4148796-0Report Type:Expedited (15-DaCompany Report #PHNU2003DE02382
Age:56 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Bite Blood Pressure Increased Disorientation Drug Interaction Drug Level Increased	Foreign Study Health Professional Other	Anafranil(Clomipramine Hydrochloride) Sugar-Coated Tablet Leponex / Clozaril (Clozapine)	PS		ORAL	SEE IMAGE	

	Electroencephalogram	(Clozapine) Tablet	SS		ORAL
SEE IMAGE					
	Abnormal	Quilonum - Slow			
	Enuresis	Release	SS		ORAL
SEE IMAGE					
	Epilepsy	Haldol "Janssen"			
	Fall	(Haloperidol)	SS	Janssen	ORAL
SEE IMAGE					
	Grand Mal Convulsion	Taxilan(Perazine)	SS		ORAL
50 MG/DAY,					
	Hypokinesia				
ORAL					
	Myoclonus				

Date:07/15/03ISR Number: 4149117-XReport Type:Expedited (15-DaCompany Report #MK200307-0401-1
Age:56 YR Gender:Female I/FU:I

Outcome	PT
	Blood Pressure Increased
	Drug Level Decreased
	Enuresis
	Epilepsy
	Fall
	Grand Mal Convulsion
	Muscle Contractions Involuntary
	Nervous System Disorder

		Schizoaffective Disorder Tic					
			Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
			Foreign	Anafranil 25mg Capsules 100	PS		
225MG							
				Leponex	SS		
				Quilonum Slow Release	SS		
				Haldol	SS		
				Taxilan	SS		

Date:07/17/03ISR Number: 4148650-4Report Type:Direct Company Report #CTU 198111
Age: Gender:Female I/FU:I

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Hospitalization -		Hyperhidrosis		Haldol 5mg	PS		
1 DOSE							
Initial or Prolonged		Pyrexia Tachycardia					

Date:07/18/03ISR Number: 4150700-6Report Type:Direct Company Report #CTU 198221
Age: Gender:Male I/FU:I

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Life-Threatening		Arrhythmia		Haloperidol 5 Mg	PS		
INTRAVENOUS	5 MG ONCE						
Hospitalization -		Torsade De Pointes					
INTRAVENOUS							
Initial or Prolonged							

Date:07/21/03ISR Number: 4152926-4Report Type:Expedited (15-DaCompany Report #FR-JNJFOC-20030600601
Age:49 YR Gender:Male I/FU:F

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Hospitalization -		Abdominal Pain Upper	Foreign	Haldol (Haloperidol)			

Initial or Prolonged	Arthralgia	Consumer	Solution	PS		ORAL
SEE IMAGE						
	Asthenia	Health	Vasobral (Vasobral)	C		
	Diabetes Mellitus	Professional	Floxyfral			
	Non-Insulin-Dependent		(Fluvoxamine			
	Erectile Dysfunction		Maleate)	C		
	Hyperglycaemia		Lexomil (Bromazepam)	C		
	Tremor					
	Vertigo					
	Weight Decreased					

Date:07/22/03ISR Number: 4152461-3Report Type:Direct Company Report #CTU 198431
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Body Temperature		Haldolpuridol	PS		
INTRAVENOUS 5MG IV Q4H						
Initial or Prolonged	Increased		Levofloxacin	C		
	Urine Output Decreased		Metronidazole	C		
			Sucralfate	C		
			Hydromorphone	C		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/23/03ISR Number: 4155223-6Report Type:Expedited (15-DaCompany Report #FR-JNJFOC-20030601299
Age:88 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Anuria	Foreign	Haldol (Haloperidol)					
Life-Threatening	Neoplasm Of Appendix	Health	Unspecified	PS		ORAL	ORAL	
Hospitalization - Initial or Prolonged	Pancreatitis Acute Renal Failure	Professional	Avlocardyl (Propranolol)	SS		ORAL	40 MG, ORAL	
			Paracetamol (Paracetamol)	SS		ORAL	ORAL	
			Zyprexa (Olanzapine)	SS		ORAL	5 MG, 1 IN 1 DAY, ORAL	
			Zyrtec (Cetirizine Hydrochloride)	SS		ORAL	10 MG, ORAL	
			Veinamitol (Troxerutin)	SS		ORAL	1000 MG, 1 IN 1 DAY, ORAL	

Date:07/24/03ISR Number: 4153374-3Report Type:Expedited (15-DaCompany Report #PHHO2003CA07100
Age:70 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Pneumonia		Clozaril	PS	Novartis Sector: Pharma			
Life-Threatening	Pneumonia Aspiration							
Hospitalization - Initial or Prolonged			Haloperidol	SS			15 mg, QD	

Date:07/24/03ISR Number: 4156860-5Report Type:Expedited (15-DaCompany Report #APCDSS2003000662
Age:42 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Other	Condition Aggravated Sinus Bradycardia	Foreign Health Professional	Risperidone (Risperidone) Risperidone Tablets	PS SS	ORAL SEE IMAGE ORAL 1 MG, 1 IN 1 DAY, ORAL
			Risperidone Solution	SS	ORAL 3 MG, 1 IN 1 DAY, ORAL
			Haloperidol Diazepam Powder	SS SS	 ORAL 15 MG, 1 IN 1 DAY, ORAL
			Biperiden Hydrochloride Sodium Valproate (Valproate Sodium) Carbamazepine Flunitrazepam Levomepromazine Maleate Trihexyphenidyl Hydrochloride Bromperidol	C C C C C C	

Date:07/28/03ISR Number: 4157767-XReport Type:Expedited (15-DaCompany Report #2003026321
Age: Gender:Male I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Anticonvulsant Drug Level Increased
Other	Convulsion

		Drug Level Decreased Hypersensitivity Lethargy	Report Source	Product	Role	Manufacturer	Route	Dose
Duration		Urinary Tract Infection Urticaria	Consumer	Dilantin (Phenytoin Sodium)	PS			SEE IMAGE
				Bactrim (Sulfamethoxazole, Trimethoprim)	SS		ORAL	ORAL
				Norfloxacin (Norfloxacin)	SS			
				Lorazepam (Lorazepam)	SS			2 MG (ONCE),
				Haloperidol (Haloperidol)	SS			5 MG (ONCE),
				Chlorpromazine (Chlorpromazine)	C			50 MG (ONCE),
				...	C			
				Ferrous Sulfate (Ferrous Sulfate)	C			
				Doxazosin Mesilate (Doxazosin Mesilate)	C			
				Metoprolol Tartrate (Metoprolol Tartrate)	C			
				Digoxin (Digoxin)	C			
				Ascorbic Acid (Ascorbic Acid)	C			
				Ferrous Gluconate (Ferrous Gluconate)	C			
				Glyceryl Trinitrate (Glyceryl Trinitrate)	C			
				Donepezil Hydrochloride (Donepezil Hydrochloride)	C			
				Amlodipine Besilate (Amlodipine Besilate)	C			

Date:07/28/03ISR Number: 4158197-7Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20030705146
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Apathy Injection Site Nodule Lethargy	Foreign Health Professional	Haldol Decanoate (Haloperidol Decanoate) Injection	PS			150 MG, 1 IN	2 WEEK
			Haloperidol (Haloperidol)	C				
			Quetiapine (Quetiapine)	C				
			Amisulpride (Amisulpride)	C				
			Sodium Valproate (Valproate Sodium)	C				
			Omeprazole (Omeprazole)	C				
			Venlafaxine (Venlafaxine)	C				

			Diazepam (Diazepam)	C		

Date:07/28/03ISR Number: 4158638-5Report Type:Expedited (15-DaCompany Report #2003168553SE
Age:75 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Anxiety Duodenal Ulcer	Foreign Health	Celebra(Celecoxib)Capsule, 200mg	PS		
400 MG, QD						
	Dyspnoea Gastroenteritis Haematemesis	Professional Other	Prednisolon Pharmacia (Prednisolone)Tablet	SS		
10 MG,QD						
	Urinary Retention		Ketogan Novum (Ketobemidone)Solution, Sterile	SS		
SUBCUTANEOUS SUBCUTANEOUS						
			Citalopram(Citalopram)Tablet	SS		
20 MG, QD						
			Haloperidol(Haloperidol)Solution	SS		ORAL
1 MG, QD,						
ORAL						
			Rivastigmine(Rivastigmine)Capsule	SS		
6 MG						
			Calcium	C		
			Vitamin D3	C		

Date:07/29/03ISR Number: 4183781-4Report Type:Periodic Company Report #USA-2002-0002077
Age:46 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Overdose	Consumer Health Professional Other	Morphine Sulfate (Similar To Nda 19-516) (Morphine Sulfate) Haloperidol	PS		

(Haloperidol)	SS	ORAL
ORAL		
Ethanol (Ethanol)	SS	
Alprazolam (Alprazolam)	SS	ORAL
ORAL		
Lithobid (Lithium Carbonate)	SS	
Effexor (Venlafaxine Hydrochloride)	SS	ORAL
ORAL		
Penicillin	C	
Desyrel	C	

Date:08/01/03ISR Number: 4162864-9Report Type:Expedited (15-DaCompany Report #2003016781
Age: Gender:Female I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Blood Creatine Phosphokinase
Other	Blood Pressure Diastolic Decreased
	Blood Pressure Systolic Increased
	Body Temperature Increased
	Electrocardiogram Qt Prolonged

	Heart Rate Increased Multiple Drug Overdose Oxygen Saturation	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
	Decreased	Health	Geodon (Ziprasidone)	PS		
	Suicide Attempt	Professional	Haloperidol			
	White Blood Cell Count	Company	(Haloperidol)	SS		
		Representative	Paroxetine Hydrochloride (Paroxetine			
			Hydrochloride)	SS		
			Quetiapine Fumarate (Quetiapine			
			Fumarate)	SS		
			Trihexyphenidyl Hydrochloride (Trihexyphenidyl			
			Hydrochloride)	SS		

Date:08/01/03ISR Number: 4204496-XReport Type:Periodic Company Report #2002UW07922
Age:52 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Life-Threatening	Drug Ineffective	Literature	Elavil	PS		
	Neuroleptic Malignant	Health	Haloperidol	SS		
10 MG DAILY						
	Syndrome	Professional	Fluvoxamine Maleate	C		
			Immunosuppressant Agent	C		

Date:08/04/03ISR Number: 4161560-1Report Type:Direct Company Report #USP 50472
Age:50 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
	Medication Error		Haloperidol	PS	Pharmaceutical Associates, Inc	

Date:08/04/03ISR Number: 4164098-0Report Type:Expedited (15-DaCompany Report #IT-JNJFOC-20030706156
Age:21 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Toxicity Dyskinesia Extrapyramidal Disorder Medication Error Torticollis	Foreign Health Professional	Haldol (Haloperidol)	PS		ORAL	30 DOSE(S), 1 IN 1 DAY, ORAL	

Date:08/04/03ISR Number: 4164201-2Report Type:Expedited (15-DaCompany Report #HQWYE801530JUN03
Age:88 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death Life-Threatening Hospitalization - Initial or Prolonged	Mass Neutrophil Count Increased Pancreatitis Acute Renal Failure	Health Professional Other	Avlocardyl (Propranolol Hydrochloride, Tablet)	PS		ORAL	1 DF DAILY	
			Haldol (Haloperidol)	SS		ORAL		
			Paracetamol (Paracetamol)	SS		ORAL		
			Veinamitol					

				(Troxerutin)	SS		
				Zyprexa (Olanzapine)	SS		ORAL
5 MG 1X PER 1 DAY	10 DAY						
				Zyrtec (Cetirizine Hydrochloride)	SS		

Date:08/05/03ISR Number: 4165538-3Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20030706893
Age:21 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Facial Palsy	Consumer	Haldol (Haloperidol) Unspecified	PS				

Date:08/06/03ISR Number: 4166207-6Report Type:Expedited (15-DaCompany Report #KII-1999-0000817
Age:74 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Abdominal Pain	Health Professional	Oxycontin Tablets(Oxycodone Hydrochloride)Cr Tablet	PS			SEE IMAGE	
	Asthenia							
	Chest Pain							
	Confusional State							
	Dehydration		Oxyfast Concentrate 20mg/Ml (Oxycodone Hydrochloride)	SS			2 ML, SEE TEXT	
	Dyspnoea							
	Hypotension							
	Lethargy							
	Mass		Benadryl(Diphenhydramine Hydrochloride)	SS			RECTAL	RECTAL
	Neoplasm Growth							
	Accelerated		Ativan(Lorazepam)	SS			RECTAL	RECTAL
			Haldol(Haloperidol)	SS			RECTAL	RECTAL
			Restoril(Temazepam)	SS			RECTAL	RECTAL

Date:08/06/03ISR Number: 4166704-3Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20030707078
Age:45 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Condition Aggravated	Foreign	Haldol (Haloperidol)	PS				
	Myelodysplastic Syndrome	Health						
		Professional						

Date:08/11/03ISR Number: 4167541-6Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20030707408
Age:19 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dyskinesia	Foreign	Haldol (Haloperidol)					
	Extrapyramidal Disorder	Health	Unspecified	PS		INTRAVENOUS	2.5 ML, 1 IN	
	Paraesthesia	Professional						1 TOTAL,

INTRAVENOUS

Date:08/11/03ISR Number: 4167547-7Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20030707403
Age:60 YR Gender:Male I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Emotional Disorder
	Extrapyramidal Disorder
Other	Hallucination, Auditory
	Impulse-Control Disorder
	Increased Appetite

	Infection					
	Medication Error					
	Oligodipsia	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
	Renal Failure Acute	Foreign	Haldol (Haloperidol)			
	Social Avoidant Behaviour	Health	Injection	PS		
INTRAMUSCULAR	SEE IMAGE					
		Professional	Levomepromazine (Levomepromazine)	C		
			Promethazine (Promethazine)	C		

Date:08/11/03ISR Number: 4167551-9Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20030801273
Age:68 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization -	Drug Dependence	Foreign	Haldol (Haloperidol)			
Initial or Prolonged	Drug Interaction	Health	Unspecified	PS		ORAL
SEE IMAGE						
	Fall	Professional	Seroquel (Quetiapine			
	Gait Disturbance		Fumarate)	SS		ORAL
SEE IMAGE						
	Pleurothotonus		Valiquid (Diazepam)	C		
			Akineton Ret (Biperiden Hydrochloride)	C		
			Bifiteral (Probucol)	C		

Date:08/11/03ISR Number: 4167775-0Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20030800332
Age:19 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Other	Aggression	Foreign	Haldol Decanoate			
	Akathisia	Health	(Haloperidol			
	Gaze Palsy	Professional	Decanoate) Injection	PS		
INTRAMUSCULAR	2 ML; 3 ML; 1					
	Human Bite					
IN 2 WEEK,						
	Self Injurious Behaviour					
INTRAMUSCULAR						

Date:08/12/03ISR Number: 4168957-4Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20030706419
Age:73 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dehydration	Foreign	Risperdal (Risperidone)					
Other	Endocarditis	Health						
	Extrapyramidal Disorder	Professional	Tablets	PS		ORAL	15 MG, ORAL	
	Myoglobinuria		Zyprexia (Olanzapine) Tablets	SS		ORAL	2 MG, 3 IN 1	DAY
	Pancytopenia							
	Psychotic Disorder		Haldol (Haloperidol) Unspecified	SS			95 MG, 1 IN 1	DAY
	Pyrexia							
	Rhabdomyolysis		Belok Zok (Metoprolol Succinate)	SS			5 MG, 2 IN 1	DAY, ORAL
			Norvasc (Amlodipine Besilate)	SS		ORAL	0.5 MG, 3 IN	1 DAY, ORAL
			Xanef (Enalapril Maleate) Tablets	SS		ORAL		
			Tavor (Lorazepam)	SS		ORAL		
			Vibolex (B-Komplex					

			"Leciva") Capsules	SS			ORAL
300 MG, 2 IN							
1 DAY, ORAL							
			Hydrochlorothiazide	C			
			Molsidomin (Molsidomine)	C			
			Kalinor (Potassium Chloride)	C			
			Dytide H (Dyazide)	C			
			Kepinol (Bactrim)	C			
			Corvaton Ret. (Molsidomine)	C			

Date:08/12/03ISR Number: 4168964-1Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20030706419
Age:73 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dehydration	Foreign	Risperdal (Risperidone)					
	Drug Interaction	Health						
Other	Endocarditis	Professional	Tablets	PS		ORAL		
ORAL								
	Extrapyramidal Disorder		Zyprexia					
	General Physical Health		(Olanzapine) Tablets	SS		ORAL		
15 MG, ORAL								
	Deterioration		Haldol (Haloperidol)	SS				
2 MG, 3 IN 1								
	Pancytopenia							
DAY								
	Rhabdomyolysis		Belok Zok (Metoprolol Succinate)	SS				
95 MG, 1 IN 1								
DAY								
			Norvasc (Amlodipine Besilate)	SS		ORAL		
5 MG, 2 IN 1								
DAY, ORAL								
			Xanef (Enalapril Maleate) Tablets	SS		ORAL		
ORAL								
			Tavor (Lorazepam)	SS		ORAL		
0.5 MG, 3 IN								

1 DAY, ORAL

Vibolex (B-Komplex "Leciva") Capsules	SS	ORAL

300 MG, 2 IN

1 DAY, ORAL

Hydrochlorothiazide (Hydrochlorothiazide)	C
Molsidomin (Molsidomine)	C
Kalinor (Potassium Chloride)	C
Dytide H (Dyazide) Tablets	C
Kepinol (Bactrim)	C
Corvaton Ret. (Molsidomine) Tablets	C

Date:08/12/03ISR Number: 4169711-XReport Type:Expedited (15-DaCompany Report #081-0073-M0100004
Age:40 YR Gender:Male I/FU:F

Outcome	PT
Other	Coma
	Drug Interaction
	Fluid Overload
	Gingival Hyperplasia
	Grand Mal Convulsion

		Hyponatraemia Inappropriate Antidiuretic Hormone Secretion Pharyngolaryngeal Pain Vomiting	Report Source: Foreign Literature; Health Professional	Product: Phenytoin Sodium (Phenytoin Sodium); Carbamazepine (Carbamazepine); Haloperidol (Haloperidol); Levomepromazine (Levomepromazine); Biperiden (Biperiden); Clonazepam (Clonazepam)	Role: PS; SS; SS; SS; SS; SS		
Dose: 300 MG; 500 MG (DAILY); 6.5 MG; 185 MG; 9 MG; 3 MG	Duration						

Date:08/13/03ISR Number: 4169934-XReport Type:Expedited (15-DaCompany Report #BR-JNJFOC-20030802234
Age:2 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Accidental Exposure	Foreign Health Professional	Haldol (Haloperidol) Unspecified	PS				

Date:08/13/03ISR Number: 4169936-3Report Type:Expedited (15-DaCompany Report #BR-JNJFOC-20030802257
Age:24 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Suicide Attempt	Foreign Health Professional	Haldol (Haloperidol) Unspecified; Tofranil (Imipramine Hydrochloride)	PS; SS				

			Tegretol (Carbamazepine)	SS		
			Fenergan (Promethazine)	SS		

Date:08/13/03ISR Number: 4169938-7Report Type:Expedited (15-DaCompany Report #BR-JNJFOC-20030802262
Age:3 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Accidental Exposure	Foreign Health Professional	Haldol (Haloperidol) Unspecified	PS				

Date:08/13/03ISR Number: 4169940-5Report Type:Expedited (15-DaCompany Report #BR-JNJFOC-20030802267
Age:3 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Accidental Exposure	Foreign Health Professional	Haldol (Haloperidol) Unspecified	PS				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/13/03ISR Number: 4169942-9Report Type:Expedited (15-DaCompany Report #BR-JNJFOC-20030802269
Age:4 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Accidental Exposure	Foreign Health Professional	Haldol (Haloperidol) Unspecified	PS		ORAL	ORAL	

Date:08/13/03ISR Number: 4169944-2Report Type:Expedited (15-DaCompany Report #BR-JNJFOC-20030802276
Age:9 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Accidental Exposure	Foreign Health Professional	Haldol (Haloperidol) Unspecified	PS				

Date:08/13/03ISR Number: 4169947-8Report Type:Expedited (15-DaCompany Report #BR-JNJFOC-20030802277
Age:4 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Accidental Exposure	Foreign Health Professional	Haldol (Haloperidol) Unspecified	PS				

Date:08/13/03ISR Number: 4169950-8Report Type:Expedited (15-DaCompany Report #BR-JNJFOC-20030802281
Age:2 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Accidental Exposure	Foreign Health Professional	Haldol (Haloperidol) Unspecified	PS				

Date:08/13/03ISR Number: 4170084-7Report Type:Expedited (15-DaCompany Report #BR-JNJFOC-20030802226
Age:36 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Suicide Attempt	Foreign Health Professional	Haldol (Haloperidol)	PS				
			Tagamet (Cimetidine)	SS				

Date:08/13/03ISR Number: 4170121-XReport Type:Expedited (15-DaCompany Report #BR-JNJFOC-20030802329
Age:40 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Suicide Attempt	Foreign Health Professional	Haldol (Haloperidol) Unspecified	PS				
			Neozine (Levomepromazine)	SS				

Date:08/13/03ISR Number: 4170122-1Report Type:Expedited (15-DaCompany Report #BR-JNJFOC-20030802344
Age:15 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Suicide Attempt	Foreign Health Professional	Haldol (Haloperidol) Unspecified	PS				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/13/03ISR Number: 4170123-3Report Type:Expedited (15-DaCompany Report #BR-JNJFOC-20030802346
Age:7 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Medication Error	Foreign Health Professional	Haldol (Haloperidol) Unspecified	PS				

Date:08/13/03ISR Number: 4170124-5Report Type:Expedited (15-DaCompany Report #BR-JNJFOC-20030802349
Age:2 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Accidental Exposure	Foreign Health Professional	Haldol (Haloperidol) Unspecified	PS				

Date:08/13/03ISR Number: 4170400-6Report Type:Expedited (15-DaCompany Report #BR-JNJFOC-20030802282
Age:15 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Overdose	Foreign Health Professional	Haldol (Haloperidol) Unspecified	PS				
			Akineton (Biperiden Hydrochloride)	SS				

Date:08/13/03ISR Number: 4170402-XReport Type:Expedited (15-DaCompany Report #BR-JNJFOC-20030802285
Age:10 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Accidental Exposure	Foreign Health Professional	Haldol (Haloperidol) Unspecified	PS				

Date:08/13/03ISR Number: 4170409-2Report Type:Expedited (15-DaCompany Report #BR-JNJFOC-20030802287
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Accidental Exposure	Foreign Health Professional	Haldol (Haloperidol) Unspecified	PS				
			Amplictil (Chlorpromazine)	SS				

Date:08/13/03ISR Number: 4170411-0Report Type:Expedited (15-DaCompany Report #BR-JNJFOC-2003802292
Age:29 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Suicide Attempt	Foreign Health Professional	Haldol (Haloperidol) Unspecified	PS				
			Risperidone (Risperidone) Unspecified	SS				
			Orap (Pimozide) Unspecified	SS				
			Anafranil (Clomipramine Hydrochloride)	SS				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/13/03ISR Number: 4170412-2Report Type:Expedited (15-DaCompany Report #BR-JNJFOC-20030802299
Age:23 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Suicide Attempt	Foreign Health Professional	Haldol (Haloperidol) Unspecified	PS				
			Voltaren (Diclofenac Sodium)	SS				
			Acetylsalicylic Acid (Acetylsalicylic Acid)	SS				

Date:08/13/03ISR Number: 4170413-4Report Type:Expedited (15-DaCompany Report #BR-JNJFOC-20030802315
Age:49 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Medication Error	Foreign Health Professional	Haldol (Haloperidol) Unspecified	PS				
			Fenergan (Promethazine)	SS				

Date:08/13/03ISR Number: 4170414-6Report Type:Expedited (15-DaCompany Report #BR-JNJFOC-20030802319
Age:3 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Accidental Exposure	Foreign Health Professional	Haldol (Haloperidol)	PS		ORAL ORAL		

Date:08/13/03ISR Number: 4170415-8Report Type:Expedited (15-DaCompany Report #BR-JNJFOC-20030802328
Age:36 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Suicide Attempt	Foreign Health Professional	Haldol (Haloperidol)	PS				

Date:08/14/03ISR Number: 4168544-8Report Type:Direct Company Report #USP 50064
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Medication Error		Dexamethasone Sodium Phosphate	PS	American Regent Labs	INJECTABLE		
			Haloperidol	SS	Solopack	INJECTABLE		

Date:08/14/03ISR Number: 4168565-5Report Type:Direct Company Report #USP 50070
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Medication Error		Haloperidol Lactate	PS	Solopak	INJ		
			Propchlorperazine Edisylate	SS	Solopak	INJ		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/14/03ISR Number: 4170304-9Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20030707078
Age:45 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Unevaluable Event	Foreign Health Professional	Haldol (Haloperidol) Unspecified	PS				FOR 12 YEARS

Date:08/14/03ISR Number: 4170305-0Report Type:Expedited (15-DaCompany Report #BR-JNJFOC-20030802222
Age:3 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Accidental Exposure	Foreign Health Professional	Haldol (Haloperidol) Unspecified	PS				

Date:08/14/03ISR Number: 4170306-2Report Type:Expedited (15-DaCompany Report #BR-JNJFOC-20030802232
Age:3 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Accidental Exposure	Foreign Health Professional	Haldol (Haloperidol) Unspecified	PS				

Date:08/14/03ISR Number: 4170307-4Report Type:Expedited (15-DaCompany Report #BR-JNJFOC-20030802238
Age:43 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Suicide Attempt	Foreign Health Professional	Haldol (Haloperidol) Unspecified	PS				

Date:08/14/03ISR Number: 4170308-6Report Type:Expedited (15-DaCompany Report #BR-JNJFOC-20030802251
Age:41 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Medication Error	Foreign Health Professional	Haldol (Haloperidol) Unspecified	PS				
			Akineton (Biperiden Hydrochloride)	SS				

Date:08/14/03ISR Number: 4170309-8Report Type:Expedited (15-DaCompany Report #BR-JNJFOC-20030802289
Age:36 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Suicide Attempt	Foreign Health Professional	Haldol (Haloperidol) Unspecified	PS				
			Risperdal (Risperidone) Unspecified	SS				
			Rivotril (Clonazepam)	SS				
			Tofranil (Imipramine Hydrochloride)	SS				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/14/03ISR Number: 4170310-4Report Type:Expedited (15-DaCompany Report #BR-JNJFOC-20030802322
Age:14 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Suicide Attempt	Foreign Health Professional	Haldol (Haloperidol) Unspecified	PS				

Date:08/14/03ISR Number: 4170311-6Report Type:Expedited (15-DaCompany Report #BR-JNJFOC-20030802323
Age:34 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Suicide Attempt	Foreign Health Professional	Haldol (Haloperidol) Unspecified	PS		ORAL		ORAL
			Fenergan (Promethazine)	SS		ORAL		ORAL
			Neozine (Levomepromazine)	SS		ORAL		ORAL

Date:08/14/03ISR Number: 4170543-7Report Type:Expedited (15-DaCompany Report #BR-JNJFOC-20030802292
Age:29 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Suicide Attempt	Foreign Health Professional	Haldol (Haloperidol) Unspecified	PS				
			Risperidone (Risperidone) Unspecified	SS				
			Orap (Pimozide) Unspecified	SS				
			Anafranil (Clomipramine Hydrochloride)	SS				

Date:08/14/03ISR Number: 4170758-8Report Type:Expedited (15-DaCompany Report #BR-JNJFOC-20030802325
Age:5 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Accidental Exposure	Foreign Health Professional	Haldol (Haloperidol) Unspecified	PS		ORAL		
			Carbolitium (Lithium Carbonate)	SS		ORAL		
			Tegretol (Carbamazepine)	SS		ORAL		

Date:08/14/03ISR Number: 4170763-1Report Type:Expedited (15-DaCompany Report #BR-JNJFOC-20030802335
Age:25 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Suicide Attempt	Foreign Health Professional	Haldol (Haloperidol) Unspecified	PS				
			Carbolitium (Lthium Carbonate)	SS				
			Rivotril (Clonazepam)	SS				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/14/03ISR Number: 4170764-3Report Type:Expedited (15-DaCompany Report #BR-JNJFOC-20030802338
Age:10 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Unevaluable Event	Foreign Health Professional	Haldol (Haloperidol) Unspecified	PS				

Date:08/15/03ISR Number: 4170172-5Report Type:Direct Company Report #USP 50132
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Medication Error		Dexamethasone Sod Phos	PS	American Regent Laboratories	INJECTION		
			Haloperidol	SS	Solopak	INJECTABLE		

Date:08/15/03ISR Number: 4170335-9Report Type:Expedited (15-DaCompany Report #2003-BP-05718RO
Age:58 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Overdose Unevaluable Event	Literature Health Professional	Propranolol Hcl Oral Solution, 40mg/5ml (Propranolol Hydrochloride)	PS		ORAL	PO	
			Haloperidol (Haloperidol)	SS		ORAL	PO	

Date:08/15/03ISR Number: 4171710-9Report Type:Expedited (15-DaCompany Report #BR-JNJFOC-20030802229
Age:4 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Accidental Exposure	Foreign	Haldol (Haloperidol)					

Initial or Prolonged		Health Professional	Unspecified	PS		

Date:08/15/03ISR Number: 4172090-5Report Type:Expedited (15-DaCompany Report #200303125
Age:19 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Intentional Misuse	Foreign Health Professional	Tylenol Analgesic (Acetaminophen)	PS		ORAL	PO	
	Somnolence							
	Suicide Attempt	Other	Metamizole	SS				
			Prometazine	SS				
			Midazolam	SS				
			Haloperidol	SS				
			Alcohol	SS				

Date:08/22/03ISR Number: 4177517-0Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20030802208
Age:68 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blood Corticotrophin Decreased	Foreign Health Professional	Haldol (Haloperidol)	PS				
	Blood Prolactin Increased		Risperdal (Risperidone)					
	Prolactinoma		Tablets	SS		ORAL	SEE IMAGE	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/22/03ISR Number: 4177525-XReport Type:Expedited (15-DaCompany Report #DE-JNJFOC-20030802208
Age:68 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blood Corticotrophin Decreased Blood Prolactin Increased Pituitary Tumour	Foreign Health Professional	Haldol (Haloperidol) Risperdal (Risperidone) Tablets	PS SS		ORAL		

SEE IMAGE

Date:08/25/03ISR Number: 4173833-7Report Type:Direct Company Report #CTU 200564
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Mental Status Changes		Haloperidol 0.5mg	PS		ORAL	0.5 MG	HS
			Risperidone 1 Mg	SS		ORAL	1 MG/2	AM/HS
			Galantamine	C		ORAL		

Date:08/25/03ISR Number: 4178384-1Report Type:Expedited (15-DaCompany Report #A0421042A
Age:51 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Flushing Gastrointestinal Motility Disorder Heat Stroke Mydriasis Rhabdomyolysis Tachycardia Urinary Retention	Literature Health Professional	Diphenhydramine (Diphenhydramine) (Generic) Haloperidol (Haloperidol) (Generic)	PS SS				

Date:08/25/03ISR Number: 4178390-7Report Type:Expedited (15-DaCompany Report #A0421042A
Age:51 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Heat Stroke Rhabdomyolysis	Literature Health Professional	Diphenhydramine (Diphenhydramine) (Generic) Haloperidol (Haloperidol) (Generic)	PS SS				

Date:08/26/03ISR Number: 4177592-3Report Type:Expedited (15-DaCompany Report #BR-JNJFOC-20030804194
Age:16 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Suicide Attempt	Foreign Consumer	Haldol (Haloperidol) Unspecified	PS				

Date:08/28/03ISR Number: 4187728-6Report Type:Periodic Company Report #US-BRISTOL-MYERS SQUIBB COMPANY-12333274
Age:72 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Delusion Hallucinations, Mixed Paranoia		Abilify Tabs	PS	Otsuka Pharmaceutical Company, Ltd.	ORAL		

Started on

22-Aug-2005 10:49 AM

7.5mg once a

day in 6/03;

3 weeks ago,

increased to

				Haldol	SS		

Date:08/29/03ISR Number: 4182293-1Report Type:Expedited (15-DaCompany Report #CH-JNJFOC-20030804512
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Disability	Drug Interaction	Foreign	Haldol (Haloperidol)	PS		ORAL	10 MG, ORAL
	Gingival Hypertrophy	Health	Semap (Penfluridol)	SS		ORAL	30 MG, ORAL
		Professional	Akineton (Biperiden Hydrochloride)	SS		ORAL	4 MG, ORAL
			Temesta (Lorazepam)	C			

Date:09/03/03ISR Number: 4184431-3Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20030805305
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Other	Pulmonary Embolism	Foreign	Haldol (Haloperidol)	PS			
		Health	Valium (Diazepam)	C			
		Professional					

Date:09/03/03ISR Number: 4184432-5Report Type:Expedited (15-DaCompany Report #EMADSS2003003117
Age:65 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Blood Creatine Phosphokinase Increased	Foreign Health	Haldol (Haloperidol) Unspecified	PS		ORAL	SEE IMAGE
Other	Depression	Professional	Lepticur				

	Dyskinesia	(Tropatepine Hydrochloride)	C
		Prothiaden (Dosulepin)	C
		Hyperium (Rilmenidine)	C
		Tranxene (Clorazepate Dipotassium)	C

Date:09/03/03ISR Number: 4184718-4Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20030805585
Age:31 YR Gender:Female I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Amnesia
Other	Aspartate Aminotransferase Increased
	Blood Creatine Phosphokinase Increased
	Blood Creatinine Increased
	Disorientation
	Fall
	Haematoma
	Hallucination, Auditory
	Suicide Attempt

White Blood Cell Count

		Report Source	Product	Role	Manufacturer	Route	Dose	Duration
		Foreign Health Professional	Haldol (Haloperidol) Unspecified	PS		ORAL	8 MG 1 IN 1	DAY ORAL
			Seroquel (Tablets) Quetiapine Fumarate	C				

Date:09/03/03ISR Number: 4184721-4Report Type:Expedited (15-DaCompany Report #CH-JNJFOC-20030804512
Age:41 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Drug Interaction Gingival Hypertrophy	Foreign Health Professional	Haldol (Haloperidol) Unspecified	PS		ORAL	10 MG ORAL	
			Semap (Penfluridol) Unspecified	SS		ORAL	30 MG ORAL	
			Akineton (Biperiden Hydrochloride)	SS		ORAL	4 MG ORAL	
			Temesta (Lorazepam)	C				

Date:09/04/03ISR Number: 4179203-XReport Type:Expedited (15-DaCompany Report #WAES 0308DEU00087
Age:18 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Status Epilepticus		Zocor	PS		ORAL		
			Haloperidol	SS	Merck & Co., Inc			

Date:09/04/03ISR Number: 4181164-4Report Type:Direct Company Report #USP 042239
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Other	Medication Error		Haldol	PS	Mc Neil	
			Haldol	SS	Mc Neil	

Date:09/04/03ISR Number: 4181385-0Report Type:Direct Company Report #USP 042222
Age:90 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Medication Error		Haldol	PS	Mylan	TABLET		
			Haloperidal	SS	Mylan	TABLET		

Date:09/04/03ISR Number: 4185072-4Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20030803165
Age:61 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Fall Femur Fracture Humerus Fracture	Foreign Health Professional	Haloperidol (Haloperidol) Unspecified	PS		ORAL		ORAL

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/05/03ISR Number: 4186009-4Report Type:Expedited (15-DaCompany Report #EMADSS2002006126
Age:26 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Activated Partial Thromboplastin Time Prolonged	Foreign Health Professional	Haldol (Haloperidol) Unspecified	PS		ORAL	ORAL	
	Antinuclear Antibody Positive		Risperdal (Risperidone) Unspecified	SS		ORAL	ORAL	
	Antiphospholipid Antibodies Positive		Seresta (Oxazepam)	C				
	Dna Antibody Positive		Theralene (Alimemazine Tartrate)	C				
	Thrombocytopenia		Implanon (Etonogestrel) Implant	C				
			Birodogyl (Rhodogil) Unspecified	C				
			Mepronizine (Mepronizine) Unspecified	C				
			Sulfarlem (Anethole Trithione)	C				

Date:09/05/03ISR Number: 4186431-6Report Type:Expedited (15-DaCompany Report #EMADSS2002006126
Age:26 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Antinuclear Antibody Positive	Foreign Health	Haldol (Haloperidol) Unspecified	PS		ORAL	ORAL	
	Antiphospholipid Antibodies Positive	Professional	Risperdal (Risperidone)					
	Circulating Anticoagulant		Unspecified	SS		ORAL	ORAL	
	Thrombocytopenia		Seresta (Oxazepam)	C				
			Theralene (Alimemazine Tartrate)	C				
			Implanon (Etonogestrel)	C				

				Birodogyl (Rhodogil)	C		
				Mepronizine (Mepronizine)	C		
				Sulfarlem (Anethole Trithione)	C		

Date:09/08/03ISR Number: 4183265-3Report Type:Direct Company Report #CTU 201405
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Injection Site Irritation		Haloperidol			
	Injection Site Rash		Decanoate	PS		
150 MG IM Q MONTH						
			Fosinopril	C		
			Folic Acid	C		
			Asorbic Acid	C		
			Ibuprofen	C		
			Terbenafine Topical	C		
			Miconazole	C		
			Tramadal	C		

Date:09/09/03ISR Number: 4188261-8Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20030900734
Age:53 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardiac Failure Neuroleptic Malignant Syndrome	Health Professional	Haldol (Hadoperidol) Unspecified	PS				

Date:09/10/03ISR Number: 4189054-8Report Type:Expedited (15-DaCompany Report #FR-JNJFOC-20030900049
Age:68 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Phlebitis	Foreign Health Professional	Haldol Decanoas (Haloperidol Decanoate) Injection	PS		INTRAMUSCULAR	200 MG, 1 IN	3 WEEK,
			Depakote (Valproate Semisodium)	C		INTRA-MUSCULAR		

Date:09/11/03ISR Number: 4185971-3Report Type:Direct Company Report #CTU 201674
Age:58 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Coma Dyspnoea Sedation		Haloperidol Lorazepam	PS SS		INTRAMUSCULAR INTRAMUSCULAR	10 MG IM 2 MG IM	

Date:09/15/03ISR Number: 4190710-6Report Type:Expedited (15-DaCompany Report #JP-JNJFOC-20030902010
Age:33 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abnormal Behaviour Amenorrhoea Anxiety Blood Prolactin Increased Dyspnoea Refusal Of Treatment By Patient Speech Disorder Suicide Attempt	Foreign Health Professional	Risperidone (Risperidone) Haloperidol (Haloperidol) Injection	PS SS		ORAL INTRAVENOUS DRIP	SEE IMAGE 20 MG, IN 1 DAY, INTRAVENOUS DRIP	

Date:09/15/03ISR Number: 4190727-1Report Type:Expedited (15-DaCompany Report #JP-JNJFOC-20030902010
Age:33 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abnormal Behaviour Amenorrhoea Blood Prolactin Increased Dyspnoea Speech Disorder Suicide Attempt	Foreign Health Professional	Risperidone (Risperidone) Unspecified Haloperidol (Haloperidol) Injection	PS SS		ORAL INTRAVENOUS DRIP	SEE IMAGE 20 MG, IN 1 DAY, INTRAVENOUS DRIP	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/16/03ISR Number: 4190993-2Report Type:Direct Company Report #USP 080568
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Medication Error		Haldol Decanoate	PS	Mc Neil			
			Haldol	SS	Mc Neil			

Date:09/16/03ISR Number: 4191128-2Report Type:Direct Company Report #USP 081185
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Medication Error		Haloperidol 0.5 Mg	PS	Mylan			
			Haloperidol 5 Mg	SS	Par			

Date:09/17/03ISR Number: 4191446-8Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20030707408
Age:19 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dyskinesia	Foreign	Haldol (Haloperidol)	PS		INTRAVENOUS	2.5 ML, 1 IN	1 TOTAL;
	Extrapyramidal Disorder	Health						
	Paraesthesia	Professional				INTRAVENOUS		

Date:09/23/03ISR Number: 4195239-7Report Type:Direct Company Report #USP 80013
Age: Gender:Not SpecifiI/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Medication Error		Haldol Haloperidol	PS	Mcneil	0.5 MG TABLET		

Date:09/24/03ISR Number: 4195435-9Report Type:Direct Company Report #CTU 202392
Age:82 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Required	Cheyne-Stokes Respiration		Haloperidol 5 Mg/ Ml	PS		
INTRAVENOUS 15 MG ONCE IV						
Intervention to	Coma					
BOLUS						
Prevent Permanent	Confusional State		Aspirin	C		
Impairment/Damage	Medication Error		Clopidogrel	C		
	Mental Status Changes		Carvedilol	C		
			Pantroprazole	C		
			Albuterol/Atrovent	C		
			Insulin	C		
			Furosemide	C		
			Hydralazine	C		
			Isosorbide	C		
			Dobutamine	C		

Date:09/24/03ISR Number: 4195437-2Report Type:Direct Company Report #CTU 202393
Age:63 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Required	Neuroleptic Malignant		Haloperidol 5 Mg/1			
Intervention to	Syndrome		Ml	PS		
INTRAMUSCULAR 5 M Q8 H PRN						
Prevent Permanent						
IM						
Impairment/Damage			Zyprexa 10 Mg Lilly	SS	Lilly	ORAL
10 MG BID						
ORAL						
			Geodon-Ziprasidone	C		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/24/03ISR Number: 4198243-8Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20030904792
Age:19 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Death	Literature	Haldol (Haloperidol)					
		Health	Unspecified	PS			PARENTERAL	PARENTERAL
		Professional	Risperdal					
		Distributor	(Risperidone)					
			Unspecified	SS			PARENTERAL	PARENTERAL
			Valproic Acid					
			(Valproic Acid)	SS			PARENTERAL	PARENTERAL

Date:09/24/03ISR Number: 4198437-1Report Type:Expedited (15-DaCompany Report #2003CG01283
Age:40 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Blood Pressure	Foreign	Mopral	PS			NI	
	Cardiac Disorder	Health	Aracytine	SS			INTRAVENOUS	1 DF MONTH;
	Cardiogenic Shock	Professional					IV	
	Cardiomyopathy	Other	Cerubidine "Bedford"	SS			INTRAVENOUS	1 DF MONTH;
	Cyanosis						IV	
	Dilatation Atrial		Haldol "Janssen"	SS			NI	
	Dyspnoea		Lexomil	SS			NI	
	Ejection Fraction		Deroxat	SS			NI	
	Decreased							
	Hepatic Failure							
	Hepatomegaly							
	Metabolic Acidosis							
	Mitral Valve Incompetence							
	Pulmonary Arterial							
	Pressure Increased							
	Tachypnoea							

Date:09/25/03ISR Number: 4194049-4Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0309369A
Age:40 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Acute Myeloid Leukaemia		Deroxat	PS	Glaxosmithkline	ORAL	20MG	Unknown
Hospitalization -	Cardiac Failure		Endoxan	SS				
INTRAVENOUS								16 WK
Initial or Prolonged	Cyanosis		Farmorubicine	SS				
INTRAVENOUS								16 WK
Other	Dyspnoea		Fluorouracil	SS				
INTRAVENOUS								16 WK
	Hepatomegaly		Aracytine	SS				
INTRAVENOUS							1UNIT	Monthly 13 WK
	Metabolic Acidosis		Cerubidine	SS				
INTRAVENOUS							1UNIT	Monthly 13 WK
	Tachypnoea		Haldol	SS		ORAL		
			Mopral	SS		ORAL		
			Lexomil	SS		ORAL		

Date:09/25/03ISR Number: 4196894-8Report Type:Direct Company Report #CTU 202483
Age:46 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Alcohol Withdrawal		Haloperidol	PS				
INTRAVENOUS							5 MG	IV X 1
	Syndrome		Nicotine Patch	C				
	Delirium Tremens		Sucralfate	C				
	Dyspnoea		Morphine	C				
	Oxygen Saturation Decreased							
	Pharyngeal Oedema							
	Swollen Tongue							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/26/03ISR Number: 4199306-3Report Type:Expedited (15-DaCompany Report #2003178072FR
Age:40 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Blood Pressure Increased	Foreign	Aracytine					
Hospitalization - Initial or Prolonged	Cardiac Failure Cyanosis	Health Professional	(Cytarabine) Powder, Sterile	PS			INTRAVENOUS	IV
	Dyspnoea Ejection Fraction Decreased	Other	Cerubidine (Daunorubicin Hydrochloride)	SS			INTRAVENOUS	IV
	Hepatomegaly		Haldol (Haloperidol)	SS		ORAL	ORAL	
	Metabolic Acidosis		Mopral (Omeprazole)	SS		ORAL	ORAL	
	Mitral Valve Incompetence		Lexomil (Bromazepam)	SS		ORAL	ORAL	
	Pulmonary Arterial Pressure Increased		Deroxat (Paroxetine Hydrochloride)	SS		ORAL	ORAL	
	Tachypnoea							

Date:09/26/03ISR Number: 4200196-0Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20030902584
Age:57 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Lymphocyte Count Decreased	Foreign Health	Haldol (Haloperidol) Tablets	PS		ORAL	0.5 MG, ORAL	
	Thrombocytopenia	Professional	Haldol (Haloperidol) Injection	SS			INTRAMUSCULAR	5 MG, INTRA-MUSCULAR
			Amisulpride (Amisulpride)	SS		ORAL	200 MG, 3 IN 1 DAY, ORAL	
			Chlorpromazine					

			(Chlorpromazine)	SS		ORAL	200 MG, ORAL
			Zuclopenthixol (Zuclopenthixol)	SS			
			Lorazepam (Injection) (Lorazepam)Inj	C			
			Lorazepam (Lorazepam)Oral	C			

Date:09/26/03ISR Number: 4209743-6Report Type:Periodic Company Report #2002UW14829
Age:32 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Required	Neuroleptic Malignant	Health	Seroquel	PS		ORAL	300 MG BIDPO
Intervention to	Syndrome	Professional	Seroquel	SS		ORAL	200 MG BID PO
Prevent Permanent			Haldol "Mcneil"	SS	"Mcneil"		5 MG PRN
Impairment/Damage			Depakote	C			
			Neurontin	C			

Date:09/29/03ISR Number: 4201626-0Report Type:Expedited (15-DaCompany Report #2003CG01283
Age:40 YR Gender:Female I/FU:F

Outcome	PT
Death	Acute Myeloid Leukaemia
Hospitalization -	Blood Pressure Abnormal
Initial or Prolonged	Cardiac Failure
	Cyanosis
	Dyspnoea

	Ejection Fraction Decreased						
	Haemodynamic Instability	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Hepatomegaly	Foreign	Mopral	PS			
	Ischaemic Hepatitis	Health	Aracytine	SS			INTRAVENOUS 1 DF MONTH IV
	Metabolic Acidosis	Professional	Cerubidine "Bedford"	SS	Bedford		INTRAVENOUS 1 DF MONTH IV
		Other	Haldol "Janssen"	SS	Janssen		
			Lexomil	SS			
			Deroxat	SS			
			Endoxan	SS			
			Farmorubicin	SS			
			Fluorouracile	SS			

Date:09/29/03ISR Number: 4201700-9Report Type:Expedited (15-DaCompany Report #2003AP03281
Age:78 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Death	Haemorrhage Subcutaneous	Foreign	Seroquel	PS		ORAL	25 MG TID PO
	Haemorrhagic Diathesis	Health	Wintermin	SS		ORAL	62.5 MG DAILY PO
	Idiopathic	Professional					
	Thrombocytopenic Purpura	Other	Wintermin	SS		ORAL	25 MG DAILY PO
			Risperdal	SS		ORAL	1 MG TID PO
			Serenace	SS			0.75 MG TID
			Seven Ep	C			

Date:09/29/03ISR Number: 4201733-2Report Type:Expedited (15-DaCompany Report #FR-JNJFOC-20030903975
Age:45 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Atrial Fibrillation	Foreign	Haldol (Haloperidol)				

Initial or Prolonged			Health	Solution	PS		
INTRAVENOUS	5 MG, 1 IN 1 DAY,		Professional				
INTRAVENOUS				Loxapac (Loxapine Succinate)	C		
				Rivotril (Clonazepam)	C		
				Zocor (Simvastatin)	C		
				..	C		

Date:09/30/03ISR Number: 4199256-2Report Type:Direct Company Report #USP 080316
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Medication Error		Haloperidol	PS	Mylan	TABLET		
			Haloperidol	SS	Mylan	TABLET		

Date:09/30/03ISR Number: 4203448-3Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20030707403
Age:60 YR Gender:Male I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Extrapyramidal Disorder
	Fluid Intake Reduced
Other	Hallucination, Auditory
	Increased Appetite
	Infection

	Parkinsonism						
	Radial Nerve Palsy						
	Renal Failure Acute	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Social Avoidant Behaviour	Foreign	Haldol (Haloperidol)				
	Weight Decreased	Health	Injection	PS		INTRAMUSCULAR	SEE IMAGE
		Professional	Levomepromazine (Levomepromazine)	C			
			Promethazine (Promethazine)	C			
			Beloc-Zok (Beloc-Zoc Comp)	C			

Date:09/30/03ISR Number: 4203454-9Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20030904315
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Death	Dysgraphia	Foreign	Haldol (Haloperidol)				
		Health	Unspecified	PS		ORAL	2 MG, ORAL
		Professional	Dipiperon (Pipamperone)	C			

Date:10/01/03ISR Number: 4198888-5Report Type:Expedited (15-DaCompany Report #FR-BRISTOL-MYERS SQUIBB COMPANY-12387593
Age:38 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Death	Acute Myeloid Leukaemia		Endoxan	PS	Bristol-Myers Squibb Company		
Hospitalization - Death						INTRAVENOUS	one course Initial or Prolonged every two days
			Haldol	SS		ORAL	
			Farmorubicin	SS		INTRAVENOUS	
			Mopral	SS		ORAL	
			Fluorouracil	SS		INTRAVENOUS	

			Deroxat	SS		ORAL
			Lexomil	SS		

Date:10/01/03ISR Number: 4204199-1Report Type:Expedited (15-DaCompany Report #03-257-2053
Age:73 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Atrial Fibrillation	Health	Haloperidol Inj.			
	Blood Pressure Increased	Professional	5mg/1 Ml, Ben Venue			
	Cardio-Respiratory Arrest		Labs	PS	Ben Venue Labs	
INTRAVENOUS 2 MG IVP X2						
			Protonix	C		
			Vancomycin	C		
			Digoxin	C		
			Lopressor	C		
			Captopril	C		
			Tylenol	C		
			Colace	C		
			Celexa	C		
			Laculose	C		
			Ciprofloxacin	C		
			Amiodarone	C		
			Hydrochlorothiazide	C		
			Vioxx	C		
			Norvasc	C		
			Fluconazole	C		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/01/03ISR Number: 4204507-1Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20030904711
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Blood Creatine	Foreign	Haldol (Haloperidol)	PS			UNKNOWN	UNKNOWN
Life-Threatening	Phosphokinase Increased	Health	Anafranil					
	Body Temperature	Professional	(Clomipramine					
	Increased		Hydrochloride)	SS		ORAL	75 MG, 150 IN	
	Intentional Misuse						1 DAY; ORAL	
	Neuroleptic Malignant		Dothiepin					
	Syndrome		(Dosulepin)	SS		ORAL	75 MG, 30 IN	
	Respiratory Arrest						1 DAY; ORAL	
	Shock							

Date:10/01/03ISR Number: 4204510-1Report Type:Expedited (15-DaCompany Report #FR-JNJFOC-20030903964
Age:40 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Blood Alkaline	Foreign	Haldol (Haloperidol)					
Hospitalization -	Phosphatase	Health	Unspecified	PS		ORAL	ORAL	
Initial or Prolonged	Blood Pressure	Professional	Aracytine					
	Cardiac Failure		(Cytarabine)					
	Cyanosis		Injection	SS			INTRAVENOUS	, 1 IN 30
	Dilatation Atrial						DAY;	
	Dyspnoea						INTRAVENOUS	
	Ejection Fraction		Lexomil (Bromazepam)	SS		ORAL	ORAL	
	Decreased		Deroxat (Paroxetine					
	Haemodynamic Instability		Hydrochloride)	SS		ORAL	ORAL	
	Hepatomegaly		Mopral (Omeprazole)	SS		ORAL	ORAL	
	Ischaemic Hepatitis		Cerubidine					
	Metabolic Acidosis		(Daunorubicin					

		Mitral Valve Incompetence		Hydrochloride)	SS		
INTRAVENOUS	1 DOSE(S), 1	Pericardial Disease					
IN 30 DAY,		Pulmonary Arterial					
INTRAVENOUS		Pressure Increased					
		Tachypnoea					

Date:10/01/03ISR Number: 4204516-2Report Type:Expedited (15-DaCompany Report #FR-JNJFOC-20030602181
Age:60 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Cardiomyopathy	Foreign	Haldol Decanoas			
Hospitalization -	Pulmonary Embolism	Health	(Haloperidol			
Initial or Prolonged	Respiratory Failure	Professional	Decanoate) Injection	PS		
INTRAMUSCULAR	1 DOSE(S), 1					
IN 4 WEEK,						
INTRA-MUSCULA						
R						
			Tercian (Cyamemazine)Solutio			
			n	SS		ORAL
50 MG, 1 IN 1						
DAY, ORAL						
			Moiten (Fluphenazine			
			Hydrochloride)	C		
			Largactil			
			(Chlorpromazine			
			Hydrochloride)	C		
			Nozinan			
			(Levomepromazine)	C		
			Neuleptil			
			(Periciazine)	C		

			Terfluzine (Trifluoperazine Hydrochloride)	C			
			Piportil (Pipotiazine)	C			
			Solian (Amisulpride)	C			

Date:10/02/03ISR Number: 4200800-7Report Type:Direct Company Report #CTU 203019
Age:20 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Cardiac Arrest		Methadone 70 Mg	PS		ORAL		
	Torsade De Pointes		Haloperidol	SS		INTRAVENOUS	I.V.	
			Metaclopramide	C				

Date:10/03/03ISR Number: 4200761-0Report Type:Expedited (15-DaCompany Report #JP-BRISTOL-MYERS SQUIBB COMPANY-12301743
Age:25 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Delirium		Gatiflo	PS	Bristol-Myers Squibb Company	ORAL	2	DAY
	Dissociation							
	Extrapyramidal Disorder		Serenace	SS		ORAL	12	MON
	Histrionic Personality Disorder		Serenace	SS		INTRAVENOUS		
	Oculogyration		Singulair	C		DRIP		
			Chinese Herbs	C		ORAL		
			Narcotine	C		ORAL		
			Solon	C		ORAL		
			Saxizon	C		INTRAVENOUS		
						DRIP		

Date:10/03/03ISR Number: 4204068-7Report Type:Direct Company Report #CTU 203154
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Muscle Spasms		Haldol	PS		INTRAMUSCULAR	IM X 1 DOSE	
			Concerta	C				
			Effexor	C				
			Seroquel	C				

Date:10/03/03ISR Number: 4204138-3Report Type:Direct Company Report #CTU 203168
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dyskinesia		Haldol	PS				
	Muscle Spasms							

Date:10/03/03ISR Number: 4205805-8Report Type:Expedited (15-DaCompany Report #2003040439
Age:67 YR Gender:Female I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Blood Creatine Phosphokinase
	Confusional State
	Dehydration
	Dialysis

		Insomnia Neuroleptic Malignant Syndrome	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
		Pyrexia	Foreign	Lustral (Sertraline)	PS		ORAL
100 MG							
		Renal Failure Acute	Health				
(DAILY), ORAL							
		Restlessness	Professional	Haloperidol			
		Stupor		(Haloperidol)	SS		
INTRAMUSCULAR	5 MG,						
		White Blood Cell Count					
INTRAMUSCULAR							
		Increased		Olanzapine			
				(Olanzapine)	SS		ORAL
10 MG (ONE							
DOSE), ORAL							

Date:10/03/03ISR Number: 4205812-5Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20030905978
Age:72 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Other	Cardiac Fibrillation	Foreign	Haldol Decanoate			
		Consumer	(Haloperidol Decanoate) Injection	PS		
INTRAMUSCULAR	INTRA-MUSCULAR					

Date:10/06/03ISR Number: 4204988-3Report Type:Expedited (15-DaCompany Report #FR-JNJFOC-20030905606
Age:49 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Life-Threatening	Coma	Foreign	Haldol (Haloperidol)			
Hospitalization -	Cyanosis	Health	Injection	PS		
Initial or Prolonged	Disseminated	Professional	Lepticur			
	Intravascular Coagulation		(Tropatepine			
	Drug Interaction		Hydrochloride)	SS		ORAL
10 MG, 3 IN 1						

	Heart Rate Increased					
DAY, ORAL						
	Hyperthermia Malignant		Tercian			
	Hyporeflexia		(Cyamemazine)	SS		ORAL
75 MG, 1 IN 1						
	Hypotonia					
DAY, ORAL						
	Loss Of Consciousness		Anafranil			
	Miosis		(Clomipramine			
	Rhabdomyolysis		Hydrochloride)	SS		
			Imovane (Zopiclone)	C		
			Xanax (Alprazolam)	C		
			Duphalac (Lactulose)	C		
			Gentalline			
			(Gentamicin Sulfate)	C		
			Dacryoserum	C		

Date:10/06/03ISR Number: 4205273-6Report Type:Expedited (15-DaCompany Report #FR-JNJFOC-20030905693
Age:40 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Acute Myeloid Leukaemia	Foreign	Haldol (Haloperidol)	PS		ORAL
ORAL						
Initial or Prolonged	Cardiac Failure	Health	Mopral (Omeprazole)	SS		ORAL
ORAL						
	Drug Interaction	Professional	Droxat			
			(Paroxetine)	SS		ORAL
ORAL						
			Lexomil (Bromazepam)	SS		ORAL
ORAL						
			Endoxan			
			(Cyclophosphamide)	SS		
INTRAVENOUS , 1 IN 2						
DAY,						
INTRAVENOUS						
			Farmorubicine			

			(Epirubicin)	SS		
INTRAVENOUS , 1 IN 2 DAY,						
INTRAVENOUS			Fluoro-Uracile (Fluorouracil)	SS		
INTRAVENOUS	INTRAVENOUS					

Date:10/06/03ISR Number: 4205274-8Report Type:Expedited (15-DaCompany Report #EMADSS2003003149
Age:41 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dysphagia	Foreign	Haldol (Haloperidol)					
	Gingival Hyperplasia	Health	Unspecified	PS		ORAL	10 MG, ORAL	
		Professional	Semap (Penfluridol)	SS		ORAL	30 MG, ORAL	
		Other	Biperiden (Biperiden)	SS		ORAL	4 MG, ORAL	
			Temesta (Unspecified) Lorazepam	C				

Date:10/07/03ISR Number: 4206903-5Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20030905920
Age:67 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dialysis	Foreign	Haloperidol (Haloperidol)					
	Drug Interaction	Health	Injection	PS		INTRAMUSCULAR	5 MG, 1 IN 1 DAY,	
	Neuroleptic Malignant Syndrome	Professional						
	Renal Failure Acute							
INTRA-MUSCULAR								
			Olanzapine					

			(Olanzapine)	Unknown	SS		

10 MG, 1 IN 1

DAY

			Sertraline (Sertraline)	Unknown	SS		

SEE IMAGE

Date:10/07/03ISR Number: 4206924-2Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20030802599
Age:68 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death Life-Threatening	Neuroleptic Malignant Syndrome Pneumonia	Foreign Health Professional	Haldol Decanoate (Haloperidol Decanoate) Injection	PS		INTRAMUSCULAR	100 MG, 1 IN	1 MONTH,

INTRA-MUSCULA

R

			Benperidol (Benperidol)	C			
			Tri-Thiazid (Dyazide)	C			
			Nifedipat Ret (Nifedipine)	C			

Date:10/07/03ISR Number: 4206929-1Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20030707403
Age:60 YR Gender:Male I/FU:F

Outcome
Hospitalization - Initial or Prolonged

Other

	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Chills	Foreign	Haldol Decanoate					
	Emotional Disorder	Health	(Haloperidol					
	Extrapyramidal Disorder	Professional	Decanoate) Injection	PS				
INTRAMUSCULAR	SEE IMAGE							
	Fluid Intake Reduced		Levopromazine					
	Hallucination, Auditory		(Levopromazine)	C				
	Hemiparesis		Promethazine					
	Increased Appetite		(Promethazine)	C				
	Infection		Beloc-Zok (Beloc-Zoc					
	Mutism		Comp)	C				
	Parkinsonism							
	Renal Failure Acute							
	Social Avoidant Behaviour							
	Weight Decreased							

Date:10/07/03ISR Number: 4207071-6Report Type:Expedited (15-DaCompany Report #2003034521
Age:36 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Acute Myocardial	Foreign	Zeldox (Capsules)					
Hospitalization -	Infarction	Health	(Ziprasidone)	PS		ORAL		
160 MG								
Initial or Prolonged	Confusional State	Professional						
(BID),ORAL								
Other	Convulsion	Company	Haloperidol					
	Coronary Artery Stenosis	Representative	(Haloperidol)	SS				
	Dilatation Ventricular		Flupentixol					
	Disorientation		Dihydrochloride					
	Drug Withdrawal Syndrome		(Flupentixol					
	Fall		Dihydrochloride)	C				
	Gastrointestinal Ulcer		Biperiden					
	Haematoma		Hydrochloride					
	Hiatus Hernia		(Biperiden					
	Inflammation		Hydrochloride)	C				
	Injury		Chlorprothixene					
	Loss Of Consciousness		Hydrochloride					
	Mental Disorder Due To A		(Chlorprothixene					
	General Medical Condition		Hydrochloride)	C				
	Neuroleptic Malignant							
	Syndrome							

	Oesophagitis					
	Rhabdomyolysis					
	Somnolence					
	Upper Gastrointestinal Haemorrhage					
	Urosepsis					

Date:10/07/03ISR Number: 4207604-XReport Type:Expedited (15-DaCompany Report #DE-JNJFOC-20030903002
Age:37 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Alcohol Poisoning Blood Lactate Dehydrogenase Increased Condition Aggravated Psychotic Disorder Treatment Noncompliance	Foreign Study Health Professional	Risperidone - Blinded (Risperidone) Tablets Haldol (Haloperidol) Akineton (Biperiden	PS SS		ORAL	3 MG, 1 IN 1 DAY 3 MG, 1 IN 1 DAY, ORAL	

				Hydrochloride) Tablets	C	

Date:10/08/03ISR Number: 4207429-5Report Type:Expedited (15-DaCompany Report #2003179688US
Age:77 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Agitation	Literature	Heparin Sodium			
Other	Aphasia	Health	Injection,Usp(Hepari			
	Cardio-Respiratory Arrest	Professional	n Sodium)Solution,			
	Cerebral Infarction		Sterile	PS		
INTRAVENOUS	UNK, UNK; IV 2 DAY					
	Coma		Heparin Sodium			
	Delirium		Injection, Usp			
	Haematocrit Decreased		Regimen #2	SS		
SUBCUTANEOUS	UNK, UNK,					
	Hypertension					
SUBCUTANEOUS						
	Pneumonia Aspiration		Trombyl			
	Post Procedural		(Acetylsalicylic			
	Complication		Acid) Tablet	SS		
UNKNOWN	325 MG/DAY;					
UNK						
			Aloperidolo Ce			
			(Haloperidol) Tablet	SS		
UNKNOWN	UNK, UNK, UNK					
			Diazepam Dorom			
			(Diazepam) Talbet	SS		
UNK, UNK, UNK						
			Clopidogrel	C		
			Warfarin	C		

Date:10/09/03ISR Number: 4208195-XReport Type:Expedited (15-DaCompany Report #2003038179
Age:59 YR Gender:Male I/FU:F

Outcome	PT
Death	Alanine Aminotransferase
Life-Threatening	Increased
Other	Aspartate
	Aminotransferase
	Increased
	Blood Alkaline

Phosphatase Increased
Blood Beta-D-Glucan
Increased
Blood Chloride Increased
Blood Creatinine
Decreased
Blood Glucose Decreased
Blood Lactate
Dehydrogenase Increased
Blood Potassium Decreased
Blood Sodium Increased
Blood Triglycerides
Decreased
Blood Urea Increased
Blood Uric Acid Decreased
Creatine Phosphokinase
Decreased
Eosinophil Percentage
Decreased
Gamma-Glutamyltransferase
Increased
Haematocrit Decreased
Haemoglobin Decreased
Herpes Zoster

		Lymphocyte Percentage Decreased Monocyte Percentage Decreased Neutrophil Percentage Increased Platelet Count Decreased Protein Total Decreased Pyrexia Red Blood Cell Count Decreased White Blood Cell Count Decreased White Blood Cell Count Increased	Report Source Foreign Health Professional Company Representative	Product	Role	Manufacturer	Route	Dose Duration
				Diflucan Tablets (Fluconazole)	PS			SEE IMAGE
				Haloperidol(Haloperidol)	SS		INTRAVENOUS	INTRAVENOUS
				Morphine Hydrochloride (Morphine Hydrochloride)	SS		INTRAVENOUS	INTRAVENOUS
				Hydrocortisone Sodium Succinate (Hydrocortisone Sodium Succinate)	SS		INTRAVENOUS	200 MG (BID), INTRAVENOUS
				Granisetron (Granisetron)	C			
				Doxorubicin Hydrochloride (Doxorubicin Hydrochloride)	C			
				Vincristine Sulfate (Vincristine Sulfate)	C			
				Cyclophosphamide (Cyclophosphamide)	C			

Date:10/10/03ISR Number: 4209127-0Report Type:Expedited (15-DaCompany Report #FR-JNJFOC-20031000865
Age:81 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Drug Interaction Klebsiella Infection Nosocomial Infection Urinary Retention	Foreign Health Professional	Haldol (Haloperidol) Solution Atarax (Hydroxyzine	PS		ORAL	2 MG/ML, 1 IN 1 DAY, ORAL

			Hydrochloride)			
			Unknown	SS		ORAL
75 MG, 1 IN 1 DAY, ORAL						

Date:10/10/03ISR Number: 4209252-4Report Type:Expedited (15-DaCompany Report #RENA-10582
Age:62 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Constipation	Foreign	Renagel	PS		ORAL	7.5 G QD PO	
Initial or Prolonged	Intestinal Obstruction	Health	Contomin	SS		ORAL	100 MG QD PO	
		Professional	Haloperidol	SS		ORAL	4.5 MG QD PO	
		Other	Artane	SS		ORAL	4 MG QD PO	
			Alfarol	C				
			Bufferin	C				
			Lasix	C				
			Cardenalin	C				
			Mevalotin	C				
			Pursennid	C				
			Adalat	C				
			Norvasc	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/15/03ISR Number: 4210552-2Report Type:Expedited (15-DaCompany Report #MK200310-0078-1
Age:49 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Alanine Aminotransferase Increased	Foreign	Anafranil 25mg Capsules	PS				
	Aspartate Aminotransferase Increased		Haldol	SS				
	Azotaemia		Lepticur	SS				
	Blood Creatinine Increased		Tercian	SS				
	Coma		Xanax	C				
	Cyanosis		Duphalac	C				
	Disseminated Intravascular Coagulation		Gentalline	C				
	Drug Interaction		Imovane	C				
	Hyperglycaemia		Dacryoserum	C				
	Hyperthermia Malignant							
	Hyporeflexia							
	Hypotonia							
	Miosis							
	Platelet Count Decreased							
	Rhabdomyolysis							

Date:10/15/03ISR Number: 4213667-8Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20030900507
Age:53 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Ventricular Extrasystoles	Foreign	Haldol (Haloperidol)					
		Health	Unspecified	PS			5 MG,	
		Professional	Taxilan (Unknown)					
			Perazine	C				

Date:10/17/03ISR Number: 4214652-2Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20030904792
Age:19 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Agitation	Literature	Haldol (Haloperidol)					

		Depressed Level Of	Distributor	Unspecified	PS		
PARENTERAL	PARENTERAL						
		Consciousness		Risperdal			
		Electroencephalogram		(Risperisone)	SS		
PARENTERAL	PARENTERAL						
		Abnormal		Valproic Acid	SS		
PARENTERAL	PARENTERAL						
		Hallucination					
		Hypotension					
		Neuroleptic Malignant					
		Syndrome					
		Rhabdomyolysis					
		Therapy Non-Responder					

Date:10/20/03ISR Number: 4214697-2Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20030802208
Age:68 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Pituitary Tumour	Foreign	Haldol (Haloperidol)	PS				
		Health	Risperdal					
		Professional	(Risperidone)					
			Tablets	SS		ORAL		

SEE IMAGE

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/20/03ISR Number: 4214815-6Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20030904791
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Literature	Haldol (Haloperidol)	PS		ORAL	ORAL	
	Multiple Drug Overdose	Health	Benztropine					
	Pyrexia	Professional	(Benzatropine					
		Distributor	Mesilate)	SS		ORAL	ORAL	
			Valproic Acid					
			(Valproic Acid)	SS		ORAL	ORAL	

Date:10/20/03ISR Number: 4215506-8Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20030802208
Age:68 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blood Corticotrophin	Foreign	Haldol (Haloperidol)					
	Decreased	Health	Unspecified	PS				
	Blood Prolactin Increased	Professional	Risperdal					
	Pituitary Tumour		(Risperidone)					
			Tablets	SS		ORAL	0.5 & 1.5 & 2	MG, 2 IN 1 DAY, ORAL- SEE IMAGE

Date:10/22/03ISR Number: 4215288-XReport Type:Direct Company Report #CTU 204300
Age:39 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Intentional Misuse		Desipramine	PS				
			Haldol	SS				
			Simvastatin	C				
			Naproxen	C				
			Sertraline	C				

			Ziprasidone	C			

Date:10/22/03ISR Number: 4217119-0Report Type:Expedited (15-DaCompany Report #2003111063
Age:81 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Klebsiella Infection Nosocomial Infection Urinary Retention	Foreign Health Professional	Atarax (Tablet) (Hydroxyzine Hydrochloride)	PS		ORAL	75 MG (TID), ORAL	
			Haloperidol (Haloperidol)	SS		ORAL	ORAL	

Date:10/23/03ISR Number: 4215759-6Report Type:Direct Company Report #CTU 204437
Age: Gender:Female I/FU:I

Outcome	PT
Life-Threatening Hospitalization - Initial or Prolonged	Agitation Aphasia Body Temperature Increased Dystonia Heart Rate Increased Intentional Misuse Mental Disorder

Toxicologic Test Abnormal

			Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
				Haloperidol	PS		ORAL
90 MG X 1; PO							
				Diphenhydramine	SS		ORAL
150 MG X1 ;							
PO							
				Metronidazole	C		
				Ibuprofen	C		
				Nicotin Patch	C		
				Lorazepam	C		

Date:10/23/03ISR Number: 4217517-5Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20031002349
Age:40 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Other	Akathisia	Foreign	Risperdal			
	Amenorrhoea	Health	(Risperidone)	PS		ORAL
6 MG, ORAL; 3						
	Bradycardia	Professional				
MG, ORAL						
	Condition Aggravated		Haldol (Haloperidol)	SS		ORAL
12 MG, ORAL						
	Delusion		Ciatyl (Clopenthixol			
	Extrapyramidal Disorder		Hydrochloride)	C		
	Liver Function Test		Tavor (Lorazepam)	C		
	Abnormal		Seroquel (Quetiapine			
	Psychotic Disorder		Fumarate)	C		

Date:10/24/03ISR Number: 4219995-4Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20031003247
Age:81 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Death	Aphagia	Consumer	Risperdal			
Other	Coma		(Risperidone)			
			Tablets	PS		ORAL
2 MG, IN 1						

DAY, ORAL

			Haldol (Haloperidol) Unspecified	SS		

Date:10/24/03ISR Number: 4220000-4Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20031003641
Age:69 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dry Skin Dyspnoea Rash Generalised Tremor	Consumer	Risperdal (Risperidone) Tablets	PS		ORAL	4 MG, 1 IN 1 DAY, ORAL	
			Haldol Decanoate (Haloperidol Decanoate) Injection	SS			INITIATED 2 YEARS-AGO, FOR APPROXIMATELY 8 MONTHS	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/27/03ISR Number: 4218228-2Report Type:Expedited (15-DaCompany Report #FR-ROCHE-349355
Age:61 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Sudden Death		Rivotril	PS	Roche	ORAL	2	DAY
			Haldol	SS				
INTRAMUSCULAR							1	DAY
			Haldol	SS		ORAL	1	DAY
			Tercian	C		ORAL	3	DAY
			Tercian	C				
INTRAMUSCULAR							1	DAY
			Moditen	C				

Date:10/28/03ISR Number: 4222874-XReport Type:Expedited (15-DaCompany Report #2003AP03281
Age:78 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Blood Glucose Fluctuation	Foreign	Seroquel	PS		ORAL	25 MG TID PO	
	Blood Glucose Increased	Health	Wintermin	SS		ORAL	62.5 MG DAILY	
	Cardio-Respiratory Arrest	Professional					PO	
	Cerebral Haemorrhage	Other	Wintermin	SS		ORAL	25 MG DAILY	
	Clostridium Colitis						PO	
	Generalised Oedema		Serenace	SS			0.75 MG TID	
	Haemorrhage Subcutaneous						UNK	
	Haemorrhagic Diathesis		Serenace	SS				
	Hepatic Function Abnormal		Risperdal	SS		ORAL	1 MG TID PO	
	Hernia		Seven Ep	C				
	Herpes Zoster							
	Hypoglycaemia							
	Hypoproteinaemia							
	Hypothyroidism							
	Immunosuppression							

Oral Candidiasis
Pneumonia
Pupils Unequal
Thrombocytopenic Purpura
Urinary Tract Infection

Date:10/28/03ISR Number: 4222898-2Report Type:Expedited (15-DaCompany Report #03P-087-0237558-00
Age:60 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hepatic Function Abnormal Jaundice	Foreign Health Professional Other	Akineton (Biperiden)(Biperiden)	PS		ORAL	4 MG, 1 IN 1 D, PER ORAL	
			Haloperidol	SS		ORAL	2 DOSAGE FORMS, 1 IN 1 D, PER ORAL	
			Chlorpromazine Hydrochloride	SS		ORAL	2 DOSAGE FORMS, 1 IN 1 D, PER ORAL	
			Vegetamin A	SS		ORAL	1 DOSAGE FORMS, 1 IN 1 D, PER ORAL	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/29/03ISR Number: 4220689-XReport Type:Expedited (15-DaCompany Report #CH-GLAXOSMITHKLINE-B0312714A
Age:41 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Amylase Increased		Valtrex	PS	Glaxosmithkline	ORAL	500MG Twice per day	26 DAY
	Lipase Increased							
	Pancreatitis		Sandimmun	SS		ORAL		31 DAY
			Cellcept	SS		ORAL		30 DAY
			Norvasc	SS		ORAL	5MG per day	4 DAY
			Haldol	SS		ORAL		4 DAY
			Voriconazole	SS		ORAL	400MG per day	26 DAY
			Navoban	C		ORAL		24 DAY
			Primolut	C				
			Pantozol	C				
			Xanax	C				
			Droperidol	C				
			Paspertin	C	Glaxosmithkline			31 DAY
			Biperiden	C				31 DAY
			Maxipime	C			INTRAVENOUS	4G per day 25 DAY

Date:10/29/03ISR Number: 4222084-6Report Type:Direct Company Report #CTU 204828
Age:43 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Dystonia		Haliperidol	PS				
			Respiridal	SS				

Date:10/31/03ISR Number: 4223763-7Report Type:Expedited (15-DaCompany Report #DE-ROCHE-348350
Age:73 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardiac Failure		Diazepam	PS	Roche	ORAL		
	Cholecystitis		Acetylsalicylic Acid	SS	Roche	ORAL		
	Diarrhoea		Ceftriaxone Sodium	SS	Roche			
							INTRAVENOUS	5 DAY
	Dyspnoea		Digoxin	SS	Roche	ORAL		
							12	DAY
	Electrolyte Imbalance		Isosorbide					
	Hypothyroidism		Mononitrate	SS	Roche	ORAL		
							12	DAY
	Multi-Organ Failure		Tranxene	SS		ORAL		
							5	DAY
	Myocardial Infarction		Plavix	SS		ORAL		
							11	DAY
	Respiratory Disorder		Ciprofloxacin					
	Restlessness		Hydrochloride	SS		ORAL		
							9	DAY
	Toxic Epidermal		Prednisolone Sodium					
	Necrolysis		Succinate	SS				
							INTRAVENOUS	1 DAY
			Dalteparin Sodium	SS				
							SUBCUTANEOUS	12 DAY
			Furosemide	SS				
							INTRAVENOUS	12 DAY
			Norvasc	SS		ORAL		
							12	DAY
			Molsidomine	SS		ORAL		
							12	DAY
			Amphotericin B	SS		ORAL		
							DOSE FORM	
							STATED AS	
							PIPETTES.	12 DAY
			Metoclopramide	SS		ORAL		
							9	DAY
			Melperone					
			Hydrochloride	SS		ORAL		
							FORM REPORTED	
							AS LIQUID	7 DAY
			Paracetamol	SS	Roche	ORAL		
							1	DAY
			Perenterol	SS		ORAL		
							DOSE STATED	
							AS 2. NO	
							UNITS	
							PROVIDED.	

	Metolazone	SS	ORAL

REPORTED AS 1

DOSE FORM	2	DAY				
				Haldol	SS	ORAL
2 DAY						
				Decortin	SS	
INTRAVENOUS			1 DAY			
				Novodigal	SS	ORAL
DOSE REPORTED						
AS 1 DOSE						
FORM						
				Atorvastatin Calcium	C	ORAL
				Insulin Glargine	C	
SUBCUTANEOUS						
				Glimepiride	C	ORAL
				Metformin Hydrochloride	C	ORAL
				Bisoprolol Fumarate	C	ORAL
				Captopril	C	ORAL
DOSE REPORTED						
AS 1 DF DAILY						
				Ramipril	C	ORAL
				Sodium Perchlorate	C	ORAL
27 DAY						
				Carbimazole	C	ORAL
24 DAY						
				Potassium Chloride	C	ORAL
DOSE STATED						
AS 2. NO						
UNITS						
PROVIDED	12	DAY				
				Bromazepam	C	ORAL
DOSE STATED						
AS 1/4. NO						
UNITS						
PROVIDED	2	DAY				
				Pantoprazole Sodium	C	ORAL

Date:10/31/03ISR Number: 4224652-4Report Type:Direct Company Report #CTU 205005
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Fall		Haloperidol 5 Mg	PS		ORAL	5 MG H.S. PO	
Initial or Prolonged			Cilostazol	C				
			Benztropine	C				
			Asa	C				
			Haloperidol Decanoate	C				
			Depakote	C				

Date:10/31/03ISR Number: 4224809-2Report Type:Expedited (15-DaCompany Report #K200301720
Age:19 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Adverse Drug Reaction	Literature	Haloperidol Decanoate	PS		PARENTERAL	PARENTERAL	
		Health	Risperidone (Risperidone)	SS		PARENTERAL	PARENTERAL	
		Professional	Valproic Acid (Valproic Acid)	SS		PARENTERAL	PARENTERAL	

Date:10/31/03ISR Number: 4225631-3Report Type:Expedited (15-DaCompany Report #BR-JNJFOC-20031002254
Age:38 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Condition Aggravated	Foreign	Haldol (Haloperidol)					
	Diabetes Mellitus	Health	Unspecified	PS			1 MG, 1 IN 1 DAY	
	Myopia	Professional						
	Vision Blurred		Topamax (Topiramate) Tablets	SS		ORAL	50 MG, 3 IN 1	

DAY, ORAL

Date:11/03/03ISR Number: 4226313-4Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20031005123
Age:84 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Immobile Parkinsonism	Foreign Health Professional	Haloperidol (Haloperidol) Unspecified	PS		ORAL	ORAL	

Date:11/03/03ISR Number: 4226380-8Report Type:Expedited (15-DaCompany Report #FR-JNJFOC-20031003807
Age:61 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death Life-Threatening	Death	Foreign Health Professional	Haldol (Haloperidol) Injection	PS		INTRAMUSCULAR	5 MG, INTRAMUSCULAR	
			Haldol (Haloperidol)	SS		ORAL	5 MG, ORAL	
			Tercian (Cyamemazine) Injection	SS		INTRAMUSCULAR	50 MG, INTRAMUSCULAR	
			Tercian (Cyamemazine)	SS		ORAL	100 MG, ORAL	
			Rivotil (Clonazepam)	SS		ORAL	2 MG, 1 IN 1 DAY, ORAL	

Date:11/03/03ISR Number: 4226617-5Report Type:Expedited (15-DaCompany Report #03P-087-0238185-00
Age:68 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dyspnoea	Foreign	Akineton (Biperiden)					
	Fall	Health	(Biperiden)	PS		ORAL	PER ORAL	
	Haemodialysis	Professional	Risperidone	SS		ORAL	PER ORAL	
	Renal Failure Acute		Haloperidol	SS		ORAL	PER ORAL	
	Rhabdomyolysis		Phenothiazine	SS		ORAL	PER ORAL	
			Amantadine Hydrochloride	SS		ORAL	PER ORAL	
			Flunitrazepam	SS				
			Dantrolene Sodium	C				

Date:11/04/03ISR Number: 4227398-1Report Type:Expedited (15-DaCompany Report #CH-JNJFOC-20031005130
Age:43 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Deep Vein Thrombosis	Foreign	Haloperidol					
	Extrapyramidal Disorder	Health	(Haloperidol)					
	Parkinsonism	Professional	Unspecified	PS		ORAL	SEE IMAGE	
			Clopixol (Zuclopenthixol Decanoate)	SS				
			Solian (Amisulpride)	SS				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/04/03ISR Number: 4227523-2Report Type:Expedited (15-DaCompany Report #03P-056-0238193-00
Age:43 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Foreign	Depakote (Divalproex Sodium) (Divalproex Sodium)	PS		ORAL	SEE IMAGE	
	Depression	Health	Haloperidol (Haloperidol)	SS		INTRAMUSCULAR	SEE IMAGE	
	Drug Interaction	Professional	Cyamemazine	C				
			Levomepromazine	C				

Date:11/04/03ISR Number: 4227526-8Report Type:Expedited (15-DaCompany Report #03P-056-0238188-00
Age:59 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Foreign	Depakote (Divalproex Sodium) (Divalproex Sodium)	PS		ORAL	SEE IMAGE	
	Drug Interaction	Health	Haloperidol	SS		INTRAMUSCULAR	SEE IMAGE	
	Intentional Misuse	Professional	Tarka (Tarkaer) (Trandolapril/-Verapamil) (Trandolapril/Verapamil)	SS				
			Rilmenidine	C				

Date:11/04/03ISR Number: 4227871-6Report Type:Expedited (15-DaCompany Report #FR-JNJFOC-20031005438
Age:30 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agitation	Foreign	Haldol Decanoas (Haloperidol Decanoate) Injection	PS		INTRAMUSCULAR	50 MG, 1 IN	
	Masked Facies	Health Professional						

30 DAY,

INTRA-MUSCULA

R

Date:11/05/03ISR Number: 4228951-1Report Type:Expedited (15-DaCompany Report #2003UW14168
Age:44 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required	Apnoea	Foreign	Nexium	PS		ORAL	100 MG QD PO	
Intervention to	Pallor	Health	Seroquel	SS		ORAL	700 MG QD PO	2 DAY
Prevent Permanent	Somnolence	Professional	Haldol	SS			5 MG	2 DAY
Impairment/Damage	Tremor	Other	Ancef	C				
			Atarax	C				
			Ativan	C				
			Demerol	C				
			Lasix	C				
			Merrem	C				
			Oxygen	C				
			Pantoloc	C				
			Sandostatin	C				
			Sodium Chloride	C				
			Tylenol	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/06/03ISR Number: 4230528-9Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20031006041
Age:32 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Complications Of Maternal Exposure To Therapeutic Drugs Thrombocytopenia	Foreign Health Professional	Haldol (Haloperidol) Unspecified	PS				

Date:11/07/03ISR Number: 4231711-9Report Type:Direct Company Report #CTU 205562
Age:19 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Dystonia Extrapyramidal Disorder		Haldol 5mg Im	PS		INTRAMUSCULAR	IM	

Date:11/07/03ISR Number: 4232080-0Report Type:Expedited (15-DaCompany Report #03P-163-0238797-00
Age:34 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Eosinophilic Pneumonia Acute Nausea Pericardial Effusion Pleural Effusion Sinus Tachycardia Vomiting	Foreign Literature Health Professional	Valproic Acid (Valproic Acid) Haloperidol Diphenhydramine	PS SS SS			1500 MG, 1 IN 1 D 15 MG, IN IN 1 D 25 MG, 1 IN 1 D	

Date:11/10/03ISR Number: 4233484-2Report Type:Expedited (15-DaCompany Report #JP-36450
Age:30 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Complications Of Maternal Exposure To Therapeutic Drugs Hellp Syndrome Placental Disorder	Foreign Health Professional	Haldol (Haloperidol) Tablets Largactil (Chlorpromazine Hydrochloride)	PS C		ORAL	5 MG, 1 IN 1 DAY, ORAL	

Date:11/10/03ISR Number: 4233816-5Report Type:Expedited (15-DaCompany Report #2003034521
Age:36 YR Gender:Male I/FU:F

Outcome	PT
Life-Threatening Hospitalization - Initial or Prolonged Other	Acute Myocardial Infarction Computerised Tomogram Abnormal Confusional State Coronary Artery Stenosis Disorientation Drug Withdrawal Syndrome Electrocardiogram Abnormal Electrocardiogram St Segment Elevation Extrapyramidal Disorder Flushing Gastric Ulcer Haemorrhage

	Haematoma Injury Limb Injury	Report Source	Product	Role	Manufacturer	Route Dose Duration
	Loss Of Consciousness Mental Disorder Due To A	Foreign Health	Zeldox (Capsules) (Ziprasidone)	PS		ORAL 160 MG (BID),
	General Medical Condition	Professional				ORAL
	Myocardial Ischaemia Neck Injury Neuroleptic Malignant	Company Representative	Haloperidol (Haloperidol)	SS		
	Syndrome Oesophagitis Rhabdomyolysis Sinus Tachycardia Somnolence Tremor Upper Gastrointestinal Haemorrhage Urosepsis		Flupentixol Dihydrochloride (Flupentixol Dihydrochloride) Biperiden Hydrochloride (Biperiden Hydrochloride) Chlorprothixene Hydrochloride (Chlorprothixene Hydrochloride)	C C C		

Date:11/10/03ISR Number: 4234245-0Report Type:Expedited (15-DaCompany Report #FR-JNJFOC-20031003807
Age:61 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Death Life-Threatening	Death	Foreign Health	Haldol (Haloperidol) Injection	PS		 INTRAMUSCULAR 5 MG,
		Professional				INTRA-MUSCULAR
			Haldol (Haloperidol)	SS		ORAL 5 MG, ORAL
			Tercian (Cyamemazine) Injection	SS		 INTRAMUSCULAR 50 MG,
			Tercian			INTRAMUSCULAR

			(Cyamemazine)	SS		ORAL
100 MG, ORAL						
			Rivotil (Clonazepam)	SS		ORAL
2 MG, 1 IN 1						
DAY, ORAL						

Date:11/10/03ISR Number: 4234308-XReport Type:Expedited (15-DaCompany Report #2003114693
Age:23 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Neuroleptic Malignant	Consumer	Geodon (Ziprasidone)	PS		
80 MG (BID),						
Initial or Prolonged	Syndrome	Health	Haloperidol			
Other		Professional	(Haloperidol)			
			(Haloperidol)	SS		
			Morphine (Morphine)	SS		
			Labetalol			
			(Labetalol)	SS		
			Fluconazole			
			(Fluconazole)	C		
			Ceftriaxone Sodium			
			(Ceftriaxone Sodium)	C		
			Salbutamol			
			(Salbutamol)	C		
			Heparin (Heparin)	C		
			Azelastine			
			Hydrochloride			

(Azelastine Hydrochloride)	C
Fluticasone Propionate (Fluticasone Propionate)	C
Jevity (Potassium Bicarbonate, Potassium Bitartrate, Soya Oil, Corn Oil,	C
Clonidine Hydrochloride (Clonidine Hydrochloride)	C
Lansoprazole (Lansoprazole)	C
Phenytoin Sodium (Phenytoin Sodium)	C
Chlordiazepoxide (Chlordiazepoxide)	C
Oxybutynin (Oxybutynin)	C
Diphenhydramine Hydrochloride (Diphenhydramine Hydrochloride)	C
Nystatin (Nystatin)	C
Tetracycline (Tetracycline)	C
Water (Water)	C

Date:11/14/03ISR Number: 4236565-2Report Type:Expedited (15-DaCompany Report #SA-JNJFOC-20031101829
Age:40 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Distension Abdominal Mass Abdominal Pain Bowel Sounds Abnormal Constipation Cyanosis	Foreign Literature Health Professional Other	Haldol (Haloperidol) Tablets Haldol Decanoate (Haloperiodl Decanoate) Injection	PS SS		INTRAMUSCULAR	5 MG, 3 IN 1 DAY 50 MG, 1 IN 2	

	Gastrointestinal Disorder						
WEEK,							
	Intestinal Dilatation						
INTRA-MUSCULA							
	Lymphoid Tissue						
R							
	Hyperplasia		Benztropine				
	Tuberculosis		(Benzatropine				
	Vomiting		Mesilate) Tablets	SS			ORAL
2 MG, 3 IN 1							
DAY, ORAL							

Date:11/18/03ISR Number: 4237905-0Report Type:Expedited (15-DaCompany Report #JP-JNJFOC-20031004818
Age:56 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Rhabdomyolysis	Foreign	Haloperidol			
		Health	Decanoate			
		Professional	(Haloperidol			
			Decanoate)			
			Unspecified	PS		
INTRAMUSCULAR INTRAMUSCULAR						

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/18/03ISR Number: 4238094-9Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20031101061
Age:4 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Accidental Exposure Apathy	Foreign Health Professional	Haldol (Haloperidol) Solution	PS		ORAL		

ORAL

Date:11/18/03ISR Number: 4238095-0Report Type:Expedited (15-DaCompany Report #FR-JNJFOC-20031100389
Age:40 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Accidental Exposure Extrapyramidal Disorder Malaise	Foreign Health Professional	Haldol (Haloperidol) Solution	PS		ORAL	IN 1 DAY,	

ORAL

Date:11/19/03ISR Number: 4239361-5Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20030700204
Age:52 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardiomegaly Drug Screen Positive Hyperhidrosis Hyperthermia Malignant Muscle Rigidity Neuroleptic Malignant Syndrome Respiratory Arrest	Health Professional	Haldol (Haloperidol)Injection Ativan (Lorazepam)	PS C			5 MG, 1 IN 1 TOTAL	

Date:11/20/03ISR Number: 4239543-2Report Type:Expedited (15-DaCompany Report #NSADSS2002026133
Age:80 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Aggression	Consumer	Haldol (Haloperidol)					
Hospitalization -	Agitation	Health	Unspecified	PS				
UNKNOWN;								
Initial or Prolonged	Aphonia	Professional						
0.5 MG, 2 IN								
	Confusional State							
1 DAY,								
	Extrapyramidal Disorder							
UNKNOWN								
	Lethargy		Neurontin					
	Respiratory Tract		(Gabapentin)	C				
	Infection		Ativan (Lorazepam)	C				
	Tonic Clonic Movements		Antibiotics Nos					
	White Blood Cell Count		(Antibiotics)	C				
	Increased		Cogentin					
			(Benzatropine					
			Mesilate)	C				

Date:11/25/03ISR Number: 4242160-1Report Type:Expedited (15-DaCompany Report #JAFRA39072
Age:30 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Coma	Foreign	Haldol (Haloperidol)					
Initial or Prolonged	Drug Interaction	Health	Unspecified	PS		ORAL		
15 ML, 1 IN 1								
Required	Gastrointestinal Necrosis	Professional						
DAY, ORAL								
Intervention to	Intestinal Perforation		Nozinan					
Prevent Permanent	Overdose		(Levomepromazine)					
Impairment/Damage	Periarthritis		Solution	SS		ORAL		
10 ML, 3 IN 1								
	Shock							
DAY, ORAL								

			Tegretol (Carbamazepine) Tablets	SS		ORAL	400 MG, 2 IN 1 DAY, ORAL
			Parkinane (Trihexyphenidyl Hydrochloride) Capsules	SS		ORAL	5 MG, 2 IN 1 DAY, ORAL
			Heptamyl (Heptaminol Hydrochloride) Capsules	SS		ORAL	1 DOSE(S), 3 IN 1 DAY, ORAL

Date:11/25/03ISR Number: 4242323-5Report Type:Expedited (15-DaCompany Report #03P-163-0240996-00
Age: Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Literature	Valproic Acid					
		Health Professional	(Depakene) (Valproic Acid) (Valproic Acid)	PS		ORAL	ORAL	
			Haloperidol	SS		ORAL	ORAL	
			Benztropine	SS		ORAL	ORAL	

Date:11/25/03ISR Number: 4242436-8Report Type:Expedited (15-DaCompany Report #KII-1999-0002074
Age:61 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Colon Cancer Metastatic	Health	Oxycontin Cr	PS				

	Condition Aggravated	Professional Company Representative	Morphine Sulfate (Similar To Nda 19-516)	SS			
			Haldol (Haloperidol)	SS			

Date:11/26/03ISR Number: 4244041-6Report Type:Expedited (15-DaCompany Report #APCDSS2003000714
Age:1 DY Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Maternal Drugs Affecting Foetus Respiratory Disorder	Foreign Health Professional	Risperdal (Risperidone) Unspecified	PS		TRANSPLACENTAL	6 MG, IN	1DAY,
	Neonatal Respiratory Rate Decreased		Haldol (Haloperidol) Unspecified	SS		TRANSPLACENTAL	1 DOSE(S), 1 IN 1DAY,	INTRAUTERINE
			Biperiden (Biperiden) Ampoules	C				

Date:11/26/03ISR Number: 4244083-0Report Type:Expedited (15-DaCompany Report #JP-JNJFOC-20031004818
Age:55 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Abdominal Pain Arthralgia Leukocytosis Neuroleptic Malignant Syndrome Oligodipsia Rhabdomyolysis	Foreign Health Professional	Haloperidol Decanoate (Haloperidol Decanoate) Unspecified	PS		INTRAMUSCULAR INTRAMUSCULAR	100 MG	

Date:11/26/03ISR Number: 4244313-5Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20031103389
Age:75 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Abasia Brain Damage Coma Lethargy Medication Error Miosis Muscle Spasms	Consumer	Reminyl (Galantamine) Tablets Haldol (Haloperidol)	PS SS		ORAL SEE IMAGE SEE IMAGE		

Date:11/28/03ISR Number: 4244472-4Report Type:Expedited (15-DaCompany Report #JP-JNJFOC-20031104433
Age:88 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Femur Fracture Forearm Fracture Sepsis	Foreign Health Professional	Risperdal (Risperidone)	PS		ORAL	4 MG, IN 1 DAY, ORAL	
		Other	Haloperidol Decanoate Injection	SS		INTRAMUSCULAR	100 MG,	

INTRA-MUSCULA

R

			Haloperidol (Haloperidol)	C		
			Flunitrazepam (Flunitrazepam)	C		

Date:11/28/03ISR Number: 4245405-7Report Type:Expedited (15-DaCompany Report #2003114693
Age:23 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Blood Creatinine Increased Neuroleptic Malignant Syndrome	Consumer Health Professional	Geodon (Ziprasidone) Haloperidol (Haloperidol) (Haloperidol) Morphine (Morphine) Labetalol (Labetalol) Fluconazole (Fluconazole) Ceftriaxone Sodium (Ceftriaxone Sodium) Salbutamol (Salbutamol) Heparin (Heparin) Azelastine	PS SS SS SS C C C C			80 MG (BID),	

Hydrochloride (Azelastine Hydrochloride)	C
Fluticasone Propionate (Fluticasone Propionate)	C
Jevity (Potassium Bicarbonate, Potassium Bitartrate, Soya Oil, Corn Oil,	C
Clonidine Hydrochloride (Clonidiine Hydrochloride)	C
Lansoprazole (Lansoprazole)	C
Phenytoin Sodium (Phenytoin Sodium)	C
Chlordiazepoxide (Chlordiazepoxide)	C
Oxybutynin (Oxybutynin)	C
Diphenhydramine Hydrochloride (Diphenhydramine Hydrochloride)	C
Nystatin (Nystatin)	C
Tetracycline (Tetracycline)	C
Water (Water)	C

Date:12/02/03ISR Number: 4245620-2Report Type:Expedited (15-DaCompany Report #JP-JNJFOC-20031104433
Age:88 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Sepsis	Foreign Health Professional	Risperdal (Risperidone) Unspecified	PS		ORAL	4 MG, 1 IN 1 DAY, ORAL	
			Haloperidol Decanoate					

		(Haloperidol Decanoate) Injection	SS
INTRAMUSCULAR	100 MG, IN 1		
4 WEEK, INTRA MUSCULAR			
		Flunitrazepam (Flunitrazepam)	C

Date:12/02/03ISR Number: 4246002-XReport Type:Expedited (15-DaCompany Report #AT-JNJFOC-20031104219
Age:21 YR Gender:Male I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Alanine Aminotransferase Increased
	Aspartate Aminotransferase Increased
	Blood Creatine

	Phosphokinase Increased Drug Interaction Gamma-Glutamyltransferase Increased	Report Source	Product	Role	Manufacturer	Route	Dose Duration
		Foreign Health Professional	Haloperidol (Haloperidol) Injection	PS		INTRAVENOUS	SEE IMAGE
			Depakine (Valproate Sodium, Injection)	SS		INTRAVENOUS	SEE IMAGE
			Seroquel (Quetiapine Fumarate)	SS		ORAL	SEE IMAGE
			Rivotril (Clonazepam) Injection	C			
			Akineton (Biperiden Hydrochloride)	C			
			Entumin (Clotiapine) Tablets	C			
			Claforan (Cefotaxime Sodium) Injection	C			
			Fragmin (Heparin-Fraction, Sodium Salt) Injection	C			
			Magnesium Sulfate (Magnesium Sulfate)	C			

Date:12/02/03ISR Number: 4246009-2Report Type:Expedited (15-DaCompany Report #AT-JNJFOC-20031104222
Age:82 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Death	Adenoma Benign Anaemia Arteriosclerosis Brain Oedema Cardiac Arrest Coronary Artery Disease	Foreign Health Professional	Haldol (Haloperidol) Unspecified	PS			10 MG, IN 1 DAY
			Corenitec (Vaseretic)	SS			LONG TERM
			Seroquel (Quetiapine				

	Dehydration	Fumarate)	SS
50 MG; 75 MG;			
	Depression		
100 MG			
	Drug Interaction	Isoptin (Verapamil Hydrochloride)	C
	Dyspnoea	Calcium Carbonate (Calcium Carbonate)	C
	Emphysema	Fosamax (Alendronate Sodium)	C
	Fall	Trittico (Trazodone Hydrochloride)	C
	Fibrosis	Kcl Retard (Potassium Chloride)	C
	Lipomatosis	Pantoloc (Pantoprazole)	C
	Marasmus	Gewacalm (Diazepam)	C
	Myocardial Fibrosis	Nacl (Sodium Chloride)	C
	Perirenal Haematoma	Akineton (Biperiden Hydrochloride)	C
	Phlebothrombosis		
	Psychomotor Agitation		
	Pulmonary Embolism		
	Pulmonary Infarction		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/02/03ISR Number: 4246087-0Report Type:Expedited (15-DaCompany Report #2003UW14168
Age:44 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required	Apnoea	Foreign	Seroquel	PS		ORAL	700 MG QD PO	2 DAY
Intervention to	Pallor	Health	Haldol	SS			5 MG	2 DAY
Prevent Permanent	Somnolence	Professional	Nozinan	SS		ORAL	100 MG QD PO	
Impairment/Damage	Tremor	Other	Ancef	C				
			Atarax	C				
			Ativan	C				
			Lasix	C				
			Merrem	C				
			Oxygen	C				
			Pantoloc	C				
			Santoloc	C				
			Sandostatin	C				
			Sodium Chloride	C				
			Tylenol	C				

Date:12/02/03ISR Number: 4246093-6Report Type:Expedited (15-DaCompany Report #2003PK01976
Age:82 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardiac Arrest	Foreign	Seroquel "Zeneca"	PS	Zeneca	ORAL	50 MG DAILY	
Life-Threatening	Emphysema	Health					PO	
	Fall	Professional	Seroquel "Zeneca"	SS	Zeneca	ORAL	75 MG DAILY	
	Pulmonary Congestion	Other					PO	
	Pulmonary Embolism		Seroquel "Zeneca"	SS	Zeneca	ORAL	100 MG DAILY	
	Pulmonary Infarction						PO	
			Haldol	SS		ORAL	10 MG DAILY	
							PO	
			Co-Renitec	SS				

Isoptin	C
Calciumcarbonat	C
Fosamax	C
Trittico	C
Kcl-Retard	C
Pantoloc	C
Gewacalm	C
Nacl	C
Akineton	C

Date:12/02/03ISR Number: 4246431-4Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20031104673
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Alopecia	Consumer	Risperdal					
	Diplopia		(Risperidone)					
	Drooling		Tablets	PS		ORAL	ORAL	
	Faecal Incontinence		Haldol (Haloperidol)					
	Memory Impairment		Unspecified	SS				
	Overdose		Cogentin					
	Posture Abnormal		(Benzatropine					
	Suicide Attempt		Mesilate)	SS				
	Tardive Dyskinesia							
	Vision Blurred							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/03/03ISR Number: 4244694-2Report Type:Expedited (15-DaCompany Report #PHNU2003DE02382
Age:56 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Bite		Leponex / Clozaril (Clozapine)	PS	Novartis Sector: Pharma	ORAL	25 mg/day	1440 MIN
	Blood Pressure Increased							
	Disorientation							
	Drug Interaction		Anafranil	SS		ORAL	50-175 mg/day	12960MIN
	Drug Level Below		Anafranil	SS		ORAL	187.5 mg/day	36000MIN
	Therapeutic Drug Level Increased		Quilonum - Slow Release	SS		ORAL	450 mg/day	2880 MIN
	Electroencephalogram Abnormal		Quilonum - Slow Release	SS		ORAL	1125 mg/day	4320 MIN
	Enuresis		Quilonum - Slow Release	SS		ORAL	225 mg/day	1440 MIN
	Epilepsy							
	Fall		Haldol "Janssen"	SS		ORAL	6-10 mg/day	56160MIN
	Grand Mal Convulsion		Haldol "Janssen"	SS		ORAL	5 mg/day	11520MIN
	Hypokinesia		Taxilan	SS		ORAL	50 mg/day	7200 MIN
	Myoclonus		Haldol "Janssen"	SS		ORAL	2.5 mg/day	2880 MIN
	Schizoaffective Disorder		Haldol "Janssen"	SS		ORAL	3 mg/day	10080MIN
	Tongue Biting		Haldol "Janssen"	SS		ORAL	15 mg/day	10080MIN
			Quilonum - Slow Release	SS		ORAL	900 mg/day	2880 MIN
			Quilonum - Slow Release	SS		ORAL	675 mg/day	1440 MIN
			Leponex / Clozaril (Clozapine)	SS	Novartis Sector: Pharma	ORAL	50 mg/day	1440 MIN
			Anafranil	SS			225 mg/day	14400MIN

Date:12/03/03ISR Number: 4246287-XReport Type:Direct Company Report #CTU 207345
Age:51 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Mental Status Changes		Rifadin	PS			600 MG DAILY	
			Haloperidol	SS			5-10 MG Q4-6H	

Date:12/03/03ISR Number: 4254162-XReport Type:Periodic Company Report #03H-163-0233813-00
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Hyperpyrexia	Health Professional	Precedex Injection, 2ml Vial (Dexmedetomidine Hydrochloride Injection)	PS		INTRAVENOUS	BOLUS	SEE IMAGE
			Haloperidol	SS			5 MG Q 8	HOURS,
			Propofol	C			UNKNOWN	
			Fentanyl	C				
			Midazolam Hydrochloride	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/03/03ISR Number: 4278720-1Report Type:Periodic Company Report #325126
Age:41 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardio-Respiratory Arrest	Literature	Valium (Diazepam)	PS		INTRAMUSCULAR	10 MG,	
	Electromechanical	Health				INTRAMUSCULAR		
	Dissociation	Professional	Benadryl (Diphenhydramine Hydrochloride)	SS		INTRAMUSCULAR	100 MG	
	Respiratory Arrest					INTRAMUSCULAR		
			Haldol (Haloperidol)	SS		INTRAMUSCULAR	10 MG,	
						INTRAMUSCULAR		
			Cogentin (Benztropine Mesylate)	SS		INTRAMUSCULAR	2 MG,	
						INTRAMUSCULAR		

Date:12/04/03ISR Number: 4247574-1Report Type:Expedited (15-DaCompany Report #2003SE05377
Age:47 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Foreign	Seroquel	PS		ORAL	300 MG BID PO	
		Health	Haloperidol	SS		ORAL	24 MG TID PO	
		Professional	Levomepromazin	C				
		Other	Diazepam	C				

Date:12/08/03ISR Number: 4246898-1Report Type:Expedited (15-DaCompany Report #98F--10389
Age:30 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Life-Threatening Hospitalization - 400 mg, BID 73440MIN	Colectomy Total Coma		Tegretol Lp	PS	Novartis Sector: Pharma	ORAL
Initial or Prolonged 5 ml, TID	Gastrointestinal Necrosis		Haldol	SS		ORAL
	Ileectomy		Nozinan	SS		ORAL
10 ml, TID						
	Ileostomy		Parkinane Lp	SS		ORAL
5 mg, BID						
	Intestinal Perforation		Hept-A-Myl	SS		ORAL
187.8 mg, TID						
	Periarthritis					
	Shock					

Date:12/08/03ISR Number: 4247594-7Report Type:Expedited (15-DaCompany Report #FLUV00303003397
Age:39 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Autism	Foreign	Fluvoxamine			
	Blood Creatine Phosphokinase Increased	Literature Other	(Fluvoxamine Maleate)	PS		
50 MG DAILY,						
	Blood Urine					
100 MG DAILY						
	Epilepsy		Haloperidol			
	Eye Rolling		(Haloperidol)	SS		
24 MG DAILY						
	Hallucination, Auditory		Levomepromazine			
	Neuroleptic Malignant		(Levomepromazine)	SS		
550 MG DAILY						
	Syndrome		Valproate			
	Obsessive-Compulsive		(Valproinsaeure)	SS		
DAILY, 600 MG						
	Disorder					
DAILY						
	Occult Blood Positive		Zonisamide			
	Persecutory Delusion		(Zonisamide)	SS		
DAILY, 200 MG						
	White Blood Cell Count					
DAILY						
	Increased		Clonazepam			
			(Clonazepam)	SS		
1 MG DAILY						

			Vegetamin A 2t ()	SS		
DAILY						
			Flunitrazepam (Flunitrazepam)	SS		
4 MG DAILY						
			Biperiden (Biperiden)	SS		
DAILY IM, 3						
MG DAILY PO,						
3 MG DAILY PO						

Date:12/08/03ISR Number: 4248814-5Report Type:Expedited (15-DaCompany Report #2003SE05377
Age:47 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Foreign	Seroquel	PS		ORAL	300 MG BID PO	
	Intentional Self-Injury	Health	Haloperidol	SS		ORAL	24 MG TID PO	
		Professional	Levomepromazin	C				
		Other	Diazepam	C				

Date:12/08/03ISR Number: 4248851-0Report Type:Expedited (15-DaCompany Report #AT-JNJFOC-20031105292
Age:49 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Atrioventricular Block	Foreign	Haldol (Haloperidol)	PS		INTRAVENOUS	20 MG, IN 1	
	Second Degree	Health					DAY,	
		Professional					INTRAVENOUS	
			Catapresan (Clonidine) Unknown	SS				
							0.67 MG/HR	
			Bevitol (Thiamine Hydrochloride) Ampoules	SS				
			Dormicum (Midazolam					

			Maleate)	C		
			Losec (Omeprazole)	C		
			Augmentin (Clavulin)	C		
			Lovenox (Heparin-Fraction, Sodium Salt)	C		

Date:12/08/03ISR Number: 4248852-2Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20031105427
Age:81 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Syncope	Foreign Health Professional	Haldol (Haloperidol) Unspecified	PS		ORAL	1 MG, ORAL	
			Hct Hexal (Hydrochlorothiazide)	C				
			Concor (Bisoprolol Fumarate)	C				
			Acerbon (Lisinopril)	C				
			Aricept (Donepezil Hydrochloride)	C				
			Dominal (Prothipendyl Hydrochloride)	C				
			Truxal (Chlorprothixene Hydrochloride)	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/08/03ISR Number: 4248873-XReport Type:Expedited (15-DaCompany Report #CH-JNJFOC-20031005130
Age:43 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Deep Vein Thrombosis	Foreign	Haloperidol					
	Drug Level Increased	Health	(Haloperidol)					
	Extrapyramidal Disorder	Professional	Unspecified	PS		ORAL	SEE IMAGE;	
	Parkinsonism						FOR DOSE AND	
							ADDITIONAL	
							THERAPY DATES	
			Clopixol (Zuclopenthixol Decanoate)	SS				
			Solian (Amisulpride)	SS				

Date:12/09/03ISR Number: 4248986-2Report Type:Direct Company Report #CTU 207737
Age:89 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardiac Arrest		Geodon (Ziprasidone					
	Coma		Mesylate) 20 Mg/Ml					
	Cyanosis		Pfizer	PS	Pfizer			
INTRAMUSCULAR							10 MG I.M. X	
	Torsade De Pointes							
							1 DOSE	
			Haldol	SS				
INTRAMUSCULAR							2 MG IM	
			Seroquel	SS		ORAL		
							25 MG PO BID	

Date:12/10/03ISR Number: 4250530-0Report Type:Expedited (15-DaCompany Report #UK053088
Age:52 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Dyskinesia	Foreign	Aranesp(Polysorbate					

Initial or Prolonged	Hallucination	Health	80)	PS			
INTRAVENOUS 100 MCG,							
	Medication Error	Professional					
EVERY 2							
	Tremor						
WEEKS, IV							
			Haloperidol	SS			

Date:12/10/03ISR Number: 4250566-XReport Type:Expedited (15-DaCompany Report #2003PK02056
Age:57 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Drug Interaction	Foreign	Seroquel	PS		ORAL	300 MG DAILY
Initial or Prolonged	Potentiation	Health					PO
	Neutropenia	Professional	Seroquel	SS		ORAL	150 MG DAILY
	White Blood Cell Count	Other					PO
	Decreased		Haldol	SS		ORAL	6 MG DAILY PO
			Orfiril	SS		ORAL	1800 MG DAILY PO
			Orfiril	SS		ORAL	2400 MG DAILY PO
			L-Thyroxin "Henning Berlin"	C			
			Neurium	C			
			Xanef	C			
			Insulin	C			

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/12/03ISR Number: 4251594-0Report Type:Expedited (15-DaCompany Report #MK200307-0401-2
Age:56 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Pressure Increased	Foreign	Anafranil 25mg Capsules	PS			225MG	
	Condition Aggravated		Leponex	SS				
	Drug Interaction		Quilonum Slow Release	SS				
	Potentiation		Haldol	SS				
	Fall		Taxilan	SS				
	Grand Mal Convulsion							
	Muscle Contractions Involuntary							
	Myoclonus							
	Schizoaffective Disorder							
	Tic							

Date:12/15/03ISR Number: 4252082-8Report Type:Direct Company Report #CTU 208012
Age:82 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Hyperpyrexia		Haloperidol 1 Mg					
Required Intervention to Prevent Permanent Impairment/Damage	Hypersensitivity		Geneva	PS	Geneva	ORAL	5MG QHS	ORAL
			Tylenol	C				
			Ativan	C				
			Bumex	C				
			Cleocin	C				
			Amiodarone	C				
			Diltiazem	C				
			Levaquin	C				
			Morphine	C				
			Nph Insulin	C				

Date:12/15/03ISR Number: 4252110-XReport Type:Direct Company Report #CTU 20800
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Anencephaly		Haldol	PS				
INTRAVENOUS	?5MG/ML PINT							

Life-Threatening	Cerebral Palsy						
BAGS							
Disability	Hemiplegia						
INTRAVENOUS							
Congenital Anomaly	Maternal Drugs Affecting Foetus Neonatal Disorder Resuscitation						

Date:12/15/03ISR Number: 4253336-1Report Type:Expedited (15-DaCompany Report #AT-JNJFOC-20031105292
Age:49 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Atrioventricular Block Second Degree	Foreign Health	Haldol (Haloperidol) Unspecified	PS		INTRAVENOUS	20 MG, IN 1 DAY,	
	Blood Pressure Systolic Increased	Professional				INTRAVENOUS		
	Cardiomyopathy Alcoholic		Catapresan (Clonidine)	SS			0.67MG/HR	
			Dormicum (Midazolam Maleate)	C				
			Losec (Omeprazole)	C				
			Augmentin (Clavulin)	C				
			Lovenox					

(Heparin-Fraction, Sodium Salt)	C	
Bevitol (Thiamine Hydrochloride) Ampoules	C	

Date:12/17/03ISR Number: 4253451-2Report Type:Direct Company Report #CTU 208213
Age:36 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Neuroleptic Malignant Syndrome		Haloperidol	PS				
			Risperidone Tab	SS		ORAL	2 MG PO	
Required Intervention to Prevent Permanent Impairment/Damage	Rhabdomyolysis		Dantrolene	C				
			Clonidine	C				
			Lorazepam	C				
			Acetaminophen	C				
			Diphenhydramine	C				
			Benztropine	C				
			Clonazepam	C				
			Ziprasidone	C				
			Midazolam	C				
			Hydrocortisone 1% Cream	C				
			Hydroxyzine	C				
			Temazepam	C				
			Nicotine Polacrilex Gum, Chewable	C				
			Trihexyphenidyl	C				
			Carbamazepine	C				
			Lorazepam	C				
			Magnesium Hydroxide	C				
			Antacid	C				
			Ranitidine	C				
			Magnesium Sulfate	C				
			..	C				
			Mvi	C				
			Thiamine	C				
			Folic Acid	C				

Date:12/18/03ISR Number: 4255951-8Report Type:Expedited (15-DaCompany Report #FR-JNJFOC-20031201877
Age:81 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anxiety Hypercholesterolaemia Hypoglycaemia Malaise Nausea Renal Failure	Foreign Health Professional	Haldol (Haloperidol) Solution	PS		ORAL	0.125 MG , IN	1 DAY,
			Motilium (Domperidone) Unspecified	SS		ORAL	10 MG, IN 1	AS NECESSARY,
			Aricept (Donepezil Hydrochloride)	C				
			Irbesartan	C				
			Clomipramine	C				
			Prazepam	C				
			Pravastatine (Pravastatin)	C				
			Citalopram	C				

Date:12/19/03ISR Number: 4256424-9Report Type:Expedited (15-DaCompany Report #FR-JNJFOC-20031202853
Age:87 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dyskinesia Salivary Hypersecretion Stupor	Foreign Health Professional	Haldol (Haloperidol) Solution	PS		ORAL	0.5 MG/ML, ORAL	

Date:12/19/03ISR Number: 4256426-2Report Type:Expedited (15-DaCompany Report #FR-JNJFOC-20031201871
Age:14 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Femoral Neck Fracture Osteoporosis Spinal Fracture	Foreign Health Professional	Haldol (Haloperidol) Solution	PS		ORAL	10 DOSE (S), IN 1 DAY, ORAL	
			Urbanyl (Clobazam)	C				
			Sabril (Vigabatrin)	C				
			Synacthene Retard (Tetracosactide)	C				

Date:12/19/03ISR Number: 4256448-1Report Type:Expedited (15-DaCompany Report #FR-JNJFOC-20031201967
Age:51 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Coma	Foreign	Haldol (Haloperidol)	PS		ORAL	ORAL	
Hospitalization - Initial or Prolonged	Dehydration Dialysis Dyskinesia Extrapyramidal Disorder Fall Hypertonia Hypothermia	Health Professional	Laroxyl (Amitriptyline Hydrochloride)	SS		ORAL	ORAL	

	Ileostomy					
	Ischaemic Ulcer					
	Loss Of Consciousness					
	Overdose					
	Paresis					
	Pneumonia Aspiration					
	Renal Failure					
	Rhabdomyolysis					
	Septic Shock					

Date:12/19/03ISR Number: 4256454-7Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20030904711
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Agitation	Foreign	Haldol (Haloperidol)					
Life-Threatening	Blood Creatine	Health	Tablets	PS				
	Phosphokinase Increased	Professional	Anafranil					
	Depressed Level Of		(Clomipramine					
	Consciousness		Hydrochloride)	SS		ORAL	75 MG, 150 IN	
	Drug Interaction						1 DAY, ORAL	
	Intentional Misuse		Dothiepin					
	Neuroleptic Malignant		(Dosulepin)	SS		ORAL	75 MG, 30 IN	
	Syndrome						1 DAY, ORAL	
	Respiratory Arrest							
	Sepsis							
	Shock							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/23/03ISR Number: 4257978-9Report Type:Expedited (15-DaCompany Report #JP-JNJFOC-20031201565
Age:51 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Apnoea Pulmonary Embolism	Foreign Health Professional	Risperdal (Risperidone) Unspecified	PS		ORAL	6 MG, IN 1 DAY,	ORAL
			Haloperidol (Haloperidol) Unspecified	SS		ORAL	18 MG, IN 1 DAY,	ORAL
			Levomepromazine Maleate	SS		ORAL	150 MG, IN 1 DAY,	ORAL
			Levomepromazine Maleate (Levomepromazine Maleate) Unspecified	SS		ORAL	50 MG, IN 1 DAY,	ORAL
			Vegetamin-A (Vegetamin A) Unspecified	SS		ORAL	1 DOSE (S), IN 1 DAY,	ORAL
			Trixhexyphenidyl Hydrochloride (Trihexyphenidyl Hydrochloride) Unspecified	C				
			Nitrazepam (Nitrazepam) Unspecified	C				
			Brotizolam (Brotizolam)					

			Unspecified	C			

Date:12/23/03ISR Number: 4257999-6Report Type:Expedited (15-DaCompany Report #JP-JNJFOC-20031201565
Age:51 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Pulmonary Embolism Respiratory Arrest	Foreign Health Professional	Risperdal (Risperidone) Unspecified	PS		ORAL	6 MG, IN 1 DAY,	ORAL
			Haloperidol (Haloperidol) Unspecified	SS		ORAL	18 MG, IN 1 DAY,	ORAL
			Levomepromazine Maleate	SS		ORAL	150 MG, IN 1 DAY,	ORAL
			Levomepromazine Maleate (Levomepromazine Maleate) Unspecified	SS		ORAL	50 MG, IN 1 DAY,	ORAL
			Vegetamin-A (Vegetamin A) Unspecified	SS		ORAL	1 DOSE(S), IN 1 DAY,	ORAL

				Chlorpromazine Hydrochloride(Chlorpromazine Hydrochloride)			
				Unspecified	SS		
				Trihexyphenidyl Hydrochloride(Trihex yphenidyl Hydrochloride)			
				Unspecified	C		
				Nitrazepam (Nitrazepam)			
				Unspecified	C		
				Brotizolam (Brotizolam)			
				Unspecifided	C		

Date:12/23/03ISR Number: 4258425-3Report Type:Direct Company Report #CTU 208647
Age:83 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Tremor		Haldol	PS				
			Metformin	C				
			Trazodone	C				
			Hctz 25/Triamterene 37.5mg	C				
			Docusate Sodium	C				
			Warfarin Sodium	C				
			Albuterol Mdi	C				
			Digoxin	C				

Date:12/24/03ISR Number: 4259015-9Report Type:Direct Company Report #CTU 208790
Age:35 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Disturbance In Attention		Haldol - 96 Year/25					
Other	Dyskinesia		Milligrams	PS			TWICE A DAY	
Required	Dyspnoea		Prolixin -1999 -2001					
Intervention to	Psychomotor Hyperactivity		/10 Miligrams	SS			TWICE A DAY	

Prevent Permanent Impairment/Damage	Tremor					

Date:12/26/03ISR Number: 4260718-0Report Type:Expedited (15-DaCompany Report #JP-JNJFOC-20031201568
Age:53 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardio-Respiratory Arrest	Foreign	Risperdal					
	Deep Vein Thrombosis	Health	(Risperidone)	PS		ORAL	8 MG, IN 1	DAY, ORAL
	Pulmonary Embolism	Professional						
			Haloperidol (Haloperidol)					
			Unspecified	SS		ORAL	1.6 MG, IN 1	DAY, ORAL
			Zotepine (Zotepine)					
			Unspecified	SS		ORAL	500 MG, IN 1	DAY, ORAL
			Levomepromazine Maleate	SS		ORAL	500 MG, IN 1	

DAY, ORAL							
			Carbamazepine (Carbmazepine)	Unspecified	C		
			Biperiden Hydrochloride (Biperiden Hydrochloride)		C		
			Bromazepam (Bromazepam)	Unspecified	C		
			Teprenone (Teprenone)	Unspecified	C		
			Gentian (Gentian)	Unspecified	C		
			Sodium Bicarbonate (Sodium Bicarbonate)	Unspecified	C		

Date:12/26/03ISR Number: 4260901-4Report Type:Expedited (15-DaCompany Report #JP-JNJFOC-20031201568
Age:53 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardio-Respiratory Arrest Deep Vein Thrombosis	Foreign Health	Risperdal (Risperidone)	PS		ORAL	8 MG, IN 1	DAY, ORAL
	Pulmonary Embolism	Professional						
			Haloperidol (Haloperidol)	SS		ORAL	1.6 MG, IN 1	DAY, ORAL
			Zotepine (Zotepine)	SS		ORAL	500 MG, IN 1	DAY, ORAL
			Levomepromazine Maleate (Levomepromazine Maleate)	SS		ORAL	50 MG, 1 IN 1	

DAY, ORAL

Carbamazepine (Carbamazepine)	C
Biperiden Hydrochloride (Biperiden Hydrochloride)	C
Bromazepam (Bromazepam)	C
Teprenone (Teprenone)	C
Gentian (Gentian)	C
Sodium Bicarbonate (Sodium Bicarbonate)	C

Date:12/29/03ISR Number: 4261161-0Report Type:Expedited (15-DaCompany Report #2003SE05377
Age:47 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Foreign	Seroquel	PS		ORAL	300 MG BID PO	
		Health	Haloperidol	SS		ORAL	24 MG TID PO	
		Professional	Levomepromazin	C				
		Other	Diazepam	C				

Date:12/29/03ISR Number: 4261187-7Report Type:Expedited (15-DaCompany Report #FR-JNJFOC-20031203790
Age:75 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Balance Disorder Difficulty In Walking Dysgraphia Dyskinesia Dystonia Extrapyramidal Disorder Fall Muscle Rigidity Parkinsonism Tardive Dyskinesia Urinary Incontinence	Foreign Health Professional	Haldol (Haloperidol) Tablets	PS		ORAL	1 MG, 1 IN 1 DAY, ORAL	

Date:12/30/03ISR Number: 4261780-1Report Type:Expedited (15-DaCompany Report #JP-JNJFOC-20031102953
Age:45 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death Hospitalization - Initial or Prolonged	Alanine Aminotransferase Increased Aspartate Aminotransferase Increased Blood Lactate Dehydrogenase Increased Brain Death Cardio-Respiratory Arrest Conversion Disorder Dizziness Drug Interaction Electrocardiogram Abnormal	Foreign Health Professional	Risperdal (Risperidone) Tablets Vegetamin-A (Vegetamin A) Tablets Haloperidol (Haloperidol) Flunitrazepam (Flunitrazepam)	PS SS SS		ORAL ORAL ORAL	2 MG, 2 IN 1 DAY, ORAL 1 DOSE (S), 1 IN 1 DAY, ORAL 2 MG, IN 1 DAY, ORAL	

	Fall
	Heart Rate Increased
	Hepatic Function Abnormal
	Hypoxic Encephalopathy
	Incontinence
	Mental Disorder
	Pupil Fixed
	Pupillary Reflex Impaired
	Syncope
	Ventricular Fibrillation

Date:12/30/03ISR Number: 4262499-3Report Type:Expedited (15-DaCompany Report #JP-JNJFOC-20031102953
Age:45 YR Gender:Female I/FU:F

Outcome	PT
Death	Alanine Aminotransferase
Hospitalization -	Increased
Initial or Prolonged	Aspartate
	Aminotransferase
	Increased
	Blood Pressure Diastolic
	Decreased
	Brain Death
	Cardio-Respiratory Arrest
	Conversion Disorder
	Dizziness

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Interaction Fall Headache							
	Heart Rate Increased Hypoxic Encephalopathy Incontinence	Foreign Health Professional	Risperdal (Risperidone) Tablets	PS		ORAL	2 MG, 2 IN 1	
	Infection						DAY, ORAL	
	Loss Of Consciousness Mental Disorder Pupil Fixed		Vegetamin-A (Vegetamin A) Tablets	SS		ORAL	1 DOSE(S), 1	
	Pupillary Reflex Impaired						IN 1 DAY,	
	Syncope						ORAL	
	Ventricular Fibrillation		Haloperidol (Haloperidol)	SS				
			Flunitrazepam (Flunitrazepam)	SS		ORAL	2 MG, IN 1	
							DAY, ORAL	

Date:12/31/03ISR Number: 4262824-3Report Type:Expedited (15-DaCompany Report #JP-JNJFOC-20031201565
Age:51 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death Hospitalization - Initial or Prolonged	Apnoea Pulmonary Embolism	Foreign Health Professional	Risperdal (Risperidone) Unspecified	PS		ORAL	6 MG, IN 1	
							DAY, ORAL	
			Haloperidol (Haloperidol)					
			Unspecified	SS		ORAL	18 MG, IN 1	
							DAY, ORAL	
			Levomepromazine					

Maleate	SS		ORAL
150 MG, IN 1 DAY, ORAL			
Levomepromazine Maleate (Levomepromazine Maleate)Unspecified	SS		ORAL
50 MG, IN 1 DAY, ORAL			
Vegetamin -A(Vegetamin A) Unspecified	SS		ORAL
1 DOSE (S), IN 1 DAY, ORAL			
Chlorpromazine Hydrochloride (Chlorpromazine Hydrochloried) Unspecified	SS		
Trihexyphenidyl Hydrochloride (Trihexyphenidyl Hydrochloried)Unspecified	C		
Nitrazepam (Nitrazepam) Unspecified	C		
Brotizolam (Brotizolam) Unspedified	C		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/31/03ISR Number: 4262887-5Report Type:Expedited (15-DaCompany Report #JP-JNJFOC-20031201568
Age:53 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardio-Respiratory Arrest	Foreign	Risperdal					
Hospitalization -	Deep Vein Thrombosis	Health	(Risperidone)	PS		ORAL	8 MG, IN 1	
Initial or Prolonged	Pulmonary Embolism	Professional						DAY, ORAL
		Other	Haloperidol (Haloperidol)					
			Unspecified	SS		ORAL	1.6 MG, IN 1	DAY, ORAL
			Zotepine (Zotepine)					
			Unspecified	SS		ORAL	500 MG, IN 1	DAY, ORAL
			Levomepromazine Maleate (Levomepromazine					
			Maleate)	SS		ORAL	50 MG, IN 1	DAY, ORAL
			Carbamazepine (Carbamazepine)					
			Unspecified	C				
			Biperiden Hydrochloride (Biperiden					
			Hydrochloride)	C				
			Bromazepam (Bromazepam)					
			Unspecified	C				
			Teprenone (Teprenone)					
			Unspecified	C				
			Gentian (Gentian)					
			Unspecified	C				
			Sodium Bicarbonate (Sodium Bicarbonate)					
			Unspecified	C				

Date:01/02/04ISR Number: 4263786-5Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20031205145
Age:36 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Interaction Hepatitis	Health Professional	Haldol (Haloperidol) Unspecified	PS		ORAL	2 MG, 1 IN 4 HOUR, ORAL	
			Clozapine (Clozapine) Tablets	SS		ORAL	625 MG, 1 IN 1 DAY, ORAL	
			Prevacid (Lansoprazole)	C				
			Ferrous Suflate (Ferrous Sulfate)	C				
			Surpak (Docusate Calcium)	C				
			Escitalopram Oxalate (All Other Therapeutic Products)	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/06/04ISR Number: 4266342-8Report Type:Expedited (15-DaCompany Report #03P-087-0245767-00
Age:50 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Ileus	Foreign Health Professional Other	Akineton (Biperiden)	PS		ORAL	6 MG, 1IN 1 D, ORAL	
			Zotepine	SS		ORAL	150 MG, 1 IN 1 D, ORAL	
			Quetiapine	SS		ORAL	25 MG, 3 IN 1D, ORAL	
			Haloperidol	SS		ORAL	26 MG, 1 IN 1 D, ORAL	
			Trihexyphenidyl Hydrochloride	SS		ORAL	6 MG, 1 IN 1 D, ORAL	
			Vegetamin	SS		ORAL	ORAL	
			Carbamazepine	C				
			Bromazepam	C				
			Flunitrazepam	C				
			Alosenn	C				
			Mosapride Citrate	C				
			Neostigmine Metilsulfate	C				

Date:01/12/04ISR Number: 4269711-5Report Type:Expedited (15-DaCompany Report #03P-163-0245882-00
Age:39 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent	Neuroleptic Malignant Syndrome	Foreign Literature Health	Valproate Sodium (Sodium Valproate) (Sodium Valproate)					

Impairment/Damage		Professional	(Sodium Valproate)	PS	
600 MG, 1 IN					
1 D					
			Biperiden (Akineton)		
			(Biperiden)		
			(Biperiden)	SS	
3 MG					
			Fluvoxamine	SS	
SEE IMAGE					
			Haloperidol	SS	
24 MG					
			Levomepromazine	SS	
550 MG					
			Zonisamide	SS	
200 MG					
			Clonazepam	SS	
1 MG					
			Vegetamin A	SS	
2 DOSAGES					
FORMS					
			Flunitrazepam	SS	
4 MG					

Date:01/13/04ISR Number: 4270906-5Report Type:Expedited (15-DaCompany Report #2004AP00024
Age:50 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required	Ileus	Foreign	Seroquel	PS		ORAL	25 MG TID PO	
Intervention to		Study	Lodopin	SS		ORAL	150 MG DAILY	
Prevent Permanent		Health					PO	
Impairment/Damage		Professional	Serenace	SS		ORAL	26 MG DAILY	
		Other					PO	
			Akineton	SS		ORAL	6 MG DAILY PO	
			Artane	SS		ORAL	6 MG DAILY PO	
			Vegetamin	SS				
			Tegretol	C				
			Lexotan	C				

			Rohypnol	C			
			Alosenn	C			
			Gasmotin	C			
			Vagostigmin #1	C			

Date:01/13/04ISR Number: 4271525-7Report Type:Expedited (15-DaCompany Report #AT-JNJFOC-20031104219
Age:21 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Alanine Aminotransferase Increased	Foreign Health Professional	Haloperidol (Haloperidol) Injection	PS		INTRAVENOUS	SEE IMAGE	
	Aspartate Aminotransferase Increased		Depakine (Valproate Sodium) Injection	SS		INTRAVENOUS	SEE IMAGE	
	Blood Alkaline Phosphatase Increased		Seroquel (Quetiapine Fumarate)	SS		ORAL	SEE IMAGE	
	Blood Creatine Phosphokinase Increased		Fragmin (Heparin-Fraction Sodium Salt) Injection	SS		INTRAVENOUS	SEE IMAGE	
	Blood Lactate Dehydrogenase Increased		Claforan (Cefotaxime Sodium) Injection	SS		INTRAVENOUS	6000 MG,	
	Drug Interaction Potentiation							
	Gamma-Glutamyltransferase Increased		Rivotril (Clonazepam)	C				
			Akineton (Biperiden Hydrochloride)	C				
			Entumin (Clotiapine)Tablets	C				
			Magnesium Sulphate (Magnesium Sulfate)	C				

Date:01/14/04ISR Number: 4272821-XReport Type:Expedited (15-DaCompany Report #2003016415
Age:21 YR Gender: I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Literature	Gabapentin					
		Health	(Gabapentin)	PS		ORAL		
ORAL								
		Professional	Haloperidol					
			(Haloperidol)	SS		ORAL		
ORAL								
			Benzatropine Mesilate (Benzatropine Mesilate)	SS		ORAL		
ORAL								

Date:01/14/04ISR Number: 4272915-9Report Type:Expedited (15-DaCompany Report #AT-JNJFOC-20031104222
Age:82 YR Gender:Female I/FU:F

Outcome	PT
Death	Adrenal Disorder
	Anaemia
	Arteriosclerosis
	Atrophy
	Brain Oedema
	Cardiac Arrest
	Cardiomegaly
	Contusion
	Coronary Artery Disease

		Dehydration					
		Depression					
		Dyspnoea	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
		Emphysema	Foreign	Haldol (Haloperidol)			
		Fall	Health	Unspecified	PS		
10 MG, IN 1							
		Fibrosis	Professional				
DAY							
		Gastric Adenoma		Corenitec			
		Hydrocephalus		(Vaseretic)	SS		
LONG TERM							
		Hypokalaemia		Seroquel (Quetiapine			
		Hyponatraemia		Fumarate)	SS		
SEE IMAGE							
		Lipomatosis		Isoptin (Verapamil			
		Myocardial Fibrosis		Hydrochloride)	C		
		Nervous System Disorder		Calcium Carbonate			
		Oedema		(Calcium Carbonate)	C		
		Pancreatic Disorder		Fosamax (Alendronate			
		Perirenal Haematoma		Sodium)	C		
		Phlebothrombosis		Trittico (Trazodone			
		Psychomotor Agitation		Hydrochloride)	C		
		Pulmonary Congestion		Kcl Retard			
		Pulmonary Embolism		(Potassium Chloride)	C		
		Pulmonary Infarction		Pantoloc			
		Renal Artery		(Pantoprazole)	C		
		Atherosclerosis		Gewacalm (Diazepam)	C		
		Splenic Neoplasm		Nacl (Sodium			
		Malignancy Unspecified		Chloride)	C		
				Akineton (Biperiden			
				Hydrochloride)	C		

Date:01/14/04ISR Number: 4273697-7Report Type:Expedited (15-DaCompany Report #2004PK00006
Age:63 YR Gender:Female I/FU:I

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Required		Cholestasis	Foreign	Antra	PS		ORAL
40 MG DAILY							
Intervention to			Health				
PO							
Prevent Permanent			Professional	Nexium	SS		
40 MG DAILY							

Impairment/Damage	Other	Dafalgan	SS	1500 MG DAILY
		Remeron	SS	30 MG DAILY
		Haldol	SS	1.5 MG DAILY
		Xanax	C	
		Dormicum	C	
		Morphine	C	
		Eltroxin	C	
		Loxoberon	C	
		Mycostatin	C	
		Ferrum Hausmann	C	
		Bisolvon	C	
		Neurodol	C	

Date:01/15/04ISR Number: 4272661-1Report Type:Direct Company Report #CTU 210156
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Effect Decreased Pharmaceutical Product Complaint		Haloperidol Generic 2mg Bid 00378-0214-01	PS		ORAL	2 MG BID PO	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/16/04ISR Number: 4273212-8Report Type:Expedited (15-DaCompany Report #PHRM2004FR00513
Age:50 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Bradycardia Drug Interaction	Health Professional	Trileptal	PS	Novartis Sector: Pharma	ORAL	600 mg daily	
Other	Hypotension		Haldol "Janssen-Cilag"	SS		ORAL	4 mg, QID	
			Previscan	C				
			Valium	C			UNK, UNK	

Date:01/19/04ISR Number: 4273503-0Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0319340A
Age:47 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Blood Phosphorus	Consumer	Lamictal	PS	Glaxosmithkline	ORAL	150MG Per day	6 WK
	Increased		Sabril	SS			1UNIT Per day	YR
	C-Reactive Protein		Mopral	SS		ORAL	20MG Per day	MON
	Increased		Haldol	SS		ORAL	7MG Per day	MON
	Cholestasis		Gardenal	SS		ORAL	10MG Per day	YR
	Gamma-Glutamyltransferase		Seresta	SS		ORAL	10MG Per day	YR
	Increased		Rivotril Iv	C				
	General Physical Health Deterioration							
	Hepatic Failure							
	International Normalised Ratio Increased							
	Mouth Haemorrhage							
	Prothrombin Level Decreased							
	Pyrexia							
	Somnolence							

Date:01/20/04ISR Number: 4276190-0Report Type:Direct Company Report #CTU 210463
Age:48 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Erythema Mass Pharmaceutical Product Complaint Swelling Tenderness		Haloperidol-D 100 Mg/Ml Bedford Labs	PS	Bedford Labs	INTRAMUSCULAR	200MG Q 3 WEEKS IM	

Date:01/20/04ISR Number: 4276205-XReport Type:Direct Company Report #CTU 210464
Age:65 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Injection Site Erythema Mass Pain Pharmaceutical Product Complaint Tenderness		Haloperidol 100 Mg Bedford Labs	PS	Bedford Labs	INTRAMUSCULAR	200 MG Q 2 WEEKS IM	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/20/04ISR Number: 4276209-7Report Type:Direct Company Report #CTU 210465
Age:63 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required	Injection Site Erythema		Haloperidol-D					
Intervention to	Mass		50mg/Ml Bedford Labs	PS	Bedford Labs			
INTRAMUSCULAR	50 MG Q 3							
Prevent Permanent	Pain							
WEEK I.M.								
Impairment/Damage	Pharmaceutical Product							
	Complaint							
	Tenderness							

Date:01/20/04ISR Number: 4276264-4Report Type:Direct Company Report #CTU 210467
Age:58 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required	Feeling Hot		Haloperidol 100					
Intervention to	Injection Site Erythema		Mg/Ml Decanoate 2mg					
Prevent Permanent	Mass		Bedford Labs	PS	Bedford Labs			
INTRAMUSCULAR	200MG Q 3							
Impairment/Damage	Pain							
WEEKS IM								

Date:01/20/04ISR Number: 4276312-1Report Type:Direct Company Report #CTU 210466
Age:34 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required	Erythema		Haloperidol-D					
Intervention to	Mass		100mg/Ml	PS	Bedford Labs			
INTRAMUSCULAR	300MG Q 4							
Prevent Permanent	Pharmaceutical Product							
WEEKS IM								
Impairment/Damage	Complaint							
	Skin Warm							
	Tenderness							

Date:01/20/04ISR Number: 4276556-9Report Type:Expedited (15-DaCompany Report #2004001063
Age:41 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Condition Aggravated	Literature	Geodon (Ziprasidone)	PS		ORAL		
	Electrocardiogram Abnormal	Health Professional	Haloperidol (Haloperidol)	SS				
	Hyperprolactinaemia		Risperidone (Risperidone)	SS				
	Psychotic Disorder		Olanzapine (Olanzapine)	SS				
	Tardive Dyskinesia		Quetiapine (Quetiapine)	SS				
	Weight Increased		Valproate (Valproic Acid)	C				

Date:01/20/04ISR Number: 4276698-8Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20040102342
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Disorientation	Health Professional	Haldol (Haloperidol) Injection	PS		INTRAVENOUS	50 MG, 1 IN 1	DAY,
			Valium (Diazepam)	C		INTRAVENOUS		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/20/04ISR Number: 4276721-0Report Type:Expedited (15-DaCompany Report #FR-JNJFOC-20040101932
Age:47 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Hospitalization - Initial or Prolonged	Activated Partial Thromboplastin Time Cholestasis Drug Ineffective Drug Interaction General Physical Health Deterioration Hyperthermia International Normalised Ratio Increased Mouth Haemorrhage Prothrombin Level Abnormal Somnolence	Foreign Health Professional	Haldol (Haloperidol) Solution Sabril (Vigabatrin) Lamictal (Lamotrigine) Mopral (Omeprazole) Gardenal (Phenobarbital) Tablets Seresta (Oxazepam) Tablets	PS SS SS SS SS SS		ORAL ORAL ORAL ORAL ORAL ORAL	7 MG, IN 1 500 MG, IN 1 150 MG, IN 1 20 MG, IN 1 10 MG, IN 1 10 MG, IN 1	DAY, ORAL DAY, ORAL DAY, ORAL DAY, ORAL DAY, ORAL DAY, ORAL

Date:01/20/04ISR Number: 4276724-6Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20031005211
Age:60 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death Hospitalization - Initial or Prolonged	Bronchopneumonia C-Reactive Protein Increased	Foreign Health Professional	Haldol-Janssen (Haloperidol) Unspecified	PS	Janssen	ORAL	10 MG, IN 1	

	Dehydration					
DAY, ORAL; 5						
	Dialysis					
MG, IN 1 DAY,						
	Hypothermia					
ORAL						
	Peritonitis		Oxazepam (Oxazepam)	C		
	Renal Failure Acute		Distraneurin (Clomethiazole Edisilate)	C		
	Sepsis		Cefuroxim (Cefuroxime)	C		
	White Blood Cell Count Increased		Ciprobay (Ciprofloxacin Hydrochloride)	C		
			Beloc Zok (Metoprolol Succinate) Tablets	C		

Date:01/22/04ISR Number: 4279683-5Report Type:Expedited (15-DaCompany Report #2004194353AT
Age:21 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Alanine Aminotransferase Increased	Foreign Health Professional	Fragmin (Dalteparin Sodium)Solution, Sterile	PS				
SUBCUTANEOUS	Aspartate						SEE IMAGE	
	Aminotransferase Increased	Other	Depakine (Valproate Sodium)	SS				
INTRAVENOUS							SEE IMAGE	
	Blood Alkaline		Haldol (Haloperidol)	SS				
INTRAVENOUS	Phosphatase Increased						5 MG, DAILY,	
IV								
	Gamma-Glutamyltransferase Increased		Seroquel (Quetiapine)	SS		ORAL	600 MG,	
	Hepatic Enzyme Increased							
DAILY, ORAL								
			Pantoprazole Sodium					

				(Pantoprazole Sodium)	SS		
INTRAVENOUS	40 MG, DAILY,						
IV							
				Rivotril	C		
				Akineton Retard	C		
				Entumin (Clotiapine)	C		
				Magnesium	C		

Date:01/23/04ISR Number: 4279172-8Report Type:Direct Company Report #CTU 210764
Age:21 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dystonia		Haloperidol Inj	PS				
TOTAL DOSE 15 MG								

Date:01/23/04ISR Number: 4279757-9Report Type:Expedited (15-DaCompany Report #200313851GDS
Age:56 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Alanine Aminotransferase Increased	Foreign Literature	Bayaspirin (Acetylsalicylic Acid)	PS				
	Aspartate Aminotransferase Increased	Health Professional Other	Cravit (Levofloxacin)	SS				
	Blood Albumin Decreased		Tienam	SS				
	Blood Alkaline Phosphatase Increased		Serenace (Haloperidol)	SS				
	Blood Creatine Phosphokinase Increased		Gramali (Tiapride Hydrochloride)	SS				
	Blood Lactate Dehydrogenase Increased		Atarax-P (Hydroxyzine Hydrochloride)	SS				
	Blood Potassium Decreased		Mucosta (Rebamipide)	SS				
	Blood Pressure Diastolic Decreased		Lasix (Furosemide)	SS				
	Blood Sodium Decreased		Mannitol	SS				
	Blood Uric Acid Increased		Warfarin	SS				
	Body Temperature Decreased		Digosin (Digoxin)	SS				
			Aldactone-A					

C-Reactive Protein Increased	
Gamma-Glutamyltransferase Increased	
Haematocrit Decreased	
Haemoglobin Decreased	
Lipase Increased	
Pain Of Skin	
Protein Total Decreased	
Pruritus	
Rash Papular	
Red Blood Cell Count Decreased	
Toxic Epidermal Necrolysis	
(Spironolactone)	SS
Gaster (Famotidine)	SS
Eurodin (Estazolam)	SS
Dalacin (Clindamycin Hydrochloride)	SS
Loxonin (Loxoprofen Sodium)	C
Hitropen (Uncodeable "Unclassifiable")	C
Selbex	C
Foipan (Camostat Mesilate)	C

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/23/04ISR Number: 4280370-8Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20040101907
Age:25 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Agitation	Foreign	Haldol (Haloperidol)					
	Convulsion	Health	Tablets	PS			0.5 MG, 3 IN	
	Difficulty In Walking	Professional						1 DAY
	Speech Disorder							
	Tremor							

Date:01/27/04ISR Number: 4280660-9Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20031005211
Age:60 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Bronchopneumonia	Foreign	Haldol-Janssen					
Hospitalization - Initial or Prolonged	C-Reactive Protein Increased	Health Professional	(Haloperidol) Unspecified	PS		ORAL	10 MG, IN 1	
	Dialysis							DAY, ORAL
	Hypothermia		Oxazepam (Oxazepam)	C				
	Peritonitis		Distraneurin (Clomethiazole Edisilate)	C				
	Sepsis		Cefuroxim (Cefuroxime)	C				
	White Blood Cell Count Increased		Ciprobay (Ciprofloxacin Hydrochloride)	C				
			Beloc Zok (Metoprolol Succinate) Tablets	C				

Date:02/02/04ISR Number: 4284793-2Report Type:Expedited (15-DaCompany Report #03P-056-0238193-00
Age:43 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Foreign	Depakote (Divalproex					

	Depression	Health	Sodium) (Divalproex		
	Drug Interaction	Professional	Sodium)	PS	ORAL

PROGRESSIVE

INCREASE TO

1500 MG, PER

ORAL

Haloperidol	SS	ORAL

15 & 20 MG, 1

IN 1 D, PER

ORAL

Cyamemazine	C
Levomepromazine	C
Venlafaxine Hydrochloride	C
Alprazolam	C
Tropatepine Hydrochloride	C

Date:02/02/04ISR Number: 4302127-1Report Type:Expedited (15-DaCompany Report #FR-JNJFOC-20031201871
Age:12 YR Gender:Male I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Drug Tolerance Decreased
	Femoral Neck Fracture
	Foot Fracture

		Osteoporosis Scapula Fracture Spinal Compression	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
		Fracture Tibia Fracture	Foreign Health Professional	Haldol (Faible (Haloperidol) Solution	PS		ORAL

15 DOSE(S), 2

IN 1 DAY,

ORAL

				Urbanyl (Clobazam)	C		

Date:02/03/04ISR Number: 4285561-8Report Type:Expedited (15-DaCompany Report #03P-056-0238188-00
Age:59 YR Gender:Male I/FU:F

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Death		Completed Suicide Drug Interaction Intentional Misuse	Foreign Health Professional	Depakote (Divalproex Sodium) (Divalproex Sodium)	PS		ORAL

SEE IMAGE

				Haloperidol	SS		

INTRAMUSCULAR SEE IMAGE

				Rilmenidine	C		
				Tarka (Tarka Er) (Trandolapril/Verapm il) (Trandolapril/Verapa mil)	C		

Date:02/03/04ISR Number: 4285812-XReport Type:Expedited (15-DaCompany Report #970203-107050730
Age:24 YR Gender:Male I/FU:F

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Disability		Abasia Asthenia Cerebrovascular Accident Dysarthria Extremity Contracture Facial Palsy	Consumer	Haldol (Haloperidol) Chlorpromazine Hydrochloride (Chlorpromazine Hydrochloride) Lithium (Lithium)	PS C C		

	Gait Disturbance						
	Memory Impairment						
	Muscle Twitching						
	Musculoskeletal Stiffness						
	Oculogyration						
	Posture Abnormal						
	Speech Disorder						

Date:02/03/04ISR Number: 4285863-5Report Type:Expedited (15-DaCompany Report #FR-JNJFOC-20031100389
Age:40 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dyskinesia	Foreign Health Professional	Haldol (Haloperidol) Solution	PS		ORAL	, IN 1 DAY, ORAL	
	Extrapyramidal Disorder							
	Malaise							
	Medication Error		Tenormin (Atenolol)	C				
	Muscle Contractions Involuntary							
	Pain							
	Somnolence							
	Trismus							

Date:02/03/04ISR Number: 4286139-2Report Type:Expedited (15-DaCompany Report #2003034521
Age:36 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Acute Myocardial Infarction	Foreign Health Professional	Zeldox (Capsules) (Ziprasidone)	PS		ORAL	160 MG (BID), ORAL	Initial or Prolonged
Other	Cold Sweat							
	Confusional State	Company Representative	Haloperidol (Haloperidol)	SS				
	Electrocardiogram Abnormal		Flupentixol Dihydrochloride (Flupentixol Dihydrochloride)	C				
			Biperiden Hydrochloride (Biperiden Hydrochloride)	C				
			Chlorprothixene Hydrochloride (Chlorprothixene Hydrochloride)	C				

Date:02/04/04ISR Number: 4285982-3Report Type:Direct Company Report #CTU 211532
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Akathisia		Haldol 2 Mg/Ml	PS		ORAL	10 MG BID ORAL	

Date:02/04/04ISR Number: 4286155-0Report Type:Direct Company Report #CTU 211507
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Required		Flat Affect	Haldol Dec. 100mg/Ml	PS
INTRAMUSCULAR	100 MG Q			
Intervention to				
MONTH				
Prevent Permanent				
INTRAMUSCULAR				
Impairment/Damage				

Date:02/04/04ISR Number: 4286736-4Report Type:Expedited (15-DaCompany Report #JP-JNJFOC-20031204892
Age:63 YR Gender:Male I/FU:F

Outcome	PT
Death	Anxiety
Hospitalization - Initial or Prolonged	Colon Cancer
	Depressed Level Of Consciousness
	Disorientation
	Drug Level Increased
	Hepatic Function Abnormal
	Insomnia
	Malignant Neoplasm Progression
	Narcotic Intoxication
	Oxygen Saturation Decreased
	Pain
	Post Procedural

	Complication Pyrexia Respiratory Depression Restlessness	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
	Somnolence Stress	Foreign Health	Durotep (Fentanyl) Patch	PS		
TRANSDERMAL	SEE IMAGE					
		Professional	Haloperidol (Haloperidol)			
			Injection	SS		
INTRAVENOUS						
						DRIP
5 MG, IN 1						
DAY,						
INTRAVENOUS						
			Chlorpromazine (Chlorpromazine)			
			Injection	SS		
INTRAVENOUS						
						DRIP
0.5 DOSE(S),						
1 IN 1 DAY,						
INTRAVENOUS						
DRIP						
			Hydroxyzine Hydrochloride (Hydroxyzine Hydrochloride)			
			Unknown	SS		
INTRAVENOUS						
						DRIP
25 MG 1 IN 1						
DAY,						
INTRAVENOUS						
DRIP						
			Morphine Hydrochloride (Morphine Hydrochloride)			

		Unknown	SS
EPIDURAL	20 MG, IN 1		
DAY, EPIDURAL			
		Ropivacaine (Ropivacaine)	C
		Flomoxef Sodium (Flomoxef Sodium)	C
		Fulcaliq (All Other Therapeutic Products)	C
		Panthenol (Panthenol)	C
		Flurbiprofen Axetil (Flurbiprofen Axetil)	C

Date:02/04/04ISR Number: 4287180-6Report Type:Expedited (15-DaCompany Report #2004004691
Age:49 YR Gender:Male I/FU:I

Outcome	PT
Life-Threatening	Blood Calcium Increased
Hospitalization - Initial or Prolonged	Blood Creatinine Increased
Other	Blood Potassium Increased
	Blood Sodium Increased
	Cardiac Arrest
	Life Support
	Neurological Examination Abnormal
	Pupil Fixed

	Respiratory Failure Sedation Unresponsive To Pain	Report Source	Product	Role	Manufacturer	Route	Dose
Duration							
	Stimuli	Health Professional	Neurontin (Tablets) (Gabapentin)	PS		ORAL	1800 (TID), ORAL
			Lorazepam (Lorazepam)	SS			
			Haloperidol (Haloperidol)	SS			
			Valproic Acid (Valproic Acid)	SS			
			Salbutamol (Salbutamol)	C			
			Amlodipine (Amlodipine)	C			
			Acetylsalicylic Acid (Acetylsalicylic Acid)	C			
			Clopidogrel Sulfate (Clopidogrel Sulfate)	C			
			Enalapril (Enalapril)	C			
			Ezetimibe (Ezetimibe)	C			
			Glibenclamide (Glibenclamide)	C			
			Isosorbide Mononitrate (Isosorbide Mononitrate)	C			
			Levofloxacin (Levofloxacin)	C			
			Olanzapine (Olanzapine)	C			
			Prenatal Vitamins (Ascorbic Acid, Biotin , Tocopherol, Nicotinic Acid, Retinol, Vitamin D	C			
			Rofecoxib (Rofecoxib)	C			
			Simvastatin				

			(Simvastatin)	C		
			Rosiglitazone (Rosiglitazone)	C		

Date:02/05/04ISR Number: 4288764-1Report Type:Expedited (15-DaCompany Report #FRWYE544229JAN04
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death Hospitalization - Initial or Prolonged	Drug Exposure During Pregnancy Foetal Distress Syndrome	Study	Effexor (Venlafaxine Hydrochloride, Unspec, 0)	PS		ORAL	ORAL	
	Premature Baby		Anafranil (Clomipramine, , 0)	SS		ORAL	37.5 MG 1X	PER 1 DAY/DURING THE THIRD

22-Aug-2005 10:49 AM

TERM OF

	Depamide (Valpromide, , O)	SS
	Haldol (Haloperidol, , 0)	SS

DURING THE

THIRD TERM OF

PREGNANCY

	Sulfarlem (Anethole Trithione, , 0)	SS
	Theralene (Alimemazine Tartrate, , O)	SS
	Xanax (Alprazolam, , 0)	SS

Date:02/06/04ISR Number: 4291361-5Report Type:Direct Company Report #CTU 211717
Age:33 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Blood Creatine Phosphokinase Increased Body Temperature Increased Musculoskeletal Stiffness Neuroleptic Malignant Syndrome		Haloperidol 10 Mg Ziprasidone 80 Mg	PS SS			10 MG BID 80 MG BID	

Date:02/09/04ISR Number: 4289110-XReport Type:Direct Company Report #CTU 211848
Age:12 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Arthralgia Oedema Tenderness		Haloperidol 0.5mg Tab N/A	PS		ORAL	1/2 TAB BID ORAL	

Effexor Xr	C	
Tegretol	C	
Risperdal	C	

Date:02/10/04ISR Number: 4289804-6Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0321980A
Age:69 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Abdominal Distension		Augmentin	PS	Glaxosmithkline			
UNKNOWN							3G Per day	12 DAY
Hospitalization -	Flatulence		Deroxat	SS	Glaxosmithkline	ORAL		
Initial or Prolonged	Intestinal Obstruction		Haldol	SS		ORAL	2UNIT Per day	
	Tachycardia		Sintrom	SS		ORAL	10MG Per day	
			Fraxiparine	SS		SUBCUTANEOUS	1UNIT Unknown	
							.6ML Twice per day	

Date:02/10/04ISR Number: 4293569-1Report Type:Expedited (15-DaCompany Report #BR-JNJFOC-20040200060
Age:63 YR Gender:Female I/FU:I

Outcome	PT
Hospitalization -	Condition Aggravated
Initial or Prolonged	Dizziness
Other	Extrapyramidal Disorder
	Loss Of Consciousness
	Muscle Rigidity

Muscular Weakness
Schizophrenia

Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Foreign Health Professional	Haldol (Haloperidol)	PS			2 MG, IN 1 DAY	
	Rad Tablet (All Other Therapeutic Products) Tablets	SS		ORAL	0.75 MG, 2 IN 1 DAY, ORAL	

Date:02/10/04ISR Number: 4293938-XReport Type:Expedited (15-DaCompany Report #FRWYE544229JAN04
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death Hospitalization - Initial or Prolonged	Complications Of Maternal Exposure To Therapeutic Drugs	Foreign Study Health Professional Other	Efexor (Venlafaxine Hydrochloride)	PS		TRANSPLACENTAL	ORAL	
	Drug Exposure During Pregnancy		Anafranil (Clomipramine, ,0)	SS		TRANSPLACENTAL	37.5 MG 1X PER 1 DAY	
	Foetal Distress Syndrome					ORAL		
			Depamide (Valpromide, ,0)	SS		TRANSPLACENTAL		
			Haldol (Haloperidol, ,0)	SS		TRANSPLACENTAL		
			Sulfarlem (Anethole Trithione, ,0)	SS		TRANSPLACENTAL		
			Theralene (Alimemazine Tartrate, ,0)	SS		TRANSPLACENTAL		

			Xanax (Alprazolam, ,0)	SS		
TRANSPLACENTAL						

Date:02/11/04ISR Number: 4293566-6Report Type:Direct Company Report #CTU 212015
Age:81 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Life-Threatening	Dyspnoea Exertional		Dofetilide (Tikosyn)	PS		ORAL
500 MG PO BID						
	Loss Of Consciousness		Haloperidol	SS		
INTRAVENOUS 1 MG IV Q4H						
	Mitral Valve Incompetence					
PRN						
	Torsade De Pointes					
	Ventricular Tachycardia					

Date:02/11/04ISR Number: 4293801-4Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20031104673
Age:46 YR Gender:Male I/FU:F

Outcome	PT
Other	Activities Of Daily
	Living Impaired
	Alopecia
	Amnesia
	Diplopia
	Drooling
	Eyelid Ptosis
	Gastrointestinal Disorder
	Muscle Atrophy
	Overdose

		Posture Abnormal Suicide Attempt Tardive Dyskinesia	Report Source	Product	Role	Manufacturer	Route	Dose Duration
		Vision Blurred	Consumer	Risperdal (Risperdal) Tablets	PS		ORAL	ORAL
				Haldol (Haloperidol) Unspecified	SS			
				Cogentin (Benzatropine Mesilate)	SS			

Date:02/12/04ISR Number: 4295935-7Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20040200722
Age:26 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Drug Ineffective Drug Interaction Infection	Foreign Health Professional	Haldol (Haloperidol) Unspecified	PS		INTRAMUSCULAR	1 DOSE(S), INTRA-MUSCULAR
	Malaise Mental Disorder Neuroleptic Malignant Syndrome Salivary Hypersecretion White Blood Cell Count Increased		Amisulpride (Amisulpride) Clozaril (Clozapine)	SS C			

Date:02/17/04ISR Number: 4299501-9Report Type:Expedited (15-DaCompany Report #2004UW01599
Age:55 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Life-Threatening	Agitation	Health	Seroquel	PS		ORAL	100 MG DAILY
Required Intervention to	Blood Creatine Phosphokinase Increased	Professional	Seroquel	SS		ORAL	PO 50 MG DAILY

Prevent Permanent Impairment/Damage	Blood Pressure Decreased					
	Confusional State		Seroquel	SS		ORAL 25 MG DAILY PO
	Dehydration					
	Dyspnoea		Haldol "Janssen"	SS	Janssen	
	Hypotension		Benzodiazepine	SS		
	Muscle Rigidity		Mellaril	C		
	Neuroleptic Malignant Syndrome		Trilafon	C		
	Pyrexia		Triavil	C		
	Renal Failure		Xanax	C		
	Restlessness					
	Sepsis					
	Temperature Regulation Disorder					
	White Blood Cell Count Increased					

Date:02/17/04ISR Number: 4300470-3Report Type:Expedited (15-DaCompany Report #SE-JNJFOC-20040201560
Age:58 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Hospitalization - Initial or Prolonged	Cerebral Atrophy	Foreign Health Professional	Risperdal (Risperidone) Unspecified	PS		
			Haldol (Haloperidol)			

Tablets	SS
Lithionit (Lithium Sulfate)	SS
Pulmicort Turbuhaler (Budesonide) Powder	C
Glucophage (Metformin Hydrochloride) Film Coated	C
Trombyl (Acetylsalicylic Acid) Tablets	C
Torem (Torasemide) Tablets	C
Laktipex (Lactulose) Powder	C
Remeron (Mirtazapine) Tablets	C
Unknown (All Other Therapeutic Products)	C
Zopiclone (Zopiclone) Film Coated Tablet	C

Date:02/17/04ISR Number: 4300472-7Report Type:Expedited (15-DaCompany Report #FR-JNJFOC-20040201242
Age:69 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Abdominal Distension	Foreign	Haldol (Haloperidol)					
Life-Threatening	Flatulence	Health	Unspecified	PS		ORAL	10 MG, IN 1	
Hospitalization -	Gastrointestinal Motility	Professional						DAY, ORAL
Initial or Prolonged	Disorder		Sintrom					
	Intestinal Dilatation		(Acenocoumarol)	SS		ORAL	4 MG, ORAL	
	Tachycardia		Augmentin (Clavulin)	SS			3 G, IN 1 DAY	
			Fraxiparine (Heparin-Fraction, Calcium Salt)	SS		SUBCUTANEOUS	0.6 ML, 2 IN	

1 DAY,

SUBCUTANEOUS

			Deroxat (Paroxetine Hydrochloride)	SS		ORAL

40 MG, IN 1

DAY, ORAL

Date:02/18/04ISR Number: 4299962-5Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20040201944
Age:58 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Bronchopneumonia	Foreign	Haloperidol					
Other	Medication Error	Health Professional	(Haloperidol) Unspecified	PS				
			Zimovane (Zopiclone)	SS		ORAL		

, IN 1 DAY

15 MG, IN 1

DAY, ORAL

Chlorpromazine (Chlorpromazine)	C		
Procyclidine (Procyclidine)	C		
Carbamazepine (Carbamazepine)	C		

Amisulpiride (Amisulpride)	C
Diazepam (Diazepam)	C
Beclomethasone (Beclmethasone)	C
Salbutamol (Salbutamol)	C
Olanzapine (Olanzapine)	C
Folic Acid (Folic Acid)	C
Movicol (Mulytely)	C
Macrogol (Macrogol)	C
Potassium Chloride (Potassium Chloride)	C

Date:02/18/04ISR Number: 4299963-7Report Type:Expedited (15-DaCompany Report #FR-JNJFOC-20030901124
Age:29 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other SEE IMAGE	Cholestasis Cytolytic Hepatitis Granulomatous Liver Disease Hepatic Fibrosis Hepatitis	Foreign Health Professional	Risperdal (Risperidone) Unspecified	PS		ORAL		
			Haldol (Haloperidol) Unspecified	SS		ORAL	20 MG, IN 1 DAY,	ORAL
			Largactil (Chlorpromazine Hydrochloride)	SS		ORAL	200 MG, IN 1 DAY,	ORAL
			Athymil (Mianserin Hydrochloride)	SS		ORAL	30 MG, IN 1 DAY,	ORAL
			Temesta (Lorazepam)	SS		ORAL	5 MG, IN 1 DAY,	ORAL

Date:02/18/04ISR Number: 4301502-9Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20031104673
Age:46 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Alopecia	Consumer	Risperdal					
	Amnesia		(Risperidone)					
	Drooling		Tablets	PS		ORAL	SEE IMAGE	
	Eyelid Disorder		Haldol (Haloperidol)					
	Hair Colour Changes		Unspecified	SS				
	Intestinal Functional		Cogentin					
	Disorder		(Benzatropine					
	Muscle Atrophy		Mesilate)	SS				
	Overdose		Effexor (Venlafaxine					
	Posture Abnormal		Hydrochloride)	C				
	Suicide Attempt							
	Tardive Dyskinesia							
	Visual Acuity Reduced							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/19/04ISR Number: 4300697-0Report Type:Direct Company Report #CTU 212587
Age:65 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Adrenal Disorder		Haloperidol					
Hospitalization -	Atrial Fibrillation		Injection 5 Mg/Ml					
Initial or Prolonged	Confusional State		(Bedford Labs)	PS	Bedford Labs	INTRAVENOUS	5 MG IV X ONE	
Required	Delirium						DOSE	
Intervention to	Disorientation		Promethazine					
Prevent Permanent	Extrapyramidal Disorder		Injection 25 Mg/Ml					
Impairment/Damage	Hypercorticoidism		(Elkins-Sinn)	SS	Elkins-Sinn	INTRAVENOUS	25 MG IV X	
	Hypertonia						SEVERAL DOSES	
	Muscle Contractions		Ondansetron	C				
	Involuntary		Asprin	C				
	Muscle Rigidity		Amlodipine	C				
	Nausea		Lisinopril	C				
	Neoplasm		Enoxaparin	C				
	Neuroleptic Malignant		Hydrochlorothiazide	C				
	Syndrome		Labetatol	C				
	Pneumonia Aspiration		Regular Insulin	C				
	Pyrexia		Furosemide	C				
	Renal Failure Acute		Acetaminophen	C				
	Rhabdomyolysis		Codeine	C				
	Tremor		Kcl	C				

Date:02/19/04ISR Number: 4300895-6Report Type:Expedited (15-DaCompany Report #DSA_23952_2004
Age:52 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blood Alkaline	Foreign	Temesta	PS			2.5 MG QD	
	Phosphatase Increased	Health	Temesta	SS			2.5 MG QD	
	Blood Glucose Increased	Professional	Temesta	SS			2.5 MG QD	
	Drug Level Below	Other	Temesta	SS			2.5 MG QD	
	Therapeutic		Temesta	SS			2.5 MG QD	

	Enuresis		Prazine	SS		
100 MG QD						
	Sedation		Prazine	SS		
100 MG QD						
	Sudden Onset Of Sleep		Prazine	SS		
50 MG						
			Haldol	SS		
20 MG QD						
			Haldol	SS		
25 MG QD						
			Haldol	SS		
4 MG QD						
			Haldol	SS		
2 MG QD						
			Fludex	C		
			Tenormin	C		
			Orfiril	C		
			Risperdal Consta	C		
			Risperdal	C		

Date:02/19/04ISR Number: 4301506-6Report Type:Expedited (15-DaCompany Report #S04-USA-00578-01
Age:36 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Drug Interaction	Health Professional	Lexapro (Escitalopram)	PS		ORAL
10 MG QD PO						
		Company Representative	Lexapro (Escitalopram)	SS		ORAL
20 MG QD PO						
			Clozapine	SS		
625 MG QD						
			Haldol	SS		
2 MG Q4HR						
			Prevacid (Lansoprazole)	C		
			Ferrous Sulfate	C		

			Surfax (Docusate Calcium)	C		

Date:02/20/04ISR Number: 4302058-7Report Type:Expedited (15-DaCompany Report #03P-087-0245767-00
Age:50 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Ileus	Foreign Health Professional Other	Akineton (Biperiden) (Biperiden)	PS		ORAL	6 MG, 1 IN 1 D, ORAL	
			Zotepine	SS		ORAL	150 MG, 1 IN 1 D, ORAL	
			Quetiapine	SS		ORAL	25 MG, 3 IN 1 D, ORAL	
			Haloperidol	SS		ORAL	26 MG, 1 IN 1 D, ORAL	
			Trihexyphenidyl Hydrochloride	SS		ORAL	6 MG, 1 IN 1 D, ORAL	
			Vegetamin	SS		ORAL	ORAL	
			Carbamazepine	C				
			Bromazepam	C				
			Flunitrazepam	C				
			Alosenn	C				
			Mosapride Citrate	C				

Date:02/23/04ISR Number: 4303347-2Report Type:Expedited (15-DaCompany Report #FR-JNJFOC-20040201939
Age:36 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Hospitalization -	Anorexia	Foreign	Haldol (Haloperidol)		
Initial or Prolonged	Blood Creatine	Health	Injection	PS	
INTRAMUSCULAR	INTRA-MUSCULA				
	Phosphokinase Increased	Professional			
R					
	Drug Interaction		Haldol (Haloperidol)		
	Extrapyramidal Disorder		Solution	SS	ORAL
ORAL					
	Hypertonia		Haldol (Haloperidol)		
			Tablets	SS	ORAL
ORAL					
			Depamide (Valpromide)	SS	
			Hept-A-Myl (Heptaminol Hydrochloride)	C	
			Noctamide (Lormetazepam)	C	
			Valium (Diazepam)	C	
			Parkinane Lp (Trihexyphenidyl Hydrochloride)	C	
			"Noctran" (Acepromet azine)	C	

Date:02/23/04ISR Number: 4303349-6Report Type:Expedited (15-DaCompany Report #AU-JNJFOC-20030903295
Age:62 YR Gender:Male I/FU:F

Outcome
Death
Life-Threatening
Hospitalization -

Initial or Prolonged

	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Adenoma Benign	Foreign	Reminyl					
	Agitation	Health	(Galantamine)					
	Blood Urea Increased	Professional	Unspecified	PS		ORAL	8 MG, 2 IN 1	
	Cholecystitis						DAY, ORAL	
	Collapse Of Lung		Mirtazepine					
	Confusional State		(Mirtazapine)	SS		ORAL	30 MG, 1 IN 1	
	Delirium						DAY, ORAL	
	Disorientation		Risperidone					
	Hypotension		(Risperidone)	SS				
	Hypoxia		Haloperidol					
	Intestinal Hypomotility		(Haloperidol)	SS				
	Klebsiella Infection		Vioxx (Rofecoxib)	C				
	Lobar Pneumonia		Lipitor					
	Lower Respiratory Tract		(Atorvastatin)	C				
	Infection		Vitamin E					
	Pneumonia		(Tocopherol)	C				
	Pneumonia Aspiration		Vitamin C (Ascorbic					
	Postoperative Ileus		Acid)	C				
	Pulmonary Embolism		Folic Acid (Folic					
	Pyrexia		Acid)	C				
	Respiratory Arrest		Ginkgo Biloba					
	Respiratory Failure		(Ginkgo Biloba)	C				
	Sepsis							
	Sputum Culture Positive							
	Staphylococcal Infection							
	Tachycardia							

Date:02/23/04ISR Number: 4303355-1Report Type:Expedited (15-DaCompany Report #JP-JNJFOC-20031204892
Age:63 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Anxiety	Foreign	Durotep (Fentanyl)					
Hospitalization -	Colon Cancer	Health	Patch	PS		TRANSDERMAL	SEE IMAGE	
Initial or Prolonged	Condition Aggravated	Professional	Haloperidol					
	Depressed Level Of		(Haloperidol)					

	Consciousness	Injection	SS	INTRAVENOUS
	Disorientation			DRIP 5 MG, IN 1
	Drug Level Increased			DAY,
	Hepatic Function Abnormal			INTRAVENOUS
	Insomnia	Chlorpromazine		
	Intestinal Obstruction	(Chlorpromazine		
	Malignant Neoplasm	Injection)	SS	INTRAVENOUS
	Progression			DRIP 0.5 DOSE(S) 1
	Narcotic Intoxication			IN 1 DAY,
	Oxygen Saturation			INTRAVENOUS
	Decreased			DRIP
	Pain	Hydroxyzine		
	Post Procedural	Hydrochloride		
	Complication	(Hydroxyzine		
	Pyrexia	Hydrochloride)		
	Respiratory Depression	Unknown	SS	INTRAVENOUS
	Somnolence			DRIP 25 MG, 1 IN 1 DAY, INTRAVENOUS DRIP
		Morphine Hydrochloride		

			(Morphine Hydrochloride) Unknown	SS	
EPIDURAL	200 MG, IN 1 DAY, EPIDURAL				
			Morphine Hydrochloride (Morphine Hydrochloride) Unknown	SS	
RECTAL	RECTAL				
			Ropivacaine (Ropivacaine)	C	
			Flomoxef Sodium (Flomoxef Sodium)	C	
			Fulcaliq (All Other Therapeutic Products)	C	
			Panthenol (Panthenol)	C	
			Flurbiprofen Axetil (Flurbiprofen Axetil)	C	

Date:02/24/04ISR Number: 4304292-9Report Type:Expedited (15-DaCompany Report #2004009095
Age:81 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Agitation Postoperative	Health	Tikosyn (Dofetilide)	PS		ORAL	ORAL	
Hospitalization - Initial or Prolonged	Dyspnoea Exertional Loss Of Consciousness	Professional	Haloperidol (Haloperidol)	SS			INTRAVENOUS	7 MG (EVERY 4 HOURS PRN), INTRAVENOUS
Other	Mitral Valve Incompetence Torsade De Pointes Ventricular Extrasystoles Ventricular Fibrillation Ventricular Tachycardia		Furosemide (Furosemide) Potassium Chloride (Potassium Chloride) Acetylsalicylic (Acetylsalicylic Acid)	C C C				

Docusate Sodium (Docusate Sodium)	C
Maalox (Magnesium Hydroxide, Aluminium Hydroxide Gel)	C
Oxycocet (Paracetamol, Oxycodone Hydrochloride)	C
Vicodin (Paracetamol, Hydrocodone Bitartrate)	C
Diphenhydramine (Diphenhidramine)	C
Hydromorphone Hydrochloride (Hydromorphone Hydrochloride)	C
Morphine (Morphine)	C
Warfarin (Warfarin)	C
Rofecoxib (Rofecoxib)	C

			Famotidine (Famotidine)	C		
			Loratadine (Loratadine)	C		

Date:02/25/04ISR Number: 4305181-6Report Type:Direct Company Report #CTU 213232
Age:69 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Atrial Fibrillation		Fluconazole	PS		ORAL	200 MG X 1 ,	
Hospitalization -	Bundle Branch Block						100 MG PO	
Initial or Prolonged	Electrocardiogram Qt		Haloperidol	SS		ORAL	7.5 MG PO	
	Corrected Interval						Q4M5 MG Q 6 H	
	Prolonged		Albuterol	C				
	Heart Rate Increased		Amiodarone	C				
	Supraventricular		Ascorbic Acid	C				
	Tachycardia		Aspirin	C				
	Ventricular Tachycardia		Chlorhydrate	C				
			Docusate	C				
			Fentanyl	C				
			Heparin	C				
			Ipratropium	C				
			Metoprolol	C				
			Midazolam	C				
			Nicotine	C				
			Nystatin	C				
			Ranitidine	C				
			Zinc	C				

Date:02/25/04ISR Number: 4305803-XReport Type:Expedited (15-DaCompany Report #US-JNJFOC-20040204097
Age:32 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Weight Increased	Consumer	Haldol Decanoate (Haloperidol Decanoate)					

			Unspecified	PS			
INTRAMUSCULAR	INTRA-MUSCULAR						
			Geodon (Ziprasidone Hydrochloride)	C			
			Depakote (Valproate Semisodium)	C			

Date:02/25/04ISR Number: 4305933-2Report Type:Expedited (15-DaCompany Report #2004-DE-00681GD
Age:63 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Pneumonia Aspiration	Foreign	Theophylline	PS		ORAL PO		
	Poisoning	Literature	Phenytoin (Phenytoin)	SS		ORAL PO		
			Haloperidol	SS		ORAL PO		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/27/04ISR Number: 4308756-3Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20040204503
Age:38 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Drug Toxicity	Health Professional	Haloperidol Decanoate (Haloperidol Decanoate)Injection	PS		INTRAMUSCULAR	200 MG, 1 IN	2 WEEK,

INTRA-MUSCULAR

Date:02/27/04ISR Number: 4308933-1Report Type:Expedited (15-DaCompany Report #FR-JNJFOC-20040203296
Age:58 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardio-Respiratory Arrest Drug Interaction	Foreign Health Professional	Haldol (Haloperidol) Tablets	PS		ORAL	15 MG, IN 1	DAY, ORAL
			Nozinan (Levomepromazine)	SS		ORAL	300 MG, IN 1	DAY, ORAL
			Neo-Mercazole (Carbimazole)	SS		ORAL	5 MG, IN 1	DAY, ORAL
			Myolastan (Tetrazepam)	C				
			Lepticur (Tropatepine Hydrochloride)	C				
			Sulfarlem (Anethole Trithione)	C				
			Forlax (Macrogel)	C				

Lioresal (Baclofen)	C
Surbronc (Ambroxol Hydrochloride)	C
Potassium Sirop (Potassium)	C

Date:02/27/04ISR Number: 4309078-7Report Type:Expedited (15-DaCompany Report #DSA_24007_2004
Age:29 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Cholestasis	Foreign	Temesta	PS		ORAL	5 MG QD PO	
	Granulomatous Liver Disease	Health Professional	Athymil	SS		ORAL	30 MG QD PO	
			Haldol	SS		ORAL	20 MG QD PO	
	Hepatic Fibrosis	Other	Largactil	SS		ORAL	200 MG QD PO	
	Portal Hypertension		Risperdal	SS		ORAL	10 MG QD PO	

Date:03/01/04ISR Number: 4308687-9Report Type:Direct Company Report #CTU 213438
Age:17 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Difficulty In Walking Dystonia Muscle Twitching Musculoskeletal Stiffness Speech Disorder Staring		Haloperidol	PS				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/01/04ISR Number: 4308849-0Report Type:Direct Company Report #CTU 213442
Age:51 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged [CHRONIC] Required Intervention to Prevent Permanent Impairment/Damage CHRONIC	Asthenia		Haldol 28:16	PS		ORAL	5 MG PO BID
	Coordination Abnormal						
	Drug Toxicity		Seroquel				
	Fall		(Quetiapine)28:16	SS			200 MG @ NOON
	Metabolic Disorder						, 600 MG QHS
			Haldol Dcanoate	C			
			Protonix	C			
			Multivitamin	C			
			Flunisolide	C			
			Norvasc	C			

Date:03/02/04ISR Number: 4311142-3Report Type:Expedited (15-DaCompany Report #FR-JNJFOC-20030901124
Age:29 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged Other	Cholestasis	Foreign	Risperdal				
	Chronic Hepatitis	Health	(Risperidone)				
	Cytolytic Hepatitis	Professional	Unspecified	PS		ORAL	4 MG, IN 1
	Drug Interaction						DAY, ORAL; 10
	Granulomatous Liver						MG, IN 1 DAY,
	Disease						ORAL
	Hepatic Fibrosis		Haldol (Haloperidol)				
	Portal Hypertension		Unspecified	SS		ORAL	20 MG, IN 1
							DAY, ORAL
			Largactil (Chlorpromazine				

			Hydrochloride)	SS		ORAL
200 MG, IN 1 DAY, ORAL						
			Athymil (Mianserin Hydrochloride)	SS		ORAL
30 MG, IN 1 DAY, ORAL						
			Temesta (Lorazepam)	SS		ORAL
5 MG, IN 1 DAY, ORAL						

Date:03/02/04ISR Number: 4311144-7Report Type:Expedited (15-DaCompany Report #SE-JNJFOC-20040201560
Age:58 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Cerebral Atrophy Parkinson'S Disease	Foreign Health Professional	Risperdal (Risperidone) Unspecified	PS				
			Haldol (Haloperidol) Tablets	SS				
			Lithionit (Lithium Sulfate)	SS				
			Pulmicort Turbuhaler (Budesonide) Powder	C				
			Glucophage (Metformin Hydrochloride)	C				
			Trombyl (Acetylsalicylic Acid)	C				
			Torem (Torasemide)	C				
			Laktipex (Lactulose)	C				

Remeron (Mirtazapine)	C
Unknown (All Other Therapeutic Products)	C
Zopiclone (Zopiclone)	C

Date:03/02/04ISR Number: 4311149-6Report Type:Expedited (15-DaCompany Report #FR-JNJFOC-20040204308
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Accident At Work Injury	Foreign Health Professional	Haldol Decanoas (Haloperidol Decanoate) Injection	PS		INTRA-MUSCULAR	1 ML,	

Date:03/03/04ISR Number: 4311949-2Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20040205464
Age:50 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Creatine Phosphokinase Increased Convulsion Postictal State Rhabdomyolysis	Foreign Health Professional	Haldol (Haloperidol) Unspecified	PS		ORAL	10 MG, 2 IN 1 DAY, ORAL	

Date:03/04/04ISR Number: 4313310-3Report Type:Expedited (15-DaCompany Report #FR-JNJFOC-20040205523
Age:69 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Medication Error	Foreign	Haldol (Haloperidol)					

Initial or Prolonged	Sinus Tachycardia	Health	Tablets	PS		ORAL
10 MG, ORAL						
	Somnolence	Professional	Nozinan (Levomepromazine)			
	Vomiting		Tablets	SS		ORAL
150 MG, ORAL						
			Akineton Retard (Biperiden Hydrochloride)			
			Tablets	SS		ORAL
4 MG, ORAL						
			Rivotril (Clonazepam) Tablets	SS		ORAL
3 MG, ORAL						
			Equanil (Meprobamate)	C		

Date:03/04/04ISR Number: 4313800-3Report Type:Periodic Company Report #2003121405
Age:43 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Electrocardiogram Qt	Health	Geodon (Ziprasidone)	PS		ORAL
160 MG						
	Corrected Interval	Professional				
(DAILY), ORAL						
	Prolonged		Haloperidol (Haloperidol)	SS		ORAL
5 MG, ORAL						
			Quetiapine Fumarate (Quetiapine Fumarate)	SS		ORAL
1100 MG, ORAL						

Hydroxine Embonate (Hydroxyzine Embonate)	C	
Gemfibrozil (Gemfibrozil)	C	
Lorazepam (Lorazepam)	C	
Levothyroxine Sodium (Levothyroxine Sodium)	C	
Ferrous Sulfate (Ferrous Sulfate)	C	
Gabapentin (Gabapentin)	C	
Nordette (Ethinylestradiol, Levonorgestrel)	C	

Date:03/05/04ISR Number: 4312441-1Report Type:Expedited (15-DaCompany Report #FR-ROCHE-359885
Age:69 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Somnolence	Consumer	Rivotril	PS	Roche	ORAL		
	Tachycardia		Haldol	SS		ORAL		
	Vomiting		Akineton Retard	SS		ORAL		
			Nozinan	SS		ORAL		
			Equanil	C				

Date:03/05/04ISR Number: 4314036-2Report Type:Expedited (15-DaCompany Report #FR-JNJFOC-20031000865
Age:81 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Interaction	Foreign	Haldol (Haloperidol) Solution	PS		ORAL	2 MG/ML, 1 IN	1 DAY, ORAL
	Klebsiella Infection	Health						
	Nosocomial Infection	Professional						
	Urinary Retention		Atarax (Hydroxyzine Hydrochloride)	SS		ORAL	75 MG, 1 IN 1	

DAY, ORAL

Date:03/08/04ISR Number: 4314454-2Report Type:Expedited (15-DaCompany Report #AU-JNJFOC-20030903295
Age:62 YR Gender:Male I/FU:F

Outcome	PT
Death	Agitation
Life-Threatening	Blood Urea Increased
Hospitalization - Initial or Prolonged	Cholecystitis
	Confusional State
	Delirium
	Disorientation
	Hypotension
	Hypoxia
	Klebsiella Infection
	Lower Respiratory Tract Infection
	Pneumonia
	Pneumonia Aspiration
	Postoperative Ileus
	Pulmonary Embolism

	Respiratory Arrest Respiratory Distress Respiratory Failure	Report Source	Product	Role	Manufacturer	Route Dose Duration
	Sepsis Staphylococcal Infection Tachycardia	Foreign Health Professional	Reminyl (Galantamine) Unspecified	PS		ORAL 8 MG, 2 IN 1
	Urine Output Decreased					DAY, ORAL
			Mirtazepine (Mirtazapine) Unknown	SS		ORAL 30 MG, 1 IN 1 DAY, ORAL
			Risperidone (Risperidone) Unspecified	SS		
			Haloperidol (Haloperidol) Unspecified	SS		
			Vioxx (Rofecoxib)	C		
			Lipitor (Atorvastatin)	C		
			Vitamin E (Tocopherol)	C		
			Vitamin C (Ascorbic Acid)	C		
			Folic Acid (Folic Acid)	C		
			Ginkgo Biloba (Ginkgo Biloba)	C		

Date:03/08/04ISR Number: 4314462-1Report Type:Expedited (15-DaCompany Report #SE-JNJFOC-20040300010
Age:54 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Hospitalization - Initial or Prolonged	Anaemia Colitis Ulcerative	Foreign Health	Haldol (Haloperidol) Unspecified	PS		ORAL ORAL
	Crohn'S Disease Infection Inflammatory Bowel	Professional				

Disease

Date:03/09/04ISR Number: 4314355-XReport Type:Expedited (15-DaCompany Report #PHFR2003GB01323
Age:34 YR Gender:Male I/FU:F

Outcome	PT
Death	Cardio-Respiratory Arrest
Hospitalization - Initial or Prolonged	Cardiomegaly
	Cardiomyopathy
Other	Dyspnoea
	Dyspnoea Exertional
	Electrocardiogram Abnormal
	Exercise Tolerance Decreased
	Fear
	Hallucination
	Heart Rate Increased
	Hyperventilation
	Hypoxia
	Mental Impairment

		Myocarditis Obesity Paranoia	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
		Pulmonary Embolism Pulmonary Oedema	Health Professional	Clozaril	PS	Novartis Sector: Pharma	ORAL
100mg/mane							
		Right Ventricular Failure					
250mg/nocte							
		Sleep Apnoea Syndrome		Haloperidol	SS		
10mg							
		Snoring		Haloperidol	SS		
20mg							
		Weight Increased		Haloperidol	SS		
30mg							
				Clonazepam	SS		
2mg							
				Clonazepam	SS		
6.5mg							
				Clonazepam	SS		
8mg							

Date:03/10/04ISR Number: 4315574-9Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20031104346
Age:63 YR Gender:Female I/FU:F

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Death Hospitalization - Initial or Prolonged		Drug Hypersensitivity Lethargy	Consumer Health Professional	Duragesic (Fentanyl) Patch	PS		
TRANSDERMAL	100 UG/HR, 1 IN 72 HOUR,						
TRANSDERMAL;							
200 UG/HR, 1 IN 72 HOUR,							
				Haldol (Haloperidol) Tablets	SS		ORAL
20 MG, 1 IN 4 HOUR PRN,							
ORAL							

			Decadron (Dexamethasone)	C		

Date:03/10/04ISR Number: 4315915-2Report Type:Expedited (15-DaCompany Report #FR-JNJFOC-20040104004
Age:40 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Abortion Spontaneous	Foreign	Haldol (Haloperidol)					
	Complications Of Maternal	Health	Unspecified	PS		ORAL		
ORAL								
	Exposure To Therapeutic Drugs	Professional	Rivotril (Clonazepam)	C				
	Maternal Drugs Affecting Foetus							

Date:03/10/04ISR Number: 4315988-7Report Type:Expedited (15-DaCompany Report #04P-056-0251660-00
Age:69 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Sinus Tachycardia	Foreign	Akineton (Biperiden)					
	Somnolence	Health	(Biperiden)	PS		ORAL		
1 DOSAGE								
	Vomiting	Professional						
FORMS, 1 IN 1								
D, PER ORAL								
			Haloperidol	SS		ORAL		
10 MG, ONCE,								
PER ORAL								
			Clonazepam	SS		ORAL		
3 MG, ONCE,								
PER ORAL								
			Levomepromazine	SS		ORAL		
150 MG, ONCE,								
PER ORAL								
			Meprobamate	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/11/04ISR Number: 4316373-4Report Type:Expedited (15-DaCompany Report #2003111063
Age:81 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Klebsiella Infection Nosocomial Infection Urinary Retention	Foreign Health Professional	Atarax (Tablet) (Hydroxozine Hydrochloride)	PS		ORAL	75 MG TID	ORAL
			Haloperidol (Haloperidol)	SS		ORAL	ORAL	

Date:03/12/04ISR Number: 4316588-5Report Type:Direct Company Report #USP 56407
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Medication Error		Haldol	PS			TABLET	

Date:03/12/04ISR Number: 4317509-1Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20040301628
Age:50 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Delusion	Health Professional	Haldol Decanoate (Haloperidol Decanoate) Injection	PS			SEE IMAGE	
			Risperdal (Risperidone)	C				

Date:03/12/04ISR Number: 4317533-9Report Type:Expedited (15-DaCompany Report #USA-2004-0013319
Age:49 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Aortic Atherosclerosis	Health	Oxycodone					

Blood Chloride Decreased	Professional	Hydrochloride		
Blood Glucose Decreased	Other	(Similar To Nda		
Blood Potassium Increased		20-553) (Oxycodone		
Blood Sodium Increased		Hydrochloride)	PS	
Blood Urea Increased		Lidocaine		
Coma		(Lidocaine)	SS	
Coronary Artery Disease		Citalopram(Citalopra		
Hypertension		m)	SS	
Overdose		Haloperidol(Haloperi		
Pulmonary Congestion		dol)	SS	
Renal Cyst		Trazodone		
Skin Injury		(Trazodone)	SS	
		Buspiron(Hyoscine		
		Butylbromide,		
		Metamizole Sodium		
		Monohydrate)	SS	

Date:03/15/04ISR Number: 4318389-0Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20040301598
Age:35 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Condition Aggravated	Foreign	Haldol (Haloperidol)					
	Neutropenia	Health	Unspecified	PS		ORAL	10 MG, 1 IN1	
	Psychiatric Symptom	Professional						

DAY, ORAL; 30

MG, 1 IN 1

DAY, ORAL; 20

MG, 1 IN 1

Tavor (Lorazepam) C

Date:03/15/04ISR Number: 4318390-7Report Type:Expedited (15-DaCompany Report #JP-JNJFOC-20040301111
Age:52 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide Intentional Self-Injury	Foreign Health Professional	Risperdal (Risperidone) Unspecified	PS		ORAL	2 MG, IN 1 DAY, ORAL	
			Haloperidol (Haloperidol) Unspecified	SS		ORAL	12 MG, IN 1 DAY, ORAL; 10 MG, IN 1 DAY, ORAL	
			Zotepine (Zotepine) Tablets	SS		ORAL	40 MG, IN 1 DAY, ORAL; 20 MG, IN 1 DAY, ORAL; 25 MG, IN 1 DAY,	
			Biperiden (Biperidine) Powder	C				
			Trihexyphenidyl (Trihexyphenidyl) Powder	C				
			Lormetazepam (Lormetazepam) Unspecified	C				
			Flunitrazepam (Flunitrazepam)					

				Unspecified	C		

Date:03/15/04ISR Number: 4318391-9Report Type:Expedited (15-DaCompany Report #AT-JNJFOC-20031105292
Age:49 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Atrioventricular Block Blood Pressure Increased Cardiomyopathy Alcoholic	Foreign Health Professional Other	Haldol (Haloperidol) Unspecified	PS		INTRAVENOUS	20 MG, IN 1 DAY, INTRAVENOUS	
			Catapresan (Clonidine) Unknown	SS			0.67 MG/HR	
			Dormicum (Midazolam Maleate)	C				
			Losec (Omeprazole)	C				
			Augmentin (Clavulin)	C				
			Lovenox (Heparin-Fraction, Sodium Salt)	C				
			Bevitol (Thiamine Hydrochloride) Ampoules	C				

Date:03/15/04ISR Number: 4318392-0Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20040301472
Age:46 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Death	Haematocrit Decreased	Foreign	Haldol (Haloperidol)				
Hospitalization - Initial or Prolonged	Neoplasm Patient Restraint Platelet Count Decreased Pulmonary Embolism	Health Professional	Unspecified	PS		ORAL	16 MG, 1 IN 1 DAY, ORAL
			Clexane (Heparin-Fraction, Sodium Salt)	C			
			Rocephin (Ceftriaxone Sodium)	C			
			Ciprobay (Ciprofloxacin Hydrochloride)	C			
			Lasix (Furosemide)	C			
			Faustin (Diazepam)	C			
			Orfiril (Valproate Sodium)	C			

Date:03/15/04ISR Number: 4318393-2Report Type:Expedited (15-DaCompany Report #FR-JNJFOC-20040301529
Age:43 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Agitation Depressed Level Of Consciousness Lung Disorder Neuroleptic Malignant Syndrome	Foreign Health Professional Other	Haldol (Haloperidol) Unspecified	PS			IN 1 DAY
			Tegretol (Carbamazepine)	SS		ORAL	IN 1 DAY, ORAL
			Tercian (Cyamemazine)	SS			IN 1 DAY
			Tranxene (Clorazepate Dipotassium)	SS			IN 1 DAY
			Parkinane (Trihexyphenidyl				

Hydrochloride)	C
Lepticur (Tropatepine Hydrochloride)	C
Alepsal (Alepsal)	C

Date:03/16/04ISR Number: 4319236-3Report Type:Expedited (15-DaCompany Report #200313851GDS
Age:56 YR Gender:Female I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Alanine Aminotransferase Increased
	Aspartate Aminotransferase Increased
	Blood Albumin Decreased
	Blood Alkaline Phosphatase Increased
	Blood Chloride Decreased
	Blood Creatine Phosphokinase Increased
	Blood Lactate Dehydrogenase Decreased
	Blood Potassium Decreased

	Blood Pressure Diastolic Decreased					
	Blood Sodium Decreased	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
	Blood Uric Acid Increased	Foreign	Bayaspirin			
	C-Reactive Protein Increased	Literature Health Professional	(Acetylsalicylic Acid)	PS		
	Dermatitis Bullous		Cravit			
	Gamma-Glutamyltransferase Increased	Other	(Levofloxacin)	SS		
	Haematocrit Decreased		Tienam	SS		
	Haemoglobin Decreased		Serenace (Haloperidol)	SS		
	Laboratory Test Abnormal		Gramalil (Tiapride Hydrochloride)	SS		
	Lipase Increased		Atarax-P (Hydroxyzine Hydrochloride)	SS		
	Nikolsky'S Sign		Mucosta (Rebmipide)	SS		
	Protein Total Decreased		Lasix (Furosemide)	SS		
	Pruritus		Mannitol	SS		
	Pyrexia		Warfarin	SS		
	Rash Papular		Digosin (Digoxin)	SS		
	Red Blood Cell Count Decreased		Aldactone-A (Spironolactone)	SS		
	Skin Ulcer		Gaster (Famotidine)	SS		
	Toxic Epidermal Necrolysis		Eruodin (Estazolam)	SS		
			Dalacin (Clindamycin Hydrochloride)	SS		
			Loxonin (Loxoprofen Sodium)	C		
			Foipan	C		
			Hitropen (Uncodeable "Unclassifiable")	C		
			.....	C		
			.....	C		
			.....	C		
			Selbex (Teprenone)	C		
			Foipan (Camostat Mesilate)	C		

Date:03/16/04ISR Number: 4319911-0Report Type:Expedited (15-DaCompany Report #2004UW01599
Age:44 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Agitation	Health	Seroquel	PS		ORAL	25 MG DAILY	
Hospitalization -	Blood Creatine	Professional					PO	
Initial or Prolonged	Phosphokinase Increased		Seroquel	SS		ORAL	50 MG DAILY	
Required	Confusional State						PO	
Intervention to	Dehydration		Seroquel	SS		ORAL	100 MG DAILY	
Prevent Permanent	Drug Withdrawal Syndrome						PO	
Impairment/Damage	Dyspnoea		Haldol "Janssen"	SS			INTRAMUSCULAR	1 MG ONCE IM
	Hypotension		Benzodiazepine	SS				
	Muscle Rigidity		Mellaril	C				
	Neuroleptic Malignant		Trilafon	C				
	Syndrome		Triavil	C				
	Renal Failure		Xanax	C				
	Restlessness							
	Sepsis							
	Temperature Regulation							
	Disorder							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/17/04ISR Number: 4318933-3Report Type:Direct Company Report #CTU 214543
Age:51 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required	Clonus		Risperidone 0.25 Mg	PS		ORAL	PO BID	
Intervention to	Hyperreflexia						STARTED	
Prevent Permanent	Hypertonia						BEFORE 3/1/04	
Impairment/Damage	Muscle Spasticity						UNTIL 3/8	
	Neuroleptic Malignant		Haloperidol 5 Mg	SS				
INTRAMUSCULAR	ONE TIME IM							
	Syndrome		Valprolic Acid	C				
	Tardive Dyskinesia		Venlapaxine	C				
			Tamsulosin	C				
			Furosemide	C				
			Kcl	C				
			Sorbitol	C				

Date:03/17/04ISR Number: 4320318-0Report Type:Expedited (15-DaCompany Report #SE-JNJFOC-20040300010
Age:54 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Anaemia	Foreign	Haldol (Haloperidol)	PS		ORAL	IN 1 DAY,	
Initial or Prolonged	Colitis Ulcerative	Health					ORAL	
	Crohn'S Disease	Professional						
	Infection							
	Inflammatory Bowel							
	Disease							

Date:03/19/04ISR Number: 4322427-9Report Type:Expedited (15-DaCompany Report #2004203561JP
Age:10 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Drug Eruption	Foreign	Luvox(Fluvoxamine					

Initial or Prolonged		Health	Maleate) Tablet	PS			ORAL
75 MG/DAY,							
		Professional					
ORAL							
		Other	Solanax(Alprazolam) Tablet	SS			ORAL
0.8 MG/DAY,							
ORAL							
			Serenace(Haloperidol)	SS			ORAL
30 MG/DAY,							
ORAL							
			Neuleptil(Periciazine)	SS			ORAL
5 MG/DAY,							
ORAL							
			Tegretol(Carbamazepine)	SS			ORAL
200 MG/DAY,							
ORAL							

Date:03/19/04ISR Number: 4322678-3Report Type:Expedited (15-DaCompany Report #AU-JNJFOC-20040201902
Age:53 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Alanine Aminotransferase Increased	Foreign Health	Risperdal Consta (Risperidone)					
	Depression	Professional	Microspheres	PS				
INTRAMUSCULAR							25 MG,	1 IN 2
	Mutism	Company						
WEEK,								
	Refusal Of Treatment By	Representative						
INTRAMUSCULAR								
	Patient		Haldol Decanoate (Haloperidol					
	Tardive Dyskinesia		Decanoate) Injection	SS				
	Treatment Noncompliance							

				Mirtazepine (Mirtazapine)			
				Unspecified	SS		ORAL
30 MG, IN 1 DAY, ORAL							
				Valproate (Valproate Sodium)	C		
				Atorvastatin	C		
				Benztropine (Benzatropine Mesilate)	C		

Date:03/22/04ISR Number: 4320890-0Report Type:Expedited (15-DaCompany Report #PHRM2004FR00610
Age:52 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Agranulocytosis		Melleril	PS	Novartis Sector:			
Hospitalization -	Anaemia				Pharma	ORAL	60 mg	1440 MIN
Initial or Prolonged	Dyspnoea		Melleril	SS	Novartis Sector:			
	Febrile Bone Marrow				Pharma	ORAL	80 mg	1440 MIN
	Aplasia		Melleril	SS	Novartis Sector:			
	Pneumonia Pneumococcal				Pharma	ORAL	27 mg	1440 MIN
	Pneumonia Staphylococcal		Haldol					
	Pyrexia		"Janssen-Cilag"	SS		ORAL	4.5 mg	1440 MIN
			Haldol					
			"Janssen-Cilag"	SS		ORAL	9 mg	1440 MIN
			Haldol					
			"Janssen-Cilag"	SS		ORAL	3 mg	1440 MIN
			Imovane	C				

Date:03/22/04ISR Number: 4320904-8Report Type:Expedited (15-DaCompany Report #PHRM2004FR01167
Age:43 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Hospitalization - Initial or Prolonged Other	Agitation Blood Creatine Phosphokinase Increased C-Reactive Protein Increased	Tegretol	PS	Novartis Sector: Pharma	ORAL ORAL ORAL	5760 MIN 5760 MIN
	Depressed Level Of Consciousness Heart Rate Increased Lung Disorder Neuroleptic Malignant Syndrome Pyrexia Somnolence White Blood Cell Count Increased	Haldol "Janssen" Tercian Tranxene Parkinane Lepticur Alepsal Levomepromazine	SS SS SS SS SS SS C		ORAL ORAL ORAL ORAL ORAL ORAL	

Date:03/23/04ISR Number: 4323654-7Report Type:Expedited (15-DaCompany Report #FR-JNJFOC-20040204308
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Pharmaceutical Product Complaint Tendon Injury	Foreign Health Professional	Haldol Decanoas (Haloperidol Decanoate) Injection	PS		INTRAMUSCULAR INTRAMUSCULAR	1 ML,	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/23/04ISR Number: 4323657-2Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20040301472
Age:46 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Aggression	Foreign	Haldol (Haloperidol)					
Hospitalization - Initial or Prolonged	Agitation	Health	Unspecified	PS		ORAL	16 MG, IN 1	DAY,
	Haematocrit Decreased	Professional						
	Platelet Count Decreased		Haldol (Haloperidol)	SS		INTRAVENOUS	5 MG, IN 1	DAY,
	Pulmonary Embolism							
			Clexane (Heparin-Fraction, Sodium Salt)	C		INTRAVENOUS;		2.5-5MG
			Rocephin (Ceftriaxone Sodium)	C				
			Ciprobay (Ciprofloxacin Hydrochloride)	C				
			Lasix (Furosemide)	C				
			Faustan (Diazepam)	C				
			Orfiril (Valproate Sodium)	C				
			Lasix (Furosemide)	C				

Date:03/23/04ISR Number: 4323823-6Report Type:Expedited (15-DaCompany Report #2004-01086
Age:34 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Interaction Potentiation	Literature Health	Chlorpromazine Hydrochloride (Watson Laboratories)					
	Pulmonary Eosinophilia	Professional	(Chlorpromazine Diphenhydramine (Watson Laboratories)	PS	Watson Laboratories			

			(Diphenhydramine Hydrochloride)	SS	Watson Laboratories	ORAL
25 MG, DAILY, ORAL						
			Haloperidol (Watson Laboratories) (Haloperidol) Tablet	SS	Watson Laboratories	ORAL
15 MG, DAILY, ORAL						
			Valproic Acid (Valproic Acid)	SS		ORAL
1500 MG, DAILY, ORAL						
			Fluphenazine (Fluphenazine)	SS		

Date:03/25/04ISR Number: 4327893-0Report Type:Expedited (15-DaCompany Report #FR-JNJFOC-20040201939
Age:36 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anorexia Blood Creatine Phosphokinase Increased	Foreign Health Professional	Haldol (Haloperidol) Injection	PS		INTRAMUSCULAR	INTRA-MUSCULAR	
	Drug Interaction Extrapyramidal Disorder	Other	Haldol (Haloperidol) Solution	SS		ORAL	ORAL	
			Haldol (Haloperidol)					

				Tablets	SS		ORAL
ORAL							
				Depamide (Valpromide)	SS		
				Hept-A-Myl (Heptaminol Hydrochloride)	C		
				Noctamide (Lormetazepam)	C		
				Valium (Diazepam)	C		
				Parkinane Lp (Trihexyphenidyl Hydrochloride)	C		
				"Noctran" (Aceprometazine)	C		

Date:03/25/04ISR Number: 4327897-8Report Type:Expedited (15-DaCompany Report #CH-JNJFOC-20040302678
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Blood Ph Decreased	Health	Haldol (Haloperidol)			
	Drug Interaction	Professional	Injection	PS		
INTRAVENOUS 5 MG, 2 IN 1						
	Respiratory Failure	User Facility				
DAY,						
	Sleep Apnoea Syndrome	Other				
INTRAVENOUS						
			Talofen (Promazine Hydrochloride) Injection	SS		
INTRAMUSCULAR 50 MG, IN 1						
DAY,						
INTRA-MUSCULA						
R						
			Lithiofor. (Lithium Sulfate) Tablets	C		
			Risperidal (Risperidone) Tablets	C		
			Efexor (Venlafaxine Hydrochloride) Tablets	C		

Date:03/25/04ISR Number: 4328056-5Report Type:Expedited (15-DaCompany Report #2004203561JP
Age:10 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Eruption Pyrexia	Foreign Health Professional	Luvox (Fluvoxamine Maleate) Tablet	PS		ORAL	75 MG/DAY,	ORAL
		Other	Solanax (Alprazolam) Tablet	SS		ORAL	0.8 MG/DAY,	ORAL
			Serenace (Haloperidol)	SS		ORAL	3 MG/DAY,	ORAL
			Neuleptil (Periciazine)	SS		ORAL	5 MG/DAY,	ORAL
			Tegretol (Carbamazepine)	SS		ORAL	200 MG/DAY,	ORAL

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/26/04ISR Number: 4325315-7Report Type:Direct Company Report #CTU 215347
Age:31 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Creatinine Increased Body Temperature Decreased Dystonia Eye Rolling Gaze Palsy Hyperhidrosis Hyperreflexia Muscle Rigidity Oculogyration Opisthotonus Renal Failure Risus Sardonicus Sinus Tachycardia		Haloperidol	PS				

Date:03/29/04ISR Number: 4329920-3Report Type:Expedited (15-DaCompany Report #FR-JNJFOC-20040303048
Age:31 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dystonia Gaze Palsy Trismus	Foreign Health Professional	Haldol (Haloperidol) Injection	PS		SUBCUTANEOUS	5 MG, IN 1 DAY,	
			Profenid (Ketoprofen)	C		SUBCUTANEOUS		
			Perfalgan (All Other Therapeutic Products)	C				
			Zophren (Ondansetron Hydrochloride)	C				
			Celebrex 200 (Celecoxib)	C				
			Fragmine (Heparin-Fraction, Sodium Salt)	C				

Date:03/30/04ISR Number: 4332594-9Report Type:Expedited (15-DaCompany Report #FR-JNJFOC-20040303092
Age:24 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dystonia Medication Error Speech Disorder Torticollis	Foreign Health Professional	Haldol (Haloperidol) Tablets	PS		ORAL ORAL		

Date:03/30/04ISR Number: 4332601-3Report Type:Expedited (15-DaCompany Report #FR-JNJFOC-20040303272
Age:82 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Asthenia Dilatation Ventricular Gait Disturbance	Foreign Health Professional	Haldol (Haloperidol) Unspecified	PS		ORAL	6 MG, IN 1 DAY, ORAL	

Date:03/30/04ISR Number: 4332602-5Report Type:Expedited (15-DaCompany Report #FR-JNJFOC-20040303948
Age:37 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Blood Thyroid Stimulating Hormone Decreased	Foreign Health Professional	Haldol (Haloperidol) Unspecified	PS		ORAL		
Hospitalization - Initial or Prolonged	C-Reactive Protein Increased		Nozinan (Levomepromazine)	SS		ORAL		
	Drug Interaction		Vancomycine (Vancomycin)	SS		INTRAVENOUS	INTRAVENOUS	
	Joint Effusion							
	Pneumonia Streptococcal		Rifadine (Rifampicin)	SS		INTRAVENOUS	1200 MG, IN 1 DAY,	
	Sudden Death							
	Thyroxine Increased							
	Tri-Iodothyronine							
	White Blood Cell Count Decreased		Skenan Lp (Morphine Sulfate)	C				
			Mopral 20 (Omeprazole)	C				
			Avlocardyl 40 (Propranolol)	C				
			Speciafoldine (Folic Acid)	C				
			Deroxat (Paroxetine Hydrochloride)	C				
			Tranxelene 20 (Clorazepate Dipotassium)	C				
			Lexomil (Bromazepam)	C				
			Neo-Mercazole (Carbimazole)	C				

Date:03/31/04ISR Number: 4328095-4Report Type:Expedited (15-DaCompany Report #JP-ROCHE-362831
Age:62 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hyperthermia Malignant	Health	Dormicum	PS	Roche	INTRAVENOUS		

Professional DRIP
2 DAY

Serenase SS
INTRAVENOUS
DRIP
2 DAY

Solinase C
INTRAVENOUS
DRIP
1 DAY

Heparin C
INTRAVENOUS DOSE REPORTED

AS 3000 DAILY 32 DAY

Morphine
Hydrochloride C
INTRAVENOUS 32 DAY

Lidocaine
Hydrochloride C
INTRAVENOUS 32 DAY

Nicardipine
Hydrochloride C
INTRAVENOUS
DRIP
32 DAY

Date:04/01/04ISR Number: 4330371-6Report Type:Direct Company Report #CTU 215755
Age:15 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Cogwheel Rigidity		Metoclopramide 10 Mg	PS		ORAL	10 MG QID	
	Eye Movement Disorder							
	Hypertonia		Haloperidol 5mg	SS		ORAL	5MG BID ORAL	
	Sensory Loss		Catapress Patch	C				
	Tremor		Diazepam	C				

				Flovent	C		
				Lactulose	C		
				Methadone Taper	C		
				Miralax	C		
				Mycostatin	C		
				Pepcid	C		

Date:04/01/04ISR Number: 4333066-8Report Type:Expedited (15-DaCompany Report #S04-USA-00578-01
Age:36 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Alkaline Phosphatase Increased	Health Professional	Lexapro (Escitalopram)	PS		ORAL	20 MG QD PO	
	Hepatitis	Company	Clozapine	SS			650 MG QD	
	Jaundice	Representative	Haldol	SS			2 MG Q4HR	
	Protein Total Decreased		Prevacid (Lansoprazole)	C				
			Ferrous Sulfate	C				
			Surfak (Docusate Calcium)	C				

Date:04/07/04ISR Number: 4334716-2Report Type:Direct Company Report #CTU 216098
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Liver Function Test		Haloperidol 1 Mg	PS		INTRAVENOUS	1 MG EVERY 2 HOURS	
	Abnormal Neuroleptic Malignant Syndrome					INTRAVENOUS		
	Pyrexia							
	Renal Impairment							

Date:04/07/04ISR Number: 4338061-0Report Type:Expedited (15-DaCompany Report #FR-JNJFOC-20040305858
Age:84 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Interaction	Foreign	Haldol (Haloperidol)	PS		ORAL	ORAL	IN 1 DAY,
	Extrapyramidal Disorder	Health	Tiapridal (Tiapride)	SS		ORAL	ORAL	
	Hepatitis	Professional						
			Aricept (Donepezil Hydrochloride)	C				

Date:04/07/04ISR Number: 4338062-2Report Type:Expedited (15-DaCompany Report #ES-JNJFOC-20040305389
Age:78 YR Gender:Male I/FU:I

Outcome	PT
Death	Blood Creatine Phosphokinase Increased
Hospitalization - Initial or Prolonged	Blood Creatine Phosphokinase Mb Increased
	Blood Creatinine Increased
	Blood Urea Increased
	Coagulopathy
	Leukocytosis
	Neuroleptic Malignant

		Syndrome Prothrombin Time Prolonged					
			Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
			Foreign Health Professional	Haloperidol (Haloperidol)	PS		
INTRAVENOUS	5 MG, 1 IN 1 DAY,						
				Furosemide Inibsa (Furosemide) Ampoules	C		
				Tavanic (Levofloxacin) Solution	C		
				Acfol (Folic Acid) Tablets	C		
				Zyloric (Allopurinol) Tablets	C		
				Babonal (Analapril Maleate) Tablets	C		

Date:04/08/04ISR Number: 4337859-2Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20040303271
Age:41 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Death	Blood Cholesterol Increased Myocardial Infarction	Foreign Health Professional	Risperdal (Risperidone) Microspheres	PS		
INTRAMUSCULAR	50 MG, 1 IN 2 WEEK, INTRA-MUSCULA R	Sudden Death				
			Haldol Decanoate (Haloperidol Decanoate) Injection	SS		
INTRAMUSCULAR	100 MG, INTRA-MUSCULA					

R

			Quetiapine	C		

Date:04/08/04ISR Number: 4338026-9Report Type:Expedited (15-DaCompany Report #K200400466
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Abdominal Wall Anomaly	Foreign	Methimazole Tablets,					
Disability	Antibody Test Abnormal	Literature	Usp (Methimazole)					
Congenital Anomaly	Caesarean Section	Health	Tablet, 40mg	PS		TRANSPLACENTAL	40 MG, QD,	
Required	Developmental Delay	Professional				TRANSPLACENTA		
Intervention to	Exomphalos	Other				L		
Prevent Permanent	Hypokinesia		Propranolol					
Impairment/Damage	Maternal Drugs Affecting		(Propranolol) 20mg	SS		TRANSPLACENTAL	20 MG, QD,	
	Foetus					TRANSPLACENTA		
	Premature Baby					L		
	Premature Separation Of Placenta		Haloperidol (Haloperidol)					
	Skin Malformation		Unknown, 10mg	SS		TRANSPLACENTAL	10 MG, QD,	
	Treatment Noncompliance					TRANSPLACENTA		
	Twin Pregnancy					L		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/09/04ISR Number: 4338804-6Report Type:Expedited (15-DaCompany Report #JP-JNJFOC-20040400845
Age:52 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Death	Foreign Health Professional	Rispedral (Risperidone) Unspecified	PS			2 MG, IN 1	DAY
			Halomonth (Haloperidol Decanoate) Injection	SS				

Date:04/09/04ISR Number: 4342125-5Report Type:Periodic Company Report #03P-163-0231324-00
Age:34 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Alanine Aminotransferase Increased	Health Professional	Depakote (Divalproex Sodium) (Divalproex					
	Aspartate Aminotransferase Increased	Company Representative	Sodium)	PS			2 GM	
			Trileptal (Oxcarbazepine)	SS			300 MG, AT	BEDTIME
	Blood Alkaline Phosphatase Increased		Seroquel (Quetiapine)	SS			600 MG, AT	BEDTIME
	Blood Sodium Decreased		Haldol (Haloperidol)	SS			10 MG, 1 IN 1	D
	Condition Aggravated							
	Night Sweats							
	Oedema							
	Overdose							
	Vomiting							
	Weight Increased							

Date:04/12/04ISR Number: 4339214-8Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20040401010
Age:71 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blood Creatinine Abnormal Lactic Acidosis	Health Professional	Haldol (Haloperidol) Unspecified	PS			25 MG, 1 IN 4	HOUR
			Vancomycin	C				
			Albuterol (Salbutamol)	C				
			Atrovent (Ipratropium Bromide)	C				
			Hydrocortisone	C				
			Flonase (Fluticasone Propionate)	C				

Date:04/12/04ISR Number: 4339219-7Report Type:Expedited (15-DaCompany Report #2004030019
Age:33 YR Gender:Male I/FU:I

Outcome	PT
Life-Threatening Hospitalization - Initial or Prolonged	Blood Pressure Systolic Decreased Body Temperature Decreased Cardiac Disorder Electrocardiogram Abnormal

	Electrocardiogram Q Waves						
	Electrocardiogram T Wave Inversion	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Head Injury	Foreign	Doral (Quazepam)	PS		ORAL	15 MG DAILY
	Hypoxia	Health					PO
	Oxygen Saturation Decreased	Professional Other	Perspirone Hcl Hydrate	SS		ORAL	8 MG DAILY PO
	Pulmonary Embolism		Haloperidol				
	Refusal Of Treatment By		(Haloperidol)	SS		ORAL	3 MG DAILY PO
	Patient		Olanzepine (Olanzapine)	SS		ORAL	5 MG DAILY PO
			Senosides (Senna Fruit)	C			
			Biperiden Hcl (Biperiden Hydrochloride)	C			
			Berizym	C			

Date:04/12/04ISR Number: 4339543-8Report Type:Expedited (15-DaCompany Report #NO-JNJFOC-20040400306
Age:89 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Death	Arrhythmia	Foreign	Haldol (Haloperidol)				
	C-Reactive Protein Increased	Health Professional	Injection	PS		INTRAVENOUS	INTRAVENOUS (NOT
	Cardiac Arrest						OTHERWISE
	Haemoglobin Decreased						SPECIFIED)
	Respiratory Arrest		Morphine (Morphine)	C			
	Ventricular Tachycardia		Acetylsalisylacid (Acetylsalicylic Acid)	C			
			Enoxaparin (Heparin-Fraction, Sodium Salt)	C			

Glycerol Trinitrate (Glyceryl Trinitrate)	C
Finasterid (Finasteride)	C
N Acetylcystein (Acetylcysteine)	C
Digitoksin (Digitoxin)	C
Furosemid (Furosemide)	C
Lisinopril (Lisinopril)	C

Date:04/14/04ISR Number: 4338501-7Report Type:Expedited (15-DaCompany Report #JP-GLAXOSMITHKLINE-B0327362A
Age:62 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Creatine Phosphokinase Increased	Health Professional	Valtrex	PS	Glaxosmithkline	ORAL	1000MG Three times per day	7 DAY
	Blood Creatine Phosphokinase Mb Increased Renal Disorder		Trihexyphenidyl Hydrochloride	SS		ORAL		
			Haloperidol	SS		ORAL		
			Chlorpromazine Hydrochloride	SS	Glaxosmithkline	ORAL		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/15/04ISR Number: 4340092-1Report Type:Direct Company Report #CTU 216715
Age:52 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Electrocardiogram Qt		Haloperidol	PS		INTRAVENOUS	5 MG PER HR	
Hospitalization -	Corrected Interval					INTRAVENOUS		
Initial or Prolonged	Prolonged		Metoprolol	SS		INTRAVENOUS	5MG Q8H PRN	
	Ventricular Tachycardia					INTRAVENOUS		
			Cozaar	C				
			Tylenol	C				
			Thiamine	C				
			Mvi	C				
			Ativan	C				
			Protonix	C				
			Primaxin	C				
			Phenergan	C				
			Cardizem	C				
			Combivent	C				
			Norcuron	C				
			Mag And K Replacement	C				
			Precedex	C				
			Tpn	C				
			Vit K	C				
			Solumedrol	C				
			Morphine	C				
			Vasotec	C				
			Insulin	C				

Date:04/15/04ISR Number: 4341482-3Report Type:Expedited (15-DaCompany Report #930812-107030646
Age:23 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardiomyopathy	Health Professional	Haldol (Haloperidol)	PS			10 MG, 2 IN 1 DAY	
			Lithium	C				
			Clonidine	C				

			Clonazepam	C		

Date:04/16/04ISR Number: 4340037-4Report Type:Expedited (15-DaCompany Report #JP-ROCHE-362831
Age:61 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Hyperthermia Malignant		Dormicum	PS	Roche	INTRAVENOUS DRIP	1	DAY
			Dormicum	SS	Roche	INTRAVENOUS DRIP	2	DAY
			Serenase	SS		INTRAVENOUS DRIP	2	DAY
			Solinase	C		INTRAVENOUS DRIP	1	DAY
			Heparin	C		INTRAVENOUS	1	DAY
			Morphine Hydrochloride	C		INTRAVENOUS	6	DAY
			Lidocaine Hydrochloride	C		INTRAVENOUS	1	DAY
			Nicardipine Hydrochloride	C		INTRAVENOUS DRIP	32	DAY
			Vecuronium Bromide	C		INTRAVENOUS	1	DAY

			Ceftriaxone Sodium	C		
INTRAVENOUS						DRIP
CONTINUOUS	15 DAY					

Date:04/19/04ISR Number: 4344406-8Report Type:Expedited (15-DaCompany Report #FR-JNJFOC-20040400987
Age:22 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization - Initial or Prolonged	Confusional State Hypertonia	Foreign Health Professional	Haldol (Haloperidol) Injection	PS		
INTRAMUSCULAR	5 MG/ML, 2 IN 1 DAY,					
	Rhabdomyolysis Somnolence					
INTRA-MUSCULAR						
			Tercian (Cyamemazine)	SS		
INTRAMUSCULAR	50 MG, 2 IN 1 DAY,					
INTRA-MUSCULAR						
			Imovane (Zopiclone)	C		
			Depakote (Valoproate Semisodium)	C		
			Atarax (Hydroxyzine Hydrochloride)	C		
			Rivotril (Clonazepam)	C		
			Lepticur (Tropatepine Hydrochloride)	C		

Date:04/19/04ISR Number: 4344439-1Report Type:Expedited (15-DaCompany Report #FR-JNJFOC-20040303948
Age:37 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Drug Interaction	Foreign	Haldol (Haloperidol)	PS		ORAL		
Hospitalization - Initial or Prolonged	General Physical Health Deterioration	Health Professional	Nozinan (Levomepromazine)	SS		ORAL		
	Joint Effusion		Vancomycine (Vancomycin)	SS		INTRAVENOUS	INTRAVENOUS	
	Lung Disorder		Rifadine (Rifampicin)	C		INTRAVENOUS	1200 MG, IN 1	DAY,
	Purulence							
	Streptococcal Infection							
	Sudden Death							
			Skenan Lp (Morphine Sulfate)	C				
			Mopral 20 (Omeprazole)	C				
			Avlocardyl 40 (Propranolol)	C				
			Speciafoldine (Folic Acid)	C				
			Deroxat (Paroxetine Hydrochloride)	C				
			Tranxelene 20 (Clorazepate Dipotassium)	C				
			Lexomil (Bromazepam)	C				
			Neo-Mercazole (Carbimazole)	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/20/04ISR Number: 4344792-9Report Type:Expedited (15-DaCompany Report #2004024540
Age:61 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dialysis Gait Disturbance Nephritis Rhabdomyolysis	Foreign Health Professional	Lipitor (Atorvastatin)	PS		ORAL	20 MG	(DAILY), ORAL
			Tiapride Hydrochloride (Tiapride Hydrochloride)	SS		ORAL	80 MG	(DAILY), ORAL
			Haloperidol (Haloperidol)	SS		ORAL	ORAL	
			Flunitrazepam (Flunitrazepam)	SS		ORAL	2 MG (DAILY),	ORAL
			Troxipide (Troxipide)	C				
			All Other Therapeutic Products (All Other Therapeutic Products)	C				
			Ethyl Loflazepate (Ethyl Loflazepate)	C				
			Mazaticol Hydrochloride (Mazaticol Hydrochloride)	C				
			Magnesium Oxide (Magnesium Oxide)	C				
			All Other Therapeutic Products (All Other Therapeutic Products)	C				
			Nicergoline (Nicergoline)	C				

			All Other Therapeutic Products (All Other Therapeutic Products)	C			

Date:04/20/04ISR Number: 4345152-7Report Type:Expedited (15-DaCompany Report #ES-JNJFOC-20040305389
Age:78 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death Hospitalization - Initial or Prolonged	Coagulopathy Neuroleptic Malignant Syndrome	Foreign Health Professional	Haloperidol (Haloperidol) Unspecified	PS		INTRAVENOUS	5 MG, 1 IN 1 DAY,	
			Furosemide Inibsa (Furosemide)			INTRAVENOUS		
			Ampoules	C				
			Tavanic (Levofloxacin)	C				
			Acfol (Folic Acid)	C				
			Zyloric					

			(Allopurinol)	C			
			Dabonal (Enalapril Maleate)	C			

Date:04/20/04ISR Number: 4345155-2Report Type:Expedited (15-DaCompany Report #FR-JNJFOC-20040401607
Age:72 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Pressure Increased C-Reactive Protein Increased	Foreign Health Professional	Haldol Faible (Haloperidol) Solution	PS			0.5MG/ML	
	Confusional State Diarrhoea Drug Interaction		Laroxyl (Amitriptyline Hydrochloride)	SS		ORAL	ORAL	
	Pyrexia		Stablon (Tianeptine)	SS		ORAL	ORAL	
	Serotonin Syndrome		Solian (Amisulpride)	SS		ORAL	ORAL	
	Tongue Biting		Efferalgan Codeine (Panadeine Co)	SS		ORAL	ORAL	
			Temesta (Lorazepam)	SS		ORAL	ORAL	
			Parkinane Lp (Trihexyphenidyl Hydrochloride)	SS		ORAL	ORAL	
			Effexor (Venlafaxine Hydrochloride)	SS		ORAL	ORAL	
			Avlocardyl (Propranolol)	C				
			Plavix (Clopidogrel Sulfate)	C				
			Sermion (Nicergoline)	C				
			Stagid (Metformin Embonate)	C				

Date:04/22/04ISR Number: 4347986-1Report Type:Expedited (15-DaCompany Report #2004209255JP
Age:50 YR Gender:Male I/FU:I

Outcome	Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Death			Blood Pressure Decreased	Foreign	Halcion (Triazolam)			
			Cardiac Arrest	Health	Tablet	PS		ORAL
ORAL								
			Cardiac Failure	Professional	Serenace			
			Heart Rate Decreased	Other	(Haloperidol)	SS		
INTRAVENOUS		IV						
			Pulmonary Infarction		Dormicum "Roche"			
			Shock		(Midazolam Maleate)	SS		
INTRAVENOUS		IV						
					Buscopan (Hyoscine Butylbromide)	C		
INTRAVENOUS		IV						
					Carteolol (Carteolol)	C		
					Proternol(Isoprenaline Hydrochloride)	C		
					Dobutamine Hydrochloride (Dobutamine Hydrochloride)	C		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/26/04ISR Number: 4345976-6Report Type:Expedited (15-DaCompany Report #FR-JNJFOC-20040404877
Age:35 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Drug Screen Positive		Haldol	PS		OROPHARINGEAL		

Date:04/26/04ISR Number: 4346201-2Report Type:Expedited (15-DaCompany Report #NO-JNJFOC-20040400306
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Arrhythmia		Haldol	PS		INTRAVENOUS		
	Cardiac Arrest		Haldol	SS		INTRAVENOUS		
	Haemoglobin Decreased		Acetylsalisylacid	C		OROPHARINGEAL		
	Respiratory Arrest		Glycerol Trinitrate	C		TRANSDERMAL		
	Ventricular Tachycardia		N Acetylcystein	C		OROPHARINGEAL		
			Furosemid	C		OROPHARINGEAL		
			Metoprolol	C		OROPHARINGEAL		
			Lisinopril	C		OROPHARINGEAL		
			Digitoksin	C		OROPHARINGEAL		
			Finasterid	C		OROPHARINGEAL		
			Enoxaparin	C		INTRAVENOUS		
			Morphine	I		UNKNOWN		

Date:04/26/04ISR Number: 4349359-4Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20040404515
Age:55 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Hospitalization - 2 MG	Contusion	Foreign	Haldol (Haloperidol)	PS	
Initial or Prolonged	Electrocardiogram St Segment Depression	Health Professional	Truxal (Chlorprothixene Hydrochloride)	SS	
SEE IMAGE	Syncope				
	Ventricular Hypertrophy		Delix (Ramipril)	SS	
SEE IMAGE	Vertigo Positional		Dytide H (Dyazide) Tablets	SS	
0.5 DOSE (S)			Lasix (Furosemide)	SS	
40 MG			Leponex (Clozapine)	SS	
SEE IMAGE			Effortil (Drops) Etilefrine Hydrochloride	C	

Date:04/26/04ISR Number: 4349362-4Report Type:Expedited (15-DaCompany Report #ES-JNJFOC-20040403947
Age:74 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Delirium	Foreign	Haldol (Haloperidol) Solution	PS		ORAL	15 DOSE (S),	IN 1 DAY,
Other	Drug Ineffective	Health Professional						
	Extrapyramidal Disorder							
	Restlessness							
ORAL								
			Disgren (Triflusal)	C				
			Propanolol (Propranolol)	C				
			Lorazepam (Lorazepam)	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/26/04ISR Number: 4349364-8Report Type:Expedited (15-DaCompany Report #FR-JNJFOC-20040404036
Age:15 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Dyskinesia Torticollis Urinary Retention	Foreign Health Professional	Haldol (Haloperidol) Solution	PS		ORAL	2.5 MG, IN 1 DAY, ORAL
			Theralene (Alimemazien Tartrate)	SS		ORAL	50 MG, IN 1 DAY, ORAL
			Anafranil (Clomipramine Hydrochloride)	SS		ORAL	75 MG, IN 1 DAY, ORAL
			Tercian (Cyamemazine)	C		ORAL	100 DOSE(S), IN 1 DAY, ORAL
			Rivotril (Clonazepam)	C			
			Lexomil (Bromazepam)	C			

Date:04/26/04ISR Number: 4349739-7Report Type:Expedited (15-DaCompany Report #2004025317
Age:25 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged Other	Aggression Amnesia Anxiety Catatonia Coma	Consumer	Antivert (Meclizine) Lorazepam (Lorazepam) Haloperidol	PS SS		ORAL	100 MG (QID), ORAL

	Confusional State		(Haloperidol)	SS	
	Convulsion				
	Delirium				
	Delusion				
	Drug Ineffective				
	Hallucination				
	Restlessness				

Date:04/27/04ISR Number: 4347761-8Report Type:Expedited (15-DaCompany Report #200410851DE
Age:55 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Circulatory Collapse		Lasix	PS	Aventis Pharmaceuticals Inc.			
	Contusion							
	Dizziness		Delix	SS		ORAL		
	Drug Interaction		Leponex	SS		ORAL	dose: UP TO 225MG	
	Ventricular Hypertrophy							
			Truxal	SS				
			Haldol	SS				
			Dytide H	SS				

Date:04/27/04ISR Number: 4349044-9Report Type:Direct Company Report #CTU 217418
Age:36 YR Gender:Female I/FU:I

Outcome
Life-Threatening
Other

Required Intervention to Prevent Permanent Impairment/Damage	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Neuroleptic Malignant Syndrome		Haloperidol 10 Mg Im	PS		INTRAMUSCULAR	10 MG IM	
			Geodon 20 Mg Im	SS		INTRAMUSCULAR	20 MG IM	
			Risperal M Tabs	C				
			Haldol	C				
			Ablitify	C				

Date:04/27/04ISR Number: 4351146-8Report Type:Expedited (15-DaCompany Report #FR-JNJFOC-20040404877
Age:35 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Toxicologic Test Abnormal	Foreign Health Professional	Haldol (Haloperidol) Tablets	PS		ORAL	ORAL	

Date:04/27/04ISR Number: 4351148-1Report Type:Expedited (15-DaCompany Report #NO-JNJFOC-20040400306
Age:89 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardiac Arrest Respiratory Arrest Ventricular Tachycardia	Foreign Health Professional	Haldol (Haloperidol) Injection	PS		INTRAVENOUS	INTRAVENOUS	
			Morphine (Morphine)	SS				
			Acetylsalicylic Acid (Acetylsalicylic Acid)	C				
			Enoxaparin (Heparin-Fraction, Sodium Salt)	C				
			Glycerol Trinitrate (Glyceryl Trinitrate)	C				
			Finasterid (Finasteride)	C				
			N Acetylcystein					

			(Acetylcysteine)	C		
			Digitoksin (Digitoxin)	C		
			Furosemid (Furosemide)	C		
			Lisinopril (Lisinopril)	C		
			Metoprolol (Metoprolol)	C		

Date:04/28/04ISR Number: 4349117-0Report Type:Expedited (15-DaCompany Report #JP-JNJFOC-20040405408
Age:49 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Abnormal Behaviour		Haldol Decanoate	PS		OROPHARINGEAL		
	Catatonia		Haldol	SS		OROPHARINGEAL		
	Dysuria		Haldol	SS		OROPHARINGEAL	10-12mg daily	
	Gaze Palsy		Biperiden	C		OROPHARINGEAL		
	Hyperhidrosis							
	Mutism							
	Oculogyration							
	Staring							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/28/04ISR Number: 4349392-2Report Type:Expedited (15-DaCompany Report #JP-GLAXOSMITHKLINE-B0327362A
Age:62 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Blood Creatine Phosphokinase Increased		Valtrex	PS	Glaxosmithkline	ORAL	1000MG Three times per day 7 DAY
	Renal Disorder		Trihexyphenidyl Hydrochloride	SS		ORAL	1U Twice per day
			Haloperidol	SS		ORAL	1U Twice per day
			Chlorpromazine Hydrochloride	SS	Glaxosmithkline	ORAL	1U Three times per day

Date:04/28/04ISR Number: 4352243-3Report Type:Expedited (15-DaCompany Report #FR-JNJFOC-20040201242
Age:69 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Death Life-Threatening Hospitalization - Initial or Prolonged	Abdominal Distension Drug Interaction Flatulence Tachycardia	Foreign Health Professional	Haldol (Haloperidol) Unspecified	PS		ORAL	10 MG, IN 1 DAY, ORAL
			Sintrom (Acenocoumarol)	SS		ORAL	4 MG, ORAL
			Augmentin (Clavulin)	SS			3 G, IN 1 DAY
			Fraxiparine (Heparin-Fraction, Calcium Salt)	SS			SUBCUTANEOUS 0.6 ML, 2 IN 1 DAY,

SUBCUTANEOUS

			Deroxat (Paroxetine Hydrochloride)	SS		ORAL

40 MG, 1 IN 1

DAY, ORAL

Date:04/28/04ISR Number: 4352244-5Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20040405187
Age:69 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Life-Threatening	Aphasia	Foreign	Haldol (Haloperidol)			
	Balance Disorder	Health	Unspecified	PS		

Dose: 2.5-5MG AS NECESSARY

	Blood Pressure Systolic Increased	Professional	Lorazepam (Lorazepam)	SS		ORAL

Dose: 1 MG, IN 1 AS NECESSARY,ORAL

	Depressed Level Of Consciousness		Levothyroxine Sodium (Levothyroxine Sodium)	C		
	Drug Interaction		Warfarin (Warfarin)	C		
	Glasgow Coma Scale Abnormal		Paracetamol (Paracetamol)	C		
	Hyperhidrosis					
	Hyperreflexia					
	Hypertonia					
	Mania					
	Muscle Rigidity					
	Pupillary Reflex Impaired					

Date:04/28/04ISR Number: 4352433-XReport Type:Expedited (15-DaCompany Report #US-JNJFOC-20040204503
Age:38 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Drug Toxicity	Health Professional	Haloperidol Decanoate (Haloperidol Deconoate) Injection	PS		INTRAMUSCULAR	200 MG, 1IN 2	WEEK,

INTRA-MUSCULA

R

Date:04/29/04ISR Number: 4349781-6Report Type:Expedited (15-DaCompany Report #BR-JNJFOC-20040405556
Age:17 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Feeding Disorder		Haldol Decanoate	PS		INTRAMUSCULAR		
	Medication Error		Fenergan	C				
	Muscle Rigidity							
	Renal Disorder							
	Salivary Hypersecretion							
	Tremor							
	Urinary Incontinence							

Date:04/29/04ISR Number: 4350041-8Report Type:Expedited (15-DaCompany Report #PHNU2004DE01565
Age:55 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Pressure Decreased		Leponex / Clozaril (Clozapine)	PS	Novartis Sector: Pharma	ORAL	up to 225	
	Circulatory Collapse						mg/day	
	Contusion							
	Dizziness							
	Dizziness Postural		Leponex / Clozaril					

		Drug Interaction Echocardiogram Abnormal	(Clozapine)	SS	Novartis Sector: Pharma	ORAL
between 100 and 375 mg/day	44640MIN	Fall Syncope Ventricular Hypertrophy	Leponex / Clozaril (Clozapine)	SS	Novartis Sector: Pharma	ORAL
up to 400mg/day			Leponex / Clozaril (Clozapine)	SS	Novartis Sector: Pharma	ORAL
300mg/day			Truxal	SS		ORAL
100mg/day	2880 MIN		Truxal	SS		ORAL
50 to 60mg/day	8640 MIN		Truxal	SS		ORAL
40mg/day	5760 MIN		Haldol "Janssen-Cilag"	SS		ORAL
2mg/day			Delix	SS		ORAL
5mg/day			Delix	SS		ORAL
3.75mg/day	5760 MIN		Dytide H	SS		ORAL
.5 DF, QD			Lasix /Swe/	SS		ORAL
40 mg, QD						

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/29/04ISR Number: 4350100-XReport Type:Expedited (15-DaCompany Report #ES-GLAXOSMITHKLINE-B0328812A
Age:43 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anxiety		Lamotrigine	PS	Glaxosmithkline	ORAL	50MG Per day	
	Blood Creatine Phosphokinase Increased		Haloperidol	SS				
	Confusional State		Lithium	C	Glaxosmithkline			
	Diarrhoea		Mirtazapine	C				
	Nervousness		Diazepam	C				
	Neuroleptic Malignant Syndrome		Venlafaxine	C				
	Rash Macular		Tranxilium	C				

Date:04/29/04ISR Number: 4353050-8Report Type:Expedited (15-DaCompany Report #2004AP02282
Age:83 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	C-Reactive Protein Increased	Foreign Health	Iressa	PS		ORAL	250 MG DAILY PO	
	Chest X-Ray Abnormal	Professional	Flomox	SS		ORAL	300 MG DAILY PO	
	Eosinophil Count Increased	Other	Serenace	SS		ORAL	1.5 MG DAILY PO	
	Lung Infiltration							
	Productive Cough		Durotep Janssen	SS			2.5 MG DAILY	
			Radiation Therapy	C				

Date:04/29/04ISR Number: 4353063-6Report Type:Expedited (15-DaCompany Report #JP-JNJFOC-20040405408
Age:49 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Catatonia	Foreign	Haldol Decanoate					

	Dysuria	Literature	(Haloperidol			
	Hyperhidrosis	Health	Decanoate)	PS		ORAL
50 MG, 1 IN 4						
	Inappropriate Affect	Professional				
WEEK, ORAL						
	Micturition Urgency		Haldol (Haloperidol)	SS		
10-12 MG						
	Mutism					
DAILY						
	Oculogyration		Biperiden			
	Staring		(Biperiden)	C		

Date:04/30/04ISR Number: 4353667-0Report Type:Expedited (15-DaCompany Report #2004203561JP
Age:10 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Drug Eruption	Foreign	Luvox (Fluvoxamine			
Initial or Prolonged	Lymphocyte Stimulation	Health	Maleate) Tablet	PS		ORAL
75 MG/DAY,						
	Test Positive	Professional				
ORAL						
	Pyrexia	Other	Solanax (Alprazolam)			
			Tablet	SS		ORAL
0.8 MG/DAY,						
ORAL						
			Serenace(Haloperidol			
			)	SS		ORAL
3 MG/DAY,						
ORAL						
			Neuleptil			
			(Periciazine)	SS		ORAL
5MG/DAY, ORAL						
			Tegretol			
			(Carbamazepine)	SS		ORAL
200 MG/DAY,						
ORAL						

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/30/04ISR Number: 4353829-2Report Type:Expedited (15-DaCompany Report #BR-JNJFOC-20040405556
Age:17 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Medication Error	Foreign Health Professional	Haldol Decanoate (Haloperidol Decanate) Injection	PS		INTRAMUSCULAR	INTRA-MUSCULAR	
	Muscle Rigidity							
	Oral Intake Reduced							
	Renal Disorder							
	Salivary Hypersecretion		Fenergan (Promethazine)	C				
	Tremor							
	Urinary Incontinence							

Date:05/04/04ISR Number: 4352610-8Report Type:Expedited (15-DaCompany Report #ES-JNJFOC-20040403947
Age:74 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Abnormal Behaviour		Haldol	PS		OROPHARINGEAL	7-0-8	
Other	Delirium		Haldol	SS		OROPHARINGEAL		
	Extrapyramidal Disorder		Disgren	C			1-0-1	
	Insomnia		Propanolol	C				
	Muscle Rigidity		Lorazepam	C			1-0-0	
	Restlessness							

Date:05/04/04ISR Number: 4355295-XReport Type:Expedited (15-DaCompany Report #200303125
Age:19 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Alcohol Use	Foreign Health Professional Other	Tylenol Analgesic (Acetaminophen)	PS		ORAL	PO	
	Intentional Misuse							
	Somnolence		Metamizole	SS				
	Suicide Attempt		Prometazine	SS				
			Midazolam	SS				
			Haloperidol	SS				

			Alcohol	SS		

Date:05/05/04ISR Number: 4355898-2Report Type:Expedited (15-DaCompany Report #ES-JNJFOC-20040403947
Age:74 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Abnormal Behaviour	Foreign	Haldol (Haloperidol)					
Other	Aggression	Health	Solution	PS		ORAL	15 DOSE (S),	
	Delirium	Professional					IN 1 DAY,	
	Extrapyramidal Disorder						ORAL	
	Insomnia		Haladol					
	Muscle Rigidity		(Haloperidol)					
	Psychomotor Hyperactivity		Solution	C				
	Restlessness		Disgren (Triflusal)	C				
			Propanolol (Propranolol)	C				
			Lorazepam (Lorazepam)	C				

Date:05/06/04ISR Number: 4354635-5Report Type:Direct Company Report #CTU 218024
Age: Gender:Female I/FU:I

Outcome
Life-Threatening
Hospitalization -

Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Neuroleptic Malignant Syndrome		Seroquel 100 Mg (Astra Zeneca)	PS	Astra Zeneca	ORAL	100 MG PO TID	
			Haldol 2 Mg Tab (Geneva); 5 Mg/Ml Vial American Pharmaceutical Partner	SS	American Pharmaceutical Partner	ORAL	2 MG PO X 1, 2 MG IM X 1	
			Neurontin	C				
			Albuterol	C				
			Vitamin C	C				
			Aspirin	C				
			Ativan	C				
			Avelox	C				
			Colace	C				
			Duragesic	C				
			Lidaderm Patch	C				
			Myticon	C				
			Calcium	C				
			Prevacid	C				
			Synthroid	C				
			Mvi	C				
			Toprol Xl	C				
			Ultram	C				
			A & D	C				
			Zocor	C				
			Ambien	C				
			Catapres	C				
			Imodium	C				
			Minalax	C				
			Mom	C				
			Senokot	C				
			Tylenol	C				

Date:05/06/04ISR Number: 4356284-1Report Type:Expedited (15-DaCompany Report #2004024540
Age:61 YR Gender:Male I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Alanine Aminotransferase Increased
	Aspartate Aminotransferase Increased
	Basophil Count Increased
	Blood Alkaline Phosphatase Increased
	Blood Chloride Decreased
	Blood Cholesterol Increased
	Blood Lactate Dehydrogenase Increased
	Blood Potassium Increased
	Blood Pressure Increased
	Blood Sodium Increased
	Convulsion

Eosinophil Count Increased Gait Disturbance	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Gamma-Glutamyltransferase Increased Haemodialysis	Foreign Health Professional	Lipitor (Atorvastatin)	PS		ORAL	20 MG (BID), ORAL
Haemoglobin Decreased Head Injury Lymphocyte Count Decreased Monocyte Count Decreased		Tiapride Hydrochloride (Tiapride Hydrochloride)	SS		ORAL	80 MG (DAILY), ORAL
Neutrophil Count Increased Platelet Count Decreased		Haloperidol (Haloperidol)	SS		ORAL	8 MG (DAILY), ORAL
Pneumonia Red Blood Cell Count Decreased		Flunitrazepam (Flunitrazepam)	SS		ORAL	2 MG (DAILY), ORAL
Renal Failure Acute Rhabdomyolysis White Blood Cell Count Increased		Neostigmine (Neostigmine)	SS		ORAL	5 MG (DAILY), ORAL
		Ethyl Loflazepate (Ethyl Loflazepate)	C			
		Magnesium Oxide (Magnesium Oxide)	C			
		Nicergoline (Nicergoline)	C			
		Verapamil Hydrochloride (Verapamil Hydrochloride)	C			
		Trihexyphenidyl Hydrochloride (Trihexyphenidil Hydrochloride)	C			
		Anethole Trithione (Anethole Trithione)	C			

Ubidecarenone (Ubidecarenone)	C
Cisapride (Cisapride)	C
Aniracetam (Aniracetam)	C
Profenamine (Profenamine)	C
Vitamedin ((Cyanocobalamin, Pyridoxine Hydrochloride, Thiamine Disulfide)	C
Nifedipine (Nifedipine)	C
Sulpiride (Sulpiride)	C
Marzulene S (Levoglutamide, Sodium Gualenate)	C
Diazepam (Diazepam)	C
Bifemelane Hydrochloride (Bifemelane Hydrochloride)	C

			Troxipide (Troxipide)	C		

Date:05/06/04ISR Number: 4356639-5Report Type:Expedited (15-DaCompany Report #04P-062-0258916-00
Age:43 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Life-Threatening Hospitalization - Initial or Prolonged	Alcohol Poisoning Loss Of Consciousness Overdose Respiratory Failure Suicide Attempt	Foreign Health Professional	Akineton (Biperiden) (Biperiden)	PS		ORAL TABLET, 1-2 TABLETS DAILY, PER ORAL
			Haldol 5	SS		ORAL 100 MG ONCE, PER ORAL
			Carbamazepine	SS		ORAL 450 MG, PER ORAL
			Lorazepam	SS		ORAL 1.5 TABLET, PER ORAL
			Ethanol	SS		ORAL 0.7 LIT, PER ORAL

Date:05/06/04ISR Number: 4357310-6Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20040106022
Age:79 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Death Hospitalization - Initial or Prolonged	Agitation Depressed Level Of Consciousness	Consumer	Haldol (Haloperidol) Unspecified	PS		55 MG

	Hypoxic Encephalopathy					
	Labile Hypertension					
	Lacunar Infarction					
	Pneumonia					
	Respiratory Failure					
	White Blood Cell Count Increased					

Date:05/06/04ISR Number: 4357421-5Report Type:Expedited (15-DaCompany Report #FRWYE722426APR04
Age:72 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Confusional State	Health Professional	Effexor (Venlafaxine Hydrochloride)	PS		ORAL	2 DOSE 1X PER 1 DAY	1 YR
	Diarrhoea							
	Hypertension	Other						
	Medication Error		Efferalgan Codeine (Paracetamol/Codeine Phosphate)	SS		ORAL	1 DOSE 1X PER 1 DAY	
	Pyrexia							
	Serotonin Syndrome							
	Tongue Biting		Haldol (Haloperidol)	SS		ORAL	1 DOSE 1X PER 1 DAY	
			Laroxyl (Amitriptyline Hydrochloride)	SS		ORAL	1 DOSE 1X PER 1 DAY	
			Parkinane (Trihexyphenidyl, Tablet)	SS		ORAL	1 DOSE 1X PER 1 DAY	
			Solian (Amisulpride)	SS		ORAL	1 DOSE 1X PER 1 DAY	
			Stablon (Tianeptine, Tablet)	SS		ORAL	3 DOSE 1X PER 1 DAY	

			Temesta (Lorazepam, Tablet, 0)	SS		ORAL

Date:05/07/04ISR Number: 4356810-2Report Type:Expedited (15-DaCompany Report #04P-056-0254196-00
Age:22 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anorexia Asthenia Confusional State Cytolytic Hepatitis Rhabdomyolysis Somnolence Thrombocytopenia	Foreign Health Professional	Depakote (Divalproex Sodium) (Divalproex Sodium)	PS		ORAL	2 DOSAGE FORMS, 1 IN 1 D, PER ORAL	
			Haloperidol	SS		INTRAMUSCULAR	5 MG, 2 IN 1 D,	
			Cyamemazine	SS		INTRAMUSCULAR	50 MG, 2 IN 1 D,	
			Clonazepam Zoplicone Tropatepine Hydrochloride	C C C		INTRAMUSCULAR		

Date:05/10/04ISR Number: 4358354-0Report Type:Expedited (15-DaCompany Report #FRWYE731529APR04
Age:65 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Disability	Disease Progression Drug Effect Decreased Extrapyramidal Disorder	Health Professional	Effexor (Venlafaxine Hydrochloride, Tablet, 0)	PS		ORAL	SEE IMAGE,	

Major Depression

ORAL

Haldol (Haloperidol, 0)	SS	ORAL	150 MG 1 X PER 1 DAY,
Ditropan (Oxybutynin)	C	ORAL	
Actonel (Risedronate)	C		
Calcium With Vitamin D (Calcium/Phosphate/Calcium Lactate/Ergocalcifer	C		

Date:05/11/04ISR Number: 4358108-5Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20040301472
Age:46 YR Gender:Male I/FU:F

Outcome	PT
Death	Biopsy Bone Marrow Abnormal
Hospitalization - Initial or Prolonged	Bone Disorder
	Cardiac Disorder
	Dementia Alzheimer'S Type
	Disease Progression
	Disease Recurrence
	Haematocrit Decreased
	Haemorrhage

		Hepatic Congestion Hyperaemia Osteoporosis	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
		Pancreatic Disorder	Foreign	Haldol (Haloperidol)	PS		ORAL
SEE IMAGE							
		Platelet Count Decreased	Health	Haldol (Haloperidol)	SS		ORAL
ORAL							
		Pulmonary Artery Thrombosis Pulmonary Congestion Pulmonary Embolism Pulmonary Haemorrhage Pulmonary Necrosis Pulmonary Oedema Renal Disorder Spleen Disorder	Professional	Clexane (Heparin-Fraction, Sodium Salt) Rocephin (Ceftriaxone Sodium) Ciprobay (Ciprofloxacin Hydrochloride) Lasix (Furosemide) Faustan (Diazepam) Orfiril (Valproate Sodium)	C C C C C		

Date:05/11/04ISR Number: 4358369-2Report Type:Expedited (15-DaCompany Report #04P-056-0259240-00
Age:49 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization - Initial or Prolonged	Confusional State Drug Interaction	Foreign Health Professional Other	Depakote Tablets (Depakote) (Divalproex Sodium) (Divalproex Sodium)	PS		ORAL
500 MG, ORAL						
			Haloperidol (Haloperidol)	SS		ORAL
5 MG, 2 IN 1 D, ORAL						

Date:05/12/04ISR Number: 4359748-XReport Type:Expedited (15-DaCompany Report #DSA_24305_2004
Age:69 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					

Life-Threatening	Balance Disorder	Foreign	Ativan	PS		ORAL
VAR PO						
	Blood Pressure Systolic	Health	Haloperidol	SS		ORAL
VAR PO						
	Increased	Professional	Thyroxine Sodium	C		
	Depressed Level Of	Other	Warfarin	C		
	Consciousness		Tinzaparin Sodium	C		
	Hyperhidrosis		Paracetamol	C		
	Hyperreflexia					
	Hypertonia					
	Mania					
	Muscle Rigidity					
	Pupillary Reflex Impaired					
	Speech Disorder					

Date:05/13/04ISR Number: 4359945-3Report Type:Expedited (15-DaCompany Report #2004AC00102
Age:48 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required	Diabetes Mellitus	Literature	Quetiapine	PS		ORAL	400 MG BID PO	
Intervention to	Drug Effect Decreased	Health	Haloperidol	SS			20 MG DAILY	
Prevent Permanent	Metabolic Acidosis	Professional	Haloperidol	SS			5 MG BID	
Impairment/Damage	Psychotic Disorder							
	Treatment Noncompliance							
	Weight Decreased							
	Weight Increased							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/13/04ISR Number: 4360058-5Report Type:Expedited (15-DaCompany Report #DSA_24340_2004
Age:72 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	C-Reactive Protein Increased	Foreign Health Professional Other	Temesta	PS				
			Effexor	SS		ORAL	2 QD PO	
	Confusional State		Efferalgan Codeine	SS				
	Diarrhoea		Haldol	SS				
	Hypertension		Laroxyl	SS				
	Medication Error		Parkinane	SS				
	Pyrexia		Solian	SS		ORAL	1 QD PO	
	Serotonin Syndrome		Stablon	C		ORAL	3 QD PO	
	Tongue Biting		Alvocardyl	C				
			Plavix	C				
			Sermion	C				
			Stagid	C				

Date:05/14/04ISR Number: 4359814-9Report Type:Expedited (15-DaCompany Report #FR-JNJFOC-20040500722
Age:39 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Thrombocytopenia	Foreign Health Professional	Haldol Decanoas (Haloperidol Decanoate) Injection	PS		INTRAMUSCULAR	INTRA-MUSCULAR	
			Lepticur (Tropatepine Hydrochloride) Capsules	SS		ORAL	1 DOSE(S), IN 1 DAY,	ORAL
			Rebetol (Ribavirin)	SS		ORAL	800 MG, IN 1 DAY,	ORAL
			Pegasys (All Other Non-Therapeutic					

			Products)	SS			
SUBCUTANEOUS 90 MG, IN 1 DAY, SUBCUTANEOUS							
			Nozinan (Levomepromazine)	SS			ORAL
50 MG, IN 1 DAY, ORAL							

Date:05/17/04ISR Number: 4359120-2Report Type:Direct Company Report #CTU 218744
Age:77 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Hypoxia		Zyprexa (Zydis) 5 Mg	PS		ORAL	2.5 MG PO	
Hospitalization -	Livedo Reticularis						BID; 25 MG PO	
Initial or Prolonged	Neuroleptic Malignant						QHS; 5 MG PO	
Required	Syndrome						PRN	
Intervention to Prevent Permanent			Haldol 5 Mg/Ml Injections	SS			INTRAVENOUS 1MG IV Q4HOUR	
Impairment/Damage							PRN; 1MG IV Q8HOUR PRN; 2 MG IV Q6HOUR PRN; 2MG IV	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/18/04ISR Number: 4359751-XReport Type:Periodic Company Report #FR-JNJFOC-20031005438
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agitation	Health	Haldol Decanoas	PS		INTRAMUSCULAR		
	Parkinsonism	Professional	Haldol Decanoas	SS		INTRAMUSCULAR		
			Depo-Provera	C		INTRAMUSCULAR	1 dose = 1 vial	
			Tercian	C				

Date:05/19/04ISR Number: 4360128-1Report Type:Expedited (15-DaCompany Report #JP-JNJFOC-20040502773
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Interaction		Risperdal	PS		OROPHARINGEAL		
	Dysphagia		Haloperidol	SS		OROPHARINGEAL		
			Trihexyphenidyl Hydrochloride	C		OROPHARINGEAL		

Date:05/19/04ISR Number: 4363982-2Report Type:Expedited (15-DaCompany Report #FR-JNJFOC-20031005438
Age:43 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agitation	Foreign	Haldol Decanos (Haloperidol Decanoate) Injection	PS		INTRAMUSCULAR	50 MG, 1 IN 30 DAY,	
	Parkinsonism	Health				INTRA-MUSCULAR; SEE IMAGE		
		Professional						

			Depo-Provera (Medroxyprogesterone Acetate)	C		
			Tercian (Cyamemazin)	C		

Date:05/20/04ISR Number: 4365931-XReport Type:Expedited (15-DaCompany Report #JP-JNJFOC-20040502773
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Aphagia	Foreign	Risperdal					
	Areflexia	Health	(Risperidone)					
	Drug Interaction	Professional	Unspecified	PS		ORAL	ORAL	
			Haloperidol (Haloperidol)					
			Unspecified	SS		ORAL	ORAL	
			Trihexyphenidyl Hydrochloride	C				

Date:05/25/04ISR Number: 4370642-0Report Type:Expedited (15-DaCompany Report #FR-JNJFOC-20040502491
Age:74 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agitation	Foreign	Haldol (Haloperidol)					
	Confusional State	Health	Unspecified	PS		ORAL	ORAL	
	Convulsion	Professional	Danoil (Glibenclamide)					
	Delusion							
	Drug Interaction		Unknown	SS		ORAL	ORAL	
	Hallucination, Visual		Sintrom (Acenocoumarol)					
	Phlebitis			SS		ORAL	ORAL	

				Cisplatin (Cisplatin) Injection	SS		
INTRAVENOUS	140 MG, IN 1 DAY, INTRAVENOUS						
				Actiskenan (Morphine Sulfate)	SS		ORAL
ORAL				'Alimta' (Pemetrexed) Injection	SS		
INTRAVENOUS	950 MG, IN 1 DAY, INTRAVENOUS						

Date:05/25/04ISR Number: 4370643-2Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20040503080
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Accidental Overdose	Foreign	Haldol (Haloperidol)					
	Convulsion	Health Professional	Solution	PS			0.5 ML; 5 ML, 1 IN 1 TOTAL	

Date:05/25/04ISR Number: 4370644-4Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20040501769
Age:31 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Interaction	Foreign	Halperidol					
	Hallucination	Health Professional	(Haloperidol) Unspecified	PS			2.5-5MG/DAY	
	Neuroleptic Malignant Syndrome		Clozaril (Clozapine)	SS		ORAL	75 MG, IN 1	

	Treatment Noncompliance					
DAY, ORAL						
	Urinary Incontinence		Amisulpride			
	Urinary Tract Infection		(Amisulpride)	SS		ORAL
400 MG, 2 IN						
1 DAY, ORAL						
			Sodium Valproate			
			(Valproate Sodium)	C		
			Procyclidine			
			(Procyclidine)	C		
			Lorazepam			
			(Lorazepam)	C		

Date:05/26/04ISR Number: 4365978-3Report Type:Expedited (15-DaCompany Report #200411900FR
Age:74 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Agitation		Daonil	PS	Aventis	
Initial or Prolonged	Confusional State				Pharmaceuticals Inc.	ORAL
	Convulsion		Cisplatine	SS		
INTRAVENOUS						
	Delirium		Haldol	SS		ORAL
	Hallucination, Visual		Sintrom	SS		ORAL
	Phlebitis		Actiskenan	SS		ORAL
			Alimta	SS		
INTRAVENOUS						

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/26/04ISR Number: 4366382-4Report Type:Direct Company Report #CTU 219464
Age:22 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Drug Ineffective		Haloperidol 10 Mg	PS		INTRAMUSCULAR	10 MG IM	
	Dyspnoea							
	Joint Stiffness							
	Stridor							

Date:05/26/04ISR Number: 4372395-9Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20040502860
Age:62 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dialysis	Foreign	Haldol-Janssen					
	Drug Interaction	Health	(Haloperidol)					
	Neuroleptic Malignant	Professional	Unspecified	PS		ORAL	6 MG, IN 1	
	Syndrome							DAY, ORAL
	Renal Failure Acute		Zeldox (Ziprasidone					
	Rhabdomyolysis		Hydrochloride)	SS		ORAL	ORAL	

Date:05/26/04ISR Number: 4372396-0Report Type:Expedited (15-DaCompany Report #JP-JNJFOC-20040502773
Age: Gender: I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Interaction	Foreign	Risperdal					
	Dysphagia	Health	(Risperidone)					
		Professional	Unspecified	PS		ORAL	ORAL	
			Haloperidol (Haloperidol)					
			Unspecified	SS		ORAL	ORAL	
			Triheyphenidyl Hydrochloride (Trihexyphenidyl					
			Hydrochloride)	C				

			Vegetamin A (Vegetamin A)	C		

Date:05/26/04ISR Number: 4372398-4Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20040502855
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Coordination Abnormal Drug Interaction Dysarthria	Foreign Health Professional	Haldol-Janssen (Haloperidol) Unspecified	PS		
5 MG, IN 1 DAY, UNKNOWN						
			Clomipramin (Clomipramine)	C		
			Maprotilin (Maprotiline)	C		
			Lithium (Lithium)	C		

Date:05/27/04ISR Number: 4366024-8Report Type:Expedited (15-DaCompany Report #US-BRISTOL-MYERS SQUIBB COMPANY-12588455
Age:54 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Agitation Drug Interaction Paranoia	Health Professional	Aripiprazole	PS	Otsuka Pharmaceutical Company, Ltd.	ORAL

				Aripiprazole	I	Otsuka Pharmaceutical Company, Ltd.	ORAL
				Haloperidol Decanoate	I		
INTRAMUSCULAR							

Date:05/27/04ISR Number: 4367012-8Report Type:Direct Company Report #CTU 219690
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Disability	Bruxism		Melarill	PS			PILLS, DAILY	
	Dyskinesia		Perlixine	SS				
	Dyspnoea		Haldol	SS				
	Feeling Abnormal		Stelazine	SS				
	Muscle Disorder		Thorazine	SS				
	Panic Reaction		Benadryl	C				

Date:05/27/04ISR Number: 4369510-XReport Type:Expedited (15-DaCompany Report #KII-1999-0000817
Age:74 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Abdominal Pain	Health Professional Company Representative	Oxycontin Tablets (Oxycodone Hydrochloride) Cr Tablet	PS			SEE IMAGE	
	Asthenia							
	Chest Pain							
	Condition Aggravated							
	Confusional State		Oxyfast Concentrate 20 Mg/Ml (Oxycodone Hydrochloride) Oral Solution	SS			2 ML, SEE TEXT	
	Dehydration							
	Dyspnoea							
	Hypotension							
	Lethargy							
	Neoplasm Malignant		Benadryl (Diphenhydramine Hydrochloride)	SS			RECTAL	RECTAL
			Ativan (Lorazepam)	SS			RECTAL	RECTAL

			Haldol (Haloperidol)	SS		
RECTAL	RECTAL					
			Restoril (Temazepam)	SS		
RECTAL	RECTAL					

Date:05/27/04ISR Number: 4369622-0Report Type:Expedited (15-DaCompany Report #USA040259861
Age:58 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Glucose Increased	Health Professional	Zyprexa-Oral (Olanzapine)					
Other	Weight Increased		(Olanzapine)	PS			30 MG/1 AT	
			Haldol (Haloperidol)	SS			BEDTIME	
			Lipitor (Atorvastatin)	SS				
			Benadryl (Diphenhydramine Hydrochloride)	C				
			Toprol Xl (Metoprolol Succinate)	C				
			Zoloft (Sertraline Hydrochloride)	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/28/04ISR Number: 4366771-8Report Type:Expedited (15-DaCompany Report #JP-JNJFOC-20040505939
Age:42 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blood Cholesterol		Haldol Decanoate	PS		INTRAMUSCULAR		
	Increased		Sultopride	SS				
	Blood Triglycerides Increased		Biperiden	SS				
	Diabetes Mellitus							
	Glycosuria							
	Type V Hyperlipidaemia							
	Xanthoma							

Date:05/28/04ISR Number: 4368558-9Report Type:Expedited (15-DaCompany Report #2004AP02282
Age:83 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Chest X-Ray Abnormal	Foreign	Iressa	PS		ORAL	250 MG DAILY	
	Eosinophil Count	Health Professional				PO		
	Increased		Flomox	SS		ORAL	300 MG DAILY	
	Injection Site Reaction	Other				PO		
	Productive Cough		Serenace	SS		ORAL	1.5 MG DAILY	
	Purulence					PO		
	Subcutaneous Abscess		Durotep Janssen	SS			2.5 MG DAILY	
			Radiation Therapy	C				

Date:06/01/04ISR Number: 4367719-2Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20040504633
Age:20 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Interaction		Haloperidol	PS		OROPHARINGEAL		

	Leukocytosis		Clozaril	SS		
OROPHARINGEAL	500 to 450					
	Tachycardia					
mg/day						
	Thrombocythaemia		Procyclidine	C		
OROPHARINGEAL						
			Sertraline	C		
OROPHARINGEAL						
			Diazepam	C		
OROPHARINGEAL						
			Co-Proxamol	C		
OROPHARINGEAL						
			Co-Proxamol	C		
OROPHARINGEAL						
			Diclofenac	C		
OROPHARINGEAL						

Date:06/01/04ISR Number: 4367889-6Report Type:Direct Company Report #CTU 219797
Age:33 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Agitation		Haldol (Peridol	PS		ORAL	20 MG DAILY	
Initial or Prolonged	Hyponatraemia						IN P ORAL	
	Neuroleptic Malignant Syndrome		Zyprexa	C				
	Polydipsia							

Date:06/01/04ISR Number: 4370817-0Report Type:Expedited (15-DaCompany Report #04P-062-0258916-00
Age:43 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Alcohol Poisoning	Foreign	Akineton (Biperiden)					
Hospitalization -	Loss Of Consciousness	Health	(Biperiden)	PS		ORAL	TABLET, 1-2	
Initial or Prolonged	Overdose	Professional					TABLETS	
	Suicide Attempt						DAILY, PER	

			Haldol 5	SS		ORAL
5 MG, 100 TABLETS, ONCE, PER ORAL						
			Carbamazepine	SS		ORAL
450 MG, PER ORAL						
			Lorazepam	SS		ORAL
1.5 TABLET, PER ORAL						
			Ethanol	SS		ORAL
0.7 LIT, PER ORAL						

Date:06/01/04ISR Number: 4370877-7Report Type:Expedited (15-DaCompany Report #JP-JNJFOC-20040505939
Age:42 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Diabetes Mellitus Type V Hyperlipidaemia Xanthoma	Foreign Literature Health Professional	Haldol Decanoate (Haloperidol Decanoate) Injection	PS		INTRAMUSCULAR	INTRA-MUSCULAR	
			Sultopride (Sultopride)	SS				
			Biperiden (Biperiden)	SS				

Date:06/01/04ISR Number: 4370967-9Report Type:Expedited (15-DaCompany Report #2004214720JP
Age:44 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Death	Multiple Drug Overdose	Foreign Literature	Solanax (Alprazolam) Tablet	PS	ORAL
ORAL					
		Health Professional	Halcion (Triazolam) Tablet	SS	ORAL
ORAL					
		Other	Serenace (Haloperidol) Tablet	SS	
			Nozinan (Levomepromazine) Tablet	SS	
			Nifedicor (Nifedipine) Capsule	SS	
			Akineton (Biperiden Hydrochloride, Biperiden Hydrochloride) Tablet	SS	
			Amfetamine (Amfetamine)	C	

Date:06/01/04ISR Number: 4371063-7Report Type:Expedited (15-DaCompany Report #2004024540
Age:61 YR Gender:Male I/FU:I

Outcome	PT
Death	Activated Partial Thromboplastin Time Prolonged
Hospitalization - Initial or Prolonged	Alanine Aminotransferase Increased
Other	Apnoea
	Aspartate

Aminotransferase Increased Basophil Count Increased Blood Calcium Decreased Blood Chloride Abnormal Blood Chloride Decreased Blood Cholesterol Increased Blood Glucose Increased Blood Potassium Abnormal Blood Potassium Decreased Blood Potassium Increased Blood Pressure Diastolic Increased Blood Pressure Systolic Decreased Blood Pressure Systolic Increased Blood Sodium Abnormal Blood Sodium Decreased Blood Triglycerides Increased Blood Uric Acid Abnormal Bradycardia Convulsion Depressed Level Of Consciousness Drug Ineffective Eosinophil Count Increased Gait Disturbance Gamma-Glutamyltransferase Increased Haematocrit Decreased Haemodialysis	Report Source Foreign Health Professional	Product Lipitor (Atorvastatin) Tiapride Hydrochloride (Tiapride Hydrochloride) Haloperidol (Haloperidol) Flunitrazepam (Flunitrazepam) Neostigmine (Neostigmine) Profenamine (Profenamine) All Other Therapeutic Products (All Other Therapeutic Products) Ethyl (Loflazepate (Ethyl Loflazepate) Mazaticol Hydrochloride (Mazaticol	Role PS SS SS SS SS C C	Manufacturer	Route ORAL ORAL ORAL ORAL ORAL

Dose	Duration
10 MG (2 IN 1 D), ORAL 80 MG (DAILY), ORAL 8 MG (DAILY), ORAL 2 MG (DAILY), ORAL 5 MG (DAILY), ORAL 50 MG (3 IN 1 D), ORAL	

Haemoglobin Decreased	Hydrochloride)	C
Head Injury	Magnesium Oxide	
Immune System Disorder	(Magnesium Oxide)	C
Lymphocyte Count	Anethole Trithione	
Decreased	(Anethole Trithione)	C
Monocyte Count Decreased	Cisapiride	
Nephritis	(Cisapiride)	C
Neutrophil Count	Vitamedin	
Increased	Intravenous	
Platelet Count Decreased	(Cyanocobalamin,	
Pneumonia	Pyridoxine	
Protein Total Decreased	Hydrochloride,	C
Prothrombin Time	Nifedipine	
Prolonged	(Nifedipine)	C
Red Blood Cell Count	Sulpiride	
Decreased	(Sulpiride)	C
Renal Failure Acute	Bifemelane	
Rhabdomyolysis	Hydrochloride	
Status Epilepticus	(Bifenmelane	
White Blood Cell Count	Hydrochloride)	C
Increased	Troxipide	
	(Troxipide)	C

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/02/04ISR Number: 4372110-9Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20040504633
Age:20 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Interaction	Foreign	Haloperidol					
	Platelet Count Increased	Health	(Haloperidol)					
	Tachycardia	Professional	Unspecified	PS		ORAL	15 MG, 2 IN 1	DAY, ORAL
	White Blood Cell Count Increased		Clozaril (Clozapine)	SS			500 TO 450	MG/DAY
			Procyclidine (Procyclidine)	C				
			Sertraline (Sertraline)	C				
			Diazepam (Diazepam)	C				
			Co-Proxamol (Aporex)	C				
			Diclofenac (Diclofenac)	C				

Date:06/02/04ISR Number: 4372211-5Report Type:Expedited (15-DaCompany Report #2004AP02772
Age:42 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Blood Glucose Increased	Foreign	Seroquel	PS				
	Glycosuria	Literature	Lodopin	SS				
	Glycosylated Haemoglobin Increased	Health Professional	Barnetil	SS				
	Urine Ketone Body Present	Other	Contomin	SS				
	White Blood Cell Count Increased		Impromen	SS				
	Xanthoma		Akineton	SS				
			Halomonth	SS				

Date:06/02/04ISR Number: 4372441-2Report Type:Expedited (15-DaCompany Report #04P-087-0261443-00
Age:42 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Hospitalization - Initial or Prolonged	Diabetes Mellitus Exercise Lack Of Hyperphagia Inadequate Diet Type V Hyperlipidaemia Xanthoma	Foreign Literature Health Professional	Akineton (Biperiden) (Biperiden) Lodopin (Zotepine) (Zotepine) Quetiapine Sultopride Chlorpromazine Hydrochloried Bromperidol Haloperidol Decanoate	PS SS SS SS SS SS SS		ORAL ORAL ORAL ORAL ORAL ORAL ORAL

INTRAMUSCULAR INTRAMUSCULAR

Date:06/07/04ISR Number: 4375856-1Report Type:Expedited (15-DaCompany Report #JAFRA41859
Age:60 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - Initial or Prolonged	Colitis Pneumatosis Cystoides Intestinalis	Foreign Health Professional	Haldol Decanoas (Haloperidol Decanoate) Injection Hydrate De Chloral (Chloral Hydrate)	PS SS		

Dose	Duration
INTRAMUSCULAR	150 MG, 1 IN 30 DAY, INTRAMUSCULAR 1 DF PER DAY

			Equanil (Meprobamate) Tablets	SS		ORAL	800 MG, IN 1 DAY, ORAL
			Rohypnol (Flunitrazepam) Tablets	SS		ORAL	2 MG, IN 1 DAY, ORAL

Date:06/07/04ISR Number: 4375860-3Report Type:Expedited (15-DaCompany Report #FR-JNJFOC-20040505696
Age:20 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Intentional Misuse Rhabdomyolysis Suicide Attempt	Foreign Health Professional	Haldol Decanoas (Haloperidol Decanoate) Injection	PS			4 DOSE (S), 1 IN 28 DAY
			Tercian (Cyamemazine)	C			

Date:06/07/04ISR Number: 4375861-5Report Type:Expedited (15-DaCompany Report #FR-JNJFOC-20040502491
Age:74 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Convulsion Drug Interaction	Foreign Health Professional	Haldol (Haloperidol) Unspecified	PS		ORAL	ORAL
			Daonil (Glibenclamide)	SS		ORAL	ORAL
			Sintrom (Acenocoumarol)	SS		ORAL	ORAL
			Cisplatin (Cisplatin)				

			Injection	SS		

INTRAVENOUS 140 MG, IN 1

DAY,

INTRAVENOUS;

SEE IMAGE

	Acitskenan (Morphine Sulfate)	SS	ORAL

ORAL

	'Alimta' (Pemetrexed) Injection	SS	

950 MG, IN 1

DAY,

INTRAVENOUS;

SEE IMAGE

Date:06/08/04ISR Number: 4376921-5Report Type:Expedited (15-DaCompany Report #JP-JNJFOC-20040505939
Age:42 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Diabetes Mellitus	Foreign	Haldol Decanoate (Haloperidol Decanoate) Injection	PS		
	Rash Generalised	Literature	Impromen (Bromperidol)	SS		
	Rash Papular	Health	Sultopride (Sultopride)	SS		
	Type V Hyperlipidaemia	Professional	Biperiden (Biperiden)	SS		
	Xanthoma					

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/08/04ISR Number: 4376922-7Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20040502855
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Coordination Abnormal Drug Interaction Dysarthria	Foreign Health Professional	Haldol - Janssen (Haloperidol) Unspecified	 PS			5 MG, IN 1	DAY,
			Clomipramin (Clomipramine)	SS				
			Maprotilin (Maprotiline)	SS				
			Lithium (Lithium)	SS				

Date:06/09/04ISR Number: 4375866-4Report Type:Direct Company Report #CTU 220443
Age:43 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Drug Ineffective Hallucination, Auditory Intentional Self-Injury Pharmaceutical Product Complaint Psychotic Disorder Screaming		Halperadol 100 Mg Weekly Halperadol 100 Mg Weekly	PS SS			100 MIL EVERY 2 WKS 1ST 8 MO 100 MG WEEKLY	

Date:06/10/04ISR Number: 4379183-8Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20040601306
Age:58 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Magnesium Decreased Electrocardiogram Qt Corrected Interval	Literature Health Professional	Haloperidol (Haloperidol) Unspecified	 PS		INTRAVENOUS	340 MG, IN 1	

	Prolonged		
DAY,			
	Torsade De Pointes		
INTRAVENOUS			
	Ventricular Tachycardia		
SEE IMAGE			
		Levofloxacin	C
		Piperacillin-Tazobac tam (Pip/Tazo)	C
		Doxycycline	C
		Midazolam	C
		Morphine	C
		Diltiazem	C
		Enoxaparin (Heparin-Fraction, Sodium Salt)	C
		Famotidine	C
		Metoclopramide	C
		Hydroxychloroquine	C
		Nicotine	C

Date:06/17/04ISR Number: 4379733-1Report Type:Expedited (15-DaCompany Report #ES-GLAXOSMITHKLINE-B0328812A
Age:43 YR Gender:Female I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Anxiety
	Blood Creatine Phosphokinase Increased
	Confusional State

	Diarrhoea						
	Nervousness						
	Neuroleptic Malignant	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Syndrome	Health	Lamotrigine	PS	Glaxosmithkline	ORAL	50MG Per day
	Rash Macular	Professional	Haloperidol	SS			
			Lithium	C	Glaxosmithkline		
			Mirtazapine	C			
			Venlafaxine	C			
			Tranxilium	C			

Date:06/17/04ISR Number: 4382684-XReport Type:Expedited (15-DaCompany Report #JP-JNJFOC-20040602239
Age:29 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Other	Body Temperature	Foreign	Risperdal				
	Increased	Literature	(Risperidone)	PS		ORAL	SEE IMAGE
	Psychomotor Hyperactivity	Health	Haldol (Haloperidol)				
	Pulmonary Thrombosis	Professional	Injection	SS			INTRAVENOUS SEE IMAGE
	Stupor						

Date:06/17/04ISR Number: 4382949-1Report Type:Expedited (15-DaCompany Report #2004-02600
Age:8 DY Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Dyskinesia Neonatal	Literature	Haloperidol (Watson				
	Maternal Drugs Affecting Foetus	Health Professional	Laboratories)(Haloperidol) Tablet	PS		TRANSPLACENTAL	200 MG Q TWO WEEKS VIA MOTHER, TRANSPLACENTAL

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Diabetes Mellitus Type V Hyperlipidaemia Xanthoma	Foreign Literature Health Professional	Akineton (Biperiden) (Biperiden)	PS		ORAL	1 MG, 3 IN 1 D, ORAL	
			Lodopin (Zotepine) (Zotepine)	SS		ORAL	100 MG, 3 IN 1 D; ORAL	
			Quetiapine	SS		ORAL	100 MG, 3 IN 1 D; ORAL	
			Sultopride	SS		ORAL	600 MG, 2 IN 1 D, ORAL	
			Chlorpromazine Hydrochloride	SS		ORAL	100 MG, 3 IN 1 D; ORAL	
			Bromperidol	SS		ORAL	7 MG, 3 IN 1 D; ORAL	
			Haloperidol Decanoate	SS		INTRAMUSCULAR	100 MG, 1 IN 1 M,	INTRAMUSCULAR

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/21/04ISR Number: 4383926-7Report Type:Expedited (15-DaCompany Report #FR-JNJFOC-20040603059
Age:25 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hepatic Steatosis	Foreign Health Professional	Haldol Decanoas (Haloperidol Decanoate) Injection	PS		INTRAMUSCULAR	250 MG , 1 IN	30 DAY,
		Company Representative				INTRA-MUSCULAR		
			Loxapac (Loxapine Succinate)	C				
			Seresta (Oxazepam)	C				

Date:06/22/04ISR Number: 4385125-1Report Type:Expedited (15-DaCompany Report #JP-JNJFOC-20040602712
Age:28 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Convulsion Rhabdomyolysis	Foreign Health Professional	Neoperidol (Haloperidol Decanoate) Injection	PS		INTRAMUSCULAR	50 MG, IN 1	DAY,
						INTRAMUSCULAR		
			Zyprexa (Olanzapine)	SS		ORAL	20 MG, IN 1	DAY, ORAL
			Perospirone (All Other Therapeutic Products)	SS		ORAL	48 MG, 1 IN 1	DAY, ORAL

Date:06/22/04ISR Number: 4420153-9Report Type:Periodic Company Report #US-JNJFOC-20040306055
Age:48 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Convulsion	Consumer	Haldol (Haloperidol)					
	Gait Disturbance		Injection	PS				
INJECTION								
	Joint Stiffness		Mellaril () Thioridazine Hydrochloride	C				

Date:06/22/04ISR Number: 4420283-1Report Type:Periodic Company Report #US-JNJFOC-20040201177
Age:33 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dyskinesia	Consumer	Haldol (Haloperidol)					
	Hallucination		Tablets	PS		ORAL		
ORAL								
	Heart Rate Irregular		Haldol (Haloperidol) Injection	SS				
			Lithium () Lithium	C				
			Benadryl () Diphenydramine Hydrochloride	C				
			Cogentin (Benzatropine Mesilate)	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/22/04ISR Number: 4420290-9Report Type:Periodic Company Report #US-JNJFOC-20040106022
Age:79 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Somnolence	Consumer	Haldol (Haloperidol) Unspecified	PS			55 MG TOTAL	ADMINISTERED ON 21 AND 22-JAN-04

Date:06/22/04ISR Number: 4420311-3Report Type:Periodic Company Report #US-JNJFOC-20040104255
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Neuroleptic Malignant Syndrome	Consumer	Haldol (Haloperidol) Unspecified	PS				
Other			Unspecified Antipsychotic Medications (Antipsychotics)	SS				

Date:06/22/04ISR Number: 4420315-0Report Type:Periodic Company Report #US-JNJFOC-20030904528
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Tardive Dyskinesia	Health Professional Company Representative	Haldol (Haloperidol) Unspecified	PS				

Date:06/22/04ISR Number: 4420319-8Report Type:Periodic Company Report #US-JNJFOC-20030703577
Age:41 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Extrapyramidal Disorder	Consumer	Haldol (Haloperidol)			
	Hallucination		Unspecified	PS		
10 MG, 1 IN 1						
DAY						
			Paxil () Paroxetine Hydrochloride	C		
			Vitamin B12 () Cyanocobalamin	C		

Date:06/22/04ISR Number: 4420324-1Report Type:Periodic Company Report #US-JNJFOC-20030703234
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Convulsion	Consumer	Haldol (Haloperidol)			
	Hallucination		Tablets	PS		
50 MG, 1 IN 1						
DAY						
			Lithium () Lithium	C		
			Thorazine () Chlorpromazine Hydrochloride	C		
			Mellaril (Thioridazine Hydrochloride)	C		
			Prolixin (Fluphenazine			

			Hydrochloride)	C		

Date:06/22/04ISR Number: 4420330-7Report Type:Periodic Company Report #US-JNJFOC-20030604021
Age:88 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Convulsion	Health Professional	Haldol (Haloperidol) Unspecified	PS			5 MG, 1 IN 4	HOUR
			Haldol (Haloperidol) Injection	SS			3 MG, 1 IN 1	DAY
			Lexapro (All Other Therapeutic Products)	SS			10 MG, 1 IN 1	DAY
			Ativan () Lorazepam	C				
			Risperdal (Unspecified)					
			Risperidone	C				
			Vasotec () Enalapril Maleate	C				
			Lopressor (Metoprolol Tartrate)	C				
			Nitro Patch (Glyceryl Trinitrate)	C				
			Hydrodiuril (Hydrochlorothiazide)	C				
			Potassium (Potassium)	C				
			Slow-Mag (Magnesiukm Chloride Anhydrous)	C				
			Premarin (Estrogens Conjugated)	C				
			Synthroid (Levothyroxine					

Sodium)	C
Alphagan (Brimonidine Tartrate)	C
Levaquin (Levofloxacin) Unspecified	C
Lidex (Fluocinonide)	C
Aspirin (Acetylsalicylic Acid)	C
Tylenol (Paracetamol)	C
Vicodin (Vicodin)	C
Protonix (Pantoprazole)	C
Prilosec (Omeprazole)	C
Gaviscon (Gaviscon)	C
Maalox (Maalox)	C
Milk Of Magnesia (Magnesium	

			Hydroxide)	C		
			Theragram (Theragran)	C		
			Vitamin E (Tocopherol)	C		
			Ensure (Ensure)	C		

Date:06/22/04ISR Number: 4420351-4Report Type:Periodic Company Report #US-JNJFOC-20040305129
Age:33 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Neuroleptic Malignant Syndrome	Health Professional	Haldol Decanoate (Haloperidol Decanoate) Injection	PS		INTRAMUSCULAR	150 MG, 1 IN	3 WEE,
			Haldol (Haloperidol) Unspecified	SS		ORAL		
			Prozac () Fluoxetine Hydrochloride	C				

Date:06/22/04ISR Number: 4420442-8Report Type:Periodic Company Report #US-JNJFOC-20040102747
Age:52 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Condition Aggravated	Consumer	Haldol Decanoate (Haloperidol Decanoate) Injection	PS		INTRAMUSCULAR	SEE IMAGE	
			Risperdal (Risperidone) Unspecified	C				
			Cogentin () Benzatropine Mesilate	C				
			Blood Pressure					

Medication (Antihypertensives)	C

Date:06/23/04ISR Number: 4383607-XReport Type:Expedited (15-DaCompany Report #PHNR2004AU00908
Age:45 YR Gender:Male I/FU:F

Outcome	PT
Death	Atrial Flutter
Hospitalization - Initial or Prolonged	Cardiac Failure
	Cellulitis
	Death
	Decreased Appetite
	Difficulty In Walking
	Fall
	Flat Affect
	Gait Disturbance
	Haemoglobin Decreased
	Hypotension
	Injury
	Lobar Pneumonia
	Lymphopenia
	Malaise
	Mycoplasma Infection

		Myocarditis Oxygen Saturation Decreased	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
		Peroneal Nerve Palsy Pyrexia		Clozaril	PS	Novartis Sector: Pharma	
12.5 - 75 mg/day	40320MIN	Restlessness					
		Rib Fracture		Valproate Sodium	SS		
		Somnolence		Efexor	SS		
		Tachycardia		Haloperidol	SS		
		Thrombocytopenia		Lorazepam	SS		
				Olanzapine	SS		
				Benztropine Mesylate	SS		

Date:06/23/04ISR Number: 4384691-XReport Type:Direct Company Report #CTU 221358
Age:49 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization - Initial or Prolonged	Condition Aggravated Drug Ineffective		Haloperidol Decanoate 100 Mg/Ml	PS		
SEE ITEM B.5 PLEASE	Pharmaceutical Product Complaint Psychotic Disorder					

Date:06/23/04ISR Number: 4386263-XReport Type:Expedited (15-DaCompany Report #JP-JNJFOC-20040400845
Age:52 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Death	Death	Foreign Health Professional	Risperdal (Risperidone)	PS		ORAL
2 MG, 1 IN 1 DAY, ORAL						
			Halomouth (Haloperidol Decanoate) Injection	SS		
INTRAMUSCULAR	150 MG, IN 2					

WEEK,

INTRAMUSCULAR

			Psychotropic Agents (Antipsychotics)	C		

Date:06/25/04ISR Number: 4385571-6Report Type:Expedited (15-DaCompany Report #CIO04014606
Age:46 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abnormal Behaviour Adverse Event Emotional Disorder Refusal Of Treatment By Patient	Consumer	Nyquil Cold/Flu Relief Alcohol 10%, Flavor Unknown(Doxylamine Succinate 12.5 Mg,	PS		ORAL	30 ML, 1/DAY	FOR 1 DAY,
			Haldol "Mcneil" (Haloperidol)	SS		INTRAMUSCULAR	UNK DOSE, 1	ONLY 1 FOR 1 DAY,

INTRAMUSCULAR

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/28/04ISR Number: 4386342-7Report Type:Direct Company Report #CTU 221633
Age:46 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Tardive Dyskinesia		Haldol D 75 Mg Im Q 4 Wks	PS		INTRAMUSCULAR	75 MG IM Q 4	WKS

Date:06/28/04ISR Number: 4389487-0Report Type:Expedited (15-DaCompany Report #FR-JNJFOC-20040604061
Age:86 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Pressure Systolic Increased	Foreign Health	Haldol (Haloperidol) Unspecified	PS		ORAL		
	Carotid Artery Atheroma	Professional	Clopixol (Zuclopenthixol Decanoate)	SS		ORAL		
	Drug Interaction							
	Fall							
	Leukoaraiosis		Ultra-Levure (Saccharomyces Boulardii)	C				
	Qrs Axis Abnormal							
	Thrombocytopenia		Daflon (Diosmin)	C				
	Ventricular Hypertrophy		Doliprane (Paracetamol)	C				
			Hept-A-Myl (Heptaminol Hydrochloride)	C				

Date:06/28/04ISR Number: 4389525-5Report Type:Expedited (15-DaCompany Report #JP-JNJFOC-20040602239
Age:29 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Cardiovascular Disorder	Foreign	Risperdal					
	Coma	Literature	(Risperidone)	PS		ORAL	SEE IMAGE	
	Psychomotor Hyperactivity	Health	Haldol (Haloperidol)					

	Pulmonary Embolism	Professional	Injection	SS			
SEE IMAGE							
	Pulmonary Thrombosis						
	Pyrexia						
	Stupor						
	Vena Cava Thrombosis						
	Venous Thrombosis Limb						

Date:06/30/04ISR Number: 4389947-2Report Type:Expedited (15-DaCompany Report #FR-JNJFOC-20040401607
Age:72 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Pressure Increased	Foreign	Haldol Faible (Haloperidol)					
	C-Reactive Protein Increased	Health Professional	Solution	PS			0.5MG/ML	
	Confusional State		Laroxyl (Amitriptyline Hydrochloride)	SS		ORAL	ORAL	
	Diarrhoea							
	Drug Interaction		Solian (Amisulpride)	SS		ORAL	ORAL	
	Medication Error		Temesta (Lorazepam)	SS		ORAL	ORAL	
	Pyrexia		Effexor (Venlafaxine Hydrochloride)	SS		ORAL	ORAL	
	Serotonin Syndrome		Parkinane Lp (Trihexyphenidyl Hydrochloride)	SS		ORAL	ORAL	
	Tongue Biting		Efferalgan Codeine					

			(Panadeine Co)	SS		ORAL
ORAL						
			Stablon (Tianeptine)	C		ORAL
ORAL						
			Avlocardyl (Propranolol)	C		
			Plavix (Clopidogrel Sulfate)	C		
			Sermion (Nicergoline)	C		
			Stagid (Metformin Embonate)	C		

Date:06/30/04ISR Number: 4390348-1Report Type:Expedited (15-DaCompany Report #FRWYE722426APR04
Age:72 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Condition Aggravated	Foreign	Effexor (Venlafaxine Hydrochloride,					
Other	Hypertension	Health	Unspec, 0)	PS		ORAL	2 DOSE 1X PER	
	Medication Error	Professional					1 DAY ORAL	1 YR
	Serotonin Syndrome	Other						
	Tongue Biting		Efferalgan Codeine (Paracetamol/Codeine Phosphate)	SS		ORAL		
ORAL								
			Haldol (Haloperidol)	SS		ORAL		
ORAL								
			Laroxyl (Amitriptyline Hydrochloride)	SS		ORAL		
ORAL								
			Parkinane (Trihexyphenidyl)	SS		ORAL		
ORAL								
			Solian (Amisulpride)	SS		ORAL	1 DOSE 1X PER	
							1 DAY ORAL	
			Stablon (Tianeptine)	SS		ORAL	3 DOSE 1X PER	
							1 DAY ORAL	

Temesta (Lorazepam)	SS	ORAL
Avlocardyl (Propranolol)	C	ORAL
Plavix (Clopidogrel Sulfate)	C	
Sermion (Nicergoline)	C	
Stagid (Metformin Embonate)	C	

Date:07/01/04ISR Number: 4388443-6Report Type:Expedited (15-DaCompany Report #PHNU2004DE02265
Age: Gender:Male I/FU:I

Outcome	PT
Death	Abdominal Distension
Hospitalization - Initial or Prolonged	Abdominal Operation
	Abdominal Pain
	Acute Abdomen
	Anorexia
	Atrioventricular Block
	Bowel Sounds Abnormal
	Cardiac Pacemaker Insertion
	Dyspepsia
	Flatulence
	Haematemesis
	Ileus Paralytic
	Leukocytosis

		Multi-Organ Failure Nausea Pneumonia Aspiration	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
		Pyrexia Respiratory Rate Increased		Leponex / Clozaril (Clozapine)	PS	Novartis Sector: Pharma	ORAL
500 mg/day							
		Salivary Hypersecretion Sepsis Somnolence		Leponex / Clozaril (Clozapine)	SS	Novartis Sector: Pharma	ORAL
300 mg/day	23040MIN						
		Vomiting		Akineton Retard	SS		ORAL
4 mg/day							
		X-Ray Gastrointestinal		Saroten	SS	Bayer Vital	ORAL
30 mg/day	5760 MIN						
		Tract Abnormal		Neurocil	SS		ORAL
50 mg/day	11520MIN						
				Neurocil	SS		ORAL
50 mg/day	1440 MIN						
				Truxal	SS		ORAL
190 mg/day	1440 MIN						
				Truxal	SS		ORAL
200 mg/day	8640 MIN						
				Truxal	SS		ORAL
50 mg/day	1440 MIN						
				Gastrozepin	SS		ORAL
150 mg/day	53280MIN						
				Truxal	SS		ORAL
160 mg/day	37440MIN						
				Truxal	SS		ORAL
250 mg/day	4320 MIN						
				Truxal	SS		ORAL
160 mg/day	2880 MIN						
				Neurocil	SS		ORAL
75 mg/day	44640MIN						
				Haldol	SS	Janssen	
INTRAVENOUS	10 mg/day	50400MIN					
				Saroten	SS	Bayer Vital	ORAL
10 mg/day	1440 MIN						
				Taxilan	C		ORAL
200 mg/day							
				Xanef	C		ORAL
20 mg/day							
				Beloc Zok	C		ORAL
47.5 mg/day							

			Bifiteral "Philips"	C		ORAL
3						
Tablesp./day	33120MIN					
			Unat Cor	C		ORAL
10 mg/day	30240MIN					
			Adalat	C		ORAL
20 mg/day	1440 MIN					
			Adalat	C		ORAL
40 mg/day	5760 MIN					

Date:07/02/04ISR Number: 4390926-XReport Type:Direct Company Report #CTU 222061
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Required	Dyskinesia		Haldol	PS		
INTRAMUSCULAR	5 MG IM					
Intervention to	Dystonia					
Prevent Permanent	Musculoskeletal Stiffness					
Impairment/Damage	Neck Pain					

Date:07/02/04ISR Number: 4393225-5Report Type:Expedited (15-DaCompany Report #ES-JNJFOC-20040605926
Age:87 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization -	Abdominal Pain	Foreign	Haloperidol			
Initial or Prolonged	Adrenal Adenoma	Health	(Haloperidol)			
	Drug Interaction	Professional	Solution	PS		ORAL
10 GTT, IN 1						
	Gastric Dilatation					
DAY, ORAL						
	Impaired Gastric Emptying		Akineton (Biperiden Hydrochloride)			
			Tablets	SS		ORAL
4 MG, IN 1						
DAY, ORAL						

Date:07/06/04ISR Number: 4390095-6Report Type:Expedited (15-DaCompany Report #JP-MERCK-0406USA02451
Age:47 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Liver Disorder	Health Professional	Pepcid Rpd [Therapy	PS	Merck & Co., Inc	ORAL		
			Unspecified]	SS		ORAL		
			Pl Gran	SS		ORAL		
			Prohance	SS			INTRAVENOUS	
			Levomepromazine	SS		ORAL		
			Arasena-A	SS			INTRAVENOUS	
			Aleviatin	SS		ORAL		
			Serenace	SS		ORAL		
			Akineton	SS		ORAL		
			Tegretol	SS		ORAL		

Date:07/06/04ISR Number: 4393112-2Report Type:Expedited (15-DaCompany Report #200411900FR
Age:74 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agitation		Daonil	PS	Aventis Pharmaceuticals Inc.	ORAL		
	Confusional State							
	Convulsion		Cisplatine	SS			INTRAVENOUS	
	Delirium		Haldol	SS		ORAL		
	Hallucination, Visual		Sintrom	SS		ORAL		
	Phlebitis		Actiskenan	SS		ORAL		
	Pleural Mesothelioma		Alimta	SS			INTRAVENOUS	

Date:07/06/04ISR Number: 4394804-1Report Type:Expedited (15-DaCompany Report #2004-06-1964
Age:47 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Alanine Aminotransferase	Foreign	Rinderon					
	Increased	Health	Like Celestone	PS				
	Aspartate	Professional	Salicylamide	SS				
	Aminotransferase	Other	Hirnamin	SS				

	Increased		Akineton	SS	
	Blood Alkaline		Serenace	SS	
	Phosphatase Increased		Aleviatin	SS	
	Blood Bilirubin Increased		Seroquel (Quetiapine		
	Gamma-Glutamyltransferase		Fumarate)	SS	
	Increased		Gaster	SS	
	Liver Disorder		Tegretol	SS	

Date:07/06/04ISR Number: 4395013-2Report Type:Expedited (15-DaCompany Report #KII-2004-0011769
Age:56 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Pressure Diastolic Decreased	Study	Morphine Sulfate (Similar To Nda					
Other	Depressed Mood	Health Professional	19-516) (Morphine					
	Depression	Other	Sulfate)	PS		ORAL		
ORAL								
	Multiple Drug Overdose		Benzodiazepine					
	Oxygen Saturation		Derivatives	SS		ORAL		
ORAL								
	Decreased		Ssri	SS		ORAL		
ORAL								
	Somnolence		Trazodone					
	Vomiting		(Trazodone)	SS		ORAL		
ORAL								
			Valproic Acid					
			(Valproic Acid)	SS		ORAL		
ORAL								

			Lopid (Gemfibrozil)	SS		ORAL	ORAL
			Haldol (Haloperidol)	SS		ORAL	ORAL
			Ditropan (Oxybutynin)	SS		ORAL	ORAL
			Aricept (Donepezil Hydrochloride)	SS		ORAL	ORAL
			Acetaminophen (Paracetamol)	SS			

Date:07/06/04ISR Number: 4395102-2Report Type:Expedited (15-DaCompany Report #04P-144-0264669-00
Age:87 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain Impaired Gastric Emptying	Foreign Health Professional	Akineton (Biperiden) (Biperiden)	PS		ORAL	4 MG, 1 IN 1 D, PER ORAL	
			Haloperidol	SS		ORAL	10 DROP, PER ORAL	

Date:07/08/04ISR Number: 4392683-XReport Type:Expedited (15-DaCompany Report #PHBS2004NO08833
Age:30 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dystonia		Leponex	PS	Novartis Sector: Pharma		UNKNOWN	
			Haldol	SS	Janssen		UNKNOWN	
			Chlorpromazine	SS			UNKNOWN	
			Melleril	SS			UNKNOWN	

			Nozinan	SS		
UNKNOWN						
			Risperdal	SS		
UNKNOWN						
			Serdolect	SS		
UNKNOWN						
			Sobril	SS		
UNKNOWN						
			Zyprexa	SS		
UNKNOWN						

Date:07/08/04ISR Number: 4392685-3Report Type:Expedited (15-DaCompany Report #PHRM2004FR02233
Age:44 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Alanine Aminotransferase Increased		Voltarene	PS	Novartis Sector: Pharma	ORAL		4320 MIN
	Cytolytic Hepatitis		Haldol	SS	Janssen-Cilag	ORAL		56160MIN
	Gamma-Glutamyltransferase Increased		Haldol Decanoate	SS			INTRAMUSCULAR	1 DF, ONCE/SINGLE 1440 MIN
	Hepatic Steatosis		Clopixol	SS				11520MIN
			Theralene	C				
			Risperdal	C				
			Lepticur	C				
							UNK, UNK	

Date:07/08/04ISR Number: 4393067-0Report Type:Expedited (15-DaCompany Report #CH-ROCHE-373006
Age:58 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Erythema Multiforme		Rivotril	PS	Roche	ORAL		
	Fixed Eruption		Lexotanil	SS	Roche	ORAL		
Disability			Haldol	SS		ORAL		1 YR
			Zyprexa	SS		ORAL		1 YR
			Dogmatil	SS		ORAL		

			Aspirine	C		ORAL	1 DAY

Date:07/08/04ISR Number: 4397158-XReport Type:Expedited (15-DaCompany Report #DE-JNJFOC-20040607199
Age:37 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Atrial Fibrillation Drug Interaction Electrocardiogram Qt Corrected Interval Prolonged Tachycardia	Foreign Health Professional	Haldol (Haloperidol)	PS		ORAL	10 MG, IN 1 DAY, ORAL
			Zyprexa (Olanzapine)	SS		ORAL	15 MG, IN 1 DAY, ORAL; 10 MG, IN 1 DAY, ORAL; 20 MG, IN 1 DAY,
			Diazepam	C			

Date:07/08/04ISR Number: 4397161-XReport Type:Expedited (15-DaCompany Report #DE-JNJFOC-20040607414
Age:68 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Death	Aspartate Aminotransferase Decreased Blood Amylase Decreased Blood Potassium Decreased Cardiac Pacemaker Insertion	Foreign Health Professional	Haldol (Haloperidol) Injection	PS		INTRAVENOUS	10 MG INTRAVENOUS
			Leponex (Clozapine)	SS		ORAL	500 MG, IN 1 DAY, ORAL; 300 MG, IN 1 DAY, ORAL

	Creatine Phosphokinase	Taxilan (Perazine)	SS	ORAL
200 MG, IN 1				
	Decreased			
DAY, ORAL				
	Drug Interaction	Akineton Retard		
	Faeces Discoloured	(Biperiden		
	Haematemesis	Hydrochloride)	SS	ORAL
4 MG, IN 1				
	Ileus Paralytic			
DAY, ORAL				
	Multi-Organ Failure	Saroten		
	Pneumonia Aspiration	(Amitriptyline		
	Respiratory Rate	Hydrochloride)	SS	ORAL
10 MG, IN 1				
	Increased			
DAY, ORAL; 30				
	Sepsis			
MG, IN 1 DAY,				
	Somnolence			
ORAL				
		Neurocil		
		(Levomeprazine		
		Maleate)	SS	ORAL
50 MG, IN 1				
DAY, ORAL; 75				
MG, IN 1 DAY,				
ORAL; 50 MG,				
IN 1 DAY,				
		Truxal		
		(Chlorprothixene		
		Hydrochloride)	SS	ORAL
SEE IMAGE				
		Gastrozepin		
		(Pirenzepine		
		Dihydrochloride)	SS	ORAL
150 MG, IN 1				
DAY, ORAL				
		Xanaf (Enalapril		
		Maleate)	C	
		Beloc-Zok (Beloc-Zoc		
		Comp)	C	
		Bifiteral (Tablets)		
		Probucol	C	

			Unat Cor (Torasemide)	C			
			Adalat (Nifedipine)	C			

Date:07/08/04ISR Number: 4397173-6Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20040607450
Age:23 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Creatine Phosphokinase Increased	Foreign Health Professional	Halodol (Haloperidol) Unspecified	PS				
SEE IMAGE								
			Seroquel (Quetiapine Fumarate)	SS		ORAL		
SEE IMAGE								

Date:07/08/04ISR Number: 4397175-XReport Type:Expedited (15-DaCompany Report #ES-JNJFOC-20040700749
Age:34 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Torsade De Pointes Ventricular Fibrillation	Foreign Health Professional	Halodol (Haloperidol) Unspecified	PS				
INTRAVENOUS							2.08 MG/HR,	
INTRAVENOUS								
			Alprazolam (Alprazolam)	C				
			Piperacillin/Tazobactam (Pip/Tazo)	C				
			Pantoprazol (Pantoprazole)	C				
			Paracetamol (Paracetamol)	C				
			Vit B1 (Thiamine Hydrochloride)	C				
			Vit B6 (Pyridoxine Hydrochloride)	C				
			Vit B12 (Cyanocobalamin)	C				

Date:07/08/04ISR Number: 4397177-3Report Type:Expedited (15-DaCompany Report #EMADSS2002001190
Age:24 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Weight Increased	Foreign Consumer	Risperdal (Risperidone) Tablets	PS		ORAL	SEE IMAGE	
			Halodol (Haloperidol) Unspecified	SS		ORAL	15 MG	ORAL
			Ergenyl (Valproate Sodium) Unspecified	C				

Date:07/09/04ISR Number: 4394545-0Report Type:Direct Company Report #CTU 222481
Age:43 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Cardiac Arrest		Haldol 5 Mg	PS		INTRAVENOUS	5 MG ONE	
	Ventricular Tachycardia					INTRAVENOUS		
			Labetalol	C				

Lactulose	C
Lorazepam	C
Metoclopramide	C
Metronidazole	C
Sandostatin	C
Pantoprazole	C
Vitamin K	C

Date:07/12/04ISR Number: 4398845-XReport Type:Expedited (15-DaCompany Report #US-JNJFOC-20040300045
Age:64 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Brain Oedema Catatonia Cogwheel Rigidity Coma Dementia Drooling Electrocardiogram T Wave Abnormal Electroencephalogram Abnormal Gastric Outlet Obstruction Gastrooesophageal Reflux Disease Hallucination Hypoxia Immobile Incontinence Ischaemia Malnutrition Muscle Rigidity Musculoskeletal Stiffness	Consumer	Risperdal (Risperidone) Haldol Decanoate (Haloperidol Decanoate) Injection Haldol (Haloperidol) Unspecified Benztropine (Benzatropine Mesilate)	PS SS SS C		ORAL INTRAMUSCULAR ORAL	2 MG, 2 IN 1 DAY, ORAL; SEE IMAGE 75 MG, 1 IN 4 WEEK, INTRA-MUSCULAR 5 MG, 2 IN 1 DAY, ORAL; SEE IMAGE	

Nervous System Disorder
Neuroleptic Malignant Syndrome
Occult Blood Positive
Parkinson'S Disease
Pituitary Tumour Benign
Pneumonia Aspiration
Posture Abnormal
Pseudomonas Infection
Psychomotor Retardation
Pyrexia
Rathke'S Cleft Cyst
Schizophrenia
Sinus Arrhythmia
Sluggishness
Staring
Therapy Non-Responder
Treatment Noncompliance
Tremor
Urinary Tract Infection

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/12/04ISR Number: 4399636-6Report Type:Expedited (15-DaCompany Report #00-11-0599
Age:77 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Dehydration	Foreign	Proglycem Capsules	PS		ORAL	SEE IMAGE	
Hospitalization - Initial or Prolonged	Drug Interaction Hyperglycaemia	Health Professional	Haldol Oral Suspension	SS		ORAL	30 DROPS ORAL	
Other	Ketoacidosis Ketosis Overdose Renal Failure		Praxilene Fonzylane	C C				

Date:07/13/04ISR Number: 4396865-2Report Type:Direct Company Report #CTU 222709
Age:13 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Abortion		Neurontin	PS			GENERIC	
Hospitalization - Initial or Prolonged	Adoption Congenital Anomaly						NEURONTIN PILLS	
Disability	Drug Exposure During		Lithium	SS			LITHIUM PILLS	
Required Intervention to Prevent Permanent Impairment/Damage	Pregnancy Injury Pregnancy Road Traffic Accident		Haldol Respridol	SS SS			HALDOL DEC SHOT RESPRIDAL PILLS	

Date:07/13/04ISR Number: 4398019-2Report Type:Expedited (15-DaCompany Report #SE-JNJFOC-20040607396
Age:50 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Alanine Aminotransferase	Foreign	Haldol (Haloperidol)					

	Increased Angiopathy Aspartate Aminotransferase Increased Blood Glucose Increased Cardiac Disorder Drug Interaction Drug Toxicity Pulmonary Oedema Refusal Of Treatment By Patient Somnolence	Health Professional Other	Injection	PS		
INTRAMUSCULAR	10 MG, IN 1 DAY, INTRA-MUSCULAR					
			Heminevrin (Clomethiazole Edisilate)	SS	ORAL	300 MG, IN 1 DAY, ORAL
			Zyprexa (Olanzapine)	SS		10 MG, IN 1 DAY
			Stesolid (Diazepam)	SS		
INTRAMUSCULAR	10 MG, IN 1 DAY, INTRA-MUSCULAR					
			Cisordinol (Clopenthixol Hydrochloride)	SS		
INTRAMUSCULAR	100 MG, IN 1 DAY, INTRA-MUSCULAR					
			Lithionit (Lithium Sulfate) Sustained Release	SS	ORAL	0.2 G, IN 1 DAY, ORAL
			Disipal (Film Coated Tablet) Orphenadrine Hydrochloride	C		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/13/04ISR Number: 4398117-3Report Type:Expedited (15-DaCompany Report #DSA_24340_2004
Age:72 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Confusional State	Foreign	Temesta	PS				
	Diarrhoea	Health	Effexor	SS		ORAL	2 QD PO	
	Hypertension	Professional	Efferalgan Codeine	SS				
	Medication Error	Other	Haldol	SS				
	Pyrexia		Laroxyl	SS				
	Serotonin Syndrome		Parkiinane	SS				
	Tongue Biting		Solian	SS		ORAL	1 QD PO	
			Stablon	SS		ORAL	3 QD PO	
			Avlocardyl	C				
			Plavix	C				
			Sermion	C				
			Stagid	C				

Date:07/19/04ISR Number: 4401829-6Report Type:Direct Company Report #USP 56692
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Medication Error		Haloperidol	PS	Geneva Pharmaceutical		TABLET	
			Haloperidol	SS	Geneva Pharmaceutical		TABLET	

Date:07/20/04ISR Number: 4404252-3Report Type:Expedited (15-DaCompany Report #S04-BEL-03049-01
Age:78 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Loss Of Consciousness	Foreign	Ebixa (Memantine)	PS		ORAL	20 MG QD PO	
	Lymphoedema	Health	Ebixa (Memantine)	SS		ORAL	10 MG QD PO	

	Salivary Hypersecretion	Professional	Ebixa (Memantine)	SS		ORAL 5 MG QD PO
	Urinary Incontinence	Other	Haldol "Janssen" (Haloperidol)	SS	Janssen	6 DROPS BID
			Buronil (Melperone Hydrochloride)	SS		ORAL 50 MG QD PO
			Cordarone (Amiodarone Hydrochloride)			
			(Amiodarone Hydrochloride)	C		
			Zestril (Lisinopril)	C		
			Catapressan (Clonidine)	C		
			Lasix (Furosemide)	C		
			Sintrom (Acenoucomarol)	C		
			Omeprazole	C		

Date:07/20/04ISR Number: 4404749-6Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20040701733
Age:40 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Other	Bradycardia	Foreign	Haldol (Haloperidol)			
	Coma	Health	Unspecified	PS		
	Hypothermia	Professional				
	Somnolence					

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/21/04ISR Number: 4402820-6Report Type:Direct Company Report #USP 56737
Age:17 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Medication Error		Haldol	PS	Sandoz/Par		TABLET	
			Haloperidol	SS				
Other								

Date:07/22/04ISR Number: 4409360-9Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20040704150
Age:62 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Death	Health Professional	Risperdal Consta (Risperidone) Microspheres	PS				
INTRAMUSCULAR	50 MG , 1 IN							
2 WEEK,								
INTRA-MUSCULAR								
			Haldol (Haloperidol) Injection	SS				
INTRAVENOUS	150 MG, IN 1							
DAY,								
INTRAVENOUS								

Date:07/23/04ISR Number: 4409531-1Report Type:Expedited (15-DaCompany Report #CH-JNJFOC-20040700547
Age:63 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain	Foreign	Haldol (Haloperidol)					
	Diarrhoea	Health	Unspecified	PS		ORAL		
ORAL								
	Fixed Eruption	Professional						
	Pyrexia							

	Skin Lesion					

Date:07/23/04ISR Number: 4409532-3Report Type:Expedited (15-DaCompany Report #CH-JNJFOC-20040700531
Age:14 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Creatine Phosphokinase Increased	Foreign Health Professional	Haldol (Haloperidol) Unspecified	PS		ORAL	1 MG, IN 1	
Disability	Extrapyramidal Disorder						DAY, ORAL	
	Tachycardia							

Date:07/23/04ISR Number: 4409543-8Report Type:Expedited (15-DaCompany Report #2004-03101
Age:58 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Hospitalization - Initial or Prolonged	Torsade De Pointes	Literature Health Professional	Haloperidol (Watson Laboratories)(Haloperidol) Tablet	PS		INTRAVENOUS	70, 30 300, 270, 340MG	DAY 1-5,
						INTRAVENOUS	5	DAY
			Levofloxacin	C				
			Piperacillin Sodium W/Tazobactam Sodium (Tazobactam Sodium, Piperaillin Sodium)	C				
			Doxycycline	C				

Midazolam	C
Morphine	C
Diltiazem	C
Enoxaparin Sodium (Heparin-Fraction, Sodium-Salt)	C
Famotidine	C
Metoclopramide	C
Hydroxychloroquine	C
Nicotine Patch	C

Date:07/26/04ISR Number: 4410500-6Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20040704106
Age:93 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abnormal Behaviour Asthenia Choking Delirium Drug Ineffective Fall Femoral Neck Fracture Oedema Peripheral Pelvic Fracture Rhinitis Salivary Hypersecretion Unevaluable Event	Consumer	Haldol (Haloperidol) Zopiclone (Zopiclone) Melperone (Melperone)	PS SS SS			4.5 MG, IN 1 DAY 25 MG, IN 1 DAY	

Date:07/26/04ISR Number: 4410502-XReport Type:Expedited (15-DaCompany Report #DE-JNJFOC-20040704599
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Aggression Extrapyramidal Disorder	Foreign Health Professional	Haloperidol (Haloperidol) Solution	PS		ORAL	, IN 1 DAY,	

ORAL

Date:07/26/04ISR Number: 4410506-7Report Type:Expedited (15-DaCompany Report #BR-JNJFOC-20040704769
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Aggression	Foreign	Haldol (Haloperidol)					
	Nervousness	Consumer	Tablets	PS		ORAL	SEE IMAGE	
	Overdose		Nociclin (Ethyinylestradiol)	C				
	Somnolence		Diazepam Mg (Diazepam)	C				
	Suicide Attempt		Fenergan (Promethazine)	C				

Date:07/26/04ISR Number: 4410509-2Report Type:Expedited (15-DaCompany Report #IT-JNJFOC-20040703266
Age:34 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Foreign	Haloperidol					
	Gun Shot Wound	Health Professional	(Haloperidol)	PS				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/27/04ISR Number: 4409367-1Report Type:Direct Company Report #CTU 223679
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Medication Error		Haloperidol Lactate Injection	PS				

Date:07/28/04ISR Number: 4409735-8Report Type:Expedited (15-DaCompany Report #200416722GDDC
Age:56 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Alkaline Phosphatase Increased		Lasix	PS	Aventis Pharmaceuticals Inc.		dose: UNK	
	Blood Chloride Decreased		Cravit	SS			dose: UNK	
	Blood Lactate		Tienam	SS			dose: UNK	
	Dehydrogenase Increased		Dalacin	SS			dose: UNK	
	Blood Potassium Decreased		Loxonin	SS			dose: UNK	
	Blood Uric Acid Increased		Serenace	SS			dose: UNK	
	Haematocrit Decreased		Eurodin	SS			dose: UNK	
	Haemoglobin Decreased		Gramalil	SS			dose: UNK	
	Lipase Increased		Foipan	SS			dose: UNK	
	Platelet Count Increased		Atarax					
	Red Blood Cell Count Decreased		/Can/	SS			dose: UNK	
	Toxic Epidermal		Gaster	SS			dose: UNK	
	Necrolysis		Mucosta	SS			dose: UNK	
			Aldactone-A	SS			dose: UNK	
			Mannitol	SS			dose: UNK	

			Nitropen	SS		
dose: UNK						
			Digosin	SS		
dose: UNK						
			Bayaspirin	SS		
dose: UNK						
			Warfarin	SS		
dose: UNK						
			Selbex	SS		
dose: UNK						

Date:07/29/04ISR Number: 4413904-0Report Type:Expedited (15-DaCompany Report #NLWYE818210JUN04
Age:41 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Condition Aggravated Drug Interaction Dyskinesia Dystonia	Health Professional	Efexor (Venlafaxine Hydrochloride, Tablet, 0)	PS		ORAL	37.5 MG 2X PER 1 DAY	
			Haldol (Haloperidol, , 0)	SS		ORAL	5 MG 3X PER 1 DAY	

Date:07/29/04ISR Number: 4415021-2Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20040701733
Age:40 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Bradycardia Hyperthermia Hypothermia Somnolence Temperature Regulation Disorder	Foreign Health Professional	Haldol (Haloperidol) Unspecified	PS				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/29/04ISR Number: 4415498-2Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20040704150
Age:62 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Therapy Non-Responder	Health Professional	Risperdal Consta (Risperdone) Microspheres	PS		INTRAMUSCULAR	50 MG, 1 IN 2	WEEK,
			Haldol (Haloperidol) Injection	SS		INTRAVENOUS	150 MG, IN 1	DAY,

INTRA-MUSCULAR

INTRAVENOUS

Date:07/29/04ISR Number: 4445392-2Report Type:Periodic Company Report #2004AP00684
Age:76 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Delirium	Literature	Elavil	PS		ORAL	75 MG PO	
		Health Professional	Haloperidol	SS			2 MG	

Date:07/29/04ISR Number: 4448420-3Report Type:Periodic Company Report #NSADSS2003024724
Age:23 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Akathisia Arthralgia Chest Pain	Consumer	Risperdal (Risperidone) Unspecified	PS		ORAL	SEE IMAGE	

Dyskinesia	Haldol (Haloperidol)
Dyspnoea	Unspecified SS
Haemorrhoids	Detrol (Tolterodine
Insomnia	L-Tartrate) C
Nasopharyngitis	Ditropan
Psychotic Disorder	(Oxybutynin) C
Swollen Tongue	Cogentin
Upper Respiratory Tract	(Benzatropine
Infection	Mesilate) C
Urinary Incontinence	Inderal (Propranolol
	Hydrochloride) C
	Zyprexia
	(Olanzapine) C

Date:07/30/04ISR Number: 4412445-4Report Type:Expedited (15-DaCompany Report #JP-MERCK-0406USA02451
Age:47 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Drug Eruption		Pepcid Rpd	PS	Merck & Co., Inc	ORAL	35	DAY
Initial or Prolonged	Liver Disorder		Pl Gran	SS		ORAL	3	DAY
	Lymphocyte Stimulation		Akineton	SS		ORAL	46	DAY
	Test Positive		Prohance	SS				
			Serenace	SS		ORAL	10	DAY
			Serenace	SS		ORAL	7	DAY
			Levomepromazine	SS		ORAL	7	DAY
			Levomepromazine	SS		ORAL	44	DAY
			Aleviatin	SS		ORAL	2	DAY
			Arasena-A	SS				
			Seroquel	SS		ORAL	29	DAY

			Seroquel	SS		ORAL
			Aleviatin	SS		ORAL
59	DAY					
			Levomepromazine	SS		ORAL
6	DAY					
			Levomepromazine	SS		ORAL
2	DAY					
			Serenace	SS		ORAL
4	DAY					
			Serenace	SS		ORAL
32	DAY					
			Tegretol	SS		ORAL
19	DAY					
			Tegretol	SS		ORAL
26	DAY					

Date:08/02/04ISR Number: 4416758-1Report Type:Expedited (15-DaCompany Report #NLWYE818210JUN04
Age:41 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Condition Aggravated Drug Interaction Dyskinesia Dystonia	Health Professional	Efexor (Venlafaxine Hydrochloride, Tablet, 0)	PS		ORAL	37.5 MG 2 X PER 1 DAY	
			Haldol (Haloperidol, , 0)	SS			5 MG 3XP ER 1 DAY	

Date:08/03/04ISR Number: 4418036-3Report Type:Expedited (15-DaCompany Report #SE-JNJFOC-20040607396
Age:50 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Alanine Aminotransferase Increased Aspartate	Foreign Health Professional	Haldol (Haloperidol) Injection	PS		INTRAMUSCULAR	10 MG, IN 1 DAY,	

		Aminotransferase Increased				
INTRA-MUSCULAR						
		Cardiomegaly Drug Toxicity Gamma-Glutamyltransferase Increased	Heminevrin (Clomethazole Edisilate) Capsules	SS		ORAL
300 MG, IN 1 DAY, ORAL						
		Hyperaemia Pulmonary Oedema	Zyprexa (Olanzapine) Injection	SS		
10 MG, IN 1 DAY,		Refusal Of Treatment By Patient Somnolence	Stesolid (Diazepam) Injection	SS		
INTRAMUSCULAR	10 MG, 1 IN DAY,					
INTRA-MUSCULAR						
			Cisordinol (Clopenthixol Hydrochloride) Injection	SS		
INTRAMUSCULAR	100 MG, IN 1 DAY,					
INTRA-MUSCULAR						
			Lithionit (Lithium Sulfate) Sustained Release Tablets	SS		ORAL
0.2 G, IN 1 DAY, ORAL						
			Disipal (Film Coated Tablet) Orphenadrine Hydrochloride	C		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/06/04ISR Number: 4419184-4Report Type:Direct Company Report #CTU 224456
Age:62 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Creatine Phosphokinase Increased		Clozapine 25mg (Mylan)	PS	Mylan	ORAL	500 MG PO/DAY	
Required Intervention to Prevent Permanent Impairment/Damage	Confusional State						TAPERED TO 25 MG PO/DAY	
	Constipation							
	Ileus		Haloperidol 10 Mg	SS		ORAL	PO 20 MG/D	
	Liver Function Test Abnormal		Clozapine	C				
	Neuroleptic Malignant Syndrome		Magnesium Hydroxide (Milk Of Magnesia)	C				
	Pneumonia Aspiration		Docusate/Senna	C				
	Urinary Tract Infection		Lovastatin	C				
			Ferrous Sulfate	C				
			Sorbitol	C				
			Albuterol Inhaler	C				
			Terazosin	C				
			Ranitidine	C				
			Clonazepam	C				

Date:08/06/04ISR Number: 4423384-7Report Type:Expedited (15-DaCompany Report #BR-JNJFOC-20040604003
Age:19 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Alcohol Use Intentional Misuse	Foreign Health	Tylenol Analgesic (Acetaminophen)	PS		ORAL	ORAL	
	Somnolence Suicide Attempt	Professional	Haloperidol (Haloperidol)	SS				
			Metamizole (Metamizole)	SS				
			Alcohol (Ethanol)	SS				
			Prometazine (Promethazine)	C				
			Midazolam (Midazolam)	C				

Date:08/09/04ISR Number: 4423959-5Report Type:Expedited (15-DaCompany Report #2004225890IT
Age:45 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Agitation	Foreign	Cortisone Acetate(Cortisone Acetate) Tablet	PS			25 MG, BID	
	Blood Culture Positive	Literature						
	Chest X-Ray Abnormal	Health						
	Hallucination	Professional	Clavumox (Amoxicillin, Clavulanate Potassium) Tablet	SS		INTRAVENOUS	1200 MB, TID,	
	Oliguria	Other						
	Pyrexia							
	Respiratory Distress							
	Septic Shock						IV	
	Toxic Epidermal Necrolysis		Diazemuls (Diazepam) Emulsion, Sterile	SS			QD	
			Aloperidolo Ce (Haloperidol) Tablet	SS			QD	
			Pantopan (Pantoprazole) Tablet	SS				
			Omeprazole	C				
			Calcitriol (Calcitriol)	C				
			Calcium					

Lactogluconate (Calcium Lactogluconate)	C
Calcium Carbonate	C
Aluminium Hydroxide W/Magnesium Hydroxide	C
Fludrocortisone (Fludrocortisone)	C
Nystatin	C
Levofloxacin (Levofloxacin)	C
Furosemide	C
Canrenoic Acid (Canrenoic Acid)	C
Itraconazole (Itraconazole)	C
Calcium Gluconate	C
Amino Acids Nos	C
Rabeprazole (Rabeprazole)	C
Fludrocortisone (Fludrocortisone)	C

Date:08/10/04ISR Number: 4422236-6Report Type:Expedited (15-DaCompany Report #FR-JNJFOC-20031004738
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - OROPHARINGEAL	Amniocentesis Abnormal		Risperdal	PS				
Initial or Prolonged OROPHARINGEAL	Condition Aggravated		Haldol	SS				
	Delusion		Depakote	C				
	Drug Exposure During Pregnancy		Imovane	C				
	Pregnancy		Speciafoldine	C				
	Pulmonary Embolism		Xenetix	C				

Date:08/10/04ISR Number: 4422490-0Report Type:Expedited (15-DaCompany Report #PHBS2004FR10486
Age:38 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Death	Arrhythmia Congestive Cardiomyopathy	Health Professional	Carbamazepine	PS	Novartis Sector: Pharma
600 mg/d					
	Sudden Death		Sultopride	SS	
800 mg/d					
			Haloperidol	SS	
30 mg/d					
			Clorazepate	SS	
25-100 mg/d					

Date:08/10/04ISR Number: 4425858-1Report Type:Expedited (15-DaCompany Report #2004201007JP
Age:78 YR Gender:Female I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Condition Aggravated
	Delusion
	Depression
	Drug Eruption
	Fall
	Femoral Neck Fracture
	Hallucination
	Parkinson'S Disease
	Persecutory Delusion

	Poriomania Pruritus Restlessness	Report Source	Product	Role	Manufacturer	Route	Dose Duration
		Foreign Study	Cabaser(Cabergoline) Tablet, 1-4mg	PS		ORAL	0.25 MG/DAY,
		Health Professional				ORAL	SEE IMAGE
		Other	Serenace(Haloperidol)	SS		ORAL	1.75 MG, ORAL
			Tryptanol (Amitriptyline Hydrochloride) Tablet	SS		ORAL	20-30 MG, ORAL
			Depakene(Valproate Sodium)	SS		ORAL	200-600 MG, ORAL
			Depas(Etizolam)	C			
			Selbex(Teprenone)	C			
			Gasmotin	C			
			Gaster	C			
			Tinelac(Sennoside A+B)	C			
			Halcion	C			
			Cercin	C			
			Gramalil (Tiapride Hydrochloride)	C			

Date:08/11/04ISR Number: 4423001-6Report Type:Expedited (15-DaCompany Report #FR-JNJFOC-20040800659
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Pemphigoid		Haldol	PS			

OROPHARINGEAL

Initial or Prolonged			Mopral	SS		
OROPHARINGEAL						
			Sectral	C		
			Vastarel	C		
			Lexomil	C		
			Stilnox	C		
			Duphalac	C		
			Aspegic	C		
			Clarityne	C		
			Discotrine	C		

Date:08/11/04ISR Number: 4423002-8Report Type:Expedited (15-DaCompany Report #FR-JNJFOC-20040800680
Age:82 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Disease Recurrence	Health	Haldol Faible	PS				
OROPHARINGEAL								
Initial or Prolonged	Extrapyramidal Disorder	Professional	Artane	SS				
OROPHARINGEAL							3	DAY
	Fall							

Date:08/11/04ISR Number: 4423003-XReport Type:Expedited (15-DaCompany Report #DE-JNJFOC-20040301598
Age:35 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Neutropenia	Health	Haldol	PS				
OROPHARINGEAL								
Initial or Prolonged		Professional	Haldol	SS				
OROPHARINGEAL								
			Haldol	SS				
OROPHARINGEAL								

			Haldol	SS		
OROPHARINGEAL						
			Haldol	SS		
OROPHARINGEAL						
			Tavor	C		
OROPHARINGEAL						

Date:08/12/04ISR Number: 4424449-6Report Type:Expedited (15-DaCompany Report #PHEH2004US08464
Age:82 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blood Pressure Decreased Catatonia	Health Professional	Exelon	PS	Novartis Sector: Pharma	ORAL	1.5 mg, QD	7200 MIN
	Drug Interaction Hypokinesia		Exelon	SS	Novartis Sector: Pharma	ORAL	1.5 mg, BID	21600MIN
			Seroquel	SS				
			Haldol "Janssen"	SS				
			Trazodone	SS				
			Estrogens	SS				
TRANSDERMAL								
			Ativan	C				
			Folic Acid	C				
			Combivent	C				

Date:08/12/04ISR Number: 4427637-8Report Type:Expedited (15-DaCompany Report #FRWYE731529APR04
Age:68 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Disability	Disease Progression Extrapyramidal Disorder Major Depression	Health Professional	Effexor (Venlafaxine Hydrochloride, Tablet, 0)	PS		ORAL	FROM 150 MG TO 200 MG DAILY, ORAL	
			Effexor (Venlafaxine Hydrochloride,					

Tablet 0)	SS	ORAL	300 MG 1X PER 1 DAY, ORAL
Effoxor (Venlafaxine Hydrochloride, Tablet, 0)	SS	ORAL	150 MG 1X PER 1 DAY, ORAL
Haldol (Haloperidol, 0)	SS	ORAL	6 MG 1X PER 1 DAY, ORAL
Ditropan (Oxybutynin)	C		
Actonel (Risedronate)	C		
Calcium With Vitamin D (Calcium Phosphate/Calcium Sodium Lactate/Ergocalcifer	C		
Lysanxia (Prazepam)	C		
Imovane (Zopiclone)	C		
Di-Antalvic (Dextropropoxyphene Hydrochloride/Paracetamol)	C		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/13/04ISR Number: 4425493-5Report Type:Expedited (15-DaCompany Report #BR-JNJFOC-20040604003
Age:19 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Intentional Misuse		Tylenol Analgesic	PS		OROPHARINGEAL		
	Somnolence		Tylenol Analgesic	SS		OROPHARINGEAL		
	Suicide Attempt		Haloperidol	SS				
			Metamizole	SS				
			Prometazine	SS				
			Midazolam	SS				
			Alcohol	SS				

Date:08/16/04ISR Number: 4427608-1Report Type:Direct Company Report #CTU 225044
Age:41 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Aggression		Haldol 5 Mg Im	PS		INTRAMUSCULAR	5 MG IM Q 4H	
Initial or Prolonged	Labile Blood Pressure							
PRN								
Required	Musculoskeletal Stiffness		Seroquel 200 Mg Po	SS			200 MG BID	
Intervention to	Neuroleptic Malignant		Protonix	C				
Prevent Permanent	Syndrome		Dantrolene	C				
Impairment/Damage	Paranoia							
	Pyrexia							
	Tachycardia							
	Treatment Noncompliance							

Date:08/16/04ISR Number: 4429777-6Report Type:Expedited (15-DaCompany Report #2004AP03066
Age:37 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Anuria	Foreign	Diprivan	PS		INTRAVENOUS	1 % IV	
Life-Threatening	Blood Pressure Decreased	Literature	Cercine	SS		ORAL	10 MG DAILY	

Disability	Cardio-Respiratory Arrest	Health		
PO				
	Choking	Professional	Fentanest	SS
250 MG DAILY				
	Convulsion	Other	Morphine	
	Diarrhoea		Hydrochloride	SS
EPIDURAL	3 MG DAILY ED			
	Dysphagia		Morphine	
	Empyema		Hydrochloride	SS
EPIDURAL	17 MG DAILY			
	Gastrointestinal			
ED				
	Infection		Sevoflurane	SS
RESPIRATORY				
	Haemodialysis			
(INHALATION)	60 ML DAILY			
	Haemorrhage			
IH				
	Procedural Complication		Serenace	SS
10 MG DAILY				
	Pulmonary Thrombosis		Horizon	SS
10 MG DAILY				
	Renal Failure Acute		Dormicum	SS
50 MG DAILY				
	Restlessness		Lepetan	SS
0.4 MG DAILY				
	Rhabdomyolysis		Carbocain	C
			Anapeine	C
			Musculax	C
			Mioblock	C
			Laughing Gas	C
			Oxygen	C
			Ephedrine	C
			Atropine Sulfate	C
			Vagostigmin	C

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/17/04ISR Number: 4429976-3Report Type:Expedited (15-DaCompany Report #2004UW16769
Age:78 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Difficulty In Walking	Consumer	Seroquel	PS				
	Drug Effect Decreased		Haloperidol	SS		ORAL	1 MG	PRN
	Drug Withdrawal Syndrome		Haloperidol	SS		ORAL	1 MG	TID
	Eating Disorder		Haloperidol	SS		ORAL	0.5 MG	TID
	Parkinsonism		Zyprexa	SS				
	Tremor		Lisinopril W/Hydrochlorothiazide	C				
	Weight Decreased		Zestril	C				
	Weight Increased							

Date:08/17/04ISR Number: 4431075-1Report Type:Expedited (15-DaCompany Report #2004CG01563
Age:98 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Pemphigoid	Foreign	Mopral	PS		ORAL	20 MG	QD
		Health Professional Other	Haldol	SS		ORAL	0.5 MG	QD
			Sectral	C				
			Vastarel	C				
			Lexomil	C				
			Stilnox	C				
			Duphalac	C				
			Aspegic	C				
			Clarytine	C				
			Discotrine	C				

Date:08/18/04ISR Number: 4428692-1Report Type:Periodic Company Report #US-BRISTOL-MYERS SQUIBB COMPANY-12440129
Age:58 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Electrocardiogram Qt		Tequin Inj	PS	Bristol-Myers Squibb			

		Corrected Interval				Company	
INTRAVENOUS							
		Prolonged		Haldol	SS		
INTRAVENOUS	2-5 mg every						
		Torsade De Pointes					
2 hours							

Date:08/18/04ISR Number: 4428789-6Report Type:Expedited (15-DaCompany Report #JP-JNJFOC-20040607188
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Anxiety	Health	Risperdal	PS		
OROPHARINGEAL	25 DAY					
Initial or Prolonged	Dermatitis Exfoliative	Professional	Haloperidol	SS		
OROPHARINGEAL						
	Drug Interaction		Haloperidol	SS		
OROPHARINGEAL						
	Parkinson'S Disease		Haloperidol	SS		
OROPHARINGEAL	In Apr-2004					
	Pemphigoid					
the dose of						
	Thrombocytopenia					
haloperidol						
was						
increased.						
			Haloperidol	SS		
OROPHARINGEAL	On 23-JAN-04					
oral admin of						
haloperidol						
was						
initiated.						
			Prednisolone	SS		
OROPHARINGEAL	169 DAY					
			Promethazine Hydrochloride	C		
OROPHARINGEAL						
			Triazolam	C		
OROPHARINGEAL						

			Lormetazepam	C		
OROPHARINGEAL						

Date:08/18/04ISR Number: 4430634-XReport Type:Expedited (15-DaCompany Report #04P-087-0269008-00
Age:47 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Contrast Media Reaction	Foreign	Akineton (Biperiden)					
	Drug Eruption	Health	(Biperiden)	PS			3 MG 1 IN 1 D	
	Hepatic Enzyme Increased	Professional	Phenytoin	SS			SEE IMAGE	
	Hepatic Function Abnormal		Haloperidol	SS			SEE IMAGE	
	Influenza Like Illness		Levomepromazine	SS		ORAL	SEE IMAGE	
	Scab		Carbamazepine	SS		ORAL	SEE IMAGE	
			Famotidine	SS				
OPHTHALMIC	40 MG, ORAL		Quetiapine	SS		ORAL	SEE IMAGE	
			Vidarabine	SS				
INTRAVENOUS	600 MG,							
INTRAVENOUS								
			Gadoteridol	SS				
INTRAVENOUS	INTRAVENOUS							
			Pl Gran.	SS		ORAL	3 GM, ORAL	
			Teprenone	SS		ORAL	ORAL	

Date:08/19/04ISR Number: 4429457-7Report Type:Expedited (15-DaCompany Report #PHRM2004FR02557
Age:83 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dermatitis Bullous		Exelon	PS	Novartis Sector: Pharma	ORAL	4.5 mg, BID	47520MIN
	Eosinophilia							
	Pruritus		Exelon	SS	Novartis Sector:			

	Rash Morbilliform				Pharma	ORAL
6 mg, QD						
	Rash Pustular		Haldol			
			"Janssen-Cilag"	SS		ORAL
1 mg daily						
			Loxapac	C		
INTRAMUSCULAR 2 DF daily						
			Equanil	C		ORAL
800 mg daily						
			Atarax	C		
75 mg, QD						

Date:08/19/04ISR Number: 4431767-4Report Type:Expedited (15-DaCompany Report #HQWYE098209AUG04
Age:45 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Adrenal Disorder	Foreign	Pantopan			
Life-Threatening	Aortic Valve Sclerosis	Literature	(Pantoprazole,			
	Blood Culture Positive	Other	Tablet, Delayed			
	Brain Oedema		Release)	PS		
SEE IMAGE 10 DAY						
	Bronchopneumonia		Aluminium Hydroxide			
	Cachexia		(Aluminium			
	Calcinosis		Hydroxide,)	SS		
4 ML 3X PER 1						
	Endometrial Atrophy					
DAY 22 DAY						
	Enterococcal Infection		Calcitrol (Calcium			
	Hepatic Fibrosis		Carbonate/Ergocalcif			
	Ovarian Atrophy		erol/Retinol,)	SS		
0.5 UG 1X PER						
	Parathyroid Disorder					
1 DAY 39 DAY						
	Pseudomonas Infection		Calcium Carbonate			
	Renal Haemorrhage		(Calcium Carbonate,)	SS		
1 GRAIN 1X						
	Septic Shock					
PER 1 DAY						
	Staphylococcal Infection		Calcium			
	Thyroid Atrophy		Lactogluconate			
	Toxic Epidermal		(Calcium			
	Necrolysis		Lactogluconate,)	SS		
1 GRAIN 1X						
PER 1 DAY						

			Clavamox (Amoxicillin Trihydrate/Clavulanate Potassium,)	SS	
INTRAVENOUS	1200 MG 3X PER 1 DAY				
INTRAVENOUS	16	DAY			
			Cortisone Acetate (Cortisone Acetate,)	SS	
25 MG 2X PER 1 DAY	37	DAY			
			Diazemuls (Diazepam,)	SS	ORAL
DOSE DAILY ORAL	27	DAY			
			Fludrocortisone (Fludrocortisone,)	SS	
4 ML 3X PER 1 DAY	28	DAY			
			Furosemide (Furosemide,)	SS	
SEE IMAGE	12	DAY			
			Haloperidol (Haloperidol,)	SS	ORAL
DOSE DAILY ORAL					
			Itraconazole (Itraconazole,)	SS	
100 MG 1X PER 1 DAY					
			Levofloxacin (Levofloxacin,)	SS	
500 MG -					
			Magnesium Hydroxide (Magnesium Hydroxide,)	SS	
4 ML 3X PER 1 DAY	22	DAY			

				Nystatin (Nystatin,)	SS			
4 ML 3X PER 1 DAY								
				Omeprazole (Omeprazole,)	SS			
20 MG 1X PER 1 DAY	37	DAY						
				Potassium Canrenoate (Potassium Canrenoate,)	SS			
SEE IMAGE	12	DAY						
				Calcium Gluconate (Calcium Gluconate)	C			
				Potassium Chloride (Potassium Chloride)	C			

Date:08/20/04ISR Number: 4430212-2Report Type:Expedited (15-DaCompany Report #FR-JNJFOC-20040803027
Age:83 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Dermatitis Bullous		Haldol	PS				
OROPHARINGEAL								
Initial or Prolonged	Eosinophilia		Exelon	SS				
OROPHARINGEAL								
	Pruritus		Exelon	SS				
OROPHARINGEAL								
	Rash Morbilliform		Loxapac	C				
			Equanil	C				
			Claritine	C				
			Atarax	C				
							3 tablets/day	
			Atarax	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/20/04ISR Number: 4432374-XReport Type:Expedited (15-DaCompany Report #2004IC000375
Age:78 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Angina Pectoris	Foreign	5-Fluorouracil (Fluorouracil)	PS		INTRAVENOUS	1070 MG;UNKNOWN;	
	Anxiety	Health Professional						
	Blood Potassium Decreased	Other						
	Cardio-Respiratory Arrest							
	Ventricular Arrhythmia		Aqupla (Nedaplatin)	SS		INTRAVENOUS	27 MG;UNKNOWN;IN TRAVENOUS	
			Lasix (Furosemide)	SS		ORAL	10 MG;UNKNOWN; ORAL	
			Normonal (Tripamide)	SS		ORAL	15 MG;UNKNOWN;OR AL	
			Anpec (Verapamil Hydrochloride)	SS		PARENTERAL	30 MG;UNKNOWN;PA RENTERAL	
			Serenace (Haloperidol)	SS		INTRAVENOUS	5 MG; UNKNOWN; INTRAVENOUS	
			Sigmart	C				
			Casanmil	C				

Date:08/20/04ISR Number: 4432396-9Report Type:Expedited (15-DaCompany Report #2004AP03066
Age:37 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Anuria	Foreign	Diprivan	PS		INTRAVENOUS	1 % IV	
Life-Threatening	Asphyxia	Literature	Cercine	SS		ORAL	10 MG DAILY	
Disability	Blood Pressure Decreased	Health				PO		
	Cardio-Respiratory Arrest	Professional	Fentanest	SS			250 UG DAILY	
	Choking	Other	Morphine Hydrochloride	SS		EPIDURAL	3 MG DAILY ED	
	Clostridium Colitis							
	Convulsion		Morphine Hydrochloride	SS		EPIDURAL	17 MG DAILY ED	
	Diarrhoea							
	Empyema							
	Haemodialysis		Sevoflurane	SS		RESPIRATORY (INHALATION)	60 ML DAILY IH	
	Post Procedural Complication							
	Pulmonary Embolism		Serenace	SS			10 MG DAILY	
	Pulmonary Thrombosis		Horizon	SS			10 MG DAILY	
	Pyrexia		Dormicum	SS			50 MG DAILY	
	Renal Failure Acute		Lepetan	SS			0.4 MG DAILY	
	Restlessness		Carbocain	C				
	Rhabdomyolysis		Anapeine Injection	C				
			Musculax	C				
			Mioblock	C				
			Laughing Gas	C				
			Oxygen	C				
			Ephedrine	C				
			Atropine Sulfate	C				
			Vagostigmin	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/24/04ISR Number: 4431141-0Report Type:Expedited (15-DaCompany Report #PHEH2004US08464
Age:82 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blood Pressure Decreased	Health	Exelon	PS	Novartis Sector:			
	Catatonia	Professional			Pharma	ORAL	1.5 mg, QD	7200 MIN
	Drug Interaction		Exelon	SS	Novartis Sector:			
	Hypokinesia				Pharma	ORAL	1.5 mg, BID	21600MIN
			Seroquel	SS				
			Haldol "Janssen"	SS				
			Trazodone	SS				
			Estrogens	SS				
						TRANSDERMAL		
			Ativan	C				
			Folic Acid	C				
			Combivent	C				

Date:08/24/04ISR Number: 4431225-7Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20040704106
Age:93 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abnormal Behaviour	Consumer	Haldol	PS				
	Asthenia		Zopiclone	SS				
Other	Choking		Melperone	SS				
	Delirium							
	Drug Ineffective							
	Dysphagia							
	Facial Palsy							
	Fall							
	Femoral Neck Fracture							
	Oedema Peripheral							
	Pelvic Fracture							
	Rhinitis							
	Salivary Hypersecretion							

Date:08/24/04ISR Number: 4431342-1Report Type:Expedited (15-DaCompany Report #JACFRA1999000232
Age:65 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Confusional State		Haldol	PS		OROPHARINGEAL		
Life-Threatening	General Physical		Mepronizine	SS		OROPHARINGEAL		
	Condition Abnormal		Mepronizine	SS		OROPHARINGEAL		
	Hepatitis Fulminant		Noctran	SS		OROPHARINGEAL		
	Renal Failure Acute		Noctran	SS		OROPHARINGEAL		
			Noctran	SS		OROPHARINGEAL	1DF per day	
			Theralene	SS		OROPHARINGEAL		
			Cholstat	SS		OROPHARINGEAL	2	WK

Date:08/24/04ISR Number: 4433497-1Report Type:Expedited (15-DaCompany Report #2004AP03400
Age:50 YR Gender:Male I/FU:F

Outcome	PT
Death	Alanine Aminotransferase
Life-Threatening	Increased
Hospitalization -	Ascites
Initial or Prolonged	Aspartate
Required	Aminotransferase
Intervention to	Increased
Prevent Permanent	Blood Bilirubin Increased
Impairment/Damage	Blood Creatine

	Phosphokinase Increased C-Reactive Protein Decreased					
	Coagulation Factor	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
	Decreased	Foreign	Seroquel	PS		ORAL
100 MG BID PO						
	Coma	Health	Haloperidol	SS		
	Delusion	Professional	Haloperidol	SS		ORAL
3 MG BID PO						
	Depressed Level Of	Other	Lullan	SS		ORAL
16 MG DAILY						
	Consciousness					
PO						
	Disseminated		Lullan	SS		ORAL
32 MG DAILY						
	Intravascular Coagulation					
PO						
	Encephalopathy		Lullan	SS		ORAL
8 MG BID PO						
	Haematemesis		Kyufu Gold	SS		
	Haemodialysis		Tasmolin	C		
	Hepatic Atrophy		Silece	C		
	Hepatic Function Abnormal		Amoban	C		
	Hepatitis Fulminant		Vegetamin A	C		
	Hyperhidrosis		Circanetten	C		
	Hypoproteinaemia		Borraginol A	C		
	Hypotension					
	Jaundice					
	Loss Of Consciousness					
	Mental Status Changes					
	Multi-Organ Failure					
	Myoglobinuria					
	Neuroleptic Malignant					
	Syndrome					
	Ocular Icterus					
	Overdose					
	Purpura					
	Pyrexia					
	Renal Failure					
	Tachycardia					
	Vomiting					
	White Blood Cell Count Decreased					

Date:08/25/04ISR Number: 4432081-3Report Type:Expedited (15-DaCompany Report #JP-JNJFOC-20040803455
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Abdominal Pain		Risperdal	PS		OROPHARINGEAL		
Initial or Prolonged	Brachial Plexus Injury		Haloperidol	SS		OROPHARINGEAL		
	Contusion		Biperiden Hydrochloride	SS		OROPHARINGEAL		
	Dialysis		Brotizolam	C		OROPHARINGEAL		
	Fall							
	Movement Disorder							
	Muscle Atrophy							
	Neuroleptic Malignant Syndrome							
	Rhabdomyolysis							

Date:08/26/04ISR Number: 4435053-8Report Type:Direct Company Report #CTU 225721
Age:46 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Drug Ineffective		Haloperidol	PS			30	DAY
Initial or Prolonged	Neuroleptic Malignant Syndrome		Olanzapine	SS			30	DAY
			Senna	C				
			Hctz	C				

			Synthroid	C		
			Nexium	C		

Date:08/27/04ISR Number: 4435324-5Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20040805045
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Interaction	Health	Haloperidol	PS				
	Mean Arterial Pressure Decreased	Professional	Alfentanil	SS				
			Hl10	SS				
ENDOTRACHEAL								
	Oxygen Saturation Decreased		Propofol	SS				
			Midazolam	SS				
			Ceftriaxone	C				
			Ranitidine	C				
			Heparin	C				
			Salbutamol	C				
			Atracurium	C				
			Addiphos	C				
			Addiphos	C				
			Addiphos	C				
			Addiphos	C				
			Sando-K	C				
			Ibuprofen	C				
			Combivent	C				
			Combivent	C				

Date:08/30/04ISR Number: 4436445-3Report Type:Periodic Company Report #US-BRISTOL-MYERS SQUIBB COMPANY-12587424
Age:16 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Ineffective		Abilify	PS	Otsuka Pharmaceutical Company, Ltd.	ORAL		
			Haldol	SS				

Date:08/30/04ISR Number: 4436854-2Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20040807661
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Death	Health	Haldol Decanoate	PS		INTRAMUSCULAR		
		Professional						

Date:09/01/04ISR Number: 4439454-3Report Type:Expedited (15-DaCompany Report #JP-JNJFOC-20040607188
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Drug Interaction		Risperdal	PS		OROPHARINGEAL		25 DAY
Initial or Prolonged	Parkinson'S Disease		Haloperidol	SS		OROPHARINGEAL		
	Thrombocytopenia		Haloperidol	SS		OROPHARINGEAL		
			Haloperidol	SS		OROPHARINGEAL	In Apr-2004	
							the dose of	
							haloperidol	
							was	
							increased.	
			Haloperidol	SS		OROPHARINGEAL	On 23-JAN-04	
							oral admin of	
							haloperidol	

was

initiated.

				Prednisolone	SS		
OROPHARINGEAL	169 DAY						
				Promethazine Hydrochloride	C		
OROPHARINGEAL							
				Triazolam	C		
OROPHARINGEAL							
				Lormetazepam	C		
OROPHARINGEAL							

Date:09/02/04ISR Number: 4439963-7Report Type:Expedited (15-DaCompany Report #JP-JNJFOC-20040808961
Age:45 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Agitation	Health	Levofloxacin	PS				16 DAY
	Brain Oedema	Professional	Itraconazole	SS				
	Enterococcal Infection		Haloperidol	SS				
	Hallucination		Haloperidol	SS				
	Hypocalcaemia		Amoxicillin Clavulanic Acid	SS		INTRAVENOUS		
	Hypokalaemia							
	Hypotension		Amoxicillin Clavulanic Acid	SS		INTRAVENOUS		
	Oliguria							
	Pseudomonas Infection		Pantoprazole	SS				
	Renal Haemorrhage		Nystatin	SS				
	Septic Shock		Diazepam	SS				
	Staphylococcal Infection		Furosemide	C		OROPHARINGEAL		12 DAY
	Toxic Epidermal Necrolysis		Canreonate	C				
	Vomiting		Rabeprazole	C				
			Metoclopramide	C				
			Calcium Lactogluconate Carbonate	C				
			Betamethasone	C				
			Cefaclor	C				
			Omeprazole	C				
			Cortisone Acetate	C				
			Calcitrol	C				

			Calcitrol	C
			Calcitrol	C
			Aluminum Magnesium Hydroxide	C
INTRAVENOUS	16	DAY		
			Aluminum Magnesium Hydroxide	C
INTRAVENOUS	16	DAY		
			Aluminum Magnesium Hydroxide	C
INTRAVENOUS	16	DAY		
			Fludrocortisone	C
			Calcium Gluconate	C
			Kcl	C

Date:09/03/04ISR Number: 4440459-7Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20040704106
Age:93 YR Gender:Female I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Accidental Exposure
Other	Apnoea
	Asthenia
	Choking
	Delirium
	Drug Ineffective
	Dysphagia
	Facial Palsy
	Fall

	Femoral Neck Fracture					
	Oedema Peripheral					
	Pelvic Fracture	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
	Respiratory Disorder	Consumer	Haldol	PS		
8-10 drops						
	Rhinitis		Zopiclone	SS		
	Salivary Hypersecretion		Melperone	SS		
	Weight Decreased					

Date:09/03/04ISR Number: 4441634-8Report Type:Expedited (15-DaCompany Report #FLUV00304000625
Age:9 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization -	Alanine Aminotransferase	Foreign	Luvox 25			
Initial or Prolonged	Increased	Health	(Fluvoxamine			
	Aspartate	Professional	Maleate)	PS		ORAL
75 MG DAILY						
	Aminotransferase	Other				
PO						
	Increased		Solanax (Alprazolam)	SS		ORAL
0.8 MG DAILY						
	Blood Lactate					
PO						
	Dehydrogenase Increased		Serenace			
	Hypersensitivity		(Haloperidol)	SS		ORAL
3 MG DAILY PO						
	Lymphocyte Stimulation		Neuleptil			
	Test Positive		(Periciazine)	SS		ORAL
5 MG DAILY PO						
	Pyrexia		Tegretol			
			(Carbamazepine)	SS		ORAL
200 MG DAILY						
PO						

Date:09/07/04ISR Number: 4442936-1Report Type:Direct Company Report #CTU 226371
Age:47 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					

Other Dysphagia Haldol 5 Mg PS
INTRAMUSCULAR 5 MG IM X 2
Swollen Tongue
IN 24 HRS
Ativan C

Date:09/07/04ISR Number: 4447130-6Report Type:Direct Company Report #USP 56821
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Medication Error		Haloperidol	PS	Novaplus	INECTABLE		

Date:09/08/04ISR Number: 4443608-XReport Type:Expedited (15-DaCompany Report #US-JNJFOC-20040900535
Age:82 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Unevaluable Event		Haldol	PS		UNKNOWN		
			Zyprexa	C				

Date:09/08/04ISR Number: 4446876-3Report Type:Expedited (15-DaCompany Report #2004201007JP
Age:78 YR Gender:Female I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Depression
	Drug Eruption
	Fall
	Femoral Neck Fracture
	Hallucination

		Parkinson'S Disease Persecutory Delusion Poriomania					
Dose	Duration		Report Source	Product	Role	Manufacturer	Route
		Pruritus Restlessness	Foreign Study Health Professional	Cabaser (Cabergoline) Tablet, 1-4mg	PS		ORAL
0.25 MG/DAY, ORAL							
			Other	Cabaser Regimen #2	SS		
0.5 MG/DAY							
				Cabaser Regimen #3	SS		
0.75 MG/DAY							
				Cabaser Regimen #4	SS		
1 MG/DAY							
				Cabaser Regimen #5	SS		
1.25 MG/DAY							
				Cabaser Regimen #6	SS		
1.5 MG/DAY							
				Cabaser Regimen #7	SS		
1.75 MG/DAY							
1.75 MG, ORAL				Serenace (Haloperidol)	SS		ORAL
20-30 MG, ORAL				Tryptanol (Amitriptyline Hydrochloride) Tablet	SS		ORAL
200-600 MG, ORAL				Depakene (Valproate Sodium)	SS		ORAL
				Ec Doparl (Benserazide Hydrochloride)	C		
				Depas (Etizolam) Tablet	C		
				Selbex (Teprenone)	C		
				Gasmotin	C		
				Gaster	C		
				Tinelac (Sennoside A+B) Tablet	C		

			Halcion Tablet	C			
			Cercin	C			
			Gramalil (Tiapride Hydrochloride)	C			

Date:09/08/04ISR Number: 4446904-5Report Type:Expedited (15-DaCompany Report #2004-BP-07335AU
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Pancytopenia	Health Professional	Persantin Sr (Dipyridamole)	PS		ORAL	400 MG (200 MG, 400 MG DAILY)	PO
		Other	Methotrexate (Methotrexate)	SS			10 MG (10 MG DAILY)	
			Nitrofurantoin (Nitrofurantoin)	SS				
OPHTHALMIC							200 MG (200 MG DAILY)	PO 7 DAY
			Augmentin Duo Forte (Clavulin)	SS		ORAL	(2 DAILY)	PO 7 DAY
			Digoxin	SS		ORAL	125 MCG (125 MCG DAILY)	PO
			Haloperidol	SS		ORAL	PO	
			Aspirin (Acetylsalicylic Acid)	SS		ORAL	150 MG (150	

MG DAILY) PO						
			Losec (Omeprazole)	SS		ORAL
20 MG (20 MG						
DAILY) PO						
			Folic Acid	SS		ORAL
10 MG (10 MG						
DAILY) PO						

Date:09/09/04ISR Number: 4449405-3Report Type:Expedited (15-DaCompany Report #B0342940A
Age:45 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Aortic Valve Sclerosis	Foreign	Betamethasone			
	Brain Oedema	Literature	(Betamethasone)	PS		
	Bronchopneumonia	Health	Augmentin			
	Cachexia	Professional	(Amox.Trihyd+Pot.Cla			
	Calcinosis		vulan.)	SS		
1200 MG THREE						
	Cerebral Disorder					
TIMES PER DAY						
	Enterococcal Infection		Sodium Rabeprazole			
	Hepatic Fibrosis		(Sodium Rabeprazole)	SS		
	Lung Infiltration		Metoclopramide			
	Lymphocytic Infiltration		(Metoclopramide)	SS		
	Pseudomonas Infection		Calcium Lactate			
	Renal Haemorrhage		Gluconate (Calcium			
	Septic Shock		Lactate Gluconate)	SS		
	Staphylococcal Infection		Nystatin (Nystatin)	SS		
4 ML THREE						
	Toxic Epidermal					
TIMES PER DAY						
	Necrolysis		Cefaclor (Cefaclor)	SS		
			Omeprazole			
			(Omeprazole)	SS		
			Cortisone Acetate			
			(Cortisone Acetate)	SS		
25 MG TWICE						
PER DAY						
			Calcitriol			
			(Calcitriol)	SS		
			Aluminum Hydroxide			

		(Aluminum Hydroxide)	SS
		Fludrocortisone (Fludrocortisone)	SS
4 ML THREE			
TIMES PER DAY			
		Levofloxacin (Levofloxacin)	SS
		Frusemide (Furosemide)	SS
		Canreonate	SS
		Diazepam (Diazepam)	SS
		Haloperidol (Haloperidol)	SS
		Frusemide (Furosemide)	SS
INTRAVENOUS			
		Itroconazole	SS
		Pantoprazole (Pantoprazole)	SS
		Calcium Gluconate (Calcium Gluconate)	SS
		Canreonate	C
INTRAVENOUS	INTRAVENOUS		
		Hydrocortisone H-Succ.	C
		Ranitidine Hydrochloride	C
		Rifamycin	C
		Gentamicin Sulphate	C
		Providone-Iodine	C

			Chlorphenamine	C		
			Albumin	C		
			Insulin	C		
			Dextrose	C		
			Ca Salt + Mg Salt	C		
			Potassium Chloride	C		

Date:09/10/04ISR Number: 4445688-4Report Type:Expedited (15-DaCompany Report #FR-JNJFOC-20040900961
Age:14 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Alanine Aminotransferase		Risperdal	PS				
OROPHARINGEAL								
Initial or Prolonged	Increased		Haldol	SS				
INTRAVENOUS	solution							
	Blood Creatine							
injectable 5								
	Phosphokinase Increased							
mg	1 DAY							
	Drug Interaction		Loxapac	C				
UNKNOWN								
			Tercian	C				
UNKNOWN								

Date:09/10/04ISR Number: 4448307-6Report Type:Expedited (15-DaCompany Report #04-00543
Age:34 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Blood Pressure Systolic	Literature	Haloperidol Lactate					
Initial or Prolonged	Increased	Health	Oral Solution Usp,					
	Body Temperature	Professional	Eq 1mg Lactate/Ml					
	Increased		(Alpharma)	PS	(Alpharma)			
	Eosinophilia		Clozapine	C				
	Fungus Serology Test		Benztropine	C				
	Positive		Olanzapine	C				
	Heart Rate Increased		Propranolol	C				
	Lethargy							
	Meningitis							
	Pleural Effusion							
	Pneumonia							
	Rash Erythematous							

Respiratory Rate
Increased
White Blood Cell Count
Increased

Date:09/15/04ISR Number: 4451641-7Report Type:Expedited (15-DaCompany Report #2004203561JP
Age:10 YR Gender:Male I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Alanine Aminotransferase Increased
	Aspartate Aminotransferase Increased
	Blood Alkaline Phosphatase Increased
	Blood Lactate Dehydrogenase Increased
	Drug Eruption
	Gamma-Glutamyltransferase Increased
	Hypersensitivity
	Lymphocyte Stimulation

	Test Positive Pyrexia Skin Hyperpigmentation						
		Report Source	Product	Role	Manufacturer	Route	Dose Duration
		Foreign Health	Luvox(Fluvoxamine Maleate) Tablet	PS		ORAL	75 MG/DAY, ORAL
		Professional					
		Other	Solanax(Alprazolam) Tablet	SS		ORAL	0.8 MG/DAY, ORAL
			Serenace(Haloperidol)	SS		ORAL	3 MG/DAY, ORAL
			Neuleptil(Periciazine)	SS		ORAL	5 MG/DAY, ORAL
			Tegretol(Carbamazepine)	SS		ORAL	200 MG/DAY, ORAL

Date:09/16/04ISR Number: 4451380-2Report Type:Expedited (15-DaCompany Report #BE-JNJFOC-20040901525
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Inappropriate Antidiuretic Hormone Secretion		Haldol	PS		INTRAVENOUS	5 X 1/2 ampule
			Tiapridal	C			
			Solu-Medrol	C			

Date:09/16/04ISR Number: 4451941-0Report Type:Expedited (15-DaCompany Report #2004S1002589
Age:27 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dystonia Laryngeal Disorder	Study Other	Haloperidol Tablets 0.5 Mg	PS		ORAL	ORAL	Other

Date:09/17/04ISR Number: 4453169-7Report Type:Expedited (15-DaCompany Report #2004AL000038
Age:46 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Interaction Potentiation	Health Professional	Lorazepam Tablets Usp, 2 Mg (Purepac)	PS	Purepac		SEE IMAGE	
	Electrocardiogram Qt Corrected Interval Prolonged		Haloperidol Lactate Oral Solution Usp, Eq. 1mg	SS			SEEE IMAGE	
	Sinus Tachycardia Ventricular Dysfunction		Risperidone	C				

Date:09/17/04ISR Number: 4458302-9Report Type:Periodic Company Report #US-JNJFOC-20040104813
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Confusional State Depression Suicidal Dissociation Paranoia Self Injurious Behaviour	Health Professional	Topamax (Topiramate) SEE IMAGE Haldol (Haloperidol) Tablets Cogentin ()	PS SS		ORAL ORAL	10 MG, 3 IN 1 DAY, ORAL	

			Benzatropine Mesilate	C		
			Zoloft () Sertraline Hydrochloride	C		
			Tylenol (Paracetamol)	C		
			Abilify (Aripiiprazole)	C		
			Remeron (Mirtazapine)	C		

Date:09/20/04ISR Number: 4453386-6Report Type:Expedited (15-DaCompany Report #BE-JNJFOC-20040901525
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Inappropriate Antidiuretic Hormone Secretion	Health Professional	Haldol	PS		INTRAVENOUS	5 X 1/2 ampule	
			Tiapridal	C				
			Solu-Medrol	C				

Date:09/20/04ISR Number: 4454753-7Report Type:Direct Company Report #CTU 227554
Age:62 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Creatine Phosphokinase Increased		Clozapine 25mg (Mylan)	PS	Mylan	ORAL	SEE IMAGE	
Required Intervention to Prevent Permanent Impairment/Damage	Confusional State		Haloperidol	SS			20 MG/D	
	Constipation		Clozapine	C				
	Ileus		Magnesium Hydroxide (Milk Of Magnesia)	C				
	Liver Function Test Abnormal		Docusate/Senna	C				
	Neuroleptic Malignant Syndrome		Lovastatin	C				
	Obstruction		Ferrous Sulfate	C				
	Pneumonia Aspiration		Sorbitol	C				
	Urinary Tract Infection		Albuterol	C				
			Terazosin	C				
			Ranitidine	C				
			Clonazepam	C				

Date:09/21/04ISR Number: 4457241-7Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20040903580
Age:46 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Alcohol Use	Literature	Cyclobenzaprine (Cyclobenzaprine Hydrochloride) Tablets	PS		ORAL		
Hospitalization - Initial or Prolonged	Blood Disorder	Health Professional						
Other	Electrocardiogram Qrs Complex Prolonged							
	Heart Rate Increased		Ibuprofen (Ibuprofen)	SS		ORAL		
	Multiple Drug Overdose							
	Respiratory Arrest		Chlorozoxazone (Chlorzoxazone)Tablets	SS		ORAL		
	Stupor							
			Methylphenidate (Methylphenidate Hydrochloride)	SS		ORAL		
			Diphenhydramine (Diphenhydramine)	SS		ORAL		
			Haloperidol (Haloperidol)	SS				

			Cephalexin (Cefalexin)	SS		ORAL
ORAL						
			Naproxen (Naproxen)	SS		ORAL
ORAL						
			Ethanol (Ethanol)	SS		ORAL
ORAL						

Date:09/22/04ISR Number: 4455609-6Report Type:Expedited (15-DaCompany Report #FR-JNJFOC-20040900961
Age:14 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Alanine Aminotransferase		Risperdal	PS				
OROPHARINGEAL								
Initial or Prolonged	Increased		Haldol	SS				
INTRAVENOUS	solution							
	Blood Creatine							
injectable 5								
	Phosphokinase Increased							
mg	1 DAY							
	Drug Interaction		Tercian	C				
UNKNOWN								
	Rhabdomyolysis		Levomepromazine	C				

Date:09/22/04ISR Number: 4457651-8Report Type:Expedited (15-DaCompany Report #2004-04010
Age:44 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Hyperthermia	Foreign	Clorazepatedipotassi					
Initial or Prolonged		Literature	um(Watson					
		Health	Laboratories)					
		Professional	(Clorazepate					
		Other	Dipotassium)	PS	Watson Laboratories	ORAL		
SEE IMAGE								
			Haloperidol (Watson					
			Laboratories)					
			(Haloperidol) Tablet	SS	Watson Laboratories	ORAL		
SEE IMAGE								
			Tetrabenazine					
			(Tetrabenazine)	SS		ORAL		
SEE IMAGE								

Date:09/22/04ISR Number: 4458221-8Report Type:Expedited (15-DaCompany Report #2004232670FR
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Coma	Foreign	Camptosar(Irinotecan) Solution, Sterile	PS				
	Drug Interaction	Health Professional	Haldol (Haloperidol)	SS				
	Vomiting	Other	Atropine (Atropine)	C				
			Fluorouracil	C				
			Leucovorin (Folinic Acid)	C				
			Neuroleptics	C				

Date:09/23/04ISR Number: 4461933-3Report Type:Expedited (15-DaCompany Report #2004203561JP
Age:9 YR Gender:Male I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Alanine Aminotransferase Increased
	Aspartate Aminotransferase Increased
	Blood Alkaline Phosphatase Increased
	Blood Lactate Dehydrogenase Increased

	Drug Eruption Eosinophil Count Increased	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Erythema Gamma-Glutamyltransferase Increased	Foreign Health Professional	Luvox (Fluvoxamine Maleate)Tablet	PS		ORAL	75MG/DAY, ORAL
	Hypersensitivity Infectious Mononucleosis Lymphocyte Count Increased Lymphocyte Stimulation Test Positive Pyrexia Skin Hyperpigmentation		Solanax (Alprazolam) Tablet Serenace (Haloperidol) Neuleptil (Periciazine) Tegretol (Carbamazepine)	SS SS SS SS		ORAL ORAL ORAL ORAL	0.8 MG/DAY, ORAL 3MG/DAY, ORAL 5MG/DAY, ORAL 200 MG/DAY, ORAL

Date:09/24/04ISR Number: 4457890-6Report Type:Expedited (15-DaCompany Report #FR-JNJFOC-20040904260
Age:23 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Agranulocytosis 13 DAY		Risperdal	PS			
OROPHARINGEAL Initial or Prolonged	Drug Interaction Tonsillitis		Haldol Loxapac Rivotril	SS SS SS			
OROPHARINGEAL			Depamide	SS			
OROPHARINGEAL			Tercian	C			
OROPHARINGEAL	40 mg/ml		Zyprexa Akineton Retard Clopixol	C C C			

Date:09/24/04ISR Number: 4457894-3Report Type:Expedited (15-DaCompany Report #JP-JNJFOC-20040803455
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dialysis		Risperdal	PS		ORAL		
	Fall		Haloperidol	SS		ORAL		
	Injury		Biperiden Hydrochloride	SS		ORAL		
	Joint Dislocation		Brotizolam	C		ORAL		
	Muscle Atrophy							
	Neuroleptic Malignant Syndrome							
	Rhabdomyolysis							

Date:09/24/04ISR Number: 4462079-0Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20040903580
Age:46 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Blood Disorder	Literature	Cyclobenzaprine (Cyclobenzaprine Hydrochloride) Tablet	PS		ORAL		
Hospitalization - Initial or Prolonged	Electrocardiogram Qrs Complex Prolonged	Health Professional						
Other	Heart Rate Increased		Ibuprofen (Ibuprofen)	SS		ORAL		
	Multiple Drug Overdose		Chlorzoxazone (Chlorzoxazone) Tablets	SS		ORAL		
	Respiratory Arrest		Methylphenidate					
	Stupor							

			(Methylphenidate Hydrochloride)	SS		ORAL
ORAL						
			Haloperidol (Haloperidol)	SS		ORAL
ORAL						
			Diphenhydramine (Diphenhydramine)	SS		ORAL
ORAL						
			Cephalexin (Cefalexin)	SS		ORAL
ORAL						
			Naproxen (Naproxen)	SS		ORAL
ORAL						
			Methanol (Ethanol)	SS		ORAL
ORAL						

Date:09/28/04ISR Number: 4461323-3Report Type:Expedited (15-DaCompany Report #FR-JNJFOC-20040905809
Age:59 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Blood Creatine	Health	Haldol	PS		OROPHARINGEAL		
Hospitalization -	Phosphokinase Increased	Professional	Nozinan	SS		OROPHARINGEAL		
Initial or Prolonged	Convulsion		Nozinan	SS		OROPHARINGEAL		
	Dermatitis Exfoliative		Clopixol	SS		INTRAMUSCULAR		
	Hyperthermia		Artane	C				
	Muscle Necrosis		Gardenal	C				
	Pyrexia							
	Rash							
	Rash Erythematous							

Date:09/28/04ISR Number: 4466619-7Report Type:Direct Company Report #CTU 228159
Age:61 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Blood Creatine		Haldol Tablets	PS		ORAL	5 MG Q AM PO	
Hospitalization -	Phosphokinase Increased		Haloperidol					

Initial or Prolonged	Blood Pressure Increased		Decanoate	SS	
INTRAMUSCULAR 150 MG IM Q					
Required	Confusional State				
28 D					
Intervention to Prevent Permanent Impairment/Damage	Drooling Dry Mouth Heart Rate Increased Muscle Rigidity Musculoskeletal Stiffness Pain Pyrexia White Blood Cell Count Increased				

Date:09/29/04ISR Number: 4462848-7Report Type:Expedited (15-DaCompany Report #04-09-1268
Age:48 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardiovascular Disorder Heart Rate Irregular Heat Stroke	Health Professional Other	Clozapine - Ivax Pharmaceuticals, Inc. Tablets	PS	Ivax Pharmaceuticals, Inc.	ORAL	600 MG HS ORAL	
			Haldol	SS			5MG HS	
			Clozapine - Ivax Pharmaceuticals, Inc. Tablets	SS		ORAL	300-400MG QD ORAL	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/29/04ISR Number: 4465744-4Report Type:Direct Company Report #CTU 228337
Age:13 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other Required Intervention to Prevent Permanent Impairment/Damage	Drooling Facial Spasm Oral Intake Reduced Tremor		Haldol 10mg	PS		ORAL	10 MG 3 X PER DAY ORAL	

Date:09/30/04ISR Number: 4463136-5Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20040908644
Age:37 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death OROPHARINGEAL OROPHARINGEAL	Aphasia Delirium Drug Interaction Excoriation Neuroleptic Malignant Syndrome Pericardial Effusion Pleural Effusion Rhabdomyolysis White Blood Cell Count Increased		Risperdal Risperdal Haldol Risperdal Benzotropine	PS SS SS SS C			gradually increased from 1 mg per day by day 10 of hospital dose taken at bedtime	

Date:09/30/04ISR Number: 4465940-6Report Type:Direct Company Report #CTU 228419
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Convulsion		Haloperidol	PS		ORAL	2 MG BID	ORAL
	Extrapyramidal Disorder		Omeprazole	C				
	Tremor		Multivitamins	C				
			Valproic Acid	C				
			Psyllium	C				
			Trazodone	C				

Date:10/01/04ISR Number: 4464112-9Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20040908650
Age:39 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Adverse Drug Reaction		Haldol	PS		UNKNOWN		
			Benztropine	SS		OROPHARINGEAL		

Date:10/01/04ISR Number: 4464113-0Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20040908710
Age:46 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardio-Respiratory Arrest		Haldol	PS		OROPHARINGEAL		
	Completed Suicide		Diphenhydramine	SS		OROPHARINGEAL		
			Cyclobenzaprine	SS		OROPHARINGEAL		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/01/04ISR Number: 4464114-2Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20040908711
Age:43 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Adverse Drug Reaction		Haldol	PS		PARENTERAL		

Date:10/01/04ISR Number: 4464115-4Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20040908712
Age:49 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Death		Haldol	PS		PARENTERAL		

Date:10/01/04ISR Number: 4464116-6Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20040908713
Age:8 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Death		Haldol	PS		PARENTERAL		
			Risperdal	SS		UNKNOWN		
			Chlorpromazine	SS		UNKNOWN		

Date:10/01/04ISR Number: 4464117-8Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20040908714
Age:45 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide		Haldol	PS		OROPHARINGEAL		
	Overdose		Quetiapine	SS		OROPHARINGEAL		
			Phenelzine	SS		OROPHARINGEAL		

Date:10/04/04ISR Number: 4464695-9Report Type:Expedited (15-DaCompany Report #BR-JNJFOC-20040908553
Age:10 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agitation		Haldol	PS				
	Extrapyramidal Disorder		Fluoxetine	SS				
	Eye Movement Disorder							
	Muscle Contractions Involuntary							
	Suicide Attempt							

Date:10/04/04ISR Number: 4468042-8Report Type:Direct Company Report #CTU 228698
Age:77 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Parkinson'S Disease		Haloperidol Decanoate 50mg/Ml	PS				

Date:10/05/04ISR Number: 4516273-0Report Type:Periodic Company Report #03-348-0772
Age:34 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Injection Site Reaction	Health Professional	Haloperidol Decanoate, 100 Mg/Ml, Ben Venue Labs	PS	Ben Venue Labs	INTRAMUSCULAR	300MG IM Q4	WEEKS

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/05/04ISR Number: 4516278-XReport Type:Periodic Company Report #04-020-0772
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Injection Site Reaction	Health Professional	Haloperidol Decanoate, 100 Mg/Ml, Ben Venue Labs	PS	Ben Venue Labs	INTRAMUSCULAR	200 MG IM Q3	WEEKS
			Norvasc	C				
			Teformin	C				
			Pepcid	C				
			Prozac	C				
			Haldol	C				
			Zydis	C				
			Actone	C				
			Vite	C				
			Lamcita	C				
			Cipro	C				

Date:10/05/04ISR Number: 4516280-8Report Type:Periodic Company Report #04-022-0772
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Injection Site Reaction	Health Professional	Haloperidol Decanoate, 100 Mg/Ml, Ben Venue Labs	PS	Ben Venue Labs	INTRAMUSCULAR	200 MG IM Q2	WEEKS
			Zydis	C				
			Gogentin	C				
			Super Aytinac, Vit. E. Cod Liver Oil	C				

Date:10/05/04ISR Number: 4516284-5Report Type:Periodic Company Report #04-023-0772
Age:48 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Other	Injection Site Reaction	Health Professional	Haloperidol Decanoate, 100 Mg/Ml	PS	Ben Venue Labs	
INTRAMUSCULAR	200 MG IM Q3					
WEEKS						
			Cogentin	C		
			Tegretol	C		
			Glucophage	C		
			Pen Vr	C		
			Zoloft	C		
			Lotensin	C		

Date:10/05/04ISR Number: 4516286-9Report Type:Periodic Company Report #04-221-0772
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Other	Injection Site Reaction	Health Professional	Haloperidol Decanoate 500 Mg	PS	Ben Venue Labs	
INTRAMUSCULAR	100MG IM Q 3					
WEEKS						

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/05/04ISR Number: 4516287-0Report Type:Periodic Company Report #04-223-0772
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Injection Site Reaction	Health Professional	Haloperidol Decanoate, 500 Mg	PS	Ben Venue Labs	INTRAMUSCULAR	150MG IM Q 4	WEEKS

Date:10/05/04ISR Number: 4516289-4Report Type:Periodic Company Report #04-224-0772
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Injection Site Reaction	Health Professional	Haloperidol Decanoate, 500 Mg	PS	Ben Venue Labs	INTRAMUSCULAR	125 MG IM Q	MONTH

Date:10/05/04ISR Number: 4516301-2Report Type:Periodic Company Report #04-225-0772
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Injection Site Reaction	Health Professional	Haloperidol Decanoate, 500 Mg	PS	Ben Venue Labs	INTRAMUSCULAR	75 MG IM Q	MONTH

Date:10/05/04ISR Number: 4516304-8Report Type:Periodic Company Report #04-226-0772
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Injection Site Reaction	Health Professional	Haloperidol Decanoate, 500 Mg	PS	Ben Venue Labs	INTRAMUSCULAR	200 MG IM Q 4	

WKS

Date:10/06/04ISR Number: 4467340-1Report Type:Expedited (15-DaCompany Report #AR-JNJFOC-20040910138
Age:76 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Morbid Thoughts		Haldol	PS		UNKNOWN		
			Lorazepam	C				

Date:10/07/04ISR Number: 4467957-4Report Type:Expedited (15-DaCompany Report #FR-JNJFOC-20040900961
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agitation	Health	Risperdal	PS		OROPHARINGEAL		
	Alanine Aminotransferase Increased	Professional	Haldol	SS		OROPHARINGEAL		1 DAY
			Tercian	C		UNKNOWN	dose=tablet	
	Blood Creatine Phosphokinase Increased		Levomepromazine	C				
			Rivotril	C		INTRAMUSCULAR		
	Rhabdomyolysis		Tranxene	C		INTRAMUSCULAR		
			Valium	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/07/04ISR Number: 4472940-9Report Type:Direct Company Report #CTU 229104
Age:35 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required	Akathisia		Haldol	PS		ORAL	10 MG PO BID	
Intervention to Prevent Permanent Impairment/Damage			Geodon	SS		ORAL	80 MG PO TID	

Date:10/07/04ISR Number: 4473153-7Report Type:Direct Company Report #USP 56904
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Medication Error		Haldol	PS		INJECTABLE		
			Haloperidol	SS		INJECTABLE		

Date:10/08/04ISR Number: 4469501-4Report Type:Expedited (15-DaCompany Report #FR-JNJFOC-20040905809
Age:59 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Muscle Necrosis		Haldol	PS		OROPHARINGEAL		
Hospitalization - Initial or Prolonged	Neuroleptic Malignant Syndrome		Nozinan	SS		OROPHARINGEAL		
			Nozinan	SS		OROPHARINGEAL		
	Rash Erythematous		Clopixol	SS		INTRAMUSCULAR		
			Artane	C				
			Gardenal	C				

Date:10/11/04ISR Number: 4470799-7Report Type:Expedited (15-DaCompany Report #JP-SOLVAY-00304000625
Age:3627 DY Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Alanine Aminotransferase Increased	Health Professional	Luvox 25	PS		ORAL	Daily Dose: 75 mg. Frequency:Unk	nown 106 DAY
	Aspartate Aminotransferase Increased		Solanax	SS		ORAL	Daily Dose: 0.8 mg. Frequency:Unk	nown 109 DAY
	Blood Alkaline Phosphatase Increased		Serenace	SS		ORAL	Daily Dose: 3 mg. Frequency:Unk	nown 109 DAY
	Blood Lactate Dehydrogenase Increased		Neuleptil	SS		ORAL	Daily Dose: 5 mg. Frequency:Unk	nown 8 DAY
	Drug Eruption		Tegretol	SS		ORAL	Daily Dose: 200 mg. Frequency:Unk	nown 27 DAY
	Gamma-Glutamyltransferase Increased							
	Hypersensitivity							
	Lymphocyte Count Increased							
	Lymphocyte Stimulation Test Positive							
	Pyrexia							
	Skin Hyperpigmentation							

Date:10/11/04ISR Number: 4470860-7Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20041000516
Age:66 YR Gender:Female I/FU:I

Outcome
Life-Threatening
Hospitalization -

Initial or Prolonged
Disability

	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Cerebral Infarction	Health	Haldol Decanoat	PS			INTRAMUSCULAR	
	Cerebrovascular Accident	Professional	Leponex	SS			OROPHARINGEAL	
	Paresis		Truxal	SS			OROPHARINGEAL	
	Speech Disorder		Flunitrazepam	SS			OROPHARINGEAL	
			Captohexal	C			OROPHARINGEAL	
			Ranitidine	C				
			Godamed	C			OROPHARINGEAL	
			Beloc	C			OROPHARINGEAL	
			Laxofalk	C			OROPHARINGEAL	

Date:10/12/04ISR Number: 4471395-8Report Type:Expedited (15-DaCompany Report #FR-JNJFOC-20041000548
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Blood Creatine	Health	Haldol	PS			INTRAMUSCULAR	
Initial or Prolonged	Phosphokinase Increased	Professional	Theralene	SS			OROPHARINGEAL	
			Tiapridal	C				

Date:10/12/04ISR Number: 4472851-9Report Type:Direct Company Report #CTU 229346
Age:20 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Neuroleptic Malignant		Haloperidol	PS				
Initial or Prolonged	Syndrome							
Other								

Date:10/12/04ISR Number: 4474551-8Report Type:Expedited (15-DaCompany Report #FLUV00304000625
Age:9 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Alanine Aminotransferase Increased Aspartate Aminotransferase Increased Blood Alkaline Phosphatase Increased Blood Lactate Dehydrogenase Increased Drug Eruption Eosinophil Count Increased Gamma-Glutamyltransferase Increased Hypersensitivity Lymphocyte Count Increased Lymphocyte Stimulation Test Positive Pyrexia Skin Hyperpigmentation	Foreign Health Professional Other	Luvox 25 (Fluvoxamine Maleate) Solanax (Alprazolam) Serenace (Haloperidol) Neuleptil (Periciazine) Tegretol (Carbamazepine)	PS SS SS SS SS		ORAL ORAL ORAL ORAL ORAL	75 MILLIGRAM(S) 0.8 MILLIGRAM(S), 3 MILLIGRAM(S), 5 MILLIGRAM(S) 20 MILLIGRAM(S)	DAILY ORAL DAILY ORAL DAILY ORAL DAILY ORAL DAILY ORAL

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/12/04ISR Number: 4474638-XReport Type:Expedited (15-DaCompany Report #2004203561JP
Age:9 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Alanine Aminotransferase Increased Aspartate Aminotransferase Increased Blood Alkaline Phosphatase Increased Blood Lactate Dehydrogenase Increased Cross Sensitivity Reaction Gamma-Glutamyltransferase Increased Hepatic Function Abnormal Hypersensitivity Lymphocyte Count Increased Lymphocyte Morphology Abnormal Lymphocyte Stimulation Test Positive Pigmentation Disorder	Foreign Health Professional Other	Luvox(Fluvoxamine Maleate) Tablet Solanax (Alprazolam) Tablet Serenace (Haloperidol) Neuleptil (Periciazine) Tegretol (Carbamazepine)	PS SS SS SS SS		ORAL ORAL ORAL ORAL ORAL	75 MG/DAY, 0.8 MG/DAY, 3 MG/DAY, 5 MG/DAY, 200 MG/DAY,	

Date:10/12/04ISR Number: 4475188-7Report Type:Expedited (15-DaCompany Report #2004203561JP
Age:9 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Alanine Aminotransferase	Foreign	Luvox (Fluvoxamine					

Initial or Prolonged	Increased	Health	Maleate) Tablet	PS		ORAL
75 MG/DAY,						
	Aspartate	Professional				
ORAL						
	Aminotransferase	Other	Solanax (Alprazolam)			
	Increased		Tablet	SS		ORAL
0.8 MG/DAY,						
	Blood Alkaline					
ORAL						
	Phosphatase Increased		Serenace			
	Blood Lactate		(Haloperidol)	SS		ORAL
3 MG/DAY,						
	Dehydrogenase Increased					
ORAL						
	Cross Sensitivity		Neuleptil			
	Reaction		(Periciazine)	SS		ORAL
5 MG/DAY,						
	Drug Eruption					
ORAL						
	Gamma-Glutamyltransferase		Tegretol			
	Increased		(Carbamazepine)	SS		ORAL
200 MG/DAY,						
	Hypersensitivity					
ORAL						
	Infectious Mononucleosis					
	Lymphocyte Stimulation					
	Test Positive					
	Pyrexia					
	Skin Hyperpigmentation					

Date:10/12/04ISR Number: 4476536-4Report Type:Expedited (15-DaCompany Report #2004071261
Age:45 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Cardio-Respiratory Arrest	Literature	Phenelzine Sulfate			
Other	Completed Suicide	Health	(Phenelzine Sulfate)	PS		
	Intentional Misuse	Professional	Haloperidol			
			(Haloperidol)	SS		

			Quetiapine (Quetiapine)	SS			
			All Other Therapeutic Products (All Other Therapeutic Products)	SS			

Date:10/12/04ISR Number: 4476922-2Report Type:Expedited (15-DaCompany Report #2004071481
Age:46 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Study	Diphenhydramine (Diphenhydramine)	PS		ORAL	ORAL	
		Literature						
		Health Professional	Haloperidol (Haloperidol)	SS		ORAL	ORAL	
			Cyclobenzaprine (Cyclobenzaprine)	SS		ORAL	ORAL	

Date:10/13/04ISR Number: 4472910-0Report Type:Expedited (15-DaCompany Report #JP-JNJFOC-20031201568
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardio-Respiratory Arrest	Health	Risperdal	PS		OROPHARINGEAL		
Hospitalization - Initial or Prolonged	Phlebothrombosis	Professional	Haloperidol	SS		OROPHARINGEAL		
	Pulmonary Embolism		Zotepine	SS		OROPHARINGEAL		
			Levomepromazine Maleate	SS		OROPHARINGEAL		
			Carbamazepine	C		OROPHARINGEAL		
			Biperiden Hydrochloride	C		OROPHARINGEAL		

			Bromazepam	C			
OROPHARINGEAL							
			Teprenone	C			
OROPHARINGEAL							
			Gentian	C			
OROPHARINGEAL							
			Sodium Bicarbonate	C			
OROPHARINGEAL							

Date:10/13/04ISR Number: 4472917-3Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20041002567
Age:48 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Heart Rate Irregular		Haldol	PS				
UNKNOWN	(5mg taken at Heat Stroke night)							
			Clozapine	SS				
OROPHARINGEAL								

Date:10/13/04ISR Number: 4472918-5Report Type:Expedited (15-DaCompany Report #BR-JNJFOC-20040908553
Age:10 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agitation Extrapyramidal Disorder Eye Movement Disorder Muscle Contractions Involuntary Suicide Attempt	Health Professional	Haldol Fluoxetine	PS SS				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/13/04ISR Number: 4477400-7Report Type:Expedited (15-DaCompany Report #2004-06-1964
Age:47 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged Other	Alanine Aminotransferase Increased Aspartate Aminotransferase Increased Blood Alkaline Phosphatase Increased Blood Lactate Dehydrogenase Increased Drug Eruption Gamma-Glutamyltransferase Increased Hepatic Function Abnormal Liver Disorder Lymphocyte Stimulation Test Positive Scab	Foreign Health Professional Other	Rinderon "Like Celestone Syrup" Tablets	PS		ORAL	3-5- 3MG QD ORAL : 5MG QD ORAL : 4MG QD ORAL : 3MG QD ORAL
			Salicylamide Oral	SS		ORAL	3G/D ORAL
			Hirnamin Oral	SS		ORAL	50-200MG QD ORAL : 50MG , 75MG, 150MG, 200MG
			Akineton Oral	SS		ORAL	3MG QD ORAL
			Serenace Oral	SS		ORAL	2-12 - 9MG QD ORAL : 2MG , 6MG , 9MG , 12 MG
			Aleviatin Oral	SS		ORAL	500-300MG QD ORAL : 500MG, 300MG
			Seroquel (Quetiapine Fumurate) Oral	SS		ORAL	200-300MG QD

ORAL ; 200			
MG, 300 MG			
	Gaster Oral	SS	ORAL
40MG QD ORAL			
	Tergretol Oral	SS	ORAL
400-600MG QD			
ORAL ;			
400MG, 600MG			
	Arasena A Injectable	SS	
600MG			
	Contrast Dye Injectable	SS	

Date:10/13/04ISR Number: 4477412-3Report Type:Expedited (15-DaCompany Report #M2004-1462
Age:45 YR Gender:Female I/FU:I

Outcome	PT
Death	Agitation
	Aortic Valve Sclerosis
	Autoimmune Hepatitis
	Blood Culture Positive
	Brain Oedema
	Bronchopneumonia
	Cachexia
	Chronic Hepatitis
	Condition Aggravated
	Endometrial Atrophy
	Enterococcal Infection
	Gastrointestinal Mucosal Disorder
	Hallucination
	Hepatic Fibrosis
	Hypokalaemia
	Hypotension
	Lung Infiltration
	Lymphocytic Infiltration
	Oliguria
	Onychomadesis

		Ovarian Atrophy Pseudomonas Infection Rash Macular	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
		Respiratory Distress	Foreign	Amox/Clav	PS		
1200 MG							
		Septic Shock	Literature				
T.D.S.; TABLE							
		Staphylococcal Infection					
OVER LEAF							
		Thyroid Atrophy		Rabeprazole	SS		
		Toxic Epidermal		Metoclopramide	SS		
		Necrolysis		Calcium			
		Vomiting		Lactogluconate/Carbo			
				nate	SS		
				Betametasone	SS		
				Nystatin	SS		
				Cefaclor	SS		
				Omeprazole	SS		
20 MG							
				Cortisone Acetate	SS		
25 MG B.I.D.							
				Calcitriol	SS		
0.5 MCG AT 8							
A.M.							
				Aluminium/Magnesium			
				Hydroxide	SS		
				Fludrocortisone	SS		
				Amoxicillin/Clavulan			
				ic Acid	SS		
INTRAVENOUS	1200 MG						
T.D.S. IV							
				Levofloxacin	SS		ORAL
500 MG P.O.							
				Furosemide	SS		ORAL
PO, IV							
				Canreonate	SS		ORAL
PO							
				Diazepam	SS		
				Haloperidol	SS		
				Itraconazole	SS		
				Pantoprazole	SS		
				Famified Chain Amino			
				Acids	SS		
				Calcium Gluconate	SS		

Date:10/14/04ISR Number: 4474518-XReport Type:Expedited (15-DaCompany Report #PHBS2004JP11365
Age:64 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Alkaline Phosphatase Increased		Diovan	PS	Novartis Sector: Pharma	ORAL	40 mg, QD	11520MIN
	Blood Creatinine Increased		Serenace	SS		ORAL	.75 mg, QD	11520MIN
			Detantol R	C		ORAL		
	C-Reactive Protein Increased		Munobal	C		ORAL	5 mg, UNK	
	Dehydration							
	Drug Eruption							
	Hyperthermia							
	Pyrexia							
	Rash							
	Rash Erythematous							
	Toxic Skin Eruption							
	White Blood Cell Count Increased							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/15/04ISR Number: 4475421-1Report Type:Expedited (15-DaCompany Report #FR-JNJFOC-20041002513
Age:23 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Hepatitis		Haldol	PS				
OROPHARINGEAL							doses=drops	
Initial or Prolonged			Nozinan	C				

Date:10/18/04ISR Number: 4478437-4Report Type:Direct Company Report #CTU 229888
Age:56 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Facial Pain		Haloperidol					
Initial or Prolonged	Leukocytosis		Decanoate 100mg/Ml	PS				
INTRAMUSCULAR							100 MG	Q
	Neuroleptic Malignant							
2WEEKS								
	Syndrome							
INTRAMUSCU								
	Photophobia		Clonazepam	C				
	Pyrexia		Haloperidol	C				
			Olanzapine	C				
			Trihexyphenidyl	C				

Date:10/19/04ISR Number: 4478419-2Report Type:Expedited (15-DaCompany Report #UY-JNJFOC-20041002972
Age:81 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardiac Failure	Health	Haldol Decanoate	PS				
INTRAVENOUS								
Hospitalization -	Congestive	Professional	Haldol Decanoate	SS				
INTRAVENOUS								
Initial or Prolonged	Chronic Obstructive		Bufferin	C				
	Airways Disease		Bufferin	C				
	Exacerbated		Bufferin	C				
	Depressed Level Of		Clarithromycin	C				
	Consciousness		Salbutamole E					
	Eating Disorder		Ipratropius	C				
	Medication Error		Salbutamole E					
	Memory Impairment		Ipratropius	C				

	Muscle Rigidity
	Respiratory Arrest
	Urinary Incontinence

Date:10/19/04ISR Number: 4478466-0Report Type:Expedited (15-DaCompany Report #FR-JNJFOC-20041002950
Age:68 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Blood Creatine	Health	Haldol	PS				
OROPHARINGEAL							80 drops tid	
Initial or Prolonged	Phosphokinase Increased	Professional	Haldol	SS				
OROPHARINGEAL							100 drops tid	
	Pyrexia		Piportil	SS				
OROPHARINGEAL								

Date:10/19/04ISR Number: 4479190-0Report Type:Direct Company Report #CTU 230011
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Abnormal Behaviour		Generic Haldol	PS				
INTRAMUSCULAR							250 MG	IM Q 4
Initial or Prolonged	Drug Effect Decreased							
WEEKS								
Other	Pharmaceutical Product							
	Complaint							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/21/04ISR Number: 4481194-9Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20040802463
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Extrapyramidal Disorder	Health	Risperdal Consta	PS		INTRAMUSCULAR		
Hospitalization -	Respiratory Failure	Professional	Risperdal Consta	SS		INTRAMUSCULAR		
Initial or Prolonged			Risperdal	SS		OROPHARINGEAL		
Other			Haldol	SS		OROPHARINGEAL		
			Tavor	SS		OROPHARINGEAL		
			Norvasc	C		OROPHARINGEAL		

Date:10/21/04ISR Number: 4483969-9Report Type:Expedited (15-DaCompany Report #2004AL000724
Age:46 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardio-Respiratory Arrest Completed Suicide Intentional Misuse	Literature	Hydramine Cough Syrup (Diphenhydramine Hydrochloride Cough Syrup (Alpharma)	PS	Alpharma	ORAL	PO	
			Hydramine Elixir (Diphenhydramine Hydrochloride Elixir) (Alpharma)	SS	Alpharma	ORAL	PO	
			Cyclobenzaprine	SS		ORAL	PO	
			Haloperidol	SS		ORAL	PO	

Date:10/21/04ISR Number: 4486528-7Report Type:Expedited (15-DaCompany Report #2004203561JP
Age:9 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Alanine Aminotransferase Increased	Foreign Health Professional	Luvox (Fluvoxamine Maleate) Tablet	PS		ORAL	75 MG/DAY, ORAL
	Aspartate Aminotransferase Increased	Other	Solanax (Alprazolam) Tablet	SS		ORAL	0.8 MG/DAY, ORAL
	Blood Alkaline Phosphatase Increased		Serenace (Haloperidol)	SS		ORAL	3 MG/DAY, ORAL
	Blood Lactate Dehydrogenase Increased		Neuleptil (Periciazine)	SS		ORAL	5 MG/DAY, ORAL
	Drug Eruption		Tegretol (Carbamazepine)	SS		ORAL	200 MG/DAY, ORAL
	Gamma-Glutamyltransferase Increased						
	Lymphocyte Stimulation Test Positive						
	Pyrexia						

Date:10/22/04ISR Number: 4482609-2Report Type:Expedited (15-DaCompany Report #IT-JNJFOC-20041003157
Age:43 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Rhabdomyolysis	Health Professional	Haldol Decanoas	PS		INTRAMUSCULAR	
			Haloperidol (Serenase)	SS		OROPHARINGEAL	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/22/04ISR Number: 4482610-9Report Type:Expedited (15-DaCompany Report #FR-JNJFOC-20041003296
Age:62 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Convulsion		Risperdal	PS				
OROPHARINGEAL								
Initial or Prolonged	Dehydration		Haldol Decanoas	SS				
INTRAMUSCULAR								
	Disorientation		Depamide	C				
	Haemoglobin Decreased		Lepticur	C				
	Hyponatraemia							
	Micturition Disorder							
	Thirst							
	Weight Increased							

Date:10/25/04ISR Number: 4483874-8Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20041006439
Age:12 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Confusional State		Haldol	PS				
OROPHARINGEAL								
	Extrapyramidal Disorder		Tenex	C				
	Eye Rolling		Zoloft	C				
	Suicidal Ideation		Seroquel	C				
			Straterra	C				

Date:10/25/04ISR Number: 4488131-1Report Type:Expedited (15-DaCompany Report #2004CG02097
Age:76 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Blood Cholesterol	Foreign	Tenormine	PS				
	Increased	Health	Temesta	SS				
	Hepatic Steatosis	Professional	Haldol	SS				
	Hepatitis Cholestatic	Other	Loxen	SS				
			Anafranil	SS				
			Rivotril	SS				
			Trivastal	SS				
			Inipomp	SS				
			Kardegic /Fra/	SS				

Date:10/25/04ISR Number: 4488729-0Report Type:Expedited (15-DaCompany Report #2004-04412
Age:48 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Tourette'S Disorder	Foreign Literature	Haloperidol (Watson Laboratories)					
		Health	(Haloperidol) Tablet	PS	Waston Laboratories			
SEE IMAGE								
		Professional	Risperidone					
		Other	(Risperidone)	C				
			Olanzapine					
			(Olanzapine)	C				

Date:10/26/04ISR Number: 4485601-7Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20040103245
Age: Gender:Female I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Apathy
	Asthenia
Other	Blood Prolactin Increased
	Condition Aggravated
	Decreased Interest

	Drug Interaction						
	Fatigue						
	Injury	Report Source	Product	Role	Manufacturer	Route	Dose
Duration							
	Menstruation Irregular		Risperdal Consta	PS			
INTRAMUSCULAR							
	Psychotic Disorder		Risperdal Consta	SS			
INTRAMUSCULAR							
	Refusal Of Treatment By		Haloperidol	SS			
OROPHARINGEAL							
	Patient		Proneurin	C			
OROPHARINGEAL	at night						
	Suicide Attempt		Proneurin	C			
OROPHARINGEAL	"changed to						
0-0-1-2"							
			Proneurin	C			
OROPHARINGEAL							
			Proneurin	C			
OROPHARINGEAL							
			Proneurin	C			
OROPHARINGEAL	taken at						
night							
			Amitriptylin	C			
OROPHARINGEAL	4x1						
			Amitriptylin	C			
OROPHARINGEAL	switched to						
promethazine							
			Biperiden	C			
			Biperiden	C			
			Lorazepam	C			
			Radedorm	C			
			Stilnox	C			
"0-0-1"							

Date:10/27/04ISR Number: 4486505-6Report Type:Expedited (15-DaCompany Report #FR-JNJFOC-20041004929
Age:76 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose
Duration							
Life-Threatening	Hepatitis Cholestatic	Health	Haldol	PS			
OROPHARINGEAL	20 mg/ml						

		Professional	Temesta	SS		
OROPHARINGEAL						
			Loxen	SS		
OROPHARINGEAL	20 mg					
			Anafranil	SS		
OROPHARINGEAL						
			Rivotril	SS		
OROPHARINGEAL						
			Tenormine	SS		
OROPHARINGEAL						
			Trivastal	C		
			Inipomp	C		
			Kardegic	C		

Date:10/27/04ISR Number: 4490845-4Report Type:Expedited (15-DaCompany Report #MK200410-0246-1
Age:76 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Blood Cholesterol Increased	Foreign	Anafranil Capsules (Clomipramine)	PS				
	Hepatic Steatosis		Loxen	SS				
	Hepatitis Cholestatic		Temesta	SS				
			Haldol	SS				
			Rivotril	SS				
			Tenormine	SS				
			Trivastal	SS				
			Inipomp	SS				
			Kardegic	SS				

Date:11/01/04ISR Number: 4489504-3Report Type:Expedited (15-DaCompany Report #PHNU2004DE03639
Age:52 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Interaction		Leponex / Clozaril (Clozapine)	PS	Novartis Sector: Pharma	ORAL	150 mg/day	27360MIN
	Parotitis							
	Ultrasound Scan Abnormal							

				Leponex / Clozaril (Clozapine)	SS	Novartis Sector: Pharma	ORAL
200 mg/day	7200 MIN						
				Haldol "Janssen"	SS		ORAL
5 mg/day	17280MIN						

Date:11/01/04ISR Number: 4491287-8Report Type:Expedited (15-DaCompany Report #B0348579A
Age:60 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Other	Blood Creatine Phosphokinase Increased	Foreign Literature	Paxil Tablet (Paroxetine			
	Depressed Level Of Consciousness	Health Professional	Hydrochloride) Risperidone	PS		ORAL
	Drug Withdrawal Syndrome		(Formulation			
	Hallucination		Unknown)			
	Neuroleptic Malignant Syndrome		(Risperidone) Haloperidol	SS		ORAL
	Oliguria		(Formulation			
	Post Procedural Complication		Unknown) (Haloperidol)	SS		
	Renal Impairment					

Date:11/04/04ISR Number: 4492897-4Report Type:Expedited (15-DaCompany Report #US-MERCK-0410USA04039
Age:39 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Death	Adverse Event		Cogentin	PS	Merck & Co., Inc	ORAL
	Death		Haloperidol	SS		ORAL

Date:11/05/04ISR Number: 4493476-5Report Type:Periodic Company Report #FR-JNJFOC-20041003296
Age:62 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					

Hospitalization - OROPHARINGEAL	Blood Glucose Increased		Risperdal	PS			
Initial or Prolonged INTRAMUSCULAR	Blood Potassium Decreased		Haldol Decanoas	SS			
	Blood Sodium Decreased		Depamide	SS			
OROPHARINGEAL Dose= 3 cp per day	Blood Urea Decreased						
	Convulsion		Lepticur	C			
	Creatine Urine Abnormal						
	Disorientation						
	Haemoglobin Decreased						
	Hyponatraemia						
	Polydipsia						
	Thirst						
	Urea Urine Abnormal						
	Urine Potassium Abnormal						
	Weight Increased						

Date:11/05/04ISR Number: 4493984-7Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20040908711
Age:43 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Hyperpyrexia		Haldol	PS		PARENTERAL		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/05/04ISR Number: 4493985-9Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20040908710
Age:46 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Blood Test Abnormal		Haldol	PS		OROPHARINGEAL		
	Completed Suicide		Diphenhydramine	SS		OROPHARINGEAL		
	Electrocardiogram Qrs		Cyclobenzaprine	SS		OROPHARINGEAL		
	Complex Shortened		Ibuprofen	SS				
	Heart Rate Increased		Cephalexin	SS				
	Intentional Misuse		Naproxen	SS				
	Respiratory Arrest		Chlorzoxazone	SS				
			Methylphenidate	SS				
			Ethanol	SS				

Date:11/05/04ISR Number: 4494198-7Report Type:Expedited (15-DaCompany Report #FR-ROCHE-384615
Age:76 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Hepatitis Cholestatic		Rivotril	PS	Roche	ORAL		
			Rivotril	SS	Roche	ORAL		
			Tenormine	SS		ORAL		
			Anafranil	SS		ORAL		
			Loxen	SS	Roche	ORAL		
			Haldol	SS		ORAL		
			Temesta	SS		ORAL		
			Kardegic	C		UNKNOWN		
			Inipomp	C				
			Trivastal	C				

Date:11/05/04ISR Number: 4494314-7Report Type:Expedited (15-DaCompany Report #JP-GLAXOSMITHKLINE-B0348579A
Age:60 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blood Creatine		Paxil	PS	Glaxosmithkline	ORAL		
	Phosphokinase Increased		Risperidone	SS		ORAL		

	Depressed Level Of Consciousness Musculoskeletal Stiffness Neuroleptic Malignant Syndrome Oliguria Pyrexia Renal Impairment		Haloperidol	SS			UNKNOWN

Date:11/05/04ISR Number: 4497607-2Report Type:Periodic Company Report #FR-JNJFOC-20041003296
Age:62 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Convulsion Hyponatraemia Thirst	Health Professional	Risperdal Haldol Decanoas Depamide	PS SS SS		OROPHARINGEAL INTRAMUSCULAR OROPHARINGEAL	Dose= 3 cp per day	
			Lepticur	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/08/04ISR Number: 4495495-1Report Type:Expedited (15-DaCompany Report #FR-JNJFOC-20041008390
Age:58 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Agitation		Haldol	PS				
OROPHARINGEAL								
Initial or Prolonged	Alanine Aminotransferase		Depamide	SS				
OROPHARINGEAL								
	Increased		Medrol	C				
	Aspartate							
	Aminotransferase							
	Increased							
	Asthenia							
	Gamma-Glutamyltransferase							
	Increased							
	Headache							
	Inflammation							
	Insomnia							
	Polyarthritis							

Date:11/08/04ISR Number: 4495496-3Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20041100092
Age:74 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Anaphylactic Reaction		Haloperidol	PS				
OROPHARINGEAL								

Date:11/08/04ISR Number: 4495497-5Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20040908713
Age:8 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Acidosis		Haldol	PS				
PARENTERAL								
	Brain Death		Risperdal	SS				
UNKNOWN								
	Bronchopneumonia		Chlorpromazine	SS				
UNKNOWN								
	Cerebral Infarction		Diphenhydramine	SS				
	Cerebrovascular Accident		Lorazepam	SS				
	Cholestasis							

	Hepatic Necrosis					
	Intracranial Pressure Increased					
	Multi-Organ Failure					
	Neuroleptic Malignant Syndrome					
	Rhabdomyolysis					
	Sepsis					

Date:11/08/04ISR Number: 4495498-7Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20040908714
Age:45 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Anoxia		Haldol	PS		OROPHARINGEAL		
	Cardio-Respiratory Arrest		Quetiapine	SS		OROPHARINGEAL		
	Coma		Phenelzine	SS		OROPHARINGEAL		
	Completed Suicide		Clonazepam	SS				
	Intentional Misuse							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/08/04ISR Number: 4495499-9Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20040908650
Age:39 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Base Excess Increased		Haldol	PS		UNKNOWN		
	Blood Creatine		Benztropine	SS		OROPHARINGEAL		
	Phosphokinase Increased		Paroxetine	SS				
	Blood Ph Decreased		Clonazepam	SS				
	Blood Pressure Decreased		Valproic Acid	SS				
	Body Temperature Increased							
	Convulsion							
	Depressed Level Of Consciousness							
	Disseminated Intravascular Coagulation							
	Mental Status Changes							
	Muscle Rigidity							
	Pco2 Decreased							
	Po2 Increased							
	Respiratory Distress							
	Respiratory Rate Increased							
	Rhabdomyolysis							
	Sepsis							
	Tachycardia							

Date:11/08/04ISR Number: 4497694-1Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20041007713
Age:52 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Interaction	Health	Haldol	PS		OROPHARINGEAL		
	Parotitis	Professional	Leponex	I		OROPHARINGEAL		
			Leponex	I		OROPHARINGEAL		

Date:11/08/04ISR Number: 4497695-3Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20041008588
Age:86 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Agitation		Haldol	PS		INTRAVENOUS	Inital dose was 4 mg. (given a total of 12 mg in 2 1/2	
	Blood Pressure Increased							
	Irritability							
	Medication Error							
	Respiratory Arrest							

Date:11/08/04ISR Number: 4497696-5Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20041100035
Age:51 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Arthritis		Haldol Decanoate	PS			150 - 300 mg	
	Diabetes Mellitus		Haldol Decanoate	SS				
	Hypertension							
	Vision Blurred							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/09/04ISR Number: 4496421-1Report Type:Expedited (15-DaCompany Report #FR-JNJFOC-20040800680
Age:82 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Cerebral Haematoma		Haldol Faible	PS				
OROPHARINGEAL								
Initial or Prolonged	Disorientation		Kardegic	C				
	Drug Interaction		Deroxat	C				
	Extrapyramidal Disorder		Adancor	C				
	Fall		Artane	I				
OROPHARINGEAL							3	DAY
	Intraventricular		Captopril	I				
OROPHARINGEAL								
	Haemorrhage							
	Orthostatic Hypotension							
	Rhabdomyolysis							

Date:11/09/04ISR Number: 4496563-0Report Type:Expedited (15-DaCompany Report #AU-JNJFOC-20041101068
Age:94 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Depressed Level Of Consciousness		Tramadol Hydrochloride	PS				
OROPHARINGEAL								
	Drug Interaction		Morphine Sulphate	SS				
INTRAVENOUS								
	Pupillary Reflex Impaired		Panadeine Forte	SS				
UNKNOWN								
	Respiratory Arrest		Panadeine Forte	SS				
UNKNOWN								
			Haloperidol	SS				
OROPHARINGEAL								
			Nitrazepam	SS				
OROPHARINGEAL								
			Olanzapine	SS				
OROPHARINGEAL								
			Captopril	C				
			Thyroxine	C				
			Allopurinol	C				
			Trimethoprim	C				

Date:11/09/04ISR Number: 4501899-0Report Type:Expedited (15-DaCompany Report #2004232670FR
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dehydration Drug Interaction Stupor Vomiting	Foreign Health Professional Other	Camptosar (Irinotecan) Solution, Sterile Haldol (Haloperidol)	PS SS		INTRAMUSCULAR	ONCE A MONTH,	
			Neuroleptics	C		INTRAMUSCULAR		
			Atropine (Atropine)	C				
			Fluorouracil	C				
			Leucovorin (Folic Acid)	C				
			Kytril	C				
			Solu-Medrol (Methylprednisoone Sodium Succinate)	C				

Date:11/10/04ISR Number: 4497542-XReport Type:Expedited (15-DaCompany Report #US-JNJFOC-20040908827
Age:59 YR Gender: I/FU:I

Outcome	PT
Death	Acidosis
	Coma
	Completed Suicide
	Haemodialysis
	Hypotension

	Intentional Misuse						
	Mental Status Changes						
	Multi-Organ Failure	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Renal Failure		Ultracet	PS		OROPHARINGEAL	
	Vomiting		Lorazepam	SS		OROPHARINGEAL	
			Naproxen	SS		OROPHARINGEAL	
			Belladonna/Ergotamine/Phenobarbital	SS			
			Losartan	SS			
			Quinine	SS			
			Levothyroxine	SS			
			Haloperidol	SS			
			Olanzapine	SS			
			Hydroxyzine	SS			
			Setraline	SS			

Date:11/12/04ISR Number: 4499913-4Report Type:Expedited (15-DaCompany Report #FR-JNJFOC-20041100870
Age:7 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Disturbance In Attention		Haldol	PS		OROPHARINGEAL	40 drops TID (2 mg/mL)
	Joint Ankylosis						
	Medication Error						
	Somnolence						
	Tremor						

Date:11/15/04ISR Number: 4501120-3Report Type:Periodic Company Report #US-JNJFOC-20040908712
Age:49 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Death	Neuroleptic Malignant		Haldol	PS		PARENTERAL	
	Syndrome						

Date:11/15/04ISR Number: 4501640-1Report Type:Direct Company Report #CTU 231874
Age:41 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Alcoholic Liver Disease		Haloperidol Lactate 5 Mg	PS		INTRAVENOUS	IV, X 1 5 MG	
	Bradycardia							
	Cardiac Arrest							
	Coagulopathy		Gabapentin	C				
	Hepatic Failure		Propranolol	C				
	Hypertension		Spironolactone	C				
	Medication Error							

Date:11/16/04ISR Number: 4504602-3Report Type:Expedited (15-DaCompany Report #HQWYE225203NOV04
Age:76 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Asthenia	Health Professional Other	Inipomp (Pantoprazole, Unspec)	PS				
	Hepatic Steatosis		Acetylsalicylate Calcium (Acetylsalicylate Calcium,)	SS				
	Hepatitis Cholestatic		Ansilan (Medazepam,					

			)	SS		ORAL
SOME TIME(S),						
SOME DF ORAL						
			Clomipramine Hydrochloride (Clomipramine Hydrochloride,)	SS		ORAL
SOME TIME(S)						
SOME DF ORAL						
			Clonazepam (Clonazepam)	SS		ORAL
SOME TIME(S)						
2 MG ORAL						
			Haloperidol (Haloperidol,)	SS		ORAL
SOME TIME(S)						
20 MG ORAL						
			Nicardipine (Nicardipine,)	SS		ORAL
SOME TIME(S)						
20 MG ORAL						
			Temesta (Lorazepam, Unspec)	SS		
			Tenormin (Atenolol,)	SS		ORAL
SOME TIME(S)						
100 MG ORAL						
			Trivastal (Piribedil,)	SS		

Date:11/16/04ISR Number: 4505096-4Report Type:Expedited (15-DaCompany Report #DSA_25247_2004
Age:76 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Blood Cholesterol	Foreign	Temesta	PS		ORAL	DF PO	
	Increased	Health	Anafranil	SS		ORAL	DF PO	

	Hepatic Steatosis	Professional	Haldol	SS	ORAL
DF PO					
	Hepatitis Cholestatic	Other	Loxen	SS	ORAL
DF PO					
			Rivotril	SS	ORAL
DF PO					
			Tenormine	SS	ORAL
DF PO					
			Trivastal	C	
			Inipomp	C	
			Kardegic	C	

Date:11/17/04ISR Number: 4503106-1Report Type:Expedited (15-DaCompany Report #FR-ROCHE-384615
Age:76 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Life-Threatening	Hepatitis Cholestatic		Rivotril	PS	Roche	ORAL
			Rivotril	SS	Roche	ORAL
			Loxen	SS	Roche	ORAL
			Tenormine	SS		ORAL
			Anafranil	SS		ORAL
			Haldol	SS		ORAL
			Temesta	SS		ORAL
			Kardegic	C		
UNKNOWN						
			Inipomp	C		
			Trivastal	C		

Date:11/18/04ISR Number: 4504334-1Report Type:Expedited (15-DaCompany Report #FR-BRISTOL-MYERS SQUIBB COMPANY-12759205
Age:88 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Dehydration	Health	Captea	PS	Apothecon	ORAL
Initial or Prolonged	Orthostatic Hypotension	Professional	Digoxine Nativelle	SS		
INTRAVENOUS	1 DAY					

			Trimetazidine	SS		ORAL
			Driptane	SS		ORAL
			Captopril Bayer	SS		ORAL
			Haldol	SS		ORAL

Date:11/18/04ISR Number: 4504386-9Report Type:Expedited (15-DaCompany Report #DE-ROCHE-385836
Age:62 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Acidosis		Valium	PS	Roche	ORAL	2	DAY
Initial or Prolonged	Balance Disorder		Valium	SS	Roche	ORAL	6	DAY
	Csf Test Abnormal		Valium	SS	Roche	ORAL	4	DAY
	Depressed Level Of		Taxilan	SS		ORAL	10	DAY
	Consciousness		Taxilan	SS		ORAL		
	Infection		Haldol	SS		ORAL	13	DAY
	Poisoning		Akineton	C		ORAL	10	DAY
	Pyrexia							
	Somnolence							
	Stupor							

Date:11/18/04ISR Number: 4504631-XReport Type:Expedited (15-DaCompany Report #DE-JNJFOC-20041102409
Age:49 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Anoxic Encephalopathy	Health	Haldol	PS		INTRAVENOUS		
Life-Threatening	Cardiac Arrest	Professional	Haldol	SS		INTRAVENOUS		
	Dilatation Ventricular		Glycylpressin	SS		INTRAVENOUS		
	Drug Level Increased		Faustan	SS		INTRAVENOUS		
	Hepatic Function Abnormal		Faustan	SS		INTRAVENOUS		

	Hypoventilation		Faustan	SS		
INTRAVENOUS						
	Multi-Organ Failure		Haemiton	SS		
INTRAVENOUS						
	Pneumonia		Mcp	C		
INTRAVENOUS						
	Sepsis		Pantozol	C		
INTRAVENOUS						
	Ventricular Fibrillation		Vitamin B Complex	C		
			Vitamin B Complex	C		
			Vitamin B Complex	C		
			Vitamin B Complex	C		
			Vitamin B Complex	C		

Date:11/18/04ISR Number: 4504632-1Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20041102550
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Acidosis	Health	Haldol	PS				
OROPHARINGEAL								
Initial or Prolonged	Balance Disorder	Professional	Valium	SS				
OROPHARINGEAL								
	Depressed Level Of		Valium	SS				
OROPHARINGEAL								
	Consciousness		Valium	SS				
OROPHARINGEAL								
	Drug Toxicity		Akineton Ret	SS				
OROPHARINGEAL								
	Gait Disturbance		Taxilan	C				
OROPHARINGEAL								
	Hypercapnia							
	Pyrexia							
	Somnolence							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/18/04ISR Number: 4504633-3Report Type:Expedited (15-DaCompany Report #CH-JNJFOC-20041006683
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Akathisia	Health	Haldol Decanoas	PS		INTRAMUSCULAR		
	Depressed Mood	Professional	Haldol Decanoas	SS		INTRAMUSCULAR		
	Drug Interaction		Citalopram	I		OROPHARINGEAL		
	Parkinson'S Disease		Citalopram	I		OROPHARINGEAL		
	Parkinsonism		Citalopram	I		OROPHARINGEAL		
	Trismus							

Date:11/22/04ISR Number: 4509010-7Report Type:Direct Company Report #CTU 232577
Age:24 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - SEE B5	Autonomic Nervous System		Haloperidol	PS				
Initial or Prolonged	Imbalance		Risperidone					
	Confusional State		-Risperdal	C				
	Creatine Phosphokinase		Olanzapine -Zyprexa	C				
	Decreased		Benztropine	C				
	Depressed Level Of		Valproic Acid	C				
	Consciousness		Donepezil -Aricept	C				
	Fatigue							
	Muscle Rigidity							
	Myalgia							

Date:11/22/04ISR Number: 4510277-XReport Type:Direct Company Report #USP 56962
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Medication Error		Haloperidol	PS		TABLET		
			Bentropine	SS		TABLET		

Date:11/23/04ISR Number: 4507767-2Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20041102397
Age:53 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anticonvulsant Drug Level		Risperdal	PS		OROPHARINGEAL	1 tablet	
	Below Therapeutic		Risperdal	SS		OROPHARINGEAL	2 tablets	
	Antipsychotic Drug Level		Risperdal	SS		OROPHARINGEAL	1 tablet	
	Above Therapeutic		Risperdal	SS		OROPHARINGEAL	1 tablet	
	Blood Creatine		Risperdal	SS		OROPHARINGEAL		
	Phosphokinase Mb		Quilonum Retard	SS		OROPHARINGEAL		
	Increased		Quilonum Retard	SS		OROPHARINGEAL		
	Csf Oligoclonal Band		Quilonum Retard	SS		OROPHARINGEAL		
	Present		Quilonum Retard	SS		OROPHARINGEAL		
	Dehydration		Ergenyl	SS		OROPHARINGEAL		
	Electrocardiogram Qt		Ergenyl	SS		OROPHARINGEAL		
	Corrected Interval		Ergenyl	SS		OROPHARINGEAL		
	Prolonged		Ergenyl	SS		OROPHARINGEAL		
	Extrapyramidal Disorder		Ergenyl	SS		OROPHARINGEAL		
	Eyelid Oedema		Ergenyl	SS		OROPHARINGEAL		
	Fall		Ergenyl	SS		OROPHARINGEAL		
	Hepatitis		Quilonum Retard	SS		OROPHARINGEAL	2.5 tablets	
	Infection		Quilonum Retard	SS		OROPHARINGEAL	2.5 tablets	
	Nephropathy Toxic		Quilonum Retard	SS		OROPHARINGEAL	1.5 tablets	
			Quilonum Retard	SS		OROPHARINGEAL	2 tablets	
			Haldol	SS		OROPHARINGEAL		
			Risperdal	SS		OROPHARINGEAL		

	Risperdal	SS
OROPHARINGEAL		
	Risperdal	SS
OROPHARINGEAL		
	Haldol	C
INTRAMUSCULAR		
	Taxilan	C
OROPHARINGEAL		
	Taxilan	C
OROPHARINGEAL		
	Diazepam	C
OROPHARINGEAL		
	Diazepam	C
OROPHARINGEAL		
	Diazepam	C
OROPHARINGEAL		
	Diazepam	C
OROPHARINGEAL		
	Diazepam	C
OROPHARINGEAL		
	Benalapril	C
OROPHARINGEAL		
	Benalapril	C
OROPHARINGEAL		
	Thyronajod	C
OROPHARINGEAL		
	Thyronajod	C
OROPHARINGEAL		
	Kalinor	C
1 tablet		
	Hydrochlorothiazide	C

Date:11/23/04ISR Number: 4511802-5Report Type:Direct Company Report #CTU 232781
Age:51 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Other	Tinnitus		Haloperidol	PS		
			Multivitamin/Mineral s Therapeut	C		
			Naproxen	C		
			Risperidone	C		
			Simvastatin	C		
			Thiothixene Hcl	C		

Date:11/23/04ISR Number: 4527896-7Report Type:Periodic Company Report #US-JNJFOC-20040907911
Age:23 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Amenorrhoea Blood Prolactin Increased Condition Aggravated Galactorrhoea Schizophrenia	Health Professional	Risperdal Consta (Risperidone)	PS		INTRAMUSCULAR	37.5 MG, 1 IN 2 WEEK, INTRA-MUSCULAR; SEE IMAGE	
			Risperdal (Risperidone) Tablets	SS		ORAL	10 MG, 1 IN 1 DAY	
			Haldol (Haloperidol) Tablets	SS		ORAL		
			Seroquel (Quetiapine Fumarate)	C				

Date:11/24/04ISR Number: 4509711-0Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20041102397
Age:53 YR Gender:Male I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Anticonvulsant Drug Level Below Therapeutic Antipsychotic Drug Level Above Therapeutic Blood Creatine Phosphokinase Mb Increased

	Csf Oligoclonal Band Present						
	Dehydration		Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
	Electrocardiogram Qt			Risperdal	PS		
OROPHARINGEAL							
	Corrected Interval			Risperdal	SS		
OROPHARINGEAL							
	Prolonged			Risperdal	SS		
OROPHARINGEAL							
	Extrapyramidal Disorder			Risperdal	SS		
OROPHARINGEAL							
	Eyelid Oedema			Risperdal	SS		
OROPHARINGEAL							
	Fall			Quilonum Retard	SS		
1 tablet							
	Hepatitis			Quilonum Retard	SS		
2 tablets							
	Infection			Quilonum Retard	SS		
1 tablet							
	Lumbar Puncture Abnormal			Quilonum Retard	SS		
1 tablet							
	Nephropathy Toxic			Ergenyl	SS		
OROPHARINGEAL							
				Ergenyl	SS		
OROPHARINGEAL							
				Ergenyl	SS		
OROPHARINGEAL							
				Ergenyl	SS		
OROPHARINGEAL							
				Ergenyl	SS		
OROPHARINGEAL							
				Ergenyl	SS		
OROPHARINGEAL							
				Ergenyl	SS		
OROPHARINGEAL							
				Quilonum Retard	SS		
2.5 tablets							
				Quilonum Retard	SS		
2.5 tablets							
				Quilonum Retard	SS		
1.5 tablets							
				Quilonum Retard	SS		
2 tablets							
				Haldol	SS		
OROPHARINGEAL							

OROPHARINGEAL	Risperdal	SS
OROPHARINGEAL	Risperdal	SS
OROPHARINGEAL	Risperdal	SS
INTRAMUSCULAR	Haldol	C
OROPHARINGEAL	Taxilan	C
OROPHARINGEAL	Taxilan	C
OROPHARINGEAL	Diazepam	C
OROPHARINGEAL	Diazepam	C
OROPHARINGEAL	Diazepam	C
OROPHARINGEAL	Diazepam	C
OROPHARINGEAL	Diazepam	C
OROPHARINGEAL	Benalapril	C
OROPHARINGEAL	Benalapril	C
OROPHARINGEAL	Thyronajod	C
OROPHARINGEAL	Thyronajod	C
OROPHARINGEAL	Kalinor	C
1 tablet	Hydrochlorothiazide	C

Date:11/24/04ISR Number: 4510045-9Report Type:Expedited (15-DaCompany Report #PHBS2004JP15637
Age:93 YR Gender:Female I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Akinesia
	Blood Creatine Phosphokinase Increased
	Drooling
	Dysphagia
	Erythema
	Excoriation
	Incoherent
	Insomnia
	Musculoskeletal Stiffness
	Myoglobin Blood Increased
	Parkinsonism
	Restlessness

Schizophrenia
Tremor

Dose	Duration	Report Source	Product	Role	Manufacturer	Route
3 DF/day	69120MIN	Health Professional	Diovan	PS	Novartis Sector: Pharma	ORAL
4 DF, UNK	14400MIN		Serenace	SS		ORAL
1 DF, UNK			Serenace	SS		
2 / 3 Amp			Serenace	SS		
			Polycarbophil Calcium	C		ORAL
3 DF, UNK	265 DAY		Calslot	C		ORAL
2 DF, UNK	110 DAY		Epinephrine	C		ORAL
1 DF, UNK	82 DAY		Menbit	C		ORAL
1 DF, UNK	34560MIN		Vasolator	C		
1 DF, TID	265 DAY		Evamyl	C		ORAL
3 DF, UNK			Tofisopam	C		

Date:11/24/04ISR Number: 4511761-5Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20041102397
Age:53 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization - Initial or Prolonged	Alanine Aminotransferase Increased		Risperdal	PS		
OROPHARINGEAL	Aspartate Aminotransferase Increased		Risperdal	SS		
OROPHARINGEAL	Blood Creatine		Risperdal	SS		
OROPHARINGEAL			Risperdal	SS		
OROPHARINGEAL			Quilonum Retard	SS		
1 tablet						

2 tablets	Phosphokinase Mb	Quilonum Retard	SS
1 tablet	Increased	Quilonum Retard	SS
1 tablet	Dehydration	Quilonum Retard	SS
OROPHARINGEAL	Drug Level Decreased	Ergenyl	SS
OROPHARINGEAL	Electrocardiogram	Ergenyl	SS
OROPHARINGEAL	Abnormal	Ergenyl	SS
OROPHARINGEAL	Electrocardiogram Qt	Ergenyl	SS
OROPHARINGEAL	Corrected Interval	Ergenyl	SS
OROPHARINGEAL	Prolonged	Ergenyl	SS
OROPHARINGEAL	Extrapyramidal Disorder	Ergenyl	SS
2.5 tablets	Eyelid Oedema	Quilonum Retard	SS
2.5 tablets	Fall	Quilonum Retard	SS
1.5 tablets	Hepatitis	Quilonum Retard	SS
2 tablets	Infection	Quilonum Retard	SS
OROPHARINGEAL	Nephropathy Toxic	Haldol	SS
OROPHARINGEAL	Oedema Peripheral	Risperdal	SS
OROPHARINGEAL	Qrs Axis Abnormal	Risperdal	SS
OROPHARINGEAL		Risperdal	SS
INTRAMUSCULAR		Haldol	C
OROPHARINGEAL		Taxilan	C
OROPHARINGEAL		Taxilan	C
OROPHARINGEAL		Diazepam	C
OROPHARINGEAL		Diazepam	C
OROPHARINGEAL		Diazepam	C
OROPHARINGEAL		Diazepam	C
OROPHARINGEAL		Diazepam	C

OROPHARINGEAL	Benalapril	C
OROPHARINGEAL	Benalapril	C
OROPHARINGEAL	Thyronajod	C
OROPHARINGEAL	Thyronajod	C
1 tablet	Kalinor	C
	Hydrochlorothiazide	C

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/26/04ISR Number: 4511165-5Report Type:Expedited (15-DaCompany Report #ES-JNJFOC-20041006997
Age:38 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Aggression		Risperdal Consta	PS		INTRAMUSCULAR		
	Completed Suicide		Haldol	SS		UNKNOWN		
			Zuclopentixol	C		INTRAMUSCULAR		
			Biperideno	C		UNKNOWN		

Date:11/29/04ISR Number: 4511865-7Report Type:Expedited (15-DaCompany Report #ES-JNJFOC-20040700749
Age:34 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Torsade De Pointes		Haldol	PS		INTRAVENOUS		
	Ventricular Fibrillation		Alprazolam	C				
			Piperacillin/Tazobactam	C				
			Piperacillin/Tazobactam	C				
			Pantoprazol	C				
			Paracetamol	C				
			Vit B1	C				
			Vit B6	C				
			Vit B12	C				

Date:11/29/04ISR Number: 4515768-3Report Type:Expedited (15-DaCompany Report #DSA_25397_2004
Age:17 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Accidental Overdose	Foreign	Tavor	PS		ORAL	2 MG ONCE	PO
	Bradycardia	Health	Haldol	SS		ORAL	5 MG ONCE	PO
	Hypotension	Professional	Nipolept "Aventis"	SS		ORAL	100 MG ONCE	

			Other				
PO							
				Truxal	SS		ORAL
225 MG ONCE							
PO							

Date:11/30/04ISR Number: 4513499-7Report Type:Expedited (15-DaCompany Report #SE-JNJFOC-20040607396
Age:50 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Alanine Aminotransferase		Haldol	PS		INTRAMUSCULAR	one ml	of
	Abnormal						solution	
	Antipsychotic Drug Level						contains 5mg	
	Increased						of haldol.	
	Aspartate		Heminevrin	SS		OROPHARINGEAL	at night	
	Aminotransferase Abnormal		Stesolid	SS		INTRAMUSCULAR	one ml	of
	Blood Glucose Increased						solution	
	Cardiac Disorder						contains 5mg	
	Drug Interaction						of diazepam	
	Drug Toxicity		Cisordinol	SS		INTRAMUSCULAR	one ml	of
	Gamma-Glutamyltransferase						solution	
	Abnormal						contains 50mg	
	Oedema						of	
	Pulmonary Oedema						clopenthixol	
	Somnolence		Zyprexa	SS				
	Treatment Noncompliance		Lithionit	SS		OROPHARINGEAL		
			Disipal	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/30/04ISR Number: 4515252-7Report Type:Direct Company Report #CTU 233217
Age:23 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Aggression		Haloperidol	PS		INTRAMUSCULAR	10 MG IM X 2	
Hospitalization - Initial or Prolonged	Agitation		Quetiapine	SS			200 MG [PRIOR TO ADMIT]	
Required Intervention to Prevent Permanent Impairment/Damage	Blood Creatine Phosphokinase Increased		Paroxetine	C				
	Blood Pressure Increased		Simvastatin	C				
	Chest Pain							
	Electrocardiogram Qt Corrected Interval Prolonged							
	Heart Rate Increased							
	Neuroleptic Malignant Syndrome							
	White Blood Cell Count Increased							

Date:11/30/04ISR Number: 4518009-6Report Type:Expedited (15-DaCompany Report #20041100482
Age:76 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Asthenia	Foreign	Temesta (Lorazepam)	PS				
	Hepatic Steatosis	Health	Inipomp (Pantoprazole)	SS				
	Hepatitis Cholestatic	Professional	Tenormin (Atenolol)	SS		ORAL	100 MG PRN PO	
		Other	Acetylsalicylate Calcium	SS				
			Ansilan (Medazepam)	SS				
			Clomipramine Hydrochloride	SS				
			Solfidin (Clonazepam)	SS		ORAL	2 MG PRN PO	
			Aloperidolo (Haloperidol)	SS		ORAL	20 MG PRN PO	
			Nicardipina Dorom					

			(Nicardipine)	SS		ORAL	20 MG PRN PO
			Trivastal (Piribedil)	SS			
			Poliflu	SS			

Date:12/01/04ISR Number: 4519234-0Report Type:Expedited (15-DaCompany Report #2004CG02279
Age:82 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Anal Stenosis	Foreign	Nexium	PS		ORAL	20 MG QD PO
	Colitis Ischaemic	Health Professional	Modopar	SS			50 MG + 12.5 MG BID
	Malaise						
	Mass	Other	Previscan	SS		ORAL	0.25 DF QD PO
			Haldol	SS		ORAL	0.2 MG TID PO
			Creon "Duphar"	SS	Duphar	ORAL	25000 U TID PO

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/03/04ISR Number: 4517663-2Report Type:Expedited (15-DaCompany Report #BR-JNJFOC-20041200053
Age:75 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Asthenia		Haldol	PS				
OROPHARINGEAL								
Initial or Prolonged	Dementia Alzheimer'S Type		Haldol	SS				
OROPHARINGEAL								
	Hypertension		Risperidone	SS				
	Increased Appetite		Fenergan	C				
	Salivary Hypersecretion							
	Urinary Incontinence							

Date:12/06/04ISR Number: 4521656-9Report Type:Expedited (15-DaCompany Report #2004SE06491
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	White Blood Cell Count	Foreign	Seroquel	PS		ORAL	100 MG DAILY	
	Decreased	Health						
PO								
		Professional	Haldol	SS		ORAL	2 MG DAILY PO	
		Other						

Date:12/07/04ISR Number: 4519854-3Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20041200308
Age:54 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Agitation		Haldol	PS				
INTRAMUSCULAR	(5-10 mg)							
	Amnesia		Lithium	C				
	Disturbance In Attention		Effexor	C				
	Nightmare		Risperdal	C				
UNKNOWN								
	Suicidal Ideation		Topamax	C				
UNKNOWN								
			Klonopin	C				

Date:12/08/04ISR Number: 4521020-2Report Type:Expedited (15-DaCompany Report #200414493FR
Age:50 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Alanine Aminotransferase Increased		Rifater	PS	Aventis Pharmaceuticals Inc.	ORAL		
	Aspartate Aminotransferase Increased		Tercian	SS		ORAL		
			Mepronizine	SS		ORAL		
			Modecate	SS				
	Blood Creatine Phosphokinase Increased		Temesta	SS		ORAL		
			Haldol	SS		ORAL		
	Epilepsy							
	Extrapyramidal Disorder							

Date:12/09/04ISR Number: 4521822-2Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20041106618
Age:12 YR Gender: I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Congenital Anomaly	Asperger'S Disorder		Haldol	PS				
Other	Tourette'S Disorder							

Date:12/09/04ISR Number: 4521823-4Report Type:Expedited (15-DaCompany Report #FR-JNJFOC-20041200215
Age:50 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Alanine Aminotransferase		Haldol	PS				
OROPHARINGEAL								
Initial or Prolonged	Increased		Temesta	SS				
	Aspartate		Mepronizine	SS				
	Aminotransferase		Mepronizine	SS				
	Increased		Modecate	SS				
	Blood Creatine		Rifater	SS				
	Phosphokinase Increased		Rifater	SS				
	Epilepsy		Rifater	SS				
	Extrapyramidal Disorder		Tercian	C				
	Hepatic Enzyme Increased							

Date:12/09/04ISR Number: 4521824-6Report Type:Expedited (15-DaCompany Report #BR-JNJFOC-20041201145
Age:17 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Blood Pressure Diastolic		Haldol	PS				
dose taken at								
Initial or Prolonged	Increased							
one time								
	Extrapyramidal Disorder							
	Salivary Hypersecretion							
	Suicide Attempt							

Date:12/10/04ISR Number: 4523162-4Report Type:Expedited (15-DaCompany Report #IT-JNJFOC-20041201388
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Aphasia		Serenase	PS				
OROPHARINGEAL								
			Sereupin	SS				

Date:12/10/04ISR Number: 4523292-7Report Type:Expedited (15-DaCompany Report #BR-JNJFOC-20041201015
Age:38 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anaemia Cardio-Respiratory Arrest Hypoalbuminaemia Hypocalcaemia Medication Error Neuroleptic Malignant Syndrome Overdose Respiratory Alkalosis Respiratory Tract Infection		Haldol Decanoate	PS		INTRAMUSCULAR	pres. dose was haloperidol 5mg; given 2 amp./day	7 DAY

Date:12/10/04ISR Number: 4523321-0Report Type:Expedited (15-DaCompany Report #BR-JNJFOC-20041201127
Age:26 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Coma Multiple Drug Overdose Overdose Suicide Attempt		Haldol	PS		OROPHARINGEAL	patient took 10 tablets at one time	
			Carbamazepine	SS		OROPHARINGEAL	10 tablets at one time	
			Phenobarbital	SS		OROPHARINGEAL	20 tablets at	

one time

Date:12/10/04ISR Number: 4523590-7Report Type:Expedited (15-DaCompany Report #FR-BRISTOL-MYERS SQUIBB COMPANY-12781902
Age:50 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Alanine Aminotransferase		Modecate Inj	PS	Apothecon	INTRAMUSCULAR	1	DAY
Initial or Prolonged	Increased		Mepronizine	SS		ORAL		
	Aspartate		Rifater	SS		ORAL		
	Aminotransferase		Temesta	SS		ORAL		
	Increased		Haldol	SS		ORAL		
	Blood Creatine		Tercian	C		ORAL		
	Phosphokinase Increased							
	Epilepsy							
	Extrapyramidal Disorder							

Date:12/10/04ISR Number: 4526352-XReport Type:Expedited (15-DaCompany Report #DSA_25397_2004
Age:17 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Accidental Overdose	Foreign	Tavor	PS		ORAL	2 MG ONCE PO	
Initial or Prolonged	Bradycardia	Health	Haldol	SS		ORAL	5 MG ONCE PO	
	Coma	Professional	Nipolept "Aventis"	SS	Aventis	ORAL	100 MG ONCE	
	Drug Screen Positive	Other					PO	
	Hypotension		Truxal	SS		ORAL	225 MG ONCE	
							PO	

Date:12/13/04ISR Number: 4525026-9Report Type:Expedited (15-DaCompany Report #PHBS2004JP15849
Age:54 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Hospitalization - Initial or Prolonged	Akinesia		Tegretol	PS	Novartis Sector: Pharma	ORAL
	Blood Creatine Phosphokinase Increased		Contomin	SS		ORAL
	Constipation		Serenace	SS		ORAL
	Depressed Level Of Consciousness		Akineton	SS		ORAL
			Eurodin	SS		ORAL
	Hyperhidrosis		Insulin	C		SUBCUTANEOUS
	Ileus					
	Musculoskeletal Stiffness					
	Mutism					
	Myoclonus					
	Nausea					
	Neuroleptic Malignant Syndrome					
	Vomiting					

Date:12/13/04ISR Number: 4526100-3Report Type:Direct Company Report #CTU 234121
Age:93 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Life-Threatening	Abnormal Behaviour		Haldol	PS		
Disability	Delirium		Antibiotic Drip	C		
Other	Disorientation		Blood Pressure Medication	C		
	Feeling Abnormal					
	Hallucination, Visual					
	Psychotic Disorder					

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/14/04ISR Number: 4527239-9Report Type:Direct Company Report #CTU 234228
Age:53 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Convulsion		Haldol 10 Mg	PS			X2/DAY	EVERY 12 HRS
	Dizziness							
	Dysphagia		Simvastatin	C				
	Eating Disorder		Trazodone	C				
	Facial Palsy		Baby Asprin	C				
	Muscle Twitching		Neurontin	C				
	Parkinson'S Disease		Depakote	C				
	Tongue Disorder		Carafate	C				
	Tremor		Robaxin	C				
			Codeine	C				
			Oxycodone	C				
			Fentanyl	C				

Date:12/15/04ISR Number: 4527808-6Report Type:Expedited (15-DaCompany Report #SE-JNJFOC-20041201306
Age:75 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Cholestasis		Haldol	PS			OROPHARINGEAL	
Initial or Prolonged	Hepatitis Cholestatic		Risperdal	SS			OROPHARINGEAL	
			Citalopram Aco	SS			OROPHARINGEAL	
			Oxascand	C				
			Heminevrin	C				
			Seloken	C				
			Movicol	C			OROPHARINGEAL	
			Movicol	C			OROPHARINGEAL	
			Movicol	C			OROPHARINGEAL	
			Movicol	C			OROPHARINGEAL	
			Trombyl	C				
			Zopiklon	C				

Date:12/15/04ISR Number: 4527809-8Report Type:Expedited (15-DaCompany Report #ES-JNJFOC-20041006997
Age:38 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide		Risperdal Consta	PS		INTRAMUSCULAR		
			Haldol	SS		UNKNOWN		
			Zuclopentixol	C		INTRAMUSCULAR		
			Biperideno	C		UNKNOWN		

Date:12/15/04ISR Number: 4528849-5Report Type:Direct Company Report #CTU 234341
Age:84 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abasia		Haldol	PS			0.5 MG Q4 H	PRN X2 DOSES
	Coma							
	Lethargy		Vicodin	C				
			Depakote	C				
			Iron	C				
			Bextra	C				
			Prilosec	C				
			Lidoderm	C				
			Seroquel	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/17/04ISR Number: 4529986-1Report Type:Expedited (15-DaCompany Report #BR-JNJFOC-20041202295
Age:44 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Intentional Misuse		Haldol	PS				
	Somnolence		Carbamazepine	SS				
	Suicide Attempt		Capoten	SS				
			Biperiden	C				

Date:12/17/04ISR Number: 4530125-1Report Type:Expedited (15-DaCompany Report #PL-JNJFOC-20041202114
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Cholelithiasis		Haloperidol	PS			up to 40mg	
	Drug Ineffective							
	Loss Of Consciousness							
	Pancreatitis							
	Pancreatitis Acute							

Date:12/17/04ISR Number: 4530126-3Report Type:Expedited (15-DaCompany Report #FR-JNJFOC-20041202474
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - OROPHARINGEAL	Erythema		Haldol	PS				
Initial or Prolonged	Pemphigoid		Sermion	SS				
	Pruritus		Renitec	SS				
	Urticaria		Trivastal	SS				
			Propofan	SS				
			Propofan	SS				
			Propofan	SS				
			Propofan	SS				
			Propofan	SS				
			Monicor	C				
			Prestole	C				
			Prestole	C				

Date:12/17/04ISR Number: 4530127-5Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20041202477
Age:21 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Alanine Aminotransferase		Haldol	PS		INTRAVENOUS		
	Increased		Amoxicillin	C				
	Blood Bilirubin Increased		Erythromycin	C				
	Cholestasis		Metoclopramide	C		INTRAVENOUS		

Date:12/17/04ISR Number: 4530128-7Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20041002567
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Heart Rate Irregular		Haldol	PS		UNKNOWN	(5mg taken at night)	
	Heat Stroke							
			Clozapine	SS		OROPHARINGEAL		

Date:12/17/04ISR Number: 4530129-9Report Type:Expedited (15-DaCompany Report #JP-JNJFOC-20041106817
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Alanine Aminotransferase		Haloperidol Decanoate	PS		INTRAMUSCULAR		
	Aspiration							
	Cardio-Respiratory Arrest		Haloperidol Decanoate	SS		INTRAMUSCULAR		
	Deep Vein Thrombosis							
	Dehydration		Haloperidol	SS		INTRAMUSCULAR		
	Disseminated		Haloperidol	SS		OROPHARINGEAL		
	Intravascular Coagulation		Haloperidol	SS		OROPHARINGEAL		
	Electrolyte Imbalance		Biperiden Lactate	C		INTRAMUSCULAR		
	Haemodialysis		Levomepromazine Hydrochloride	C		INTRAMUSCULAR		
	Mental Disorder							
	Neuroleptic Malignant Syndrome		Promethazine Hydrochloride	C		INTRAMUSCULAR		
	Oral Intake Reduced		Biperiden Hydrochloride	C		OROPHARINGEAL		
	Pneumonia							
	Procedural Complication		Carbamazepine	C		OROPHARINGEAL		
	Pulmonary Infarction		Flunitrazepam	C		OROPHARINGEAL		
	Renal Failure Acute		Nitrazepam	C		OROPHARINGEAL		
			Brotizolam	C		OROPHARINGEAL		
			Triazolam	C		OROPHARINGEAL		

Date:12/20/04ISR Number: 4532160-6Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20041202568
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Arrhythmia		Haldol	PS				

	Torsade De Pointes					

Date:12/20/04ISR Number: 4532161-8Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20041202846
Age:28 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dry Mouth		Haloperidol	PS				
OROPHARINGEAL								
	Dysarthria		Codeine Phosphate	C				
OROPHARINGEAL								
	Headache							
	Pharmaceutical Product							
	Complaint							
	Tremor							

Date:12/21/04ISR Number: 4533581-8Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20041202575
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Alanine Aminotransferase		Haldol	PS				
	Increased		Quilonum	C				
	Aspartate							
	Aminotransferase							
	Increased							
	Gamma-Glutamyltransferase							
	Increased							
	Hepatic Enzyme Increased							
	Lipase Increased							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/21/04ISR Number: 4533582-XReport Type:Expedited (15-DaCompany Report #US-JNJFOC-20041006439
Age:12 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Confusional State		Haldol	PS		OROPHARINGEAL		
	Extrapyramidal Disorder		Tenex	C				
	Respiratory Rate Increased		Zoloft	C				
	Suicidal Ideation		Seroquel	C				
			Straterra	C				
			Ativan	C		OROPHARINGEAL		

Date:12/21/04ISR Number: 4533583-1Report Type:Expedited (15-DaCompany Report #BR-JNJFOC-20041201127
Age:26 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Coma		Haldol	PS		OROPHARINGEAL		
Hospitalization - Initial or Prolonged	Intentional Misuse		Carbamazepine	SS		OROPHARINGEAL		
	Overdose		Phenobarbital	SS		OROPHARINGEAL		
	Suicide Attempt							

Date:12/21/04ISR Number: 4533594-6Report Type:Expedited (15-DaCompany Report #JP-JNJFOC-20041200936
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Abnormal Behaviour		Risperdal	PS		OROPHARINGEAL		
Hospitalization - Initial or Prolonged	Blood Pressure Increased		Risperdal	SS		OROPHARINGEAL		
	Blood Test Abnormal		Halomonth	SS				
	Cachexia		Olanzapine	SS		OROPHARINGEAL		
	Cardiac Failure Acute		Olanzapine	SS		OROPHARINGEAL		
	Dehydration		Cimetidine	C				
	Delusion		Biperiden					

Diet Refusal	Hydrochloride	C
Dyspnoea	Isoleucine Leucine	
Eye Disorder	Valine	C
Haematemesis	Flunitrazepam	C
Hepatic Cirrhosis	Zopiclone	C
Hyperhidrosis	Sennoside	C
Hypoxia	Aspartate Potassium	C
Loss Of Consciousness		
Neuroleptic Malignant Syndrome		
Pulmonary Oedema		
Respiratory Arrest		
Tremor		
Wheezing		

Date:12/21/04ISR Number: 4534364-5Report Type:Direct Company Report #CTU 234842
Age:93 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Delirium		Haldol	PS				
Disability	Disorientation		Antibiotic Drip	C				
Other	Hallucination, Visual		High Blood Pressure Medication	C				
	Psychotic Disorder							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/22/04ISR Number: 4535345-8Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20041203973
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Gastrointestinal		Haldol	PS		UNKNOWN		
	Haemorrhage							

Date:12/22/04ISR Number: 4535346-XReport Type:Expedited (15-DaCompany Report #US-JNJFOC-20041204675
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Bronchitis		Haldol	PS		UNKNOWN		
	Bronchitis Acute		Clozapine	SS		OROPHARINGEAL		
	Coma		Hydrochlorothiazide	C		OROPHARINGEAL		
	Drug Ineffective		Lisinopril	C		OROPHARINGEAL		
	Drug Interaction		Metformin	C		OROPHARINGEAL		
	Respiratory Failure		Amaryl	C		OROPHARINGEAL		

Date:12/22/04ISR Number: 4535351-3Report Type:Expedited (15-DaCompany Report #FR-JNJFOC-20040403010
Age:28 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Albuminuria		Haldol	PS		OROPHARINGEAL		
	Drug Exposure During Pregnancy							
	Gestational Diabetes							
	Pregnancy							

Date:12/23/04ISR Number: 4536738-5Report Type:Expedited (15-DaCompany Report #FR-JNJFOC-20041002513
Age:24 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Blood Creatine		Haldol	PS				
OROPHARINGEAL								
Initial or Prolonged	Phosphokinase Increased		Nozinan	SS				
OROPHARINGEAL								
	Hepatic Enzyme Increased		Lepticur	SS				
	Hepatitis							
	Neuroleptic Malignant							
	Syndrome							
	Pyrexia							

Date:12/23/04ISR Number: 4538341-XReport Type:Direct Company Report #CTU 235050
Age:26 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Agitation		Haloperidol 5mg					
	Pharmaceutical Product		Sandoz	PS	Sandoz	ORAL		
1 TAB PO QID								
	Complaint							
	Restlessness							
	Tremor							

Date:12/23/04ISR Number: 4538484-0Report Type:Direct Company Report #CTU 235067
Age:49 YR Gender:Male I/FU:I

Outcome	PT
Death	Agitation
	Blood Creatinine
	Increased

	Blood Gases Abnormal						
	Cholinergic Syndrome						
	Dialysis	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Diarrhoea		Clozapine 800 Mg/Day	PS			SEE IMAGE
	Electrolyte Imbalance		Abilify 15 Mg/Day	SS			15 MG /DAY
	Hallucination		Haldol Prn	SS			
	Incoherent		Geodon X 1	SS			SEE IMAGE
	Lethargy						
	Neuroleptic Malignant Syndrome						
	Urinary Retention						

Date:12/27/04ISR Number: 4538481-5Report Type:Expedited (15-DaCompany Report #PL-JNJFOC-20041202114
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Life-Threatening	Cholelithiasis	Health	Haloperidol	PS			up to 40mg
	Drug Ineffective	Professional					
	Pancreatitis						

Date:12/27/04ISR Number: 4541582-9Report Type:Expedited (15-DaCompany Report #DSA_25485_2004
Age:50 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Alanine Aminotransferase	Foreign	Temesta	PS		ORAL	2.5 MG TID PO
Initial or Prolonged	Increased	Health	Haldol	SS		ORAL	5 MG Q DAY PO
	Aspartate	Professional	Mepronizine	SS		ORAL	2 TAB Q DAY
	Aminotransferase	Other					PO
	Increased		Modecate	SS			DF
	Blood Creatine		Rifater /Sch/	SS		ORAL	1 TAB Q DAY

	Phosphokinase Increased						
PO							
	Condition Aggravated		Tercian	C			
	Epilepsy						
	Extrapyramidal Disorder						

Date:12/27/04ISR Number: 4541640-9Report Type:Expedited (15-DaCompany Report #DSA_25492_2004
Age:89 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Dermatitis Bullous	Foreign	Enalapril Maleate	PS		ORAL	1 TAB BID PO
Initial or Prolonged	Pemphigoid	Health	Haloperidol	SS		ORAL	DF, PO
	Rash Erythematous	Professional	Piribedil	SS		ORAL	100 MG QD
	Skin Lesion	Other					DAY, PO
	Therapy Non-Responder		Acetaminophen-Caffei ne	C			
			Isosorbide Mononitrate	C			
			Nicergoline	C			
			Propoxyphene Hcl	C			

Date:12/30/04ISR Number: 4541863-9Report Type:Expedited (15-DaCompany Report #PHBS2004JP15637
Age:93 YR Gender:Female I/FU:F

Outcome	PT
Hospitalization -	Akinesia
Initial or Prolonged	Blood Creatine
	Phosphokinase Increased

	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drooling							
	Dysphagia							
	Erythema		Diovan	PS	Novartis Sector: Pharma	ORAL	240 mg/day	69120MIN
	Excoriation							
	Incoherent							
	Insomnia		Serenace	SS		ORAL	3 mg/day	14400MIN
	Musculoskeletal Stiffness		Serenace	SS			1 DF, UNK	
	Myoglobin Blood Increased		Serenace	SS			2 / 3 Amp	
	Parkinsonism		Polycarbophil Calcium	C		ORAL	3.6 g, UNK	265 DAY
	Restlessness							
	Rhabdomyolysis		Calslot	C		ORAL	20 mg, UNK	110 DAY
	Schizophrenia		Epinephrine	C		ORAL	60 mg, UNK	82 DAY
	Tremor		Menbit	C		ORAL	0.4 mg, UNK	34560MIN
			Vasolator	C			27 mg, TID	265 DAY
			Evamyl	C		ORAL	3 DF, UNK	
			Tofisopam	C				

Date:12/30/04ISR Number: 4542129-3Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20041205592
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Cleft Lip		Topamax	PS				
	Drug Exposure During Pregnancy		Haldol	SS				
			Haldol Decanoate	SS				
	Pregnancy		Geodon	C				
	Renal Hypoplasia		Prozac	C				
			Seroquel	C				

TRANSPLACENTAL

Date:12/30/04ISR Number: 4544248-4Report Type:Expedited (15-DaCompany Report #105252ISR
Age:57 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cyanosis	Health	Etoposide	PS				
INTRAVENOUS	255 MILLIGRAM	3	DAY					
	Sudden Death	Professional	Haloperidol	SS				
INTRAMUSCULAR								
			Glimepiride	C				
			Metformin Hydrochloride	C				
			Pantoprazole	C				
			Moxonidine	C				
			Candesartan Cilexetil	C				
			Verapamil	C				
			Furosemide	C				
			Valpromide	C				
			Mepronizine	C				
			Tropatepine Hydrochloride	C				
			Movicol	C				
			Fenofibrate	C				
			Paracetamol	C				
			Dacryoserum	C				

Date:12/30/04ISR Number: 4544607-XReport Type:Expedited (15-DaCompany Report #2004114895
Age: Gender:Female I/FU:I

Outcome	PT	Report Source
Death	Sudden Death	Health
Other		Professional

		Company Representative	Product	Role	Manufacturer	Route	Dose Duration
			Geodon (Im) (Ziprasidone)	PS			
			Haloperidol (Haloperidol)	SS			

Date:01/03/05ISR Number: 4543188-4Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20041205632
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Other	Difficulty In Walking Jaw Disorder Visual Disturbance		Haldol	PS			

Date:01/03/05ISR Number: 4546341-9Report Type:Expedited (15-DaCompany Report #2004116594
Age:51 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Death Hospitalization - Initial or Prolonged Other	Bronchitis Acute Coma Diabetes Mellitus Inadequate Control Headache Mania Psychotic Disorder Respiratory Failure Resuscitation Therapeutic Response Decreased Wheezing	Health Professional	Geodon (Ziprasidone) Haloperidol (Haloperidol) Valproate Semisodium (Valproate Semisodium) Clozapine (Clozapine) Glimepiride (Glimepiride) Azithromycin (Azithromycin) Hydrochlorothiazide (Hydrochlorothiazide) Lisinopril (Lisinopril) Metformin (Metformin)	PS SS SS SS C C C C C		ORAL	300 MG, ORAL

Date:01/04/05ISR Number: 4548053-4Report Type:Direct Company Report #CTU 235617
Age:41 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Tardive Dyskinesia		Haldol	PS		INTRAMUSCULAR	DECALITER	MONTHLY
						INTRAMUSCU		

Date:01/05/05ISR Number: 4545274-1Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20041207258
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Crying		Haldol	PS		UNKNOWN	(a handful)	
Other	Depression		Ribavirin	SS		UNKNOWN		
	Intentional Misuse		Peginterferon Alfa-2b	SS		SUBCUTANEOUS		
	Suicide Attempt		Flonase	C				

			Zantac	C			

Date:01/06/05ISR Number: 4546237-2Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20041100092
Age:24 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Anaphylactic Reaction		Haloperidol	PS		OROPHARINGEAL		

Date:01/07/05ISR Number: 4547140-4Report Type:Expedited (15-DaCompany Report #FR-JNJFOC-20041207594
Age:21 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Meige'S Syndrome		Haldol Decanoas	PS		INTRAMUSCULAR		

Date:01/07/05ISR Number: 4547380-4Report Type:Expedited (15-DaCompany Report #DE-ROCHE-385836
Age:62 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Depressed Level Of		Valium	PS	Roche	ORAL	2	DAY
Initial or Prolonged	Consciousness		Valium	SS	Roche	ORAL	6	DAY
	Metabolic Disorder		Valium	SS	Roche	ORAL	4	DAY
	Stupor		Taxilan	SS		ORAL	10	DAY
			Taxilan	SS		ORAL		
			Haldol	SS		ORAL	13	DAY
			Akineton	C		ORAL	10	DAY

Date:01/10/05ISR Number: 4551904-0Report Type:Expedited (15-DaCompany Report #2004027924
Age:24 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abnormal Behaviour Delirium	Foreign Study	Ziprasidone (Ziprasidone)	PS		ORAL	SEE IMAGE	
	Disease Recurrence Drug Interaction	Health Professional	Haloperidol (Haloperidol)	SS			INTRAMUSCULAR	SEE IMAGE
	Hallucinations, Mixed Paranoia Psychotic Disorder		Clonazepam (Clonazepam)	C				
			Biperiden (Biperiden)	C				

Date:01/14/05ISR Number: 4553120-5Report Type:Expedited (15-DaCompany Report #FR-JNJFOC-20041207598
Age:67 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Anoxic Encephalopathy		Haldol	PS		OROPHARINGEAL		
Life-Threatening	Bradypnoea		Di-Antalvic	SS		OROPHARINGEAL		
Hospitalization - Initial or Prolonged	Cardiac Arrest		Di-Antalvic	SS		OROPHARINGEAL		
	Coma		Lepticur	SS		OROPHARINGEAL		
	Depressed Level Of Consciousness Mendelson'S Syndrome Nervous System Disorder Respiratory Disorder Status Epilepticus		Athymil	SS		OROPHARINGEAL		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/14/05ISR Number: 4553121-7Report Type:Expedited (15-DaCompany Report #BR-JNJFOC-20050101768
Age:42 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Intentional Misuse Suicide Attempt		Haldol	PS				

Date:01/14/05ISR Number: 4553122-9Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20041102550
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Acidosis		Haldol	PS		OROPHARINGEAL		
	Balance Disorder		Valium	SS		OROPHARINGEAL		
	Depressed Level Of Consciousness		Valium	SS		OROPHARINGEAL		
	Drug Toxicity		Akineton Ret	SS		OROPHARINGEAL		
	Lethargy		Taxilan	C		OROPHARINGEAL		
	Metabolic Disorder Pyrexia Sopor							

Date:01/14/05ISR Number: 4553123-0Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20041106618
Age:12 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Congenital Anomaly Other	Asperger'S Disorder Tourette'S Disorder		Haldol	PS				

Date:01/14/05ISR Number: 4553124-2Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20041008588
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Agitation		Haldol	PS		INTRAVENOUS	Inital dose was 4 mg. (given a total of 12 mg over a	
	Blood Pressure Increased							
	Cardio-Respiratory Arrest							
	Hypertension							
	Irritability							
	Medication Error							
	Overdose							

Date:01/18/05ISR Number: 4554287-5Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0517629A
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Withdrawal Syndrome		Paxil	PS	Glaxosmithkline	UNKNOWN		
	Hallucination, Auditory		Haldol	SS				
	Irritability							
	Paranoia							
	Suicidal Ideation							

Date:01/18/05ISR Number: 4554405-9Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20050100916
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Aphonia		Haldol	PS		OROPHARINGEAL		
	Laryngeal Cancer		Haldol	SS		OROPHARINGEAL		
	Laryngeal Neoplasm							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/19/05ISR Number: 4555685-6Report Type:Expedited (15-DaCompany Report #PHBS2004JP17213
Age:38 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blood Pressure Increased		Hydralazine	PS	Novartis Sector: Pharma			
	Caesarean Section							
	Drug Exposure During Pregnancy		Serenace	SS				
			Akineton	SS				
	Excitability		Magnesium	C				
	Foetal Distress Syndrome							
	Foetal Heart Rate Abnormal							
	Insomnia							
	Spinal Anaesthesia							

Date:01/21/05ISR Number: 4560727-8Report Type:Expedited (15-DaCompany Report #2004AP06253
Age:50 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Abnormal Behaviour	Foreign	Seroquel	PS		ORAL	100 MG DAILY	
	Alanine Aminotransferase Increased	Health Professional	Akineton	SS		ORAL	1 MG TID PO	
	Anoxic Encephalopathy	Other	Hirnamin	SS		ORAL	50 MG TID PO	
	Aspartate Aminotransferase Increased		Linton	SS		ORAL	9 MG TID PO	
			Risperdal	SS		ORAL	2 MG TID PO	
	Bacteria Urine Identified		Rohypnol	SS				
	Blood Lactate Dehydrogenase Increased		Vegetamin B	SS		ORAL	50 MG DAILY	
	Blood Pressure Decreased		Pursennid	C				
	Bradycardia							
	Brain Death							
	Cardio-Respiratory Arrest							
	Delirium							
	Diabetes Insipidus							

Diverticulitis
Inflammation
Insomnia
Large Intestine Carcinoma
Loss Of Consciousness
Memory Impairment
Pulmonary Artery
Thrombosis
Renal Infarct
Respiratory Rate
Decreased
Restlessness
Shock
Supraventricular
Extrasystoles
Ventricular Fibrillation

Date:01/21/05ISR Number: 4562766-XReport Type:Expedited (15-DaCompany Report #2004GB02958
Age:38 YR Gender:Male I/FU:F

Outcome
Disability
Required
Intervention to
Prevent Permanent

Impairment/Damage

	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Diabetes Mellitus	Foreign	Quetiapine	PS		ORAL	25 MG BID PO	
	Inadequate Control	Health	Haloperidol	SS			5 MG DAILY	
	Drug Interaction	Professional	Procyclidine	C				
		Other	Insulin	C				

Date:01/24/05ISR Number: 4559186-0Report Type:Expedited (15-DaCompany Report #CH-JNJFOC-20041006683
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Akathisia	Health	Haldol Decanoas	PS			INTRAMUSCULAR	
Initial or Prolonged	Depressed Mood	Professional	Haldol Decanoas	SS			INTRAMUSCULAR	
Other	Drug Interaction		Citalopram	I			OROPHARINGEAL	
	Parkinsonism		Citalopram	I			OROPHARINGEAL	
	Trismus		Citalopram	I			OROPHARINGEAL	

Date:01/24/05ISR Number: 4559190-2Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20050102369
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Circulatory Collapse	Health	Haldol	PS				
		Professional	Dipiperon	SS			OROPHARINGEAL	

Date:01/24/05ISR Number: 4559191-4Report Type:Expedited (15-DaCompany Report #GR-JNJFOC-20050102377
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Other	Panic Disorder		Aloperidin	PS	
OROPHARINGEAL					
	Psychomotor Hyperactivity				

Date:01/25/05ISR Number: 4560324-4Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20050103374
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Rhabdomyolysis		Haldol Decanoate	PS				
			Ciatyl	C				

Date:01/26/05ISR Number: 4561360-4Report Type:Expedited (15-DaCompany Report #PHBS2004JP15637
Age:93 YR Gender:Female I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Abnormal Behaviour
	Akinesia
	Blood Creatine Phosphokinase Increased
	Drooling
	Dysphagia
	Dysphonia
	Erythema
	Excoriation
	Incoherent
	Insomnia
	Muscle Contracture
	Musculoskeletal Stiffness

	Myoglobin Blood Increased Parkinsonism Restlessness	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Rhabdomyolysis Schizophrenia		Diovan	PS	Novartis Sector: Pharma	ORAL	240 mg/day 69120MIN
	Tremor		Serenace	SS		ORAL	3 mg/day 1440 MIN
			Serenace	SS		ORAL	0.75 mg/day 12960MIN
			Serenace	SS			2 / 3 Amp
			Polycarbophil Calcium	C		ORAL	3.6 g, UNK 265 DAY
			Calslot	C		ORAL	20 mg, UNK 110 DAY
			Epinephrine	C		ORAL	60 mg, UNK 82 DAY
			Menbit	C		ORAL	0.4 mg, UNK 34560MIN
			Vasolator	C			27 mg, TID 265 DAY
			Evamyl	C		ORAL	3 DF, UNK
			Tofisopam	C			

Date:01/26/05ISR Number: 4561363-XReport Type:Expedited (15-DaCompany Report #PHBS2004JP15637
Age:93 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Akinesia Blood Creatine		Diovan	PS	Novartis Sector: Pharma	ORAL	240 mg/day 69120MIN
	Phosphokinase Increased		Serenace	SS		ORAL	3 mg/day 1440 MIN
	Drooling		Serenace	SS		ORAL	0.75 mg/day 12960MIN
	Dysphagia		Serenace	SS			2 / 3 Amp
	Erythema Excoriation		Polycarbophil Calcium	C		ORAL	3.6 g, UNK 265 DAY

	Incoherent		Calslot	C		ORAL
20 mg, UNK 110 DAY						
	Insomnia		Epinephrine	C		ORAL
60 mg, UNK 82 DAY						
	Musculoskeletal Stiffness		Menbit	C		ORAL
0.4 mg, UNK 34560MIN						
	Myoglobin Blood Increased		Vasolator	C		
27 mg, TID 265 DAY						
	Parkinsonism		Evamyl	C		ORAL
3 DF, UNK						
	Restlessness		Tofisopam	C		
	Rhabdomyolysis					
	Schizophrenia					
	Tremor					

Date:01/26/05ISR Number: 4561840-1Report Type:Expedited (15-DaCompany Report #FR-MERCK-0501FRA00064
Age:84 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Malaise		Cozaar	PS	Merck & Co., Inc	ORAL		
			Haloperidol	SS		ORAL	15	DAY
			Pipemidic Acid	SS		ORAL		
			Omeprazole	SS		ORAL	20	DAY
			Zolpidem Tartrate	SS		ORAL	47	DAY
			Diclofenac Sodium And Misoprostol	SS		ORAL	20	DAY

Date:01/26/05ISR Number: 4564176-8Report Type:Expedited (15-DaCompany Report #2004SE06491
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	White Blood Cell Count Decreased	Foreign	Seroquel	PS		ORAL	100 MG DAILY PO	
		Health Professional	Haldol	SS		ORAL	2 MG DAILY PO	
		Other	Orfiril	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/27/05ISR Number: 4565146-6Report Type:Direct Company Report #CTU 238314
Age:22 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Dystonia		Haloperidol	PS		INTRAMUSCULAR	5 MG	IM
Initial or Prolonged	Tongue Disorder							

Date:01/27/05ISR Number: 4565152-1Report Type:Direct Company Report #CTU 238309
Age:22 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Aggression		Haloperidol	PS		5M G IM PRN		
Initial or Prolonged	Catatonia							
	Drooling							
	Dyskinesia							
	Joint Stiffness							
	Speech Disorder							
	Tongue Discolouration							
	Tongue Disorder							

Date:01/27/05ISR Number: 4565231-9Report Type:Direct Company Report #CTU 238471
Age:45 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Dystonia		Haloperidol	PS		ORAL	25 MG, 5 MG	Q4 H , ORAL
			Benztropine	C				
			Atenolol	C				
			Alprazolam	C				
			Acetaminophen	C				
			Naproxen	C				
			Magnesium Hydroxide	C				
			Kaolin/Pectin	C				
			Aloh/Mgoh/Simeth					
			Xtra Strength	C				
			Haloperidol	C				

Date:01/27/05ISR Number: 4567386-9Report Type:Expedited (15-DaCompany Report #2005-DE-00157GD
Age:63 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Delirium	Literature	Ipratropium-Bromide (Ipratropium Bromide)	PS				
	Lung Infection		Tiapride (Tiapride)	SS				
			Haloperidol (Haloperidol)	SS				

Date:01/27/05ISR Number: 4575365-0Report Type:Direct Company Report #CTU 238297
Age:39 YR Gender:Female I/FU:I

Outcome	PT
	Cogwheel Rigidity
	Drooling
	Joint Hyperextension
	Joint Range Of Motion Decreased
	Joint Stiffness

Muscle Rigidity
Tremor

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
			Haloperidol	PS		INTRAMUSCULAR	5MG	IM

(DURATION: 1

DOSE)

Date:01/28/05ISR Number: 4564484-0Report Type:Expedited (15-DaCompany Report #CH-BRISTOL-MYERS SQUIBB COMPANY-12828638
Age:5 DEC Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Blood Prolactin Increased		Dapotum Tabs	PS	Apothecon	ORAL	47	DAY
Initial or Prolonged			Akineton	SS		ORAL		
			Haldol Decanoate	SS		INTRAMUSCULAR		3069 DAY
			Melleril	C				

Dose taken in

the evening.

Duration of

therapy:

"some months"

Date:01/31/05ISR Number: 4564984-3Report Type:Expedited (15-DaCompany Report #CH-JNJFOC-20050103751
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Blood Prolactin Increased		Haldol Decanoate	PS		INTRAMUSCULAR		
Initial or Prolonged	Chest Pain		Haldol Decanoate	SS		INTRAMUSCULAR		
	Drug Interaction		Haldol	SS		OROPHARINGEAL		

	Galactorrhoea	Akineton Ret	C
OROPHARINGEAL			
	Menstrual Disorder	Melleril	C
at night			
	Psychotic Disorder		
since several			
	Treatment Noncompliance		
months but			
not taken			
regularly.			
		Dapotum	I
OROPHARINGEAL			
		Dapotum	I
OROPHARINGEAL			
		Dapotum	I
OROPHARINGEAL			
		Dapotum	I
OROPHARINGEAL			
		Dapotum	I
OROPHARINGEAL			
		Dapotum	I
OROPHARINGEAL			
		Dapotum	I
OROPHARINGEAL			

Date:01/31/05ISR Number: 4564997-1Report Type:Expedited (15-DaCompany Report #PHBS2005JP00728
Age:69 YR Gender:Female I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Asthenia
Other	Bladder Catheterisation
	Blood Creatine Phosphokinase Increased
	Blood Pressure Increased
	Body Temperature Increased
	Depressed Level Of Consciousness
	Drug Interaction
	Feeling Hot
	Heart Rate Increased
	Malaise

Rhabdomyolysis

		Report Source	Product	Role	Manufacturer	Route	Dose	Duration
			Lamisil	PS	Novartis Sector: Pharma	ORAL	125 mg, QD	97 DAY
			Serenace	SS		ORAL	3 mg/day	
			Meleril	SS		ORAL	75 mg/day	

Date:02/02/05ISR Number: 4567910-6Report Type:Expedited (15-DaCompany Report #FR-JNJFOC-20050105217
Age:84 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Atrioventricular Block		Haldol	PS				
OROPHARINGEAL								
Initial or Prolonged	First Degree		Pipram	SS				
OROPHARINGEAL								
	Carotid Bruit		Cozaar	SS				
OROPHARINGEAL								
	Dizziness		Mopral	SS				
OROPHARINGEAL								
	Iatrogenic Injury		Stilnox	SS				
OROPHARINGEAL								
	Malaise		Artotec	SS				
OROPHARINGEAL								
	Sinus Arrhythmia		Artotec	SS				
OROPHARINGEAL								
	Syncope							

Date:02/02/05ISR Number: 4568258-6Report Type:Expedited (15-DaCompany Report #FR-SANOFI-SYNTHELABO-A02200500189
Age:85 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Atrioventricular Block		Stilnox	PS		ORAL		47 DAY
Initial or Prolonged	First Degree		Artotec	SS		ORAL		20 DAY
	Carotid Bruit		Mopral	SS		ORAL		

	Malaise		Cozaar	SS		ORAL
	Sinus Arrhythmia		Haldol	SS		ORAL
			Pipram	C		ORAL

Date:02/02/05ISR Number: 4578385-5Report Type:Direct Company Report #CTU 238930
Age:57 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Agitation		Haloperidol	PS		INTRAMUSCULAR	5 MG IM Q 4 H	
Initial or Prolonged	Parkinsonism					PM		
Disability			Clonazepam	C				
			Depakote	C				
			Risperidal	C				

Date:02/03/05ISR Number: 4572301-8Report Type:Expedited (15-DaCompany Report #2005CG00189
Age:85 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Atrioventricular Block	Foreign	Mopral	PS		ORAL	20 MG DAILY	
Initial or Prolonged	First Degree	Health				PO		
	Carotid Bruit	Professional	Haldol	SS		ORAL	1 MG BID PO	
	Electrocardiogram	Other	Pipram	SS		ORAL	400 MG DAILY	
	Repolarisation					PO		
	Abnormality		Cozaar	SS		ORAL	25 MG DAILY	
	Iatrogenic Injury					PO		
	Malaise		Stilnox/Fra/	SS		ORAL	10 MG DAILY	
	Sinus Arrhythmia					PO		
			Artotec	SS			50 MG + 0.2	
							MG BID	

Date:02/04/05ISR Number: 4570346-5Report Type:Expedited (15-DaCompany Report #FR-ROCHE-393409
Age:32 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agitation Delirium Priapism		Rivotril Loxapac	PS SS	Roche	ORAL	INTRAMUSCULAR REPORTED AS "FLASKS"	UNITS 2 DAY
			Mepronizine Fraxiparine	SS SS		ORAL	SUBCUTANEOUS	
			Haldol	SS			INTRAMUSCULAR REPORTED AS "FLASKS"	UNITS
			Nozinan Lysanxia Imovane	SS C C		ORAL		

Date:02/04/05ISR Number: 4570481-1Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20050106248
Age:38 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Interaction Glycosylated Haemoglobin Increased Hyperglycaemia		Haloperidol Insuline Procyclidine Quetiapine	PS C C I			10-38 iu OROPHARINGEAL	

Date:02/04/05ISR Number: 4573006-XReport Type:Expedited (15-DaCompany Report #2004110541
Age:77 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Alanine Aminotransferase	Foreign	Sulperazon					

Initial or Prolonged Other		Increased Aspartate Aminotransferase Increased Blood Alkaline Phosphatase Increased Blood Lactate Dehydrogenase Increased Gastric Ulcer Hepatic Function Abnormal Hyperthyroidism Pneumonia Syphilis	Health Professional Company Representative	(Sulbactam, Cefoperazone)	PS		
INTRAVENOUS	2 GRAM (1 GRAM, 2 IN 1 D), INTRAVENOUS			Norvasc (Amlodipine)	SS		ORAL 5 MG (5 MG, 1 IN 1 D), ORAL
				Haloperidol (Haloperidol)	SS		ORAL 1 MG (1 MG, 1 IN 1 D), ORAL
				Tiapride Hydrochloride (Tiapride Hydrochloride)	C		
				Haloperidol (Haloperidol)	C		
				Bufferin(Acetylsalicylic Acid, Aluminium Glycinate, Magnesium Carbonate)	C		
				Mexiletine Hydrochloride (Mexiletine Hydrochloride)	C		
				Polaprezinc (Polaprezinc)	C		
				Temocapril Hydrochloride (Temocapril			

Hydrochloride)	C	
Magnesium Oxide (Magnesium Oxide)	C	
Famotidine (Famotidine)	C	
Rebamipide (Rebamipide)	C	

Date:02/04/05ISR Number: 4598311-2Report Type:Periodic Company Report #PHEH2004US06629
Age:25 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Creatine Phosphokinase Increased	Health Professional	Clozaril (Clozapine)Tablet	PS		ORAL	300 MG/DAY,	
	Infection						ORAL	
	Neuroleptic Malignant Syndrome		Haldol "Janssen" (Haloperidol)	SS		ORAL	2 MG/KG, ORAL	
	Rhabdomyolysis		Depakote (Valproate Semisodium)	C				

Date:02/08/05ISR Number: 4574962-6Report Type:Periodic Company Report #CH-JNJFOC-20050103751
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Prolactin Increased	Health Professional	Haldol Decanoate	PS		INTRAMUSCULAR		
	Breast Pain		Haldol Decanoate	SS		INTRAMUSCULAR		
	Drug Interaction		Haldol	C		OROPHARINGEAL	taken in the morning	
	Galactorrhoea							
	Menstrual Disorder		Akineton Ret	C		OROPHARINGEAL	at night	
	Psychotic Disorder		Melleril	C			since several	

months but

not taken

regularly.

	Akineton Ret	C
OROPHARINGEAL		
	Dapotum	I
OROPHARINGEAL		
	Dapotum	I
OROPHARINGEAL		
	Dapotum	I
OROPHARINGEAL		
	Dapotum	I
OROPHARINGEAL		
	Dapotum	I
OROPHARINGEAL		
	Dapotum	I
OROPHARINGEAL		

Date:02/08/05ISR Number: 4575136-5Report Type:Expedited (15-DaCompany Report #FR-MERCK-0501FRA00064
Age:84 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Malaise		Cozaar	PS	Merck & Co., Inc	ORAL		
			Haloperidol	SS		ORAL	15	DAY
			Pipemidic Acid	SS		ORAL		
			Omeprazole	SS		ORAL	20	DAY
			Zolpidem Tartrate	SS		ORAL	47	DAY
			Diclofenac Sodium And Misoprostol	SS		ORAL	20	DAY

Date:02/08/05ISR Number: 4577435-XReport Type:Expedited (15-DaCompany Report #A02200500189
Age:85 YR Gender:Female I/FU:I

Outcome	Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - Initial or Prolonged	10 MG OD, ORAL	47 DAY	Atrioventricular Block First Degree Carotid Bruit Malaise	Health Professional	Stilnox - (Zolpidem) - Tablet - 10 Mg	PS		ORAL
	1 MG OD, ORAL	2 WK			Haldol "Janssen-Cilag" - (Haloperidol) - Tablet - 1 Mg	SS	Janssen-Cilag	ORAL
	400 MG OD, ORAL				Pipram - (Pipemidic Acid) - Tablet - 400 Mg	SS		ORAL
	25 MG OD, ORAL				Cozaar - (Losartan Potassium) - Tablet - 50 Mg	SS		ORAL
	20 MG OD, ORAL	19 DAY			Mopral - (Omeprazole) - Capsule - 20 Mg	SS		ORAL
	50 MG BID, ORAL	2 WK			Artotec - (Diclofenac/Misoprostol) - Tablet - 50 Mg	SS		ORAL

Date:02/09/05ISR Number: 4576017-3Report Type:Expedited (15-DaCompany Report #PHBS2005JP00728
Age:69 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Asthenia Bladder Catheterisation		Lamisil	PS	Novartis Sector: Pharma	ORAL	125 mg, QD	97 DAY
Other	Blood Creatine		Serenace	SS		ORAL	3 mg/day	
	Phosphokinase Increased		Meleril	SS		ORAL	75 mg/day	
	Blood Pressure Increased Body Temperature Increased Depressed Level Of Consciousness Drug Interaction Feeling Hot Heart Rate Increased Hepatitis C Antibody Positive Lymphocyte Stimulation Test Positive Malaise Myalgia Rhabdomyolysis							

Date:02/09/05ISR Number: 4577256-8Report Type:Expedited (15-DaCompany Report #2004AL000724
Age:46 YR Gender:Male I/FU:F

Outcome	PT
Death	Completed Suicide
Hospitalization - Initial or Prolonged	Electrocardiogram Qrs Complex Prolonged

	Heart Rate Increased Multiple Drug Overdose Respiratory Arrest	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Stupor	Literature Health Professional	Hydramine Cough Syrup (Diphenhydramine Hydrochloride Cough Syrup)(Alpharma)	PS	Alpharma	ORAL	PO
			Hydramine Elixir (Diphenhydramine Hydrochloride Elixir) (Alpharma)	SS	Alpharma	ORAL	PO
			Cyclobenzaprine	SS		ORAL	PO
			Haloperidol	SS		ORAL	PO
			Ibuprofen Oral Suspension Usp, 100 Mg/5 Ml (Otc) (Alpharma)	SS	Alpharma	ORAL	PO
			Ibuprofen Oral Suspension Usp, 100 Mg/5 Ml (Rx) (Alpharma)	SS	Alpharma	ORAL	PO
			Methylphenidate	SS		ORAL	PO
			Cephalexin	SS		ORAL	PO
			Naproxen	SS		ORAL	PO
			Chlorzoxazone	SS		ORAL	PO
			Ethanol	SS		ORAL	PO

Date:02/10/05ISR Number: 4576688-1Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20041205632
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration

Other	Accommodation Disorder	Haldol	PS
	Difficulty In Walking	Haldol	SS
INTRAMUSCULAR			
	Extrapyramidal Disorder	Neurocil	C
	Jaw Disorder		
	Paralysis		
	Photosensitivity Reaction		
	Tremor		
	Visual Disturbance		

Date:02/10/05ISR Number: 4579609-0Report Type:Expedited (15-DaCompany Report #2004AL000508
Age:59 YR Gender:Female I/FU:F

Outcome	PT
Death	Acidosis
Hospitalization -	Analgesic Drug Level
Initial or Prolonged	Increased
	Aspartate
	Aminotransferase
	Increased
	Blood Creatine
	Phosphokinase Increased
	Blood Potassium Increased
	Coma
	Completed Suicide
	Haemodialysis
	Hypotension
	Mental Status Changes

		Miosis Multi-Organ Failure Overdose	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
		Renal Failure Therapeutic Agent	Literature Health	Lorazepam Tablets Usp, 2 Mg (Purepac)	PS	Purepac	ORAL
PO							
		Toxicity Vomiting	Professional	Naproxen Delayed-Release Tablets, 500 Mg (Purepac)	SS	Puepac	ORAL
PO							
				Acetaminophen/Tramadol	SS		ORAL
PO							
				Belladonna W/Ergotamine/Phenobarbital	SS		ORAL
PO							
				Losartan	SS		ORAL
PO							
				Quinine	SS		ORAL
PO							
				Levothyroxine	SS		ORAL
PO							
				Haloperidol Lactate Oral Solution Usp, Eq. 1 Mg Lactate/Ml (Udl)	SS	Usp	ORAL
PO							
				Phenytoin Oral Suspension Usp, 125 Mg/5 Ml (Alpharma)	SS	Alpharma	ORAL
PO							
				Sertraline	SS		ORAL
PO							
				Olanzapine	SS		ORAL
PO							
				Hydroxyzine Hydrochloride Syrup Usp, 10 Mg/5 Ml (Alpharma)	SS	Alparma	ORAL
PO							

Date:02/10/05ISR Number: 4579620-XReport Type:Direct Company Report #CTU 240096
Age:25 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agitation Cogwheel Rigidity Coma Hyperthermia Locked-In Syndrome Mental Status Changes Neuroleptic Malignant Syndrome Somnolence		Haloperidol 2mg/Ml Ortho Mcneil Pharmaceuticals	PS	Ortho Mcneil Pharmaceuticals	INTRAVENOUS	100MG (20ML) IV CONT INFUSED 5MG IV Q 1 H PRN, 1 MG IV Q 1 H	
			Risperidone 0.5mg And 1 Mg Janssen Pharmaceuticals	SS	Janssen Pharmaceuticals	ORAL	0.5MG PO BID 3 D 5 MG PO BID X 5 D	
			Risperidone 1 Mg Janssen Pharmaceuticals	SS	Janssen Pharmaceuticals	ORAL	1MG PO BID X1 D	
			Linezolid	C				
			Levofloxacin	C				
			Cefepime	C				
			Azithromycin	C				
			Metronidazole	C				
			Bacitracin Zinc					

Ointment	C
Metoclopramide	C
Sulcrafate	C
Dalteparin	C
Docusate Sodium	C
Ferrous Sulfate	C
Magnesium Hydroxide	C
Fentanyl	C
Promethazine Hcl	C
Bisacodyl	C
Buspirone	C
Tpn	C

Date:02/10/05ISR Number: 4579725-3Report Type:Direct Company Report #CTU 240112
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Extrapyramidal Disorder		Haloperidol 100mg	PS		INTRAMUSCULAR	100MG	Q4W
						INTRAMUSCULAR		

Date:02/11/05ISR Number: 4578477-0Report Type:Expedited (15-DaCompany Report #FR-JNJFOC-20050105217
Age:84 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Atrioventricular Block		Haldol	PS		OROPHARINGEAL		
	First Degree		Haldol	SS		OROPHARINGEAL		
	Blood Sodium Decreased		Pipram	SS		OROPHARINGEAL		
	Carotid Bruit		Mopral	SS		OROPHARINGEAL		
	Cerebral Atrophy		Artotec	SS		OROPHARINGEAL		
	Chest X-Ray Abnormal		Artotec	SS		OROPHARINGEAL		
	Creatinine Renal		Stilnox	SS		OROPHARINGEAL		
	Clearance Decreased		Cozaar	SS		OROPHARINGEAL		

	Dizziness Postural		Haldol	SS		
OROPHARINGEAL						
	Leukoaraiosis					
	Malaise					
	Sinus Arrhythmia					
	Syncope					

Date:02/11/05ISR Number: 4578808-1Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20041100035
Age:51 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Arthritis		Haldol Decanoate	PS		
150 - 300 mg						
Initial or Prolonged	Diabetes Mellitus		Haldol Decanoate	SS		
Other	Hair Growth Abnormal					
	Hypertension					
	Oedema Peripheral					
	Vision Blurred					

Date:02/11/05ISR Number: 4583521-0Report Type:Expedited (15-DaCompany Report #2005CG00189
Age:84 YR Gender:Female I/FU:F

Outcome	PT
Hospitalization -	Aggression
Initial or Prolonged	Agitation
	Arrhythmia
	Atrioventricular Block
	First Degree

Carotid Bruit Cerebral Atrophy Chest X-Ray Abnormal	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Confusional State	Foreign	Mopral	PS		ORAL	20 MG DAILY
Creatinine Renal	Health					PO
Clearance Decreased	Professional	Haldol	SS		ORAL	1 MG BID PO
Leukoaraiosis	Other	Pipram	SS		ORAL	400 MG DAILY
Malaise						PO
		Cozaar	SS		ORAL	25 MG DAILY
						PO
		Stilnox	SS		ORAL	10 MG DAILY
						PO
		Artotec	SS			50 MG + 0.2
						MG BID
		Uteplex	C			
		Propofan	C			

Date:02/14/05ISR Number: 4580002-5Report Type:Expedited (15-DaCompany Report #FR-JNJFOC-20050201048
Age:57 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Drug Interaction		Risperdal	PS			OROPHARINGEAL
Initial or Prolonged	Dysstasia		Haldol Decanoas	SS			INTRAMUSCULAR
	Fall		Imovane	C			
	Hypotension		Tegretol	C			
			Temesta	C			
			Parkinane	C			
			Tercian	I			OROPHARINGEAL

			Tercian	I		
OROPHARINGEAL						

Date:02/15/05ISR Number: 4582500-7Report Type:Expedited (15-DaCompany Report #BR-JNJFOC-20050201896
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Cardio-Respiratory Arrest		Haldol	PS				
Hospitalization -	Coma		Carbamazepine	C				
Initial or Prolonged	Intentional Misuse		Phenobarbital	C				
	Suicide Attempt							

Date:02/15/05ISR Number: 4587324-2Report Type:Expedited (15-DaCompany Report #2005AP01098
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required	Homicidal Ideation	Foreign	Seroquel	PS				
Intervention to	Suicidal Ideation	Health	Fluoxetine					
Prevent Permanent		Professional	Hydrochloride	SS				
Impairment/Damage		Other	Haloperidol	SS				
			Efexor	SS				

Date:02/17/05ISR Number: 4585824-2Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20050202943
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Death		Haldol Decanoate	PS		INTRAVENOUS		
	Medication Error							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/18/05ISR Number: 4586922-XReport Type:Expedited (15-DaCompany Report #DE-JNJFOC-20050102369
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Circulatory Collapse		Haldol	PS		OROPHARINGEAL		
			Dipiperon	SS		OROPHARINGEAL		
			Tavor	SS		OROPHARINGEAL		
			Neurocil	SS		OROPHARINGEAL		
			Neurocil	SS		OROPHARINGEAL		

Date:02/22/05ISR Number: 4588358-4Report Type:Expedited (15-DaCompany Report #FR-JNJFOC-20050203109
Age:37 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Bone Marrow Depression		Risperdal	PS		OROPHARINGEAL		
Initial or Prolonged	Dyspnoea Exertional		Haldol	SS		OROPHARINGEAL	2 mg/ml	
	Epistaxis		Akineton Retard	SS		OROPHARINGEAL		
	Epstein-Barr Virus		Stagid	SS		OROPHARINGEAL		
	Antibody Positive		Atarax	SS		OROPHARINGEAL		
	Metrorrhagia		Levothyrox	C				
	Petechiae							

Date:02/22/05ISR Number: 4588378-XReport Type:Expedited (15-DaCompany Report #BR-JNJFOC-20041201127
Age:26 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Overdose		Haldol	PS		OROPHARINGEAL		
Hospitalization -	Suicide Attempt		Carbamazepine	SS		OROPHARINGEAL		

Initial or Prolonged Phenobarbital SS
OROPHARINGEAL

Date:02/22/05ISR Number: 4588622-9Report Type:Expedited (15-DaCompany Report #PHBS2005DE02352
Age:27 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Asthenia		Clozapine	PS	Novartis Sector: Pharma		UNKNOWN	250 mg/d
	Disturbance In Attention							
	Libido Decreased		Lorazepam	SS			UNKNOWN	1 mg/d
	Weight Increased		Haloperidol	SS				
			Zotepine	SS				
			Risperidone	SS			UNKNOWN	6 mg/d

Date:02/22/05ISR Number: 4588799-5Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20050203113
Age:19 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dysarthria		Haloperidol	PS		OROPHARINGEAL		
	Musculoskeletal Stiffness		Cannabis	C			15 joints/day	
			Lorazepam	C		OROPHARINGEAL	taken prn	
			Olanzapine	C				

Date:02/22/05ISR Number: 4591936-XReport Type:Expedited (15-DaCompany Report #2004114895
Age: Gender:Female I/FU:F

Outcome	PT	Report Source
Death	Drug Abuser	Health
Other	Overdose	Professional
	Sudden Death	Company

Representative

			Product	Role	Manufacturer	Route	Dose	Duration
			Geodon (Im) (Ziprasidone)	PS				
			Haloperidol (Haloperidol)	SS				
			Cocaine (Cocaine)	SS				

Date:02/23/05ISR Number: 4589517-7Report Type:Expedited (15-DaCompany Report #FR-JNJFOC-20050203176
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Inappropriate		Haloperidol	PS		INTRAMUSCULAR		
Initial or Prolonged	Antidiuretic Hormone Secretion							

Date:02/23/05ISR Number: 4589836-4Report Type:Expedited (15-DaCompany Report #FR-ABBOTT-05P-056-0290843-00
Age:37 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Aplasia		Akineton	PS		ORAL		
Initial or Prolonged	Biopsy Bone Marrow		Risperidone	SS		ORAL		3 MON
	Abnormal		Metformin	SS		ORAL		3 YR
	Bone Marrow Myelogram Abnormal		Hydroxyzine Hydrochloride	SS		ORAL		
	Dyspnoea Exertional		Haloperidol	SS		ORAL		
	Epistaxis		Haloperidol	SS		ORAL		15 to 20 drops
	Gingival Bleeding							
	Metrorrhagia		Levothyroxine	C		ORAL		
	Petechiae							

Date:02/24/05ISR Number: 4590406-2Report Type:Expedited (15-DaCompany Report #JP-JNJFOC-20041200936
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Cardiac Failure Acute		Risperdal	PS		OROPHARINGEAL		
Hospitalization - Initial or Prolonged	Neuroleptic Malignant Syndrome		Risperdal	SS		OROPHARINGEAL		
			Halomonth	SS		OROPHARINGEAL		
			Olanzapine	SS		OROPHARINGEAL		
			Olanzapine	SS		OROPHARINGEAL		
			Cimetidine	C				
			Biperiden Hydrochloride	C				
			Isoleucine Leucine Valine	C				
			Flunitrazepam	C				
			Zopiclone	C				
			Sennoside	C				
			Aspartate Potassium	C				

Date:02/24/05ISR Number: 4590421-9Report Type:Expedited (15-DaCompany Report #AU-JNJFOC-20050203774
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Systemic Lupus Erythematosus		Haldol	PS		OTHER		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/24/05ISR Number: 4590422-0Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20050204139
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Death		Haldol	PS				
			Clozapine	SS				
OROPHARINGEAL								
			Ativan	C				
			Lithium Carbonate	C				

Date:02/24/05ISR Number: 4590423-2Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20050204429
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Death		Haldol Decanoate	PS				
INTRAMUSCULAR								

Date:02/24/05ISR Number: 4595774-3Report Type:Expedited (15-DaCompany Report #A044-002-005478
Age:63 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Interaction	Foreign	Aricept (Donepezil Hydrochloride)	PS		ORAL	10 MG, 1 IN 1	
	Haemodialysis	Health						
	Neuroleptic Malignant Syndrome	Professional						
			Seroquel (Quetiapine Fumarate)	SS			400 MG	
	Renal Failure Acute							
	Rhabdomyolysis		Tavor (Lorazepam)	SS			6 MG	
			Thombran (Trazodone Hydrochloride)	SS			400 MG	
			Quilonum (Lithium Acetate)	SS			675 MG	
			Zyprexa (Olanzapine)	SS			20 MG	

			Zeldox (Ziprasidone Hydrochloride)	SS		
80 MG						
			Haldol (Haloperidol)	SS		
6 MG						

Date:02/25/05ISR Number: 4591085-0Report Type:Expedited (15-DaCompany Report #200414493FR
Age:50 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Neuroleptic Malignant Syndrome		Rifater	PS	Aventis Pharmaceuticals Inc.	ORAL		
			Tercian	SS		ORAL		
			Mepronizine	SS		ORAL		
			Modecate	SS				
			Temesta	SS		ORAL		
			Haldol	SS		ORAL		

Date:02/25/05ISR Number: 4591180-6Report Type:Expedited (15-DaCompany Report #FR-JNJFOC-20050204386
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Congenital Anomaly	Clavicle Fracture		Haldol	PS				
							INTRA-UTERINE	
Other	Drug Exposure During Pregnancy		Theralene	C				
	Small For Dates Baby							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/28/05ISR Number: 4592351-5Report Type:Periodic Company Report #US-BRISTOL-MYERS SQUIBB COMPANY-12797148
Age:49 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Neuroleptic Malignant Syndrome		Abilify	PS	Otsuka Pharmaceutical Company, Ltd.	ORAL		
Hospitalization - Initial or Prolonged	Renal Failure							
Interrupted	Respiratory Distress							
Other								
on								
06-Nov-2004								
when the								
patient was								
			Haldol	SS				
			Clozaril	SS				
Interrupted								
on								
06-Nov-2004								
when the								
patient was								
			Pavulon	C			1	DAY
			Diprivan	C			1	DAY
			Geodon	C			1	DAY
			Dantrium	C			1	DAY

Date:02/28/05ISR Number: 4593025-7Report Type:Expedited (15-DaCompany Report #DE-ABBOTT-05P-062-0291749-00
Age:36 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Akathisia		Akineton Tabletten	PS		ORAL		
	Drug Interaction		Olanzapine	SS		ORAL		
	Tremor		Olanzapine	SS				

			Potassium Iodide	SS		ORAL
			Diazepam	C		ORAL
25 DAY						
			Diazepam	C		ORAL
25 DAY						
			Diazepam	C		ORAL
25 DAY						
			Amisulpride	I		ORAL
5 DAY						
			Haloperidol	I		ORAL
12 DAY						

Date:02/28/05ISR Number: 4596331-5Report Type:Expedited (15-DaCompany Report #2005PK00290
Age:63 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Anuria	Foreign	Seroquel	PS		ORAL	400 MG DAILY	
Initial or Prolonged	Blood Creatinine	Health					PO	
Required	Increased	Professional	Tavor	SS			6 MG DAILY	
Intervention to	Drug Interaction	Other	Thombran	SS			400 DAILY	
Prevent Permanent	Haemodialysis		Aricept	SS			10 MG DAILY	
Impairment/Damage	Neuroleptic Malignant		Zeldox /Gfr/	SS			80 MG DAILY	
	Syndrome		Haldol "Janssen"	SS			6 MG DAILY	
	Renal Failure Acute							
	Rhabdomyolysis							

Date:03/01/05ISR Number: 4594076-9Report Type:Expedited (15-DaCompany Report #DE-BRISTOL-MYERS SQUIBB COMPANY-12874905
Age:46 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Confusional State		Glucophage	PS	Bristol-Myers Squibb			
Initial or Prolonged	Delirium				Company			
	Disorientation		Hypnorex	I				
	Drug Interaction		Convulex	I				
	Restlessness		Ciatyl-Z	I				

			Novonorm	I		
			Haldol	I		
15mg						
15-Oct-2003						
to						
28-Oct-2003,						
20mg						
			Leponex	I		
			Tavor	I		

Date:03/01/05ISR Number: 4594117-9Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20050204728
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Bundle Branch Block Right		Risperdal Consta	PS		INTRAMUSCULAR		
Hospitalization -	Cardiomegaly		Risperdal Consta	SS		INTRAMUSCULAR		
Initial or Prolonged	Condition Aggravated		Haldol	SS		OROPHARINGEAL		
	Drug Ineffective		Fluanxol	SS		Fluanxol		
	Sudden Death					depot 10%		
			Risperdal Consta	SS		INTRAMUSCULAR		
			Risperdal	C		OROPHARINGEAL	4-5 mg	
			Risperdal	C		OROPHARINGEAL	2-4 mg	
			Levomepromazin	C				
			Akineton	C				
			Tavor	C		0.5-1 mg as		
						needed		
			Concor	C				
			Vesdil	C				
			Neurotrat	C				
			Neurotrat	C				

			Neurotrat	C		
			Neurotrat	C		

Date:03/01/05ISR Number: 4594131-3Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20050204806
Age:21 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Coordination Abnormal		Haldol	PS				
			Haldol	SS				
			Solian	C				
			Tavor	C				
			Tavor	C				
			Tavor	C				
			Akineton	C				

Date:03/01/05ISR Number: 4594767-XReport Type:Expedited (15-DaCompany Report #PHRM2005FR00923
Age:0 DY Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Atrial Septal Defect Drug Exposure During		Ludiomil	PS	Novartis Sector: Pharma	TRANSPLACENTAL		
Congenital Anomaly	Pregnancy		Haldol	SS		TRANSPLACENTAL		
	Facial Dysmorphism		Largactil	SS		TRANSPLACENTAL		
	Ventricular Septal Defect		Lepticur	SS		TRANSPLACENTAL		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/02/05ISR Number: 4596012-8Report Type:Expedited (15-DaCompany Report #FR-JNJFOC-20031203790
Age:75 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Extrapyramidal Disorder		Haldol	PS				
OROPHARINGEAL	11979DAY							
Initial or Prolonged	General Physical Health Deterioration							
	Parkinsonism							
	Tardive Dyskinesia							
	Urinary Incontinence							
	Urinary Retention							

Date:03/03/05ISR Number: 4597581-4Report Type:Periodic Company Report #DE-JNJFOC-20050204728
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardiomegaly		Risperdal Consta	PS				
INTRAMUSCULAR								
Hospitalization -	Condition Aggravated		Risperdal Consta	SS				
INTRAMUSCULAR								
Initial or Prolonged	Drug Ineffective		Haldol	SS				
OROPHARINGEAL								
	Sudden Death		Fluanxol	SS				
Fluanxol								
depot 10%								
			Risperdal Consta	SS				
INTRAMUSCULAR								
			Risperdal	C				
OROPHARINGEAL							4-5 mg	
			Risperdal	C				
OROPHARINGEAL							2-4 mg	
			Levomepromazin	C				
			Akineton	C				
			Tavor	C				
0.5-1 mg as								
needed								
			Concor	C				
			Vesdil	C				
			Neurotrat	C				
			Neurotrat	C				

				Neurotrat	C		
				Neurotrat	C		

Date:03/03/05ISR Number: 4597688-1Report Type:Expedited (15-DaCompany Report #BR-JNJFOC-20050206350
Age:25 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dizziness		Haldol	PS				
	Somnolence		Imipramine	SS				
	Suicide Attempt		Diazepam	SS				

Date:03/04/05ISR Number: 4598333-1Report Type:Expedited (15-DaCompany Report #PHBS2005JP00700
Age:67 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Neuroleptic Malignant Syndrome		Tofranil	PS	Novartis Sector: Pharma	ORAL	150 mg/d	8640 MIN
			Serenace	SS		ORAL	2.25 mg/d	30240MIN
			Serenace	SS			INTRAMUSCULAR	0.5 %, ONCE/SINGLE 1440 MIN
			Serenace	SS			INTRAMUSCULAR	0.5 %, ONCE/SINGLE 1440 MIN
			Anafranil	SS			INTRAVENOUS	50 mg/d 21600MIN
			Depromel	SS		ORAL	75 mg/d	30240MIN
			Anafranil	SS		ORAL	75 mg/d	23040MIN
			Depas	C		ORAL	1.5 mg/d	30240MIN
			Tasmolin	C		ORAL	3 to 6 mg/d	30240MIN

25 mg/d	23040MIN		Ludiomil	C	ORAL
30 mg/d	8640 MIN		Tetramide	C	ORAL
5 to 10 mg/d	30240MIN		Benzalin	C	ORAL
1 DF to 2 DF/d	11520MIN		Vegetamin B	C	ORAL
1 DF, QD	5760 MIN		Vegetamin A	C	ORAL
3.0 g/d	14400MIN		Kolantyl	C	ORAL
1.5 mg/d	14400MIN		Elieten	C	ORAL
1.0 g/d	14400MIN		Alosenn	C	ORAL
1.0 g/d	2880 MIN		Magnesium Oxide	C	ORAL
36 mg/d	10080MIN		Pursennid	C	ORAL
750 mg/d	5760 MIN		Kefral	C	ORAL
25 mg PR	1440 MIN		Indacin	C	
INTRAMUSCULAR	0.5 %/d	31680MIN	Akineton	C	
INTRAMUSCULAR ONCE/SINGLE	10 mg,	1440 MIN	Dormicum	C	
500 ml (DR)/d	21600MIN		Dextrose	C	
500 ml (DR)/d	21600MIN		Soldem 3a	C	

Date:03/04/05ISR Number: 4598489-0Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20050103374
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Renal Failure Acute		Haldol Decanoate	PS		INTRAMUSCULAR		

Other	Rhabdomyolysis		Ciatyl	SS		
INTRAMUSCULAR						
			Diazepam	C		
OROPHARINGEAL						

Date:03/07/05ISR Number: 4599523-4Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20050206211
Age:75 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Convulsion		Haldol	PS		
Hospitalization -	Lymphoma		Haldol	SS		
Initial or Prolonged	Medication Error		Ativan	C		
	Transfusion Reaction		Ativan	C		
as needed						
			Hydrocodone	C		
			Atenalol	C		
drug taken						
for many						
years						
			Digoxin	C		
			Prinivel	C		
			Zocor	C		
on it for						
several years						
			Asa	C		
on several						
years						
			Terazol	C		
			Norvasc	C		

Date:03/07/05ISR Number: 4599525-8Report Type:Expedited (15-DaCompany Report #BR-JNJFOC-20050206365
Age:24 MON Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Accidental Exposure		Haldol	PS		
Initial or Prolonged	Decreased Activity					
	Neuromyopathy					
	Somnolence					

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/07/05ISR Number: 4602526-4Report Type:Expedited (15-DaCompany Report #2005035736
Age:63 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Interaction Haemodialysis	Foreign Health	Zeldox					
Other	Neuroleptic Malignant Syndrome	Professional Other	(Ziprasidone)	PS		ORAL	80 MG (1 D), ORAL	
			Aricept (Donepezil)	SS		ORAL	10 MG (1 D), ORAL	
			Quetiapine Fumarate (Quetiapine Fumarate)	SS			400 MG (1 D)	
			Lorazepam (Lorazepam)	SS			6 MG (1 D)	
			Trazodone Hydrochloride (Trazodone Hydrochloride)	SS			400 MG (1 D)	
			Haloperidol (Haloperidol)	SS			6 MG (1 D)	
			Lithium Acetate (Lithium Acetate)	C				
			Olanzapine (Olanzapine)	C				

Date:03/07/05ISR Number: 4602936-5Report Type:Expedited (15-DaCompany Report #2005035266
Age:63 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Anuria	Foreign	Lithium (Lithium)	PS			675 MG	

Initial or Prolonged	Drug Interaction Haemodialysis Neuroleptic Malignant Syndrome Renal Failure Acute Rhabdomyolysis	Health Professional	Lorazepam (Lorazepam)	SS	ORAL
6 MG, ORAL					
			Trazodone Hydrochloride (Trazodone Hydrochloride)	SS	
400 MG					
			Ziprasidone (Caps) (Ziprasidone)	SS	
80 MG					
			Haloperidol (Haloperidol)	SS	
6 MG					
			Donepezil Hydrochloride (Donepezil Hydrochloride)	SS	
10 MG (1 IN 1 D)					
			Quetiapine Fumarate (Quetiapine Fumarate)	SS	
400 MG					
			Olanzapine (Olanzapine)	SS	
20 MG					

Date:03/07/05ISR Number: 4602995-XReport Type:Expedited (15-DaCompany Report #2005035736
Age:63 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Body Temperature Increased Chills Delirium Diarrhoea Drug Interaction Haemodialysis Neuroleptic Malignant Syndrome Renal Failure Acute Rhabdomyolysis	Foreign Health Professional	Zeldox (Capsules) (Ziprasidone) Aricept (Donepezil) Quetiapine Fumarate (Quetiapine Fumarate) Lorazepam (Lorazepam) Trazodone Hydrochloride (Trazodone Hydrochloride) Haloperidol (Haloperidol) Lithium Acetate (Lithium Acetate) Olanzapine (Olanzapine)	PS SS SS SS SS C C		ORAL ORAL ORAL ORAL ORAL	80 MG (1 D), 10 MG (1 D), 400 MG (1 D) 6 MG (1 D) 400 MG (1 D) 6 MG (1 D)	

Date:03/08/05ISR Number: 4603846-XReport Type:Expedited (15-DaCompany Report #2005038149
Age:28 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Operation Abnormal Behaviour Agitation Blood Pressure Diastolic Increased	Literature Health Professional	Ziprasidone (Caps) (Ziprasidone) Haloperidol (Haloperidol)	PS SS			40 MG	

	Cogwheel Rigidity
	Confusional State
	Creatine Phosphokinase
	Decreased
	Drooling
	Drug Toxicity
	Feeling Jittery
	Heart Rate Increased
	Leukocytosis
	Mental Status Changes
	Movement Disorder
	Poverty Of Speech
	Psychotic Disorder
	Pyrexia
	Sepsis
	Tremor

Date:03/09/05ISR Number: 4602453-2Report Type:Expedited (15-DaCompany Report #FR-JNJFOC-20050205875
Age:43 YR Gender:Male I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Bradyphrenia
	Drug Interaction
	Dysphonia
	Eyelid Ptosis
	Hyperhidrosis

	Hypertonia						
	Rhabdomyolysis						
	Syncope	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Tremor	Health	Haldol	PS			
OROPHARINGEAL							167 DAY
		Professional	Lepticur	SS			
OROPHARINGEAL							
			Tranxene	SS			
OROPHARINGEAL							

Date:03/09/05ISR Number: 4602778-0Report Type:Expedited (15-DaCompany Report #RO-JNJFOC-20041204160
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Life-Threatening	Suicide Attempt		Haloperidol	PS			

Date:03/09/05ISR Number: 4602779-2Report Type:Expedited (15-DaCompany Report #FR-JNJFOC-20050205971
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Atrial Septal Defect	Health	Haldol	PS			
INTRA-UTERINE							
Initial or Prolonged	Drug Exposure During	Professional	Ludiomil	SS			
INTRA-UTERINE							
Congenital Anomaly	Pregnancy		Largactil	SS			
INTRA-UTERINE							
	Facial Dysmorphism		Lepticur	SS			
INTRA-UTERINE							
	Ventricular Septal Defect						

Date:03/09/05ISR Number: 4602780-9Report Type:Expedited (15-DaCompany Report #FR-JNJFOC-20050300008
Age:81 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Akinesia		Haldol	PS			
OROPHARINGEAL							
Initial or Prolonged	Cognitive Disorder		Cordarone	C			

	Dementia		Hyperium	C		
	Disorientation		Reminyl	C		
	Gait Disturbance		Seropram	C		
	Muscle Rigidity		Ikorel	C		
	Tremor					

Date:03/09/05ISR Number: 4604944-7Report Type:Direct Company Report #CTU 242491
Age:42 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Life-Threatening	Body Temperature		Haloperidol	PS		
INTRAVENOUS 5 MG IV G 6						
Required	Increased					
HOURS & Q 4						
Intervention to	Muscle Rigidity					
HOURS PRN						
Prevent Permanent			Ativan	C		
Impairment/Damage			Fentanyl	C		
			Clindamycin	C		
			Aranesp	C		
			Rocephin	C		
			Motrin	C		
			Lovenox	C		

Date:03/11/05ISR Number: 4608379-2Report Type:Direct Company Report #CTU 242966
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Dysarthria		Haldol	PS		
5 MG 6H PRN						
	Extrapyramidal Disorder					

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/11/05ISR Number: 4608886-2Report Type:Expedited (15-DaCompany Report #2004110541
Age:77 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Cholecystitis Gastric Ulcer Hyperthyroidism Pneumonia Syphilis	Foreign Health Professional Company Representative	Sulperazon (Sulbactam, Cefoperazone)	PS			INTRAVENOUS 2 GRAM (1 GRAM, 2 IN 1 D),	
			Norvasc (Amlodipine)	SS		ORAL	5 MG (5 MG, 1 IN 1 D),	ORAL
			Haloperidol (Haloperidol)	SS		ORAL	1 MG (1 MG, 1 IN 1 D),	ORAL
			Tiapride Hydrochloride (Tiapride Hydrochloride)	C				
			Bufferin (Acetylsalicylic Acid, Aluminium Glycinate, Magnesium Carbonate)	C				
			Mexiletine Hydrochloride (Mexiletine Hydrochloride)	C				
			Polaprezinc (Polaprezinc)	C				
			Temocapril Hydrochloride (Temocapril Hydrochloride)	C				
			Magnesium Oxide (Magnesium Oxide)	C				
			Famotidine (Famotidine)	C				

			Rebamipide (Rebamipide)	C		

Date:03/14/05ISR Number: 4606967-0Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20050300757
Age:52 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Neuroleptic Malignant Syndrome Pleurothotonus		Haldol	PS		
			Haldol	SS		
			Zyprexa	SS		
			Zyprexa	SS		
start date:						
since months						
			Tavor	C		
			Tavor	C		
			Tavor	C		
start date:						
since weeks						
			Climopax	C		
			Climopax	C		
0.625/5mg						
start date:						
since months						
			Euthyrox	C		
start date:						
since months						
			Felis	C		
start date:						

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

since weeks

Date:03/14/05ISR Number: 4607617-XReport Type:Expedited (15-DaCompany Report #DE-JNJFOC-20050300605
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Cyanosis		Risperdal	PS			UNKNOWN	
	Extrapyramidal Disorder		Haldol	SS			INTRAVENOUS	
	Gaze Palsy							
	Laryngospasm							
	Oropharyngeal Spasm							

Date:03/14/05ISR Number: 4609172-7Report Type:Expedited (15-DaCompany Report #DSA_25983_2005
Age:63 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Blood Glucose Increased	Foreign	Tavor	PS			6 MG Q DAY	
Initial or Prolonged	Drug Interaction	Health	Aricept	SS			10 MG Q DAY	
	Haemodialysis	Professional	Geodon	SS			80 MG Q DAY	
	Neuroleptic Malignant	Other	Geodon	SS			160 MG Q DAY	
	Syndrome		Haldol "Janssen"	SS	Janssen		6 MG Q DAY	
	Renal Failure Acute		Seroquel	SS			400 MG Q DAY	
	Rhabdomyolysis		Thrombran	SS			400 MG Q DAY	
			Zeldox	SS			DF	
			Quilonum	C				
			Zyprexa	C				

Date:03/15/05ISR Number: 4608656-5Report Type:Expedited (15-DaCompany Report #BR-JNJFOC-20050302265
Age:3 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Accidental Exposure		Haldol	PS			UNKNOWN	
	Glasgow Coma Scale Abnormal							
	Hypotonia							

Date:03/15/05ISR Number: 4613230-0Report Type:Expedited (15-DaCompany Report #2005042524
Age:21 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Anencephaly	Foreign	Lithium (Lithium)	PS		ORAL	900 MG, ORAL	
	Drug Exposure During Pregnancy	Literature Health Professional	Haloperidol (Haloperidol)	SS				
	Drug Ineffective							
	Neuroleptic Malignant Syndrome							
	Refusal Of Treatment By Patient							
	Retroplacental Haematoma							
	Spine Malformation							
	Ultrasound Antenatal Screen Abnormal							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/15/05ISR Number: 4613231-2Report Type:Expedited (15-DaCompany Report #2005042143
Age: Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Congenital Anomaly	Anencephaly	Foreign	Lithium (Lithium)	PS				
	Complications Of Maternal Exposure To Therapeutic Drugs	Literature	Haloperidol					
		Health Professional	(Haloperidol)	SS				
	Foetal Disorder							
	Small For Dates Baby							
	Spinal Disorder							

Date:03/15/05ISR Number: 4613277-4Report Type:Expedited (15-DaCompany Report #4999
Age:24 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Hypertonia		Midazolam	PS			INTRAVENOUS	10 MG ONCE IV
			Haloperidol	SS			INTRAVENOUS	15 MG ONCE IV

Date:03/16/05ISR Number: 4610075-2Report Type:Expedited (15-DaCompany Report #PHNU2005HU01347
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Abdominal Pain		Tegretol Cr	PS	Novartis Sector: Pharma	ORAL	200 mg/day	72000MIN
	Blood Sodium Decreased							
	Body Temperature		Haldol	SS		ORAL	20 mg/day	72000MIN
	Increased Bowel Sounds Abnormal		Tegretol Cr	SS	Novartis Sector: Pharma	ORAL	200 mg/day	
	Constipation		Seropram	C		ORAL	40 mg/day	72000MIN
	Ileus		Seropram	C		ORAL	40 mg/day	
	Weight Decreased		Rivotril	C		ORAL	4 mg/day	72000MIN

			Rivotril	C		ORAL
4 mg/day						
			Lithicarb	C		ORAL
1000 mg/day	72000MIN					
			Lithicarb	C		ORAL
1000 mg/day						

Date:03/16/05ISR Number: 4610135-6Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20050301445
Age:22 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Pleurothotonus		Haldol	PS				
OROPHARINGEAL								
Initial or Prolonged			Haldol	SS				
OROPHARINGEAL								
Other			Haldol	SS				
OROPHARINGEAL								
			Haldol	SS				
OROPHARINGEAL								

Date:03/17/05ISR Number: 4611160-1Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20050301466
Age:59 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Anaemia		Haldol	PS				
OROPHARINGEAL								
Initial or Prolonged	Bone Marrow Toxicity		Haldol	SS				
OROPHARINGEAL								
Other	Iron Deficiency		Orfiril	SS				
OROPHARINGEAL								
	Leukopenia		Orfiril	SS				
OROPHARINGEAL								
	Lymphopenia		Orfiril	SS				
OROPHARINGEAL								
	Neutropenia		Orfiril	SS				
OROPHARINGEAL								
			Orfiril	SS				
OROPHARINGEAL								
			Orfiril	SS				
OROPHARINGEAL								
			Orfiril	SS				
OROPHARINGEAL	dose							
increased								

from 0-1800

mg

		Atosil	SS
OROPHARINGEAL			
		Atosil	SS
OROPHARINGEAL			
		Atosil	SS
OROPHARINGEAL			
		Atosil	SS
OROPHARINGEAL	start date:		
for months			
		Ciatyl Z	C
OROPHARINGEAL			
		Ciatyl Z	C
OROPHARINGEAL			
		Ciatyl Z	C
OROPHARINGEAL			
		Ciatyl Z	C
OROPHARINGEAL			
		Ciatyl Z	C
OROPHARINGEAL			
		Remestan	C
OROPHARINGEAL	dose unknown		
		Remestan	C
OROPHARINGEAL	start date:		
for months			

Date:03/17/05ISR Number: 4611161-3Report Type:Expedited (15-DaCompany Report #BR-JNJFOC-20050302920
Age:12 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Coma		Haldol	PS		
UNKNOWN						
Initial or Prolonged	Suicide Attempt		Carbamazepine	SS		
			Fenobarbital	SS		

Date:03/17/05ISR Number: 4619597-1Report Type:Direct Company Report #CTU 243478
Age:58 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Asthenia		Risperdal	PS		ORAL	1 MG PO Q AM	
Life-Threatening	Atrial Fibrillation						AND HS (X5)	
	Cardio-Respiratory Arrest		Haloperidol	SS		ORAL	2 MG PO Q6 H	
	Cerebral Atrophy						RN (X1)	
	Cerebrovascular Accident		Carbidopa/Levodepa					
	Condition Aggravated		25/250 Mg Po, 8					
	Facial Palsy		Tabls Daily	SS		ORAL	25/250 PO, 8	
	Gastrointestinal						TABS DAILY	
	Haemorrhage		Ativan	C				
	Lethargy		Captopril	C				
	Neuroleptic Malignant		K-Dur	C				
	Syndrome		Zocor	C				
			Wellbutrin Sr	C				
			Digoxin	C				
			Coumadin	C				
			Humulin 70/30	C				
			Metoprolol	C				
			Plavix	C				
			Lovenox	C				
			Demadex	C				
			Diltiazem Cd	C				
			Lexapro	C				

Date:03/18/05ISR Number: 4613001-5Report Type:Expedited (15-DaCompany Report #IN-ABBOTT-05P-078-0293897-00
Age:31 YR Gender:Male I/FU:I

Outcome	PT
Other	Diabetic Ketoacidosis
	Euphoric Mood
	Irritability
	Pancreatitis Acute

		Restlessness Sleep Disorder					
			Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
				Valproate Sodium	PS		
				Chlorpromazine	SS		
				Haloperidol	SS		

Date:03/21/05ISR Number: 4616049-XReport Type:Expedited (15-DaCompany Report #S05-FRA-01009-01
Age:83 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization - Initial or Prolonged	Anorexia Dehydration	Foreign Health	Seropram (Citalopram Hydrobromide)	PS		
INTRAVENOUS	20 MG QD IV					
	Flatulence General Physical Health	Professional Other	Cetornan (Ornithine Oxoglurate)	SS		ORAL
10 G QD PO						
	Deterioration		Haloperidol	SS		ORAL
2 MG QD PO						
	Hepatic Steatosis Vomiting		Calciparine (Heparin Calcium) (Heparin Calcium)	SS		
SUBCUTANEOUS	0.8 ML QD SCS					
			Debridat	C		
			Daktarin (Miconazole Nitrate)	C		
			Aricept (Donepezil Hydrochloride)	C		
			Cordarone (Amiodarone Hydrochloride)	C		
			Amlor (Amlodipine Besilate)	C		
			Previscan (Fluindione)	C		
			Aldalix	C		
			Imovane (Zopiclone)	C		

Date:03/21/05ISR Number: 4616906-4Report Type:Expedited (15-DaCompany Report #2005035736
Age:63 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged Other	Anuria Body Temperature Increased Catatonia Chills Delirium Diarrhoea Drug Interaction Haemodialysis Neuroleptic Malignant Syndrome Renal Failure Acute Rhabdomyolysis	Foreign Health Professional	Zeldox (Capsules) (Ziprasidone) Aricept (Donepezil) Lithium Acetate (Lithium Acetate) Trazaodne (Trazadone) Haloperidol (Haloperidol) Lorazepam (Lorazepam) Quetiapone Fumarte (Quetiapine Fumarate) Olanzapine	PS SS SS SS SS SS C		ORAL ORAL ORAL ORAL	80 MG (1 IN 1 D), ORAL 10 MG (1 IN 1 D), ORAL 675 MG (1 IN 1 D) 400 MG (1 IN 1 D) 6 MG (1 IN 1 D), ORAL 6 MG (1 IN 1 D), ORAL

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

(Olanzapine) C

Date:03/21/05ISR Number: 4619722-2Report Type:Direct Company Report #CTU 243823
Age:42 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Blindness		Haldol	PS				
	Medication Error		Lithuim	SS				
			Prolixin	SS				
			Seroquel	SS				
			..	C				
			..	C				

Date:03/21/05ISR Number: 4619723-4Report Type:Direct Company Report #CTU 243821
Age:42 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Amnesia		Haldol 5 Mg Daily	PS		ORAL	DAILY PO	
Disability	Balance Disorder		Mellaril 50 Mg Daily	SS		ORAL	DAILY PO	
Other	Blindness							
	Blood Disorder							
	Communication Disorder							
	Coordination Abnormal							
	Incontinence							
	Mental Impairment							
	Micturition Urgency							
	Tardive Dyskinesia							

Date:03/23/05ISR Number: 4616126-3Report Type:Expedited (15-DaCompany Report #AU-JNJFOC-20050203774
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Antiphospholipid		Haldol	PS		OTHER	15-200 mg	
	Antibodies Positive							
	Galactorrhoea							

Date:03/23/05ISR Number: 4620065-1Report Type:Direct Company Report #CTU 244082
Age:48 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product		Role	Manufacturer	Route	Dose	Duration
Other	Tremor		Haloperidol	100mg	PS				
INTRAMUSCULAR								200MG	Q4W

INTRAMUSCU

Date:03/24/05ISR Number: 4617488-3Report Type:Expedited (15-DaCompany Report #BR-JNJFOC-20050304986
Age:45 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Overdose		Haldol	PS				
	Somnolence		Clonazepam	SS				
	Stupor							
	Suicide Attempt							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/24/05ISR Number: 4617527-XReport Type:Expedited (15-DaCompany Report #PHBS2005BE04067
Age:47 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Abuser Medication Error		Lamisil	PS	Novartis Sector: Pharma			
UNKNOWN							6 x 56 tablets = 336 tablets	
			Sirdalud	SS			8 packages of 100 Sirdalud 4 mg tablets	92160MIN
UNKNOWN			Sirdalud	SS			32 packages of 100 Sirdalud 4 mg tablets	106 DAY
UNKNOWN			Methadone	SS			10 x 60 tablets = 600 tablets	
UNKNOWN			Serenase	SS			3 x 50 tablets = 150 tablets	
UNKNOWN			Temgesic	SS			50 DF, ONCE/SINGLE	
UNKNOWN			Ranitidine	SS			9 x 28 or 56	

tablets

Amoxycillin SS

UNKNOWN 500 mg,

ONCE/SINGLE

Brufen SS

UNKNOWN 400 mg,

ONCE/SINGLE

Ciproxine SS

UNKNOWN 3 x 20

tablets = 60

tablets

Date:03/24/05ISR Number: 4620017-1Report Type:Expedited (15-DaCompany Report #DSA_25492_2004
Age:89 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Dermatitis Bullous	Foreign	Enalapril Maleate	PS		ORAL	5 MG BID PO
	Pemphigoid	Health Professional Other	Haloperidol	SS		ORAL	DF PO
	Therapy Non-Responder		Piribedil	SS		ORAL	100 MG Q DAY PO
			Omeprazole	SS			20 MG Q DAY
			Hctz/Triameterene	C			
			Acetaminophen-Caffeine	C			
			Alprazolam	C			
			Isosorbide Mononitrate	C			
			Nicergoline	C			
			Propoxyphene Hcl	C			

Date:03/25/05ISR Number: 4618987-0Report Type:Expedited (15-DaCompany Report #200414493FR
Age:50 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Epilepsy		Rifater	PS	Aventis Pharmaceuticals Inc.	ORAL	
	Neuroleptic Malignant Syndrome		Tercian	SS		ORAL	

Mepronizine	SS	ORAL

			Modecate	SS			
			Temesta	SS			ORAL
			Haldol	SS			ORAL

Date:03/25/05ISR Number: 4619490-4Report Type:Expedited (15-DaCompany Report #BR-JNJFOC-20050305258
Age:5 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dysphonia		Haldol	PS				
	Malaise		Promethazine	C				
	Somnolence		Lithium Carbonate	C				
"chronic use"								
	Tremor							
	Vomiting							

Date:03/25/05ISR Number: 4620791-4Report Type:Expedited (15-DaCompany Report #2005044379
Age:47 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardiac Arrest	Health	Geodon (Im)					
	Psychotic Disorder	Professional	(Ziprasidone)	PS			INTRAMUSCULAR	60 MG (20 MG,
		Company					3 IN 1 D),	
		Representative					INTRAMUSCULAR	
			Haloperidol (Haloperidol)	SS			10 MG	

Date:03/28/05ISR Number: 4623126-6Report Type:Direct Company Report #CTU 244465
Age:70 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Arrhythmia		Olanzapine 2.5 Eli					
Hospitalization -	Blood Creatine		Lilly	PS	Eli Lilly	ORAL	15 MG OVER 4	

Initial or Prolonged		Phosphokinase Increased					
HOURS ORAL							
		Blood Pressure Abnormal		Haloperidol 5 Mg/Ml			
		Dehydration		Amp Ortho-Mcneil	SS	Orth-Mcneil	
INTRAMUSCULAR	2 MG ONE TIME						
		Feeling Abnormal					
INTRAMUSCULAR							
		Fluid Intake Reduced		Pramipexole	C		
		Hyperhidrosis		Selegiline	C		
		Hyperpyrexia		Carbidopa/Levodopa	C		
		Lethargy		Glyburide	C		
		Leukocytosis		Lisinopril	C		
		Mental Status Changes		Diltiazem	C		
		Muscle Rigidity		Digoxin	C		
		Oral Intake Reduced		Gabapentin	C		
		Pain					
		Renal Failure Acute					
		Tachycardia					
		Tachypnoea					
		Urinary Incontinence					

Date:03/30/05ISR Number: 4622630-4Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20050306691
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Death		Haldol	PS				over 6 days
	Overdose		Olanzapine	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/30/05ISR Number: 4622634-1Report Type:Expedited (15-DaCompany Report #BE-JNJFOC-20050203212
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Benign Breast Neoplasm		Risperdal	PS		OROPHARINGEAL		
	Hyperprolactinaemia		Haldol	SS			10 drops for	
	Pain							+-1 year

Date:03/30/05ISR Number: 4623447-7Report Type:Expedited (15-DaCompany Report #2005042524
Age:21 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Neuroleptic Malignant Syndrome	Foreign	Lithium (Lithium)	PS		ORAL	900 MG, ORAL	
	Retroplacental Haematoma	Literature	Haloperidol					
	Unintended Pregnancy	Health Professional	(Haloperidol)	SS				

Date:03/30/05ISR Number: 4625707-2Report Type:Expedited (15-DaCompany Report #2005042143
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Congenital Anomaly	Anencephaly	Foreign	Lithium (Lithium)	PS				
	Congenital Spinal Cord Anomaly	Literature	Haloperidol					
	Drug Exposure During Pregnancy	Health Professional	(Haloperidol)	SS				
	Retroplacental Haematoma							

Date:03/31/05ISR Number: 4624025-6Report Type:Expedited (15-DaCompany Report #PHBS2005DE02352
Age:27 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Asthenia		Clozapine	PS	Novartis Sector:			

		Disturbance In Attention				Pharma	
UNKNOWN	250 mg/d						
		Fatigue		Lorazepam	SS		
UNKNOWN	1 mg/d						
		Increased Appetite		Haloperidol	SS		
		Libido Decreased		Zotepine	SS		
		Salivary Hypersecretion		Risperidone	SS		
UNKNOWN	6 mg/d						
		Weight Increased					

Date:04/01/05ISR Number: 4625453-5Report Type:Expedited (15-DaCompany Report #IL-BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.-2005-
DAge: 70GD Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Congenital Anomaly	Drug Exposure During Pregnancy		Theophylline	PS	Roxane Laboratories, Inc.			
INTRA-UTERINE								
	Noonan Syndrome		Lansoprazole	SS				
INTRA-UTERINE								
			Ketotifen	SS				
INTRA-UTERINE								
			Haloperidol	SS				
INTRA-UTERINE								
			Hydroxyzine	SS				
INTRA-UTERINE								

Date:04/01/05ISR Number: 4627639-2Report Type:Direct Company Report #CTU 245076
Age:56 YR Gender:Male I/FU:I

Outcome
Life-Threatening
Hospitalization -

Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Body Temperature Increased		Haloperidol 5 Mg	PS		INTRAVENOUS	5 MG	PRN
	Confusional State		Ziprasidone 20 Mg	SS		INTRAMUSCULAR	20 MG	X1
	Convulsion					DOSEIN		
	Therapeutic Product Ineffective					INTRAMUSCU		

Date:04/01/05ISR Number: 4628078-0Report Type:Expedited (15-DaCompany Report #2005-DE-01770GD
Age: Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Congenital Anomaly	Drug Exposure During Pregnancy	Foreign Literature	Lansoprazole (Lansoprazole)	PS		INTRA-UTERINE	IU	
	Noonan Syndrome		Theophylline	SS		INTRA-UTERINE	IU	
			Ketotifen (Ketotifen)	SS		INTRA-UTERINE	IU	
			Haloperidol (Haloperidol)	SS		INTRA-UTERINE	IU	
			Hydroxyzine (Hydroxyzine)	SS				

Date:04/04/05ISR Number: 4625986-1Report Type:Expedited (15-DaCompany Report #PL-JNJFOC-20050307083
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Suicide Attempt		Haldol	PS				

Date:04/04/05ISR Number: 4627957-8Report Type:Direct Company Report #CTU 245140
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Medication Error		Haloperidol Solution 2mg/Ml Pai -Pharmaceutical Assoc	PS	Pai -Pharmaceutical Assoc	ORAL	ORAL	

Date:04/05/05ISR Number: 4626960-1Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20041205632
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Accommodation Disorder		Haldol	PS				
	Difficulty In Walking		Haldol	SS			INTRAMUSCULAR	
	Extrapyramidal Disorder		Neurocil	C				
	Jaw Disorder							
	Photosensitivity Reaction							
	Schizophrenia, Paranoid Type							
	Tremor							
	Visual Disturbance							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/05/05ISR Number: 4626981-9Report Type:Expedited (15-DaCompany Report #PHBS2005BE04067
Age:47 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Abuser Medication Error		Lamisil	PS	Novartis Sector: Pharma		UNKNOWN	6 x 56 tablets = 336 tablets
			Sirdalud	SS			8 packages of 100 Sirdalud 4 mg tablets	92160MIN
			Sirdalud	SS			UNKNOWN	32 packages of 100 Sirdalud 4 mg tablets	106 DAY
			Methadone	SS			UNKNOWN	10 x 60 tablets = 600 tablets
			Serenase	SS			UNKNOWN	3 x 50 tablets = 150 tablets
			Temgesic	SS			UNKNOWN	50 DF, ONCE/SINGLE
			Ranitidine	SS			UNKNOWN	9 x 28 or 56

tablets

		Amoxycillin	SS	
UNKNOWN	500 mg,			
ONCE/SINGLE				
		Brufen	SS	
UNKNOWN	400 mg,			
ONCE/SINGLE				
		Ciproxine	SS	
UNKNOWN	3 x 20			

tablets = 60

tablets

Date:04/06/05ISR Number: 4628243-2Report Type:Expedited (15-DaCompany Report #BR-JNJFOC-20050306874
Age:24 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Hyperhidrosis		Haldol	PS				
OROPHARINGEAL							2 blisters	
Initial or Prolonged	Overdose							
	Somnolence							
	Suicide Attempt							
	Tremor							

Date:04/06/05ISR Number: 4628244-4Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20041205632
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Accommodation Disorder		Haldol	PS				
	Difficulty In Walking		Haldol	SS				
INTRAMUSCULAR								
	Extrapyramidal Disorder		Neurocil	C				
	Jaw Disorder							
	Photophobia							
	Photosensitivity Reaction							
	Schizophrenia, Paranoid							
	Type							
	Tremor							
	Trismus							
	Visual Disturbance							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/07/05ISR Number: 4631134-4Report Type:Direct Company Report #CTU 245535
Age:54 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product		Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Neuroleptic Malignant		Haloperidol	2mg	PS		INTRAMUSCULAR	2MG	X2 DOSES
Initial or Prolonged	Syndrome						INTRAMUSCU		
	Salivary Hypersecretion								
	Tachycardia								

Date:04/08/05ISR Number: 4630008-2Report Type:Expedited (15-DaCompany Report #MX-JNJFOC-20050400386
Age:15 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Brain Oedema		Haldol	PS		INTRAVENOUS		
	Hepatic Congestion							
	Medication Error							

Date:04/08/05ISR Number: 4630477-8Report Type:Expedited (15-DaCompany Report #FR-JNJFOC-20050307357
Age:74 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Constipation		Durogesic	PS		TRANSDERMAL		
Initial or Prolonged	Impaired Gastric Emptying		Haldol	SS		UNKNOWN	6 gte.	
			Di-Antalvic	SS		OROPHARINGEAL		
			Di-Antalvic	SS		OROPHARINGEAL		
			Debridat	SS		OROPHARINGEAL		
			Modane	C				
			Modane	C				
			Lanzor	C				

Date:04/08/05ISR Number: 4630638-8Report Type:Expedited (15-DaCompany Report #BR-JNJFOC-20050306899
Age:2 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Accidental Exposure		Haldol	PS		OROPHARINGEAL		
	Hypertonia							
	Somnolence							
	Tremor							

Date:04/08/05ISR Number: 4633216-XReport Type:Expedited (15-DaCompany Report #DSA_26208_2005
Age:77 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Somnolence	Foreign	Mono-Tildiem	PS		ORAL	200 MG Q DAY	PO
	Suicide Attempt	Health Professional	Equanil	SS		ORAL	800 MG ONCE	PO
		Other	Haldol Faible	SS		ORAL	DF	PO

Date:04/11/05ISR Number: 4632354-5Report Type:Expedited (15-DaCompany Report #JP-SOLVAY-00305000085
Age:24726 DYGender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Neuroleptic Malignant Syndrome		Depromel 25	PS		ORAL	Daily dose: 75 milligram(s)	21 DAY
Disability			Serenace	SS		ORAL	Daily dose:	

2.25
milligram(s) 21 DAY
INTRAMUSCULAR Daily dose: 1
millilitre(s) 1 DAY

Serenace SS

INTRAMUSCULAR Daily dose: 1
millilitre(s) 1 DAY

Serenace SS

Daily dose:
150
milligram(s) 6 DAY

Tofranil C ORAL

Daily dose:
1.5
milligram(s) 21 DAY

Depas C ORAL

Daily dose: 3
milligram(s) 14 DAY

Tasmolin C ORAL

Daily dose: 6
milligram(s) 7 DAY

Tasmolin C ORAL

Daily dose:
75
milligram(s) 16 DAY

Anafranil C ORAL

UNKNOWN Daily dose:
50
milligram(s) 15 DAY

Anafranil C

Daily dose:
25

Ludiomil C ORAL

milligram(s)	16	DAY	Tetramide	C	ORAL
Daily dose: 30					
milligram(s)	6	DAY	Benzalin	C	ORAL
Daily dose: 5					
milligram(s)	14	DAY	Benzalin	C	ORAL
Daily dose: 10					
milligram(s)	7	DAY	Vegetamin-B	C	ORAL
Daily dose: 1					
dosage form	5	DAY	Vegetamin-B	C	ORAL
Daily dose: 2					
dosage form	3	DAY	Vegetamin-A	C	ORAL
Daily dose: 1					
dosage form	4	DAY	Kolantyl	C	ORAL
Daily dose: 9					
milligram(s)	10	DAY	Elieten	C	ORAL
Daily dose: 4.5					
milligram(s)	10	DAY	Alosenn	C	ORAL
Daily dose: 1					
gram(s)	10	DAY	Heavy Magnesium Oxide	C	ORAL
Daily dose: 1					
gram(s)	2	DAY	Pursennid	C	ORAL
Daily dose: 3					
dosage form	7	DAY			

Kefral	C	ORAL
Indacin	C	
Serenace	C	
Serenace	C	
Akineton	C	

Daily dose:

750

milligram(s) 4 DAY

RECTAL Daily dose:

25

milligram(s) 1 DAY

INTRAMUSCULAR Daily dose: 1

millilitre(s) 1 DAY

INTRAMUSCULAR Daily dose: 1

millilitre(s) 1 DAY

INTRAMUSCULAR Daily dose: 1

millilitre(s) 1 DAY

Akineton C

INTRAMUSCULAR Daily dose: 1

millilitre(s) 1 DAY

Dormicum C

INTRAMUSCULAR Daily dose:

10

milligram(s) 1 DAY

Urokinase C

UNKNOWN Daily dose:

500

millilitre(s) 15 DAY

Soldem 3 A C

UNKNOWN Daily dose:

500

millilitre(s) 15 DAY

Date:04/11/05ISR Number: 4632423-XReport Type:Expedited (15-DaCompany Report #PHNU2005DE01035
Age:56 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Neurodermatitis Oedema		Elidel	PS	Novartis Sector: Pharma			
TOPICAL							UNK, UNK	2880 MIN
	Vasculitis		Beloc Mite	SS		ORAL	1 DF, QD	
			Haldol	SS		ORAL	10 mg, BID	

Date:04/12/05ISR Number: 4632917-7Report Type:Expedited (15-DaCompany Report #BR-JNJFOC-20050306899
Age:2 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Hospitalization - Initial or Prolonged	Accidental Exposure Hypertonia Somnolence Tremor		Haldol	PS			OROPHARINGEAL 3 or 4 tablets

Date:04/13/05ISR Number: 4634148-3Report Type:Expedited (15-DaCompany Report #JP-JNJFOC-20041106817
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Cardio-Respiratory Arrest Deep Vein Thrombosis		Haloperidol Decanoate	PS		INTRAMUSCULAR		
	Dehydration		Haloperidol	SS		INTRAMUSCULAR		
	Disseminated		Haloperidol	SS		OROPHARINGEAL		
	Intravascular Coagulation		Haloperidol	SS		OROPHARINGEAL		
	Electrolyte Imbalance		Biperiden Lactate	SS		INTRAMUSCULAR		
	Neuroleptic Malignant Syndrome		Levomepromazine Hydrochloride	SS		INTRAMUSCULAR		
	Pneumonia Pulmonary Infarction		Promethazine Hydrochloride	SS		INTRAMUSCULAR		
			Biperiden Hydrochloride	C		OROPHARINGEAL		
			Carbamazepine	C		OROPHARINGEAL		
			Flunitrazepam	C		OROPHARINGEAL		
			Nitrazepam	C		OROPHARINGEAL		
			Brotizolam	C		OROPHARINGEAL		
			Triazolam	C		OROPHARINGEAL		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/13/05ISR Number: 4636190-5Report Type:Direct Company Report #CTU 246106
Age:41 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Blood Creatine		Gemfibrozil	PS		ORAL	600 MG PO BID	
Hospitalization - Initial or Prolonged	Phosphokinase Increased		Haloperidol	SS		ORAL	10 MG PO BID	
	Dizziness		Olanzapine	C				
	Hypotension		Benztropine	C				
	Renal Failure Acute		Modafinil	C				
			Atenolol	C				
			Enalapril	C				
			Hydrochlorothiazide	C				
			Amlodipine	C				

Date:04/14/05ISR Number: 4634938-7Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20050400706
Age:35 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Electrocardiogram Qt		Haldol	PS			OROPHARINGEAL	
	Corrected Interval		Risperdal	SS			OROPHARINGEAL	
	Prolonged		Eunerpan	SS			OROPHARINGEAL	
			Diazepam	SS			OROPHARINGEAL	

Date:04/14/05ISR Number: 4634939-9Report Type:Expedited (15-DaCompany Report #BR-JNJFOC-20050306874
Age:24 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hyperhidrosis		Haldol	PS		OROPHARINGEAL	2 blisters	
	Overdose							
	Somnolence							
	Suicide Attempt							
	Tremor							

Date:04/14/05ISR Number: 4635187-9Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20050401260
Age:57 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Head Injury		Haldol Decanoate	PS		INTRAMUSCULAR		
Initial or Prolonged	Hyponatraemia		Olanzapine	C				

Date:04/14/05ISR Number: 4635684-6Report Type:Expedited (15-DaCompany Report #HQWYE646304APR05
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Homicidal Ideation	Foreign	Efexor (Venlafaxine					
	Suicidal Ideation	Health	Hydrochloride,					
		Professional	Tablet)	PS		ORAL	ORAL	
		Other	Fluoxetine					
			(Fluoxetine,)	SS		ORAL	ORAL	
			Haloperidol					
			(Haloperidol,)	SS		ORAL	ORAL	
			Haloperidol					
			(Haloperidol,)	SS		ORAL	ORAL	
			Quetiapine					
			(Quetiapine,)	SS		ORAL	ORAL	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/15/05ISR Number: 4635992-9Report Type:Expedited (15-DaCompany Report #200512767GDDC
Age:77 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agitation		Amarel	PS	Aventis Pharmaceuticals Inc.	ORAL		
	Drug Toxicity		Mono-Tildiem	SS		ORAL		
	Haematemesis		Equanil	SS		ORAL		
	Hyperglycaemia		Haldol Faible Solution Buvable A 0.5 Mg/Ml	SS		ORAL		
	Intentional Misuse		Metformin	SS				
	Somnolence		Mono-Tildiem	C		ORAL	dose: UNK	
	Suicide Attempt		Imovane	C		ORAL	Dose unit: units	
			Lodales	C		ORAL		
			Fluoxetine	C		ORAL		
			Mianserin	C		ORAL	dose: UNK	

Date:04/16/05ISR Number: 4637191-3Report Type:Expedited (15-DaCompany Report #PHNU2005DE01035
Age:56 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Hypersensitivity		Elidel	PS	Novartis Sector: Pharma			
	Inflammation							
	Neurodermatitis		Beloc Mite	SS		ORAL	TOPICAL	UNK, UNK 2880 MIN
	Oedema		Haldol	SS		ORAL	1 DF, QD	
	Oedema Peripheral						10 mg, BID	
	Vasculitis							

Date:04/18/05ISR Number: 4638753-XReport Type:Direct Company Report #CTU 246437
Age:84 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product		Role	Manufacturer	Route	Dose	Duration
Death	Balance Disorder		Haldol	Injectable	PS			3MG	EVERY
	Coma							8 HOURS	
	Condition Aggravated								
	Confusional State								
	Dysphagia								
	Facial Palsy								
	Lethargy								
	Mental Impairment								
	Oral Intake Reduced								
	Pneumonia								
	Speech Disorder								
	Swollen Tongue								
	Tongue Disorder								
	Tongue Ulceration								

Date:04/19/05ISR Number: 4638883-2Report Type:Expedited (15-DaCompany Report #PL-JNJFOC-20050401008
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardiac Arrest		Haldol	PS			1-4 mg/day	
	Depressed Level Of Consciousness		Wide-Spectrum Antibiotics	C				
	Loss Of Consciousness		Catecholamines	C				
			Parentheral Nutrition	C				

			H2-Blockers	C		

Date:04/19/05ISR Number: 4641224-8Report Type:Direct Company Report #CTU 246587
Age:79 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Aggression		Risperdal 2 Mg	PS			1//2 TAB AT	
Hospitalization -	Agitation						BEDTIME AND	
Initial or Prolonged	Bacteriuria						AS NEEDED	
	Blood Creatine		Haloperidol 2 Mg	SS			2 MG THREEE	
	Phosphokinase Increased						TIMES A DAY	
	Body Temperature		Aspirin	C				
	Increased		Atenolol	C				
	Hypotension		Docusate	C				
	Leukocytosis		Galantamine	C				
	Muscle Rigidity		Lisinopril	C				
	Neuroleptic Malignant		Mvi	C				
	Syndrome		Valproate	C				
	Pain							
	Sepsis							
	Shift To The Left							
	Somnolence							

Date:04/20/05ISR Number: 4642094-4Report Type:Direct Company Report #CTU 246733
Age:20 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Agitation		Haloperidol					
Initial or Prolonged	Neuroleptic Malignant		Decanoate	PS			INTRAMUSCULAR	75 MG IM X 1
	Syndrome						1 WEEK	
	Tachypnoea						PRIOR TO	
							ADMISSION	

			Risperdal	SS		ORAL

4MG BID PO

1 WEEK PRIOR

TO ADMISSION

Date:04/21/05ISR Number: 4641546-0Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20050402678
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Overdose		Haldol	PS				
	Suicide Attempt		Clozapine	C				
							33	MON

Date:04/21/05ISR Number: 4642133-0Report Type:Direct Company Report #CTU 246819
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Opisthotonus		Haldol	PS				
							Q 12 H	
			Seroquel	C				
			Ativan	C				
			Benadryl	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/22/05ISR Number: 4646743-6Report Type:Direct Company Report #CTU 246850
Age:52 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Athetosis		Haldol	PS				

Date:04/25/05ISR Number: 4643607-9Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20050102369
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Circulatory Collapse		Haldol	PS		OROPHARINGEAL		
	Loss Of Consciousness		Dipiperon	SS		OROPHARINGEAL		
	Panic Disorder		Tavor	SS		OROPHARINGEAL		
			Neurocil	SS		OROPHARINGEAL		
			Neurocil	SS		OROPHARINGEAL		

Date:04/25/05ISR Number: 4643608-0Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20050206211
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Convulsion		Haldol	PS				
Hospitalization - Initial or Prolonged	Lymphoma		Haldol	SS				
	Medication Error		Ativan	C				as needed
	Transfusion Reaction		Ativan	C				drug taken for many years
			Hydrocodone	C				
			Atenalol	C				
			Digoxin	C				
			Prinivel	C				

			Zocor	C		
on it for several years						
			Asa	C		
on several years						
			Terazol	C		
			Norvasc	C		

Date:04/26/05ISR Number: 4645126-2Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20050405095
Age:47 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Interaction		Sublimaze	PS				
	Hypertension		Haloperidol	I				
			Zyvox	I				
			Doxazosin	I				
			Procyclidine	I				
			Atenolol	I				
			Rifampicin	I				
			Amisulpride	I				
			Omeprazole	I				
			Pantoprazole	I				
			Zopiclone	I				

INTRAVENOUS
UNKNOWN
INTRAVENOUS
OROPHARINGEAL
OROPHARINGEAL
OROPHARINGEAL
INTRAVENOUS
OROPHARINGEAL
UNKNOWN
UNKNOWN
UNKNOWN

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/26/05ISR Number: 4645127-4Report Type:Expedited (15-DaCompany Report #IE-JNJFOC-20050403379
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hypoaesthesia		Haldol Decanoate	PS		INTRAMUSCULAR		
	Musculoskeletal Stiffness		Risperdal	C				
			Risperdal	C				
			Serenace	C				
			Valium	C				
			Dalmane	C				
			Cogentin	C				

Date:04/26/05ISR Number: 4645128-6Report Type:Expedited (15-DaCompany Report #CH-JNJFOC-20050405572
Age:92 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Fall		Haldol	PS		OROPHARINGEAL	Strength 10 mg/ml	
	Intentional Misuse		Lexotanil	SS		OROPHARINGEAL	Dose: 1.5 DF dosage form	
			Seresta	SS		OROPHARINGEAL	1 DF dosage form as necessary	

Date:04/26/05ISR Number: 4645205-XReport Type:Expedited (15-DaCompany Report #05-03-0532
Age:14 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Aggression		Lithium	PS	Glaxosmithkline	UNKNOWN		
	Blood Creatine		Haldol	SS		UNKNOWN		

Other	Phosphokinase Increased Body Temperature Increased Confusional State Drooling Drug Interaction Dyspnoea Neuroleptic Malignant Syndrome		Clozapine	SS		ORAL

Date:04/26/05ISR Number: 4648059-0Report Type:Expedited (15-DaCompany Report #17976
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
	Circumstance Or Information Capable Of Leading To Medication Error	Health Professional User Facility Company Representative	Haloperidol Latate Inj. Usp 5mg/1ml Ben Venue Labs Inc.	PS		
			Prochioperazine 10mg/2ml	SS		

Date:04/27/05ISR Number: 4646650-9Report Type:Expedited (15-DaCompany Report #PHRM2005FR01362
Age:45 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Macular Degeneration		Tegretol Lp	PS	Novartis Sector: Pharma	ORAL
400 mg, QD						
			Haldol	SS		ORAL

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/29/05ISR Number: 4649046-9Report Type:Expedited (15-DaCompany Report #AU-JNJFOC-20050203774
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Antiphospholipid		Haldol	PS		OTHER	15-200 mg	
	Antibodies Positive							
	Galactorrhoea							

Date:04/29/05ISR Number: 4649051-2Report Type:Expedited (15-DaCompany Report #JP-JNJFOC-20050205999
Age:54 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Bradycardia		Risperdal	PS				
OROPHARINGEAL								
Hospitalization -	Medication Error		Haloperidol	SS				
INTRAVENOUS								
Initial or Prolonged	Sinus Arrest		Midazolam	C				
INTRAVENOUS								

Date:05/02/05ISR Number: 4649637-5Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20040903580
Age:46 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Blood Disorder		Cyclobenzaprine	PS				
OROPHARINGEAL								
Hospitalization -	Completed Suicide		Ibuprofen	SS				
OROPHARINGEAL								
Initial or Prolonged	Electrocardiogram Qrs		Chlorzoxazone	SS				
OROPHARINGEAL								
Other	Complex Shortened		Methylphenidate	SS				
OROPHARINGEAL								
	Heart Rate Increased		Haloperidol	SS				
OROPHARINGEAL								
	Intentional Misuse		Diphenhydramine	SS				
OROPHARINGEAL								
	Respiratory Arrest		Cephalexin	SS				
OROPHARINGEAL								
	Stupor		Naproxen	SS				
OROPHARINGEAL								

			Ethanol	SS		
OROPHARINGEAL						

Date:05/02/05ISR Number: 4649916-1Report Type:Expedited (15-DaCompany Report #GXKR2005GB00959
Age:47 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Blood Pressure Systolic Increased		Rifampicin (Ngx)	PS	Novartis Sector: Generics	
INTRAVENOUS						
	Drug Interaction		Doxazosin (Ngx)	SS		ORAL
	Hypertension		Zyvox	SS		
INTRAVENOUS 600 mg, BID 5760 MIN						
			Fentanyl	SS		
INTRAVENOUS						
			Omeprazol (Ngx)	SS		
UNKNOWN						
			Zopiclone	SS		
UNKNOWN						
			Haloperidol	SS		
UNKNOWN						
			Pantoprazole	SS		
UNKNOWN						
			Amisulpride	SS		ORAL
			Procyclidine	SS		ORAL
			Atenolol (Ngx)	SS		ORAL

Date:05/02/05ISR Number: 4652515-9Report Type:Expedited (15-DaCompany Report #DSA_26208_2005
Age:77 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Agitation	Foreign	Mono-Tildiem	PS		ORAL
200 MG ONCE						
Initial or Prolonged	Haematemesis	Health				
PO						
	Hyperglycaemia	Professional	Equanil	SS		ORAL
800 MG ONCE						
	Intentional Misuse	Other				
PO						
	Multiple Drug Overdose		Haldol Faible	SS		ORAL
6 DROPPEFUL						
	Somnolence					
ONCE PO						
	Suicide Attempt		Alcohol	SS		ORAL
DF ONCE PO						

				Mono-Tildiem	SS		ORAL
DF PO							
				Amarel	SS		
OPHTHALMIC	4 MG PO						
				Metformin	SS		
DF							
				Lodales	SS		ORAL
20 MG PO							
				Fluoxetine	SS		ORAL
20 MG PO							
				Mianserin	SS		ORAL
DF PO							
				Imovane	C		

Date:05/02/05ISR Number: 4652868-1Report Type:Expedited (15-DaCompany Report #2005PK00665
Age:35 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Condition Aggravated	Foreign	Seroquel	PS		ORAL	950 MG DAILY, PO	
	Drug Interaction	Health						
	Hallucination	Professional	Lasix /Swe/	SS				
	Hallucination, Auditory	Other	Haloperidol	SS			1.3 ML DAILY	
	Metabolic Syndrome							
	Oedema Peripheral							
	Psychotic Disorder							
	Schizophrenia							
	Weight Increased							

Date:05/04/05ISR Number: 4652591-3Report Type:Expedited (15-DaCompany Report #JP-JNJFOC-20050406902
Age:78 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Torsade De Pointes		Risperidone	PS				
OROPHARINGEAL							9	DAY
			Haloperidol	SS				

Date:05/04/05ISR Number: 4653574-XReport Type:Expedited (15-DaCompany Report #GXKR2005GB00959
Age:47 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Interaction	Foreign	Zyvox (Linezolid)	PS		INTRAVENOUS	600 MG, BID,	
	Hypertension	Health				INTRAVENOUS		
		Professional	Doxazosin (Ngx)					
		Other	(Doxazosin)	SS		ORAL		
			Atenolol (Ngx)					
			(Atenolol)	SS		ORAL		
			Rifampicin (Ngx)					
			(Rifampicin)	SS		ORAL		
			Omeprazol (Ngx)					
			(Omeprazole)	SS				
			Procyclindine					
			(Procyclidine)	SS		ORAL		
			Fentanyl (Fentanyl)	SS		INTRAVENOUS	INTRAVENOUS	
			Amisulpride					
			(Amisulpride)	SS		ORAL		
			Pantoprazole					
			(Pantoprazole)	SS				
			Zopiclone					
			(Zopiclone)	SS				
			Haloperidol					
			(Haloperidol)	SS				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/05/05ISR Number: 4654814-3Report Type:Direct Company Report #CTU 247880
Age:85 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Activities Of Daily Living Impaired		Haloperidol 5mg/1ml App	PS	App	INTRAMUSCULAR	HALOPERIDOL 2MG	Disability
	Social Avoidant Behaviour							
	Tremor							

Date:05/06/05ISR Number: 4654535-7Report Type:Expedited (15-DaCompany Report #BR-JNJFOC-20050500047
Age:15 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Gaze Palsy		Haldol	PS		OROPHARINGEAL		
	Intentional Misuse		Biperiden	SS		OROPHARINGEAL		
	Somnolence							
	Suicide Attempt							
	Torticollis							

Date:05/06/05ISR Number: 4654536-9Report Type:Expedited (15-DaCompany Report #BR-JNJFOC-20050500068
Age:2 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Accidental Drug Intake By		Haldol	PS		OROPHARINGEAL		
	Child							
	Disorientation							
	Tachycardia							
	Tremor							

Date:05/09/05ISR Number: 4658732-6Report Type:Expedited (15-DaCompany Report #2005-01525
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Confusional State Convulsion Pharmaceutical Product Complaint	Health Professional Other	Metoprolol (Watson Laboratories) (Metoprolol Tartrate) Tablet	PS	Watson Laboratories	
			Ativan (Lorazepam)	SS		
			Haldol "Mcneil" (Haloperidol)	SS	Mcneil	

Date:05/09/05ISR Number: 4658748-XReport Type:Expedited (15-DaCompany Report #2005-01466
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Confusional State Convulsion	Health Professional Other	Metoprolol (Watson Laboratories) (Metoprolol Tartrate)Tablet	PS	Watson Laboratories	
			Ativan (Lorazepam)	SS		
			Haladol "Mcneil" (Haloperidol)	SS	Mcneil	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/09/05ISR Number: 4658751-XReport Type:Expedited (15-DaCompany Report #2005-01465
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Confusional State Convulsion Neurological Symptom	Health Professional Other	Metoprolol (Watson Laboratories) (Metoprolol Tartrate)Tablet	PS	Watson Laboratories			
			Ativan (Lorazepam)	SS				
			Haldol "Mcneil" (Haloperidol)	SS	Mcneil			

Date:05/10/05ISR Number: 4657893-2Report Type:Expedited (15-DaCompany Report #PHNU2005DE01755
Age:39 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Condition Aggravated Hypertriglyceridaemia		Leponex / Clozaril (Clozapine)	PS	Novartis Sector: Pharma	ORAL	175 mg, QD	10080MIN
			Leponex / Clozaril (Clozapine)	SS	Novartis Sector: Pharma	ORAL	125 mg, QD	
			Haldol	SS		ORAL	10 mg, QD	

Date:05/10/05ISR Number: 4659384-1Report Type:Expedited (15-DaCompany Report #2005AL001668
Age:92 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Accidental Overdose Blood Pressure Increased	Foreign Other	Serax (Oxazepam)	PS		ORAL	PO	
	Fall Heart Rate Increased Medication Error		Haloperidol Lexotanil	SS SS				

Date:05/11/05ISR Number: 4658530-3Report Type:Expedited (15-DaCompany Report #CH-JNJFOC-20050500111
Age: Gender:Male I/FU:I

Outcome	PT
Death	Abdominal Pain
	Abdominal Pain Lower
	Abdominal Rigidity
	Aggression
	Cardiac Failure
	Cerebral Atrophy
	Coagulation Time
	Prolonged
	Dementia
	Disorientation
	Dyspnoea
	Fall
	Gait Disturbance
	Haematoma
	Hyperphagia
	Insomnia
	International Normalised
	Ratio Increased
	Pain
	Polydipsia
	Urinary Incontinence

	Vomiting					
		Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
			Haldol	PS		
OROPHARINGEAL	5 - 9 mg					
			Depakine	SS		
OROPHARINGEAL	150 - 2000 mg					
			Akineton Retard	SS		
OROPHARINGEAL						
			Dilatrend	C		
OROPHARINGEAL						
			Aldactone	C		
OROPHARINGEAL						
			Torem	C		
OROPHARINGEAL	40 - 70 mg					
			Sortis	C		
OROPHARINGEAL						
			Conversum	C		
OROPHARINGEAL	4 - 8 mg					
			Marcumar	C		
OROPHARINGEAL	1.5 - 3 mg					
			Nitroderm	C		

Date:05/11/05ISR Number: 4658531-5Report Type:Expedited (15-DaCompany Report #PL-JNJFOC-20041202114
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Death	Cardiac Arrest		Haloperidol	PS		
1-4 mg/day						
	Cholelithiasis		Wide-Spectrum			
	Drug Ineffective		Antibiotics	C		
	Loss Of Consciousness		Catecholamines	C		
	Pancreatitis		Parentheral			
			Nutrition	C		
			H2-Blockers	C		

Date:05/11/05ISR Number: 4658920-9Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20050501358
Age:60 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					

Hospitalization - Initial or Prolonged	Ileus	Haldol	PS
OROPHARINGEAL			
OROPHARINGEAL		Tegretol	SS
OROPHARINGEAL		Seropram	C
OROPHARINGEAL		Clonazepam	C
OROPHARINGEAL		Liticarb	C

Date:05/11/05ISR Number: 4659006-XReport Type:Expedited (15-DaCompany Report #05-03-0532
Age:14 YR Gender:Male I/FU:F

Outcome	PT
Life-Threatening	Aggression
Hospitalization - Initial or Prolonged	Blood Creatine Phosphokinase Increased
Other	Body Temperature Increased
	Confusional State
	Developmental Coordination Disorder
	Difficulty In Walking
	Drooling
	Drug Interaction
	Dysphagia
	Dyspnoea
	Eating Disorder
	Hyperventilation
	Lethargy
	Neuroleptic Malignant Syndrome

Somnolence Unresponsive To Verbal Stimuli Urinary Incontinence White Blood Cell Count Increased	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
		Lithium Sr	PS	Glaxosmithkline	ORAL	300MG Three times per day	7 DAY
		Lithium Citrate	SS		ORAL	300MG per day	118 DAY
		Haloperidol	SS			INTRAMUSCULAR	10MG Weekly
		Clozapine	SS		ORAL	12 DAY	
		Benztropine	C		ORAL	2MG Twice per day	
		Ddavp	C		ORAL	.2MG At night	
		Guanfacine	C		ORAL	1MG Three times per day	
		Synthroid	C	Glaxosmithkline	ORAL	50MCG In the morning	
		Valproic Acid	C		ORAL	500MG Three times per day	
		Docusate Sodium	C		ORAL	100MG Twice per day	
		Diphenhydramine	C			INTRAMUSCULAR	
		Lorazepam	C			INTRAMUSCULAR	2MG Weekly
		Trileptal	C		ORAL	300MG Three times per day	21 DAY
		Risperdal	C				
		Bromocriptine	C			2.5MG Three	

times per day

Date:05/12/05ISR Number: 4660482-7Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20050500027
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Congenital Anomaly	Congenital Anomaly		Haloperidol	PS				taken during
Other	Drug Exposure During Pregnancy							third trimester of
	Gastroschisis							pregnancy
			Risperidone	SS		TRANSPLACENTAL		taken during third trimester of pregnancy

Date:05/12/05ISR Number: 4660483-9Report Type:Expedited (15-DaCompany Report #IT-JNJFOC-20050501691
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dysarthria		Haldol Decanoate	PS		INTRAMUSCULAR	Dose: 2 vials/month	
	Dysphagia							
	Dysphonia							Duration: >10 yrs
	Tardive Dyskinesia							

Date:05/12/05ISR Number: 4661805-5Report Type:Direct Company Report #CTU 248364
Age:27 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Dyspnoea		Haloperidol	PS				
Required	Dystonia							
Intervention to	Swollen Tongue							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/13/05ISR Number: 4661164-8Report Type:Expedited (15-DaCompany Report #JP-JNJFOC-20050502615
Age:43 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Convulsion		Risperdal	PS		OROPHARINGEAL		
	Disseminated		Impromen	SS		OROPHARINGEAL		
	Intravascular Coagulation		Haldol	SS		OROPHARINGEAL		
	Polydipsia		Chloropromazine	SS		OROPHARINGEAL		
	Systemic Inflammatory Response Syndrome		Levopromazine	C		OROPHARINGEAL		
	Water Intoxication		Biperiden Hydrochloride	C		OROPHARINGEAL		
			Promethazine Hydrochloride	C		OROPHARINGEAL		
			Etizolam	C				
			Cloxazolam	C				
			Haloxazolam	C				
			Flunitrazepam	C				

Date:05/13/05ISR Number: 4661547-6Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20041100035
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Arthritis		Haldol Decanoate	PS		150 - 300 mg		
	Diabetes Mellitus		Haldol Decanoate	SS				
	Hair Growth Abnormal							
	Hypertension							
	Oedema Peripheral							
	Vision Blurred							

Date:05/16/05ISR Number: 4662727-6Report Type:Expedited (15-DaCompany Report #IN-GLAXOSMITHKLINE-B0379827A
Age:31 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Abdominal Pain		Chlorpromazine	PS	Glaxosmithkline			
UNKNOWN							200MG per day	
	Abdominal Tenderness		Haloperidol	SS				
UNKNOWN							10MG per day	
	Blood Amylase Increased		Sodium Valproate	SS				
UNKNOWN							600MG per day	
	Blood Cholesterol Increased							
	Blood Glucose Increased							
	Blood Ketone Body							
	Blood Triglycerides							
	Blood Triglycerides Increased							
	Dehydration							
	Diabetic Ketoacidosis							
	Drug Interaction							
	Dyspnoea							
	Glucose Urine Present							
	High Density Lipoprotein Decreased							
	Low Density Lipoprotein Increased							
	Pancreatitis Acute							
	Tachycardia							
	Tachypnoea							
	Urine Ketone Body Present							
	Vomiting							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/16/05ISR Number: 4662736-7Report Type:Expedited (15-DaCompany Report #CH-GLAXOSMITHKLINE-B0380569A
Age:75 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agitation		Deroxat	PS	Glaxosmithkline	ORAL	20MG Per day	7 DAY
	Blood Pressure Increased		Tramal	SS		ORAL	50MG Four times per day	3 DAY
	Glasgow Coma Scale Abnormal		Haldol	SS		INTRAMUSCULAR	2.5MG Per day	1 DAY
	Hepatic Enzyme Increased		Fraxiparine	C	Glaxosmithkline	SUBCUTANEOUS	.4ML Per day	7 DAY
	Neuroleptic Malignant Syndrome		Clamoxyl	C	Glaxosmithkline	ORAL	750MG Three times per day	5 DAY
	Oxygen Saturation Decreased							
	Pyrexia							
	Serotonin Syndrome							

Date:05/17/05ISR Number: 4663482-6Report Type:Expedited (15-DaCompany Report #BR-JNJFOC-20050502265
Age:3 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Accidental Exposure		Haldol	PS				
	Somnolence							

Date:05/17/05ISR Number: 4664841-8Report Type:Expedited (15-DaCompany Report #HQWYE554305MAY05
Age:47 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blood Pressure Systolic Increased	Health Professional	Protium (Pantoprazole, Unspec)	PS				
	Drug Interaction	Other	Amisulpride (Amisulpride,)	SS		ORAL	"SOME TIME	

(S) SOME DF"

ORAL

"SOME TIME(S)

SOME DF" ORAL

"SOME TIME(S)

SOME DF" ORAL

INTRAVENOUS "SOME TIME(S)

SOME DF"

INTRAVENOUS

"SOME TIME(S)

SOME DF" ORAL

INTRAVENOUS "SOME TIME(S)

SOME DF"

INTRAVENOUS

INTRAVENOUS 600 MG 2X PER

1 DAY

INTRAVENOUS

Atenolol (Atenolol)	SS	ORAL
Doxazosin (Doxazosin,)	SS	ORAL
Fentanyl (Fentanyl,)	SS	
Haloperidol (Haloperidol,)	SS	
Omeprazole (Omeprazole,)	SS	
Procyclidine (Procyclidine,)	SS	ORAL
Rifampicin (Rifampicin,)	SS	
Zopiclone (Zopiclone,)	SS	
Zyvox (Linezolid,)	SS	

Date:05/17/05ISR Number: 4665141-2Report Type:Expedited (15-DaCompany Report #2005070397
Age:47 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blood Pressure Systolic Increased	Foreign Health Professional	Zyvox Solution, Sterile (Linezolid)	PS		INTRAVENOUS	600 MG (2 IN 1 D), INTRAVENOUS	
			Pantoprazole Sodium (Pantoprazole Sodium)	SS				
			Doxazosin (Doxazosin)	SS		ORAL		
			Atenolol (Atenolol)	SS		ORAL		
			Zopiclone (Zopiclone)	SS				
			Haloperidol (Haloperidol)	SS				
			Procyclidine (Procyclidine)	C				
			Rifampicin (Rifampicin)	C				
			Fentanyl (Fentanyl)	C				
			Amisulpride (Amisulpride)	C				
			Omeprazole (Omeprazole)	C				

Date:05/17/05ISR Number: 4665298-3Report Type:Expedited (15-DaCompany Report #2004106748
Age:29 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Abnormal Behaviour Agitation Condition Aggravated Delusion	Consumer	Neurontin (Tablets) (Gabapentin) Haldol (Haloperidol)	PS SS			600 MG (300 MG, 2 IN 1 D)	

	Depression		Risperidone	
	Drug Ineffective		(Risperidone)	SS
6 MG (3 MG, 2				
	Homicidal Ideation			
IN 1 D)				
	Intentional Misuse		Metformin	
	Multiple Drug Overdose		(Metformin)	C
	Psychotic Disorder			
	Suicide Attempt			
	Treatment Noncompliance			

Date:05/17/05ISR Number: 4665998-5Report Type:Direct Company Report #CTU 248894
Age:44 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Dystonia		Haloperidol 2 Mg	PS		
INTRAMUSCULAR 2 MG ONCE IM						
Initial or Prolonged			Ptu	C		
			Methyldopa	C		
			Prenatal Vitamins	C		
			Tac	C		
			Propanolol	C		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/17/05ISR Number: 4666187-0Report Type:Direct Company Report #CTU 248744
Age:30 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Acinetobacter Infection		Haldol 10 Mg Po Tid	PS		ORAL	10 MG PO TID	
	Apallic Syndrome		Prolixin 5 Mg Po Bid And 10 Mg Im Bid	SS		ORAL	5 MG PO BID AND 10 MG IM	
	Atelectasis							
	Atrioventricular Block							
	Bradycardia		Cogentin	C				
	Bronchial Obstruction		Depakote	C				
	Cardiac Arrest							
	Deep Vein Thrombosis							
	Dialysis							
	Disseminated Intravascular Coagulation							
	Encephalitis							
	Hypotension							
	Ischaemic Hepatitis							
	Multi-Organ Disorder							
	Neuroleptic Malignant Syndrome							
	Oxygen Saturation Decreased							
	Renal Failure Acute							
	Renal Tubular Necrosis							
	Septic Shock							
	Shock							
	Urosepsis							

Date:05/18/05ISR Number: 4664805-4Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20050501023
Age:25 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Aggression		Haldol Decanoat	PS		INTRAMUSCULAR		
	Oculogyration		Pipamperon	SS		OROPHARINGEAL		
Other			Pipamperon	SS		OROPHARINGEAL		

OROPHARINGEAL	As needed	Haldol	SS
OROPHARINGEAL		Haldol	SS
OROPHARINGEAL		Clozapin	C
OROPHARINGEAL	As needed	Tavor Expidet	C
OROPHARINGEAL		Diazep	C
OROPHARINGEAL		Novalgin	C
OROPHARINGEAL	As needed	Novalgin	C
OROPHARINGEAL		Gastrozepin	C
OROPHARINGEAL		Lactulose Ratiopharm	C
As needed		Dulcolax	C
OROPHARINGEAL		Boro-Scopol N	C
OROPHARINGEAL		Biperiden-Neuraxpham 4	C
1 drop four		Floxal At	C
times a day		Floxal At	C
Batrafen Gel		Batrafen	C
applied twice			
a day			
12 drops per		Corneregel	C
day			
As needed		Maaloxan	C
		Maaloxan	C
1 drop 3		Floxal-As	C
		Floxal-As	C

times a day

Date:05/18/05ISR Number: 4664924-2Report Type:Expedited (15-DaCompany Report #2005AP01639
Age:22679 DYGender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Electrocardiogram Qt Prolonged		Propofol	PS	Zeneca Pharmaceutical			
						INTRAVENOUS		2 DAY
	Torsade De Pointes		Midazolam	SS				
						INTRAVENOUS		11 DAY
	Ventricular Tachycardia		Digoxin	SS				
						INTRAVENOUS		8 DAY
			Haloperidol	SS				
						INTRAVENOUS		5 DAY
			Losec	C				
			Canesten	C				
			Clonidine	C				
			Panadol	C				
			Nilstat	C				
			Imipenem	C				

Date:05/18/05ISR Number: 4664926-6Report Type:Expedited (15-DaCompany Report #2005AP02792
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Condition Aggravated		Seroquel	PS	Zeneca Pharmaceutical	ORAL		
	Death							
	Huntington'S Chorea		Serenace	SS				

Date:05/18/05ISR Number: 4668450-6Report Type:Expedited (15-DaCompany Report #B0379827A
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Diabetic Ketoacidosis	Foreign	Chlorpromazine					
	Pancreatitis Acute	Literature	Hydrochloride					
		Health	(Formulation					
		Professional	Unknown)					

(Chlorpromazine Hcl)	PS	
Haloperidol (Haloperidol)	SS	
Valproate Sodium (Valproate Sodium)	SS	

Date:05/19/05ISR Number: 4665585-9Report Type:Expedited (15-DaCompany Report #JP-JNJFOC-20050406902
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Drug Administration Error		Risperidone	PS				
OROPHARINGEAL							9	DAY
	Drug Interaction		Soybean Oil	C				
INTRAVENOUS								
	Restlessness		Furosemide	C				
INTRAVENOUS								
	Torsade De Pointes		Famotidine	C				
INTRAVENOUS								
			Multivitamin	C				
INTRAVENOUS								
			Multivitamin	C				
INTRAVENOUS								
			Multivitamin	C				
INTRAVENOUS								
			Multivitamin	C				
INTRAVENOUS								
			Proteamin	C				
INTRAVENOUS								
			Tazobactam	C				
INTRAVENOUS								
			Ciprofloxacin	C				
INTRAVENOUS								
			Aminophyline	C				
INTRAVENOUS								
			Proteamin	C				
INTRAVENOUS								
			Multivitamin	C				
INTRAVENOUS								

			Multivitamin	C		
INTRAVENOUS						
			Multivitamin	C		
INTRAVENOUS						
			Multivitamin	C		
INTRAVENOUS						
			Haloperidol	I		
INTRAVENOUS						
			Haloperidol	I		
INTRAVENOUS						

Date:05/19/05ISR Number: 4666141-9Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20050501814
Age:77 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Cerebrovascular Accident		Risperdal	PS				
OROPHARINGEAL								
Initial or Prolonged	Drug Withdrawal Syndrome		Haldol	SS				
UNKNOWN								
Other	Extrapyramidal Disorder							
	Gastroenteritis							
	General Physical Health Deterioration							

Date:05/19/05ISR Number: 4666400-XReport Type:Expedited (15-DaCompany Report #2005SE02900
Age:54 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Breast Cancer Female		Seroquel	PS	Zeneca			
	Metastases To Bone				Pharmaceutical	ORAL		
7 MON								
	Metastases To Liver		Seroquel	SS	Zeneca			
	Metastases To Pleura				Pharmaceutical	ORAL		
			Haldol	SS		ORAL		
			Inderal	C				
			Zoloft	C				

Date:05/19/05ISR Number: 4668706-7Report Type:Expedited (15-DaCompany Report #PHBS2005GB06328
Age:47 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blood Pressure Systolic Increased	Foreign Health	Protium(Pantoprazole) Unknown	PS				
INTRAVENOUS	INTRAVENOUS							
	Drug Interaction	Professional Other	Rifampicin (Ngx) (Rifampicin)	SS				
INTRAVENOUS	INTRAVENOUS							
			Zyvox(Linezolid)	SS				
INTRAVENOUS	1200 MG/DAY,							
INTRAVENOUS								
			Doxazosin(Doxazosin)	SS		ORAL		
ORAL								
			Procyclidine(Procyclidine)	SS		ORAL		
ORAL								
			Atenolol(Atenolol)	SS		ORAL		
ORAL								
			Fentanyl (Fentanyl)	SS				
INTRAVENOUS	INTRAVENOUS							
			Amisulpride(Amisulpride)	SS		ORAL		
ORAL								
			Omeprazole(Omeprazole)	SS				
			Zopiclone(Zopiclone)	SS				
			Haloperidol(Haloperidol)	SS				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/20/05ISR Number: 4667268-8Report Type:Expedited (15-DaCompany Report #JP-JNJFOC-20050502615
Age:43 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Convulsion		Risperdal	PS		OROPHARINGEAL		
Hospitalization -	Depressed Level Of		Impromen	SS		OROPHARINGEAL		
Initial or Prolonged	Consciousness		Haldol	SS		OROPHARINGEAL		
Other	Disseminated		Chloropromazine	SS		OROPHARINGEAL		
	Intravascular Coagulation		Levopromazine	C		OROPHARINGEAL		
	Electroencephalogram Abnormal		Biperiden Hydrochloride	C		OROPHARINGEAL		
	Fibrin Degradation Products Increased		Promethazine Hydrochloride	C		OROPHARINGEAL		
	Hyponatraemia		Etizolam	C				
	Polydipsia		Cloxazolam	C				
	Prothrombin Time Prolonged		Haloxazolam	C				
	Psychomotor Hyperactivity		Flunitrazepam	C				
	Pyrexia							
	Self Injurious Behaviour							
	Systemic Inflammatory Response Syndrome							
	Systolic Hypertension							
	Tachycardia							
	Thrombocytopenia							
	Water Intoxication							

Date:05/23/05ISR Number: 4668810-3Report Type:Expedited (15-DaCompany Report #CH-JNJFOC-20050502688
Age:75 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Neuroleptic Malignant		Haldol	PS		INTRAMUSCULAR	1	DAY
Initial or Prolonged	Syndrome		Haldol	SS		INTRAMUSCULAR	1	DAY

	Serotonin Syndrome			Tramal	SS		
OROPHARINGEAL	3	DAY					
				Deroxat	SS		
OROPHARINGEAL	7	DAY					
				Fraxiparine	C		
SUBCUTANEOUS	7	DAY					
				Clamoxyl	C		
OROPHARINGEAL	5	DAY					
				Zestril	C		
OROPHARINGEAL	5	DAY					
				Torem	C		
OROPHARINGEAL	7	DAY					
				Beloc	C		
OROPHARINGEAL	5	DAY					
				Adalat	C		
OROPHARINGEAL	5	DAY					

Date:05/23/05ISR Number: 4673551-2Report Type:Expedited (15-DaCompany Report #2004071481
Age:46 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Blood Disorder	Literature	Diphenhydramine					
Hospitalization -	Completed Suicide	Health	(Diphenhydramine)	PS				
Initial or Prolonged	Depressed Level Of	Professional	Ibuprofen					
	Consciousness		(Ibuprofen)	SS				
	Electrocardiogram Qrs		Haloperidol					
	Complex Prolonged		(Haloperidol)	SS				
	Heart Rate Increased		Chlorzoxazone					
	Intentional Misuse		(Chlorzoxazone)	SS				
	Multiple Drug Overdose		Cyclobenzaprine					
	Respiratory Arrest		(Cyclobenzaprine)	SS				
	Stupor		Methylphenidate					
			(Methylphenidate)	SS				
			Cefalexin					
			(Cefalexin)	SS				

				Naproxen (Naproxen)	SS		
				Ethanol (Ethanol)	SS		

Date:05/24/05ISR Number: 4674103-0Report Type:Direct Company Report #CTU 249389
Age:61 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Agitation		Lithium	PS				
	Autonomic Nervous System Imbalance		Haldoperidol	SS				
	Bradycardia		Lisinopril	SS				
	Confusional State		Risperidone	SS				
	Decreased Appetite							
	Diarrhoea							
	Dyskinesia							
	Dystonia							
	Faeces Discoloured							
	Fatigue							
	Heart Rate Increased							
	Hypernatraemia							
	Memory Impairment							
	Mental Status Changes							
	Nephrogenic Diabetes Insipidus							
	Tardive Dyskinesia							
	Therapeutic Agent Toxicity							
	Tremor							
	Verbigeration							

Date:05/25/05ISR Number: 4673129-0Report Type:Expedited (15-DaCompany Report #JP-JNJFOC-20050503162
Age:36 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Atrial Thrombosis		Haldol	PS				
	Electrocardiogram St-T Change		Haldol	SS				
			Bromperidol	SS			6-9 mg daily	
	Tachycardia		Perospirone	SS			16-36 mg	

daily (36 mg

at the time

of the event)

	Olanzapine	SS
	Trihexyphenidyl	SS
	Clonazepam	SS
	Olanzapine	SS
	Zotepine	SS

50-200 mg

daily (100 mg

at the time

of the event)

	Haldol	SS

Date:05/25/05ISR Number: 4673130-7Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20050503916
Age:26 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Condition Aggravated		Haldol	PS				
OROPHARINGEAL								59 DAY
Initial or Prolonged	Platelet Count Decreased		Remergil	SS				
OROPHARINGEAL								59 DAY
Other			Ferosanol	C				
OROPHARINGEAL								

			Kalinor	C			
OROPHARINGEAL							
			Magnesia	C			
OROPHARINGEAL							
			Tavor	C			
OROPHARINGEAL							

Date:05/25/05ISR Number: 4673131-9Report Type:Periodic Company Report #M-780261
Age:43 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Dystonia		Haldol	PS				
OROPHARINGEAL	Did not							
	Sudden Death							
exceed 25 mg.								
			Benztropine Mesylate	C				
			Digoxin	C				
			Propranolol	C				
			Phenobarbital Sodium	C				

Date:05/25/05ISR Number: 4673132-0Report Type:Periodic Company Report #M-780130
Age:35 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Dystonia		Haldol	PS				
OROPHARINGEAL								
	Sudden Death		Benztropine Mesylate	C				
			Diphenhydramine	C				
			Chlorpromazine	C				
			Chlorpromazine	C				

Date:05/25/05ISR Number: 4673133-2Report Type:Expedited (15-DaCompany Report #M-780277
Age:26 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dystonia		Haldol	PS				
OROPHARINGEAL								
	Respiratory Distress							

Date:05/25/05ISR Number: 4673134-4Report Type:Expedited (15-DaCompany Report #M-780276
Age:21 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Choking		Haldol	PS				
OROPHARINGEAL								
	Dystonia							
	Respiratory Distress							

Date:05/25/05ISR Number: 4673135-6Report Type:Periodic Company Report #M-810431
Age:21 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dystonia		Haldol	PS				
INTRAMUSCULAR								
			Diazepam	C				

Date:05/25/05ISR Number: 4673136-8Report Type:Expedited (15-DaCompany Report #M-810566
Age:44 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Dystonia		Haldol	PS				
OROPHARINGEAL								
	Sudden Death		Haldol	SS				
OROPHARINGEAL								
			Haldol	SS				
INTRAMUSCULAR								

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/25/05ISR Number: 4673408-7Report Type:Expedited (15-DaCompany Report #JP-ROCHE-404874
Age:36 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anorexia		Clonazepam	PS	Roche	UNKNOWN		
	Atrial Fibrillation		Haloperidol	SS	Roche	UNKNOWN		
	Atrial Thrombosis		Clocapramine	SS		UNKNOWN		
	Catatonia		Zotepine	SS		UNKNOWN		
	Dehydration		Bromperidol	SS		UNKNOWN		
	Delusion		Perospirone					
	Electrocardiogram St-T Change		Hydrochloride Hydrate	SS		UNKNOWN		
	Hallucination, Auditory		Olanzapine	SS		UNKNOWN		
	Insomnia							
	International Normalised Ratio Decreased							
	Palpitations							
	Tachycardia							

Date:05/25/05ISR Number: 4677360-XReport Type:Direct Company Report #CTU 249498
Age:75 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Post Procedural Complication		Haloperidol	PS		INTRAVENOUS	1-2MG IV Q 4 HOURS PRN	
	Pyrexia							

Date:05/26/05ISR Number: 4674250-3Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20050501358
Age:60 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Ileus		Haldol	PS				
OROPHARINGEAL								
Initial or Prolonged			Tegretol	SS				
OROPHARINGEAL								
			Seropram	C				
OROPHARINGEAL								
			Clonazepam	C				
OROPHARINGEAL								
			Liticarb	C				
OROPHARINGEAL								

Date:05/26/05ISR Number: 4674341-7Report Type:Expedited (15-DaCompany Report #CH-JNJFOC-20050503936
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Hepatitis A Antibody		Haldol	PS				
OROPHARINGEAL	15 DAY							
Initial or Prolonged	Positive		Haldol	SS				
OROPHARINGEAL	15 DAY							
	Liver Disorder		Haldol	SS				
OROPHARINGEAL	15 DAY							
	Nausea							
	Syncope							
	Vomiting							

Date:05/26/05ISR Number: 4677525-7Report Type:Direct Company Report #CTU 249750
Age:32 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Neuroleptic Malignant		Haloperidol					
	Syndrome		5mg/Ml American					
			Pharmaceutical	PS	American			
					Pharmaceutical			
INTRAMUSCULAR	4 MG	Q2-4						
HRS								

INTRAMUSCU							
				Ativan	C		
				Normal Saline	C		

Date:05/31/05ISR Number: 4677787-6Report Type:Expedited (15-DaCompany Report #FR-JNJFOC-20050504041
Age:12 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Abnormal Behaviour		Haldol Decanoas	PS				
INTRAMUSCULAR							1	DAY
Initial or Prolonged	Anxiety							
	Coma							
	Morbid Thoughts							
	Off Label Use							

Date:05/31/05ISR Number: 4677788-8Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20050504944
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Dysphagia		Haldol Decanoat	PS				
INTRAMUSCULAR								
Initial or Prolonged	Medication Error							

Date:06/02/05ISR Number: 4679654-0Report Type:Expedited (15-DaCompany Report #SE-JNJFOC-20050505721
Age:53 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Breast Cancer Metastatic		Haldol	PS				
OROPHARINGEAL								
	Metastases To Bone		Seroquel	SS				
OROPHARINGEAL								
	Metastases To Liver							
	Metastases To Pleura							

Date:06/02/05ISR Number: 4679655-2Report Type:Expedited (15-DaCompany Report #BR-JNJFOC-20050507170
Age:16 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blood Sodium Decreased		Haldol	PS				
OROPHARINGEAL	Suicide Attempt						patient ingested 40 tablets at one time	
			Methylphenidate	SS				
			Lamotrigine	SS				

Date:06/02/05ISR Number: 4682376-3Report Type:Direct Company Report #CTU 250162
Age:20 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Dystonia		Haldol	PS		ORAL	5 MG PO Q 12 HR	
	Jaw Disorder							
			Haldol	SS		ORAL	2 MG PO Q 1 HR PRN	

Date:06/03/05ISR Number: 4681245-2Report Type:Expedited (15-DaCompany Report #CH-JNJFOC-20050505347
Age:32 YR Gender:Male I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Dyspnoea
	Dystonia

Panic Attack
Tachycardia

Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Haldol	PS		OROPHARINGEAL	3	DAY
	Haldol	SS		OROPHARINGEAL	3	DAY
	Dafalgan	SS		OROPHARINGEAL	Dose: 4	dosage forms (strength not specified) total
	Voltaren	SS		INTRAMUSCULAR		
	Dalmadorm	C		OROPHARINGEAL	3	WK

Date:06/03/05ISR Number: 4681246-4Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20050501023
Age:25 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Aggression		Pipamperon	PS		OROPHARINGEAL		
	Eye Injury		Pipamperon	SS		OROPHARINGEAL		
Other	Oculogyration		Haldol	SS		OROPHARINGEAL	As needed	
			Haldol	SS		OROPHARINGEAL		
			Haldol	SS				
			Clozapin	C		OROPHARINGEAL		
			Tavor Expidet	C		OROPHARINGEAL	As needed	
			Diazep	C		OROPHARINGEAL		
			Novalgin	C		OROPHARINGEAL		

				Novalgin	C			
OROPHARINGEAL	As needed							
				Gastrozepin	C			
OROPHARINGEAL								
				Lactulose Ratiopharm	C			
OROPHARINGEAL								
				Dulcolax	C			
As needed								
				Boro-Scopol N	C			
OROPHARINGEAL								
				Biperiden-Neuraxpham 4	C			
OROPHARINGEAL								
				Floxal At	C			
				Floxal At	C			
1 drop four								
times a day								
				Batrafen	C			
Batrafen Gel								
applied twice								
a day								
				Corneregel	C			
12 drops per								
day								
				Maaloxan	C			
				Maaloxan	C			
As needed								
				Floxal-As	C			
				Floxal-As	C			
1 drop 3								
times a day								
				Gentamycin Eye Salve	C			
OPHTHALMIC		5	DAY					

Date:06/06/05ISR Number: 4682310-6Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20050600812
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Platelet Count Decreased		Haldol	PS				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/06/05ISR Number: 4682726-8Report Type:Expedited (15-DaCompany Report #JP-JNJFOC-20050406902
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Drug Administration Error		Risperidone	PS				
OROPHARINGEAL								9 DAY
Other	Drug Interaction		Hyperalimentative					
	Torsade De Pointes		Basic Solution	C				
			Hyperalimentative					
			Basic Solution	C				
			Hyperalimentative					
			Basic Solution	C				
			Soybean Oil	C				
						INTRAVENOUS		
			Famotidine	C				
						INTRAVENOUS		
			Multivitamin	C				
						INTRAVENOUS		
			Multivitamin	C				
						INTRAVENOUS		
			Multivitamin	C				
						INTRAVENOUS		
			Methylprednisolone					
			Sodium Succinate	C				
			Saccharated					
			Ferricoxide	C				
			Tazobactam	C				
						INTRAVENOUS		
			Ciprofloxacin	C				
						INTRAVENOUS		
			Aminophyline	C				
						INTRAVENOUS		
			Proteamin	C				
						INTRAVENOUS		
			Proteamin	C				
						INTRAVENOUS		
			Multivitamin	C				
						INTRAVENOUS		
			Multivitamin	C				
						INTRAVENOUS		
			Multivitamin	C				
						INTRAVENOUS		
			Multivitamin	C				
						INTRAVENOUS		
			Multivitamin	C				
						INTRAVENOUS		

			Furosemide	C			
INTRAVENOUS							
			Hyperalimentative Basic Solution	C			
			Haloperidol	I			
INTRAVENOUS							
			Haloperidol	I			
INTRAVENOUS							

Date:06/06/05ISR Number: 4682728-1Report Type:Expedited (15-DaCompany Report #JP-JNJFOC-20050600327
Age:74 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Ventricular Fibrillation		Risperdal	PS				
OROPHARINGEAL								
			Haloperidol	SS				
			Haloperidol	SS				
			Haloperidol	SS				
INTRAMUSCULAR								
			Haloperidol	SS				
INTRAMUSCULAR								
			Lorazepam	C				
OROPHARINGEAL								
			Biperiden Hydrochloride	C				
OROPHARINGEAL								
			Itopride Hydrochloride	C				
OROPHARINGEAL								
			Magnesium Oxide	C				
OROPHARINGEAL								
			Mianserin Hydrochloride	C				
OROPHARINGEAL								
			Nitrazepam	C				
OROPHARINGEAL								
			Flunitrazepam	C				
OROPHARINGEAL								
			Zopiclone	C				
OROPHARINGEAL								

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/07/05ISR Number: 4683813-0Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20050506247
Age:89 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Parkinsonism		Haldol	PS			UNKNOWN	

Date:06/08/05ISR Number: 4685291-4Report Type:Expedited (15-DaCompany Report #FR-JNJFOC-20050506237
Age:51 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hyperthyroidism		Haldol Decanoas	PS			INTRAMUSCULAR	

Date:06/08/05ISR Number: 4687405-9Report Type:Expedited (15-DaCompany Report #2004106748
Age:29 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abnormal Behaviour Aggression	Consumer	Neurontin (Tablets) (Gabapentin)	PS			900 MG (300 MG, 3 IN 1 D),	
Other	Agitation Delusion Depression		Haldol (Haloperidol)	SS			6 MG (3 MG, 2 IN 1 D),	
	Drug Ineffective Homicidal Ideation Intentional Misuse		Risperidone (Risperidone)	SS				
	Lethargy Multiple Drug Overdose Psychotic Disorder Somnolence Suicidal Ideation Suicide Attempt		Seroquel (Quetiapine Fumarate) Metformin (Metformin)	C C				

Date:06/08/05ISR Number: 4687512-0Report Type:Direct Company Report #CTU 250677
Age:17 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Neuroleptic Malignant Syndrome		Haloperidol 5mg	PS		ORAL	5MG	BID
	Transaminases Increased					ORAL		
			Haloperidol Decanoate	SS		INTRAMUSCULAR	100MG	EVERY 4TH DAY
						INTRAMUSCU		

Date:06/08/05ISR Number: 4687532-6Report Type:Direct Company Report #CTU 250690
Age:20 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Depression		Haldol	PS		ORAL	TABLETS;	
	Hypersomnia					INJECTION		
	Muscle Twitching		Adivan	C				
	Suicidal Ideation		Lithium	C				
	Suicide Attempt							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/09/05ISR Number: 4686037-6Report Type:Expedited (15-DaCompany Report #JP-JNJFOC-20050600327
Age:74 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Ventricular Fibrillation		Risperdal	PS		OROPHARINGEAL		
			Haloperidol	SS				
			Haloperidol	SS				
			Haloperidol	SS		INTRAMUSCULAR		
			Haloperidol	SS		INTRAMUSCULAR		
			Lorazepam	C		OROPHARINGEAL		
			Biperiden Hydrochloride	C		OROPHARINGEAL		
			Itopride Hydrochloride	C		OROPHARINGEAL		
			Magnesium Oxide	C		OROPHARINGEAL		
			Mianserin Hydrochloride	C		OROPHARINGEAL		
			Nitrazepam	C		OROPHARINGEAL		
			Flunitrazepam	C		OROPHARINGEAL		
			Zopiclone	C		OROPHARINGEAL		

Date:06/09/05ISR Number: 4686039-XReport Type:Expedited (15-DaCompany Report #FR-JNJFOC-20050600075
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Thrombocytopenia		Haldol	PS		OROPHARINGEAL		
			Rifampicin	C				

Date:06/10/05ISR Number: 4687472-2Report Type:Expedited (15-DaCompany Report #AU-ABBOTT-02P-008-0200591-00
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Coma		Epilim Tablets	PS		ORAL		
Hospitalization - Initial or Prolonged	Condition Aggravated		Epilim Tablets	SS		ORAL		
	Delirium		Epilim Tablets	SS				
	Hallucination, Auditory		Olanzapine	SS		ORAL		
	Intentional Misuse		Olanzapine	SS		ORAL		
	Loss Of Consciousness		Haloperidol	SS		ORAL		
	Multiple Drug Overdose		Haloperidol	SS		ORAL		
	Suicide Attempt		Trifeme	C		ORAL		
			Bekunis	C		ORAL		

Date:06/10/05ISR Number: 4687672-1Report Type:Expedited (15-DaCompany Report #FR-JNJFOC-20050600081
Age:54 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Confusional State		Haldol Decanoate	PS		INTRAMUSCULAR		
	Drug Toxicity		Glucophage	C				
	Fall		Zyloric	C				
	Hypertension		Triatec	C				
	Leukocytosis		Mediatensyl	C				
	Orthostatic Hypotension		Glucor	C				
	Somnolence							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/10/05ISR Number: 4690965-5Report Type:Expedited (15-DaCompany Report #S05-FRA-01009-01
Age:83 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hepatic Steatosis	Foreign Health	Seropram (Citalopram Hydrobromide)	PS		INTRAVENOUS	20 MG QD	IV
		Professional Other	Cetornan (Ornithine Oxoglurate)	SS		ORAL	10 G QD	PO
			Haloperidol	SS		ORAL	2 MG QD	PO
			Calciparine (Heparin Calcium) (Heparin Calcium)	SS		SUBCUTANEOUS	0.8 ML QD	SC
			Debridat	C				
			Daktarin (Miconazole Nitrate)	C				
			Aricept (Donepezil Hydrochloride)	C				
			Cordarone (Amiodarone Hydrochloride)	C				
			Amlor (Amlodipine Besilate)	C				
			Previscan (Fluindione)	C				
			Aldalix	C				
			Imovane (Zopiclone)	C				

Date:06/16/05ISR Number: 4695747-6Report Type:Direct Company Report #CTU 251300
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Hallucinations, Mixed		Seroquel	PS			612 MGS	
Disability			Benztropine	SS				
			Haloperidol	SS				

Date:06/17/05ISR Number: 4693157-9Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20050601927
Age:34 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Suicide Attempt		Haldol	PS				
			Abilify	C				
			Tavor	C				

Date:06/17/05ISR Number: 4693386-4Report Type:Expedited (15-DaCompany Report #JP-JNJFOC-20050600327
Age:74 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Encephalopathy		Risperdal	PS		OROPHARINGEAL		
	Prostration		Haloperidol	SS			10 mg daily	
	Restlessness		Haloperidol	SS				
	Ventricular Fibrillation		Haloperidol	SS		INTRAMUSCULAR	30 mg daily	
			Haloperidol	SS		INTRAMUSCULAR		
			Lorazepam	C		OROPHARINGEAL		
			Biperiden Hydrochloride	C		OROPHARINGEAL		
			Itopride Hydrochloride	C		OROPHARINGEAL		
			Magnesium Oxide	C		OROPHARINGEAL		
			Mianserin					

			Hydrochloride	C		
OROPHARINGEAL						
			Nitrazepam	C		
OROPHARINGEAL						
			Flunitrazepam	C		
OROPHARINGEAL						
			Zopiclone	C		
OROPHARINGEAL						

Date:06/17/05ISR Number: 4694813-9Report Type:Expedited (15-DaCompany Report #DSA_26562_2005
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Confusional State	Health	Ativan	PS				
DF								
Other	Convulsion	Professional	Haldol "Janssen"	SS				
DF								
	Nervous System Disorder		Metoprolol	SS				
DF								
	Post Procedural Complication							

Date:06/17/05ISR Number: 4694871-1Report Type:Expedited (15-DaCompany Report #2004106748
Age:29 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abnormal Behaviour Aggression	Consumer	Neurontin (Tablets) (Gabapentin)	PS			UNKNOWN	900 MG, (300
Other	Agitation						MG, 3 IN 1	
	Delusion						D), UNKNOWN	
	Depression		Haldol (Haloperidol)	SS			UNKNOWN	UNKNOWN
	Drug Ineffective Homicidal Ideation		Risperidone (Risperidone)	SS			UNKNOWN	6 MG (3 MG, 2
	Intentional Misuse						IN 1 D),	
	Lethargy						UNKNOWN	

Multiple Drug Overdose	Seroquel (Quetiapine		
Psychotic Disorder	Fumarate)	C	
Somnolence	Metformin		
Suicidal Ideation	(Metformin)	C	
Suicide Attempt			

Date:06/20/05ISR Number: 4694271-4Report Type:Expedited (15-DaCompany Report #JP-SOLVAY-00305000085
Age:24726 DYGender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Disability	Neuroleptic Malignant Syndrome		Depromel 25	PS		ORAL	Daily dose: 75 milligram(s)	21 DAY
			Serenace	SS		ORAL	Daily dose: 2.25 milligram(s)	21 DAY
			Serenace	SS			INTRAMUSCULAR	Daily dose: 1 millilitre(s) 1 DAY
			Serenace	SS			INTRAMUSCULAR	Daily dose: 1 millilitre(s) 1 DAY
			Tofranil	C		ORAL	Daily dose: 150 milligram(s)	6 DAY
			Depas	C		ORAL	Daily dose: 1.5 milligram(s)	21 DAY
			Tasmolin	C		ORAL	Daily dose: 3 milligram(s)	14 DAY
			Tasmolin	C		ORAL	Daily dose: 6 milligram(s)	7 DAY

Anafranil	C	ORAL

Daily dose:

75
milligram(s) 16 DAY
UNKNOWN Daily dose:
50
milligram(s) 15 DAY
Daily dose:
25
milligram(s) 16 DAY
Daily dose:
30
milligram(s) 6 DAY
Daily dose: 5
milligram(s) 14 DAY
Daily dose:
10
milligram(s) 7 DAY
Daily dose: 1
dosage form 5 DAY
Daily dose: 2
dosage form 3 DAY
Daily dose: 1
dosage form 4 DAY
Daily dose: 9
gram(s) 10 DAY

Anafranil	C	
Ludiomil	C	ORAL
Tetramide	C	ORAL
Benzalin	C	ORAL
Benzalin	C	ORAL
Vegetamin-B	C	ORAL
Vegetamin-B	C	ORAL
Vegetamin-A	C	ORAL
Kolantyl	C	ORAL

Daily dose: 4.5 milligram(s)	10	DAY	Elieten	C	ORAL
Daily dose: 1 gram(s)	10	DAY	Alosenn	C	ORAL
Daily dose: 1 gram(s)	2	DAY	Heavy Magnesium Oxide	C	ORAL
Daily dose: 3 dosage form	7	DAY	Pursennid	C	ORAL
Daily dose: 750 milligram(s)	4	DAY	Kefral	C	ORAL
RECTAL Daily dose: 25 milligram(s)	1	DAY	Indacin	C	
INTRAMUSCULAR Daily dose: 1 millilitre(s)	1	DAY	Akineton	C	
INTRAMUSCULAR Daily dose: 1 millilitre(s)	1	DAY	Akineton	C	
INTRAMUSCULAR Daily dose: 10 milligram(s)	1	DAY	Dormicum	C	
UNKNOWN Daily dose: 500 millilitre(s)	15	DAY	Urokinase	C	
UNKNOWN Daily dose:			Soldem 3 A	C	

500

millilitre(s) 15   DAY

Date:06/21/05ISR Number: 4695623-9Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20050603326
Age:34 YR   Gender:Female   I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Overdose		Haloperidol	PS				
UNKNOWN							dose	

unspecified

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/21/05ISR Number: 4695629-XReport Type:Expedited (15-DaCompany Report #JP-JNJFOC-20050205999
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Bradycardia		Risperdal	PS		OROPHARINGEAL		
Hospitalization -	Drug Administration Error		Haloperidol	SS		INTRAVENOUS		
Initial or Prolonged	Incorrect Route Of Drug		Midazolam	C		INTRAVENOUS		
	Administration		Propofol	C				
	Sinus Arrest							

Date:06/22/05ISR Number: 4696918-5Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20050603384
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Bronchopneumonia		Haldol	PS		OROPHARINGEAL		
	Death							

Date:06/22/05ISR Number: 4698110-7Report Type:Direct Company Report #CTU 251671
Age:84 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product		Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Arthralgia		Lorazepam	1mg	PS		ORAL	1MG	HS
Initial or Prolonged	Back Pain						ORAL		
	Blood Pressure Systolic		Haloperidol	0.5mg	SS		ORAL	0.5MG	TID
	Decreased						ORAL		
	Confusional State								
	Fall								
	Hypotension								
	Tremor								

Date:06/23/05ISR Number: 4698211-3Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20050603246
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Agranulocytosis		Haloperidol	PS		UNKNOWN		
	Depression		Risperdal Consta	SS		INTRAMUSCULAR		
			Seroquel	SS				
			Solian	SS				
			Cipralex	SS		OROPHARINGEAL	Start date =	

End of

APR-2005

Date:06/23/05ISR Number: 4698213-7Report Type:Expedited (15-DaCompany Report #JP-JNJFOC-20050406902
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Drug Administration Error		Risperidone	PS		OROPHARINGEAL	9	DAY
Other	Drug Interaction		Hyperalimentative Basic Solution	C				
	Torsade De Pointes		Hyperalimentative Basic Solution	C				
			Hyperalimentative Basic Solution	C				
			Soybean Oil	C		INTRAVENOUS		
			Famotidine	C		INTRAVENOUS		
			Multivitamin	C		INTRAVENOUS		
			Multivitamin	C		INTRAVENOUS		
			Multivitamin	C		INTRAVENOUS		

				Methylprednisolone Sodium Succinate	C		
				Saccharated Ferricoxide	C		
				Tazobactam	C		
INTRAVENOUS							
				Ciprofloxacin	C		
INTRAVENOUS							
				Aminophyline	C		
INTRAVENOUS							
				Proteamin	C		
INTRAVENOUS							
				Proteamin	C		
INTRAVENOUS							
				Multivitamin	C		
INTRAVENOUS							
				Multivitamin	C		
INTRAVENOUS							
				Multivitamin	C		
INTRAVENOUS							
				Multivitamin	C		
INTRAVENOUS							
				Multivitamin	C		
INTRAVENOUS							
				Furosemide	C		
INTRAVENOUS							
				Hyperalimentative Basic Solution	C		
				Haloperidol	I		
INTRAVENOUS							
				Haloperidol	I		
INTRAVENOUS							

Date:06/24/05ISR Number: 4699516-2Report Type:Expedited (15-DaCompany Report #CA-JNJFOC-20050604482
Age:74 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Atrial Fibrillation		Haldol	PS				
INTRAVENOUS	Ileus						(4,9,8,5 mg daily	1 to 4 days

respectively)

5 to 7 days

Date:06/27/05ISR Number: 4700255-XReport Type:Expedited (15-DaCompany Report #GB-JNJFOC-20050604594
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Hypertension		Haloperidol	PS				
Life-Threatening	Subarachnoid Haemorrhage							

Date:06/27/05ISR Number: 4700256-1Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20050306691
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Bronchopneumonia		Haldol	PS				
OROPHARINGEAL								
	Overdose		Haldol	SS				
OROPHARINGEAL								
			Olanzapine	C				
			Amisulpiride	C				
			Carbamazepine	C				
			Diazepam	C				
to be taken								
when								
required.								
			Procyclidine	C				
			Chlorpromazine	C				
or to be								
taken when								
required, up								
to a maximum								
dose of 25								
			Zopidone	C				
taken as								
needed							7	MON
			Zopidone	C				
up to 15mg at								

highest dose 7 MON
or to be
taken when
required.
dose= puffs
Strength: 100
Dose = puff
taken as
needed
stength= 200.
dose= puff
to be taken
when
required.
for 1 1/2
days until
death.

Salbutamol	C
Beclomethasone	C
Beclomethasone	C
Paracetamol	C
Keflex	C

Date:06/27/05ISR Number: 4700257-3Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20050605035
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Foetal Growth Retardation Foot Deformity Jaundice Premature Baby		Haldol Decanoat	PS				

Date:06/27/05ISR Number: 4701622-0Report Type:Expedited (15-DaCompany Report #2005088168
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Bedridden	Foreign	Atarax-P (Iv/Im)					
Disability	Depressed Level Of Consciousness	Consumer	(Hydroxyzine Hydrochloride)	PS				
	Dyspnoea		Serenace Injection					
	Movement Disorder		(Haloperidol)	SS				

Date:06/27/05ISR Number: 4701891-7Report Type:Expedited (15-DaCompany Report #2004106748
Age:29 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abnormal Behaviour	Consumer	Neurontin (Tablets)				900 MG (300	
Other	Aggression		(Gabapentin)	PS			MG,3 IN 1 D)	
	Agitation							
	Condition Aggravated		Neurontin					
	Depression		(Gabapentin)	SS			900 MG (300	
	Drug Ineffective						MG,3 IN 1 D)	
	Hallucination, Auditory		Haldol (Haloperidol)	SS				
	Homicidal Ideation		Risperidone					
	Intentional Misuse		(Risperidone)	SS			6 MG (3 MG,2	
	Lethargy						IN 1 D)	
	Multiple Drug Overdose		Seroquel (Quetiapine					
	Psychotic Disorder		Fumarate)	C				
	Somnolence		Metformin					
	Stress		(Metformin)	C				
	Suicidal Ideation							
	Suicide Attempt							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/28/05ISR Number: 4701173-3Report Type:Expedited (15-DaCompany Report #IE-JNJFOC-20050606350
Age:26 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blood Creatine Phosphokinase Increased		Haldol Olanzapine	PS C				

Date:06/28/05ISR Number: 4701190-3Report Type:Expedited (15-DaCompany Report #JP-JNJFOC-20050600327
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Blood Glucose Increased		Risperdal	PS		OROPHARINGEAL		
	Blood Pressure Decreased		Risperdal	SS		OROPHARINGEAL		
	Body Temperature Increased		Haloperidol Haloperidol	SS SS		10 mg daily		
	Cardiac Arrest		Haloperidol	SS		INTRAMUSCULAR	30 mg daily	
	Delirium		Haloperidol	SS		INTRAMUSCULAR		
	Diet Refusal		Lorazepam	C		OROPHARINGEAL		
	Encephalopathy Excitability		Biperiden Hydrochloride	C		OROPHARINGEAL		
	Prostration Respiratory Arrest		Itopride Hydrochloride	C		OROPHARINGEAL		
	Restlessness		Magnesium Oxide	C		OROPHARINGEAL		
	Ventricular Fibrillation		Mianserin Hydrochloride	C		OROPHARINGEAL		
			Nitrazepam	C		OROPHARINGEAL		
			Flunitrazepam	C		OROPHARINGEAL		
			Zopiclone	C		OROPHARINGEAL		

Date:06/29/05ISR Number: 4702969-4Report Type:Expedited (15-DaCompany Report #GB-ROCHE-408183
Age:65 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Hiccups		Capecitabine	PS	Roche	ORAL	PATIENT'S TO RECEIVE A 12 WEEK CYCLE, CAPECITABINE GIVEN 5 DAYS	
			Oxaliplatin	SS		INTRAVENOUS		
			Haloperidol	SS	Roche	ORAL	4	DAY

Date:06/29/05ISR Number: 4705972-3Report Type:Expedited (15-DaCompany Report #142358USA
Age:52 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Injection Site Cellulitis Wrong Technique In Drug Usage Process	Health Professional	Haloperidol Decanoate	PS				

Date:06/30/05ISR Number: 4704352-4Report Type:Expedited (15-DaCompany Report #FR-JNJFOC-20050600075
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Autoimmune		Haldol	PS		OROPHARINGEAL	2mg/2ml	
Hospitalization -	Thrombocytopenia						solution	10 DAY
Initial or Prolonged			Rifampicin	SS		OROPHARINGEAL	Dose= 1 tablet	7 DAY

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/30/05ISR Number: 4704987-9Report Type:Direct Company Report #CTU 252260
Age:50 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required	Dystonia		Haloperidol	PS		ORAL	2 MG BID	ORAL
Intervention to Prevent Permanent Impairment/Damage			Lorazepam	C				
			Valproic Acid	C				
			Citalopram Hydrobromide	C				
			Diphenhydramine Hcl	C				
			Trazodone Hcl	C				
			Simvastatin	C				
			Ranitidine Hcl	C				

Date:07/01/05ISR Number: 4705108-9Report Type:Expedited (15-DaCompany Report #JP-JNJFOC-20050607156
Age:55 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blood Creatine		Risperdal	PS			OROPHARINGEAL	
	Phosphokinase Increased		Haloperidol	SS				
	Bradykinesia							
	Parkinsonism							

Date:07/01/05ISR Number: 4705408-2Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0321980A
Age:69 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Abdominal Distension		Augmentin	PS	Glaxosmithkline		UNKNOWN	3G Per day 12 DAY
Hospitalization - Initial or Prolonged	Flatulence		Fraxiparine	SS	Glaxosmithkline		SUBCUTANEOUS	.6ML Twice per day
	Intestinal Obstruction							
	Tachycardia		Deroxat	SS	Glaxosmithkline	ORAL	2UNIT Per day	
			Haldol	SS		ORAL	10MG Per day	

			Sintrom	SS		ORAL
1UNIT Unknown						

Date:07/06/05ISR Number: 4707542-XReport Type:Expedited (15-DaCompany Report #DE-JNJFOC-20050607104
Age:42 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Oedema Peripheral		Haldol	PS		OROPHARINGEAL		
			Haldol	SS		OROPHARINGEAL		
			Taxilan	SS		OROPHARINGEAL		
			Taxilan	SS		OROPHARINGEAL		
			Taxilan	SS		OROPHARINGEAL		
			Haldol	SS		OROPHARINGEAL		
			Akineton	C		OROPHARINGEAL		

Date:07/06/05ISR Number: 4709379-4Report Type:Direct Company Report #CTU 252624
Age:66 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Neuroleptic Malignant		Seroquel 100mg	PS		ORAL	100MG	
Hospitalization - Initial or Prolonged	Syndrome		Haldol 10mg	SS		INTRAVENOUS	10 MG	PRN
						INTRAVENOU		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/06/05ISR Number: 4710905-XReport Type:Direct Company Report #CTU 252666
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Medication Error		Haloperidol Dec. 100 Mg / Ml	PS				
			Haloperidol Inj 5 Mg/Ml	SS				

Date:07/08/05ISR Number: 4709151-5Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20050607093
Age:54 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Alanine Aminotransferase		Haldol	PS				
OROPHARINGEAL								
	Increased		Haldol	SS				
OROPHARINGEAL								
	Aspartate		Tavor	C				
OROPHARINGEAL								
	Aminotransferase		Tavor	C				
OROPHARINGEAL								
	Increased		Bvk Vitamin	C				
1 Kps = 1								
	Drug Interaction							
Dose								
	Gamma-Glutamyltransferase		Neurocil	I				
OROPHARINGEAL								
	Increased		Neurocil	I				
OROPHARINGEAL								
	Liver Function Test		Neurocil	I				
OROPHARINGEAL								
	Abnormal		Neurocil	I				
OROPHARINGEAL								
			Leponex	I				
OROPHARINGEAL								
			Leponex	I				
OROPHARINGEAL								
			Leponex	I				
OROPHARINGEAL								
			Leponex	I				
OROPHARINGEAL								
			Leponex	I				
OROPHARINGEAL								

			Leponex	I		
OROPHARINGEAL						

Date:07/08/05ISR Number: 4709152-7Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20050607112
Age:52 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Pleurothotonus		Haldol	PS				
OROPHARINGEAL								
Initial or Prolonged			Haldol	SS				
OROPHARINGEAL								
			Haldol	SS				
OROPHARINGEAL								
			Haldol	SS				
OROPHARINGEAL								
			Haldol	SS				
OROPHARINGEAL								
			Melperon	SS				
OROPHARINGEAL								
			Melperon	SS				
OROPHARINGEAL								
			Melperon	SS				
OROPHARINGEAL								
			Solian	SS				
OROPHARINGEAL								
			Haldol	SS				
OROPHARINGEAL								
			Haldol	SS				
OROPHARINGEAL								
			Haldol	SS				
OROPHARINGEAL								

Date:07/08/05ISR Number: 4709852-9Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20050606818
Age:17 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Muscle Spasms		Haldol	PS				
INTRAMUSCULAR								
	Oculogyration		Haldol	SS				
INTRAMUSCULAR								
	Oropharyngeal Spasm		Haldol Decanoate	SS				
INTRAMUSCULAR								
			Risperdal	SS				
OROPHARINGEAL	patient							
received								

between 2 and

4 mg

Risperdal SS

OROPHARINGEAL

			Risperdal	SS		
OROPHARINGEAL						
			Haldol Decanoate	SS		
INTRAMUSCULAR						
			Haldol	SS		
INTRAMUSCULAR						
			Haldol	C		
OROPHARINGEAL	5 to 10mg as					
needed.						
			Haldol	C		
OROPHARINGEAL						
			Tegretal	C		
OROPHARINGEAL						
			Eunerpan	C		
OROPHARINGEAL						
			Akineton	C		
OROPHARINGEAL						

Date:07/08/05ISR Number: 4709854-2Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20050606832
Age:54 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Bradycardia		Haldol	PS				
UNKNOWN								
	Electroencephalogram		Haldol	SS				
UNKNOWN								
	Abnormal		Haldol	SS				
UNKNOWN								
	Fatigue		Zyprexa	SS				
UNKNOWN								
	Head Injury		Haldol	SS				
UNKNOWN								
	Hypotension		Haldol	SS				
UNKNOWN								
	Loss Of Consciousness		Diazepam	C				
UNKNOWN								
	Restlessness		Diazepam	C				
UNKNOWN								
	Syncope							

Date:07/11/05ISR Number: 4710480-XReport Type:Expedited (15-DaCompany Report #BR-JNJFOC-20050701235
Age:3 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Accidental Exposure		Haldol	PS		OROPHARINGEAL		
Initial or Prolonged	Somnolence		Biperiden	SS		OROPHARINGEAL		
	Tremor							

Date:07/12/05ISR Number: 4712052-XReport Type:Expedited (15-DaCompany Report #DE-JNJFOC-20050607353
Age:95 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Cerebrovascular Accident		Haloperidol	PS		OROPHARINGEAL		
	Extrapyramidal Disorder							

Date:07/12/05ISR Number: 4712053-1Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20050700027
Age:68 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardiac Arrest		Haldol	PS		OROPHARINGEAL	dosage reported as 9-20mg	
			Akineton	C		OROPHARINGEAL		
			Carbimazol	C		OROPHARINGEAL		

Date:07/12/05ISR Number: 4712054-3Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20050700390
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Depressed Mood		Haldol	PS		UNKNOWN		
	Psychiatric Symptom							
	Suicide Attempt							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/12/05ISR Number: 4712055-5Report Type:Expedited (15-DaCompany Report #BR-JNJFOC-20050700732
Age:2 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Accidental Exposure		Haldol	PS				
	Convulsion							
	Cyanosis							
	Extrapyramidal Disorder							
	Hypotonia							
	Somnolence							

Date:07/12/05ISR Number: 4712067-1Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20050504944
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Dysphagia		Haldol Decanoat	PS		INTRAMUSCULAR		
Initial or Prolonged	No Adverse Drug Effect							

Date:07/13/05ISR Number: 4713247-1Report Type:Expedited (15-DaCompany Report #PHRM2005FR01362
Age:45 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Macular Degeneration		Tegretol Lp	PS	Novartis Sector: Pharma	ORAL	600 mg, QD	
			Haldol	SS		ORAL	5 mg, QD	

Date:07/13/05ISR Number: 4713379-8Report Type:Expedited (15-DaCompany Report #PHNU2005DE01675
Age:16 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Echocardiogram Abnormal		Leponex / Clozaril (Clozapine)	PS	Novartis Sector: Pharma	ORAL	150 mg/day	77760MIN
	Fatigue							
	Hypertensive Crisis							

	Ventricular Hypertrophy		Risperdal	SS		ORAL 6 mg/day
	Weight Increased		Akineton /Sch/	SS		
			Haldol	SS		
			Tavor	SS		

Date:07/14/05ISR Number: 4714277-6Report Type:Expedited (15-DaCompany Report #JP-JNJFOC-20050607156
Age:55 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blood Creatine		Risperdal	PS		OROPHARINGEAL		
	Phosphokinase Increased		Haloperidol	SS				
	Bradykinesia							
	Parkinsonism							

Date:07/14/05ISR Number: 4714692-0Report Type:Direct Company Report #CTU 253243
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Electrocardiogram Qt Prolonged		Haloperidol 50 Mg /10 Ml	PS		INTRAVENOUS	IV	
	Neuroleptic Malignant Syndrome							
	Torsade De Pointes							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/14/05ISR Number: 4716648-0Report Type:Expedited (15-DaCompany Report #2004106748
Age:29 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abnormal Behaviour	Consumer	Neurontin (Tablets)					
	Aggression		(Gabapentin)	PS			900 MG (300	
Other	Agitation						MG, 3 IN 1 D)	
	Condition Aggravated		Neurontin					
	Delusion		(Gabapentin)	SS			900 MG (300	
	Depression						MG, 3 IN 1 D)	
	Drug Ineffective		Haldol (Haloperidol)	SS				
	Hallucination, Auditory		Risperidone					
	Hallucination, Visual		(Risperidone)	SS			6 MG (3 MG, 2	
	Homicidal Ideation						IN 1 D)	
	Intentional Misuse		Seroquel (Quetiapine					
	Lethargy		Fumarate)	C				
	Multiple Drug Overdose		Metformin					
	Psychotic Disorder		(Metformin)	C				
	Refusal Of Treatment By Patient							
	Somnolence							
	Stress							
	Suicidal Ideation							
	Suicide Attempt							
	Treatment Noncompliance							

Date:07/15/05ISR Number: 4714673-7Report Type:Expedited (15-DaCompany Report #FR-ABBOTT-05P-056-0304958-00
Age:23 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Depressed Level Of		Depakote Tablets	PS		ORAL	7	DAY
	Consciousness		Cyamemazine	I			UNKNOWN	
	Disorientation		Haloperidol	I			UNKNOWN	
	Drug Interaction							

	Hyperammonaemia					

Date:07/15/05ISR Number: 4714959-6Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20050605035
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Foetal Growth Retardation		Haldol Decanoat	PS				
	Foot Deformity							
	Jaundice							
	Premature Baby							

Date:07/15/05ISR Number: 4715034-7Report Type:Expedited (15-DaCompany Report #BR-JNJFOC-20050701235
Age:3 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Accidental Exposure		Haldol	PS		ORAL		
Initial or Prolonged	Somnolence		Biperiden	SS		ORAL		
	Tremor							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/15/05ISR Number: 4715500-4Report Type:Direct Company Report #CTU 253326
Age:88 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Parkinsonism		Haldol	PS				

Date:07/18/05ISR Number: 4716078-1Report Type:Expedited (15-DaCompany Report #FR-JNJFOC-20041202474
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Pemphigoid		Haldol	PS		ORAL		
			Sermion	SS				
			Renitec	SS				
			Trivastal	SS				
			Propofan	SS				
			Propofan	SS				
			Propofan	SS				
			Propofan	SS				
			Propofan	SS				
			Monicor	C				
			Prestole	C				
			Prestole	C				

Date:07/19/05ISR Number: 4716958-7Report Type:Expedited (15-DaCompany Report #2005UW08930
Age:15761 DYGender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Hospitalization - Initial or Prolonged	Delayed Recovery From Anaesthesia		Diprivan	PS	Zeneca Pharmaceutical	INTRAVENOUS	INDUCTION AND MAINTENANCE	8 DAY
			Diprivan	SS	Zeneca Pharmaceutical	INTRAVENOUS	INDUCTION AND MAINTENANCE	8 DAY
			Haldol	SS				8 DAY

			Ativan		SS		
8 DAY							

Date:07/20/05ISR Number: 4724717-4Report Type:Direct Company Report #CTU 253746
Age:23 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product		Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Agitation		Haldol	Unk					
Hospitalization -	Drooling		Unk		PS			5 MG	IM
Initial or Prolonged	Drug Toxicity							Q6H PRN	
Required	Dyskinesia		Zoloft	Unk					
Intervention to	General Physical Health		Unk		SS			50 MG	QD
Prevent Permanent	Deterioration		Risperdal		C				
Impairment/Damage	Grimacing								
	Hand Deformity								
	Mania								
	Masked Facies								
	Mental Impairment								
	Mental Status Changes								
	Musculoskeletal Stiffness								
	Oral Intake Reduced								
	Tongue Biting								

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/21/05ISR Number: 4720657-5Report Type:Expedited (15-DaCompany Report #JP-JNJFOC-20050703584
Age:56 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blood Creatine Phosphokinase Increased		Risperdal	PS		ORAL		
			Risperdal	SS		ORAL		
			Haldol	SS				
INTRAVENOUS								
			Carbamazepine	C				
			Biperiden Hydrochloride	C				
			Levomepromazine Maleate	C				

Date:07/22/05ISR Number: 4722037-5Report Type:Expedited (15-DaCompany Report #GB-ROCHE-408183
Age:65 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Hiccups		Capecitabine	PS	Roche	ORAL		
PATIENT'S TO RECEIVE A 12 WEEK CYCLE, CAPECITABINE GIVEN 5 DAYS								
			Oxaliplatin	SS				
INTRAVENOUS								
			Haloperidol	SS	Roche	ORAL		
4 DAY								

Date:07/22/05ISR Number: 4722535-4Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20050702150
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - UNKNOWN	Grand Mal Convulsion		Haloperidol	PS				
taken when								

Initial or Prolonged	Obstructive Airways					
required						
	Disorder		Clozaril	SS		ORAL
			Olanzapine	SS		
UNKNOWN	dose reduced					
			Olanzapine	SS		
UNKNOWN	nocte					

Date:07/22/05ISR Number: 4725584-5Report Type:Direct Company Report #CTU 254054
Age:47 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Cogwheel Rigidity		Haloperidol	PS		
Initial or Prolonged	Dystonia					

Date:07/22/05ISR Number: 4725745-5Report Type:Direct Company Report #CTU 254005
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Life-Threatening	Fall		Haldol Decanoate			
Hospitalization -	Hyponatraemia		100mg/Ml	PS		
INTRAMUSCULAR MONTHLY						
Initial or Prolonged	Loss Of Consciousness					
INTRAMUSCULAR						
Required	Polydipsia		Zyprexa	C		
Intervention to						
Prevent Permanent						
Impairment/Damage						

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/25/05ISR Number: 4723777-4Report Type:Expedited (15-DaCompany Report #IT-JNJFOC-20050702544
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Pancytopenia		Serenase	PS		ORAL	solution strength	2mg/ml 24 DAY

Date:07/25/05ISR Number: 4723778-6Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20050606818
Age:17 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Muscle Spasms		Haloperidol	PS		ORAL		
	Oculogyration		Haloperidol	SS		ORAL	5-10 mg as needed	
	Oropharyngeal Spasm		Haloperidol	SS		ORAL		
			Haldol Decanoate	SS			INTRAMUSCULAR	concentration : 50 mg/ml
			Risperdal	SS		ORAL		
			Risperdal	SS		ORAL		
			Risperdal	SS		ORAL	patient received between 2 and 4 mg	
			Haldol Decanoate	SS			INTRAMUSCULAR	concentration : 50 mg/ml
			Haloperidol	SS		ORAL		
			Tegretal	C		ORAL		
			Eunerpan	C		ORAL		
			Akineton	C		ORAL		

Date:07/25/05ISR Number: 4723801-9Report Type:Expedited (15-DaCompany Report #PHEH2005US08104
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Anxiety		Trileptal	PS	Novartis Sector: Pharma	ORAL	150 mg, QD	
	Hysterectomy							
	Panic Disorder		Xanax	SS			10 mg, UNK	
	Renal Disorder		Sonata	SS				
	Vomiting		Haldol	SS			10 mg, UNK	
			Serax	SS				
			Lithium	SS				
			Carbamazepine	SS				

Date:07/25/05ISR Number: 4726192-2Report Type:Expedited (15-DaCompany Report #2005BH000697
Age:67 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Acute Respiratory Failure	Foreign	Fentanyl Citrate					
	Blood Bilirubin Increased	Literature	(Fentanyl Citrate)	PS			INTRAVENOUS	IV
	Drug Interaction	Health	Haloperidol					
	Haemoglobin Decreased	Professional	(Haloperidol)	SS			INTRAVENOUS	IV
	Neuroleptic Malignant Syndrome							
	Pneumonia Aspiration							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/26/05ISR Number: 4724211-0Report Type:Expedited (15-DaCompany Report #PHBS2005JP00700
Age:67 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Neuroleptic Malignant Syndrome		Tofranil	PS	Novartis Sector: Pharma	ORAL	150 mg/d	8640 MIN
			Serenace	SS		ORAL	2.25 mg/d	30240MIN
			Serenace	SS			INTRAMUSCULAR	0.5 %, ONCE/SINGLE 1440 MIN
			Serenace	SS			INTRAMUSCULAR	0.5 %, ONCE/SINGLE 1440 MIN
			Anafranil	SS			INTRAVENOUS	50 mg/d 21600MIN
			Depromel	SS		ORAL	75 mg/d	30240MIN
			Anafranil	SS		ORAL	75 mg/d	23040MIN
			Depas	C		ORAL	1.5 mg/d	30240MIN
			Tasmolin	C		ORAL	3 to 6 mg/d	30240MIN
			Ludiomil	C		ORAL	25 mg/d	23040MIN
			Tetramide	C		ORAL	30 mg/d	8640 MIN
			Benzalin	C		ORAL	5 to 10 mg/d	30240MIN
			Vegetamin B	C		ORAL	1 DF to 2 DF/d	11520MIN
			Vegetamin A	C		ORAL	1 DF, QD	5760 MIN
			Kolantyl	C		ORAL	3.0 g/d	14400MIN
			Elieten	C		ORAL	1.5 mg/d	14400MIN
			Alosenn	C		ORAL	1.0 g/d	14400MIN

			Magnesium Oxide	C		ORAL
1.0 g/d	2880 MIN					
			Pursennid	C		ORAL
36 mg/d	10080MIN					
			Kefral	C		ORAL
750 mg/d	5760 MIN					
			Indacin	C		
25 mg PR	1440 MIN					
			Akineton	C		
INTRAMUSCULAR	0.5 %/d	31680MIN				
			Dormicum	C		
INTRAMUSCULAR	10 mg,					
ONCE/SINGLE	1440 MIN					
			Dextrose	C		
500 ml (DR)/d	21600MIN					
			Soldem 3a	C		
500 ml (DR)/d	21600MIN					

Date:07/26/05ISR Number: 4724961-6Report Type:Expedited (15-DaCompany Report #BR-ROCHE-410860
Age:27 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Convulsion		Rivotril	PS	Roche	ORAL		
			Haldol	SS				
UNKNOWN								
			Fenergan	SS				
UNKNOWN								
			Melleril	SS				
UNKNOWN								

Date:07/27/05ISR Number: 4726018-7Report Type:Expedited (15-DaCompany Report #JP-JNJFOC-20050704140
Age:66 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Arrhythmia		Risperdal	PS		ORAL		
	Cerebral Infarction		Risperdal	SS		ORAL		
			Haldol	SS				
			Levomepromazine Maleate	C		ORAL	5-25 mg per day	
			Flunitrazepam	C		ORAL		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/27/05ISR Number: 4727535-6Report Type:Direct Company Report #CTU 254519
Age:45 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Hypotension		Haloperidol 5mg	PS		INTRAMUSCULAR	5MG ONCE	
Initial or Prolonged	Hypoxia					INTRAMUSCULAR		
	Lethargy							
	Oxygen Saturation Decreased							
	Poisoning							

Date:07/28/05ISR Number: 4727103-6Report Type:Expedited (15-DaCompany Report #BR-JNJFOC-20050705156
Age:28 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Drug Interaction		Haldol	PS		ORAL	patient took	
Initial or Prolonged	Miosis						30 tablets at	
	Overdose						once	
	Suicide Attempt		Biperiden	SS			patient took	
							30 tablets at	
							once	
			Clonazepam	SS			patient took	
							30 tablets at	
							once	

Date:07/29/05ISR Number: 4728243-8Report Type:Expedited (15-DaCompany Report #JP-SOLVAY-00305000085
Age:24726 DYGender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Hospitalization - Initial or Prolonged Disability	Neuroleptic Malignant Syndrome	Depromel 25 75 milligram(s) 21 DAY Daily dose: 2.25 milligram(s) 21 DAY INTRAMUSCULAR Daily dose: 1 millilitre(s) 1 DAY INTRAMUSCULAR Daily dose: 1 millilitre(s) 1 DAY Daily dose: 150 milligram(s) 6 DAY Daily dose: 1.5 milligram(s) 21 DAY Daily dose: 3 milligram(s) 14 DAY Daily dose: 6 milligram(s) 7 DAY Daily dose: 75 milligram(s) 16 DAY UNKNOWN Daily dose: 50 milligram(s)	PS	ORAL
		Serenace Daily dose: 2.25 milligram(s) 21 DAY	SS	ORAL
		Serenace	SS	
		Serenace	SS	
		Tofranil Daily dose: 150 milligram(s) 6 DAY	C	ORAL
		Depas Daily dose: 1.5 milligram(s) 21 DAY	C	ORAL
		Tasmolin Daily dose: 3 milligram(s) 14 DAY	C	ORAL
		Tasmolin Daily dose: 6 milligram(s) 7 DAY	C	ORAL
		Anafranil Daily dose: 75 milligram(s) 16 DAY	C	ORAL
		Anafranil UNKNOWN Daily dose: 50 milligram(s)	C	

/ 2 ml

injection/dri 15 DAY

Ludiomil C ORAL

Daily dose:

25

milligram(s) 16 DAY

			Tetramide	C	ORAL
Daily dose: 30					
milligram(s)	6	DAY			
			Benzalin	C	ORAL
Daily dose: 5					
milligram(s)	14	DAY			
			Benzalin	C	ORAL
Daily dose: 10					
milligram(s)	7	DAY			
			Vegetamin-B	C	ORAL
Daily dose: 1					
dosage form	5	DAY			
			Vegetamin-B	C	ORAL
Daily dose: 2					
dosage form	3	DAY			
			Vegetamin-A	C	ORAL
Daily dose: 1					
dosage form	4	DAY			
			Kolantyl	C	ORAL
Daily dose: 9					
gram(s)	10	DAY			
			Elieten	C	ORAL
Daily dose: 4.5					
milligram(s)	10	DAY			
			Alosenn	C	ORAL
Daily dose: 1					
gram(s)	10	DAY			
			Heavy Magnesium Oxide	C	ORAL
Daily dose: 1					
gram(s)	2	DAY			

Daily dose: 3 dosage form 7 DAY Daily dose: 750 milligram(s) 4 DAY RECTAL Daily dose: 25 milligram(s) 1 DAY INTRAMUSCULAR Daily dose: 1 millilitre(s) 1 DAY INTRAMUSCULAR Daily dose: 1 millilitre(s) 1 DAY INTRAMUSCULAR Daily dose: 10 milligram(s) injection/dri p infusion 1 DAY UNKNOWN Daily dose: 500 millilitre(s) injection/dri p infusion 15 DAY UNKNOWN Daily dose: 500 millilitre(s) injection/dri	Pursennid Kefral Indacin Akineton Akineton Dormicum Urokinase Soldem 3 A	C C C C C C C C	ORAL ORAL

p infusion 15 DAY

Date:07/29/05ISR Number: 4733690-4Report Type:Expedited (15-DaCompany Report #MAG-2005-0000379
Age:79 YR Gender:Male I/FU:F

Outcome	PT	Report Source
Death	Hepatic Atrophy	Foreign
	Hepatic Failure	Study
		Health
		Professional

Other

Product	Role	Manufacturer	Route	Dose	Duration
Oxycodone Hcl Controlled Release Tablets (Oxycodone Hydrochloride) Cr Tablet	PS		ORAL	SEE IMAGE	
Oxycodone Hydrochloride (Oxycodone Hydrochloride) Other	SS		ORAL	5 MG, QD PRN,	ORAL
Pursennid (Senna Leaf)	SS		ORAL	180 MG,	DAILY, ORAL
Loxonin (Loxoprofen Sodium)	SS		ORAL	180 MG,	DAILY, ORAL
Serenace (Haloperidol)	SS		ORAL	0.75 MG,	DAILY, ORAL
Bayaspirin (Acetylsalicylic Acid)	SS		ORAL	100 MG,	DAILY, ORAL
Blopress (Candesartan Cilexetil)	SS		ORAL	8 MG, DAILY,	ORAL
Zyloric "Glaxo Wellcome"					

(Allopurinol)	SS	Glaxo Wellcome	ORAL	100 MG, DAILY, ORAL
Rythmodan (Disopyramide)	SS		ORAL	300 MG, DAILY, ORAL
Tofranil (Imipramine Hydrochloride)	SS		ORAL	10 MG, DAILY, ORAL
Takepron (Lansoprazole)	SS		ORAL	15 MG, DAILY, ORAL
Magnesium Oxide (Magnesium Oxide)	C			
Vitamedine Capsule (Benfotiamine, Cyanocobalamin, Pyridoxine Hydrochloride)	C			
Fentanyl (Fentanyl)	C			
Cravit (Levofloxacin)	C			
Soldem 3a (Sodium Lactate, Potassium Chloride, Sodium Chloride, Carbohydrates Nos)	C			
Vitamedin Intravenous (Cyanocobalamin,				

Thiamine Disulfide,	
Pyridoxine	C
Glucose (Glucose)	C
Physio 35	C

Date:08/01/05ISR Number: 4730315-9Report Type:Expedited (15-DaCompany Report #FR-JNJFOC-20050703435
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Agitation		Haldol Decanoas	PS		INTRAVENOUS	dose given	
Initial or Prolonged	Incorrect Route Of Drug Administration					intravenously		
rather than	Medication Error					intramuscular		
ly	Psychotic Disorder							

Date:08/01/05ISR Number: 4730316-0Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20050705510
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Diarrhoea		Haldol Decanoate	PS		TRANSPLACENTAL		
Initial or Prolonged	Dyskinesia							
	Irritability							
	Metabolic Acidosis							

Date:08/01/05ISR Number: 4733349-3Report Type:Direct Company Report #CTU 255039
Age:78 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Body Temperature Increased		Haloperidol 5mg/Ml App	PS	App	INTRAVENOUS	2; 4 MG IV	
	Dyspnoea		Succinyl Choline					

	Neuroleptic Malignant		20mg / Ml Abbott	SS	Abbott	
INTRAVENOUS 40 MG IV	Syndrome					

Date:08/01/05ISR Number: 4733456-5Report Type:Direct Company Report #CTU 255094
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Required	Dystonia		Haloperidol 10mg Iv	PS		
INTRAVENOUS						
Intervention to Prevent Permanent Impairment/Damage	Extrapyramidal Disorder					

Date:08/02/05ISR Number: 4731648-2Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20050704690
Age:63 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Eosinophilia		Haldol	PS		ORAL
3 DAY						
			Trimipramin	SS		ORAL
			Lorazepam	C		ORAL
			Zyprexa	C		ORAL
			Solian	C		ORAL

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/02/05ISR Number: 4731649-4Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20050704703
Age:41 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blood Creatine		Haldol	PS				
	Phosphokinase Increased					INTRAMUSCULAR	given once	

Date:08/03/05ISR Number: 4734750-4Report Type:Direct Company Report #CTU 255295
Age:78 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Palpitations		Haldol	PS				

Date:08/04/05ISR Number: 4734710-3Report Type:Expedited (15-DaCompany Report #BR-JNJFOC-20050800223
Age:31 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Miosis		Haldol	PS		ORAL		
	Respiratory Depression		Midazolam	SS				
	Salivary Hypersecretion		Diazepam	SS				
	Suicide Attempt							

Date:08/04/05ISR Number: 4734712-7Report Type:Expedited (15-DaCompany Report #BR-JNJFOC-20050705156
Age:28 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Miosis		Haldol	PS		ORAL		
patient took								
Initial or Prolonged	Overdose							
30 tablets at								
	Suicide Attempt							
once								
			Biperiden	SS				
patient took								
30 tablets at								

once

Clonazepam SS

patient took

30 tablets at

once

Date:08/05/05ISR Number: 4735787-1Report Type:Expedited (15-DaCompany Report #FR-JNJFOC-20050504041
Age:12 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Abnormal Behaviour		Haldol Decanoas	PS		INTRAMUSCULAR		1 DAY
Initial or Prolonged	Anger							
	Anxiety							
	Coma							
	Disturbance In Attention							
	Extrapyramidal Disorder							
	Morbid Thoughts							
	Off Label Use							

Date:08/09/05ISR Number: 4738327-6Report Type:Expedited (15-DaCompany Report #JP-JNJFOC-20050704140
Age:66 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Arrhythmia		Risperdal	PS		ORAL		
Life-Threatening	Cerebral Infarction		Risperdal	SS		ORAL		
			Haldol	SS				
			Levomepromazine					

			Maleate	C		ORAL
5-25 mg per day						
			Flunitrazepam	C		ORAL

Date:08/09/05ISR Number: 4738471-3Report Type:Expedited (15-DaCompany Report #BR-JNJFOC-20050800229
Age:33 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Nausea		Haldol	PS		ORAL		
	Somnolence		Clonazepam	SS				
	Suicide Attempt		Fenitoina	SS				

Date:08/09/05ISR Number: 4738472-5Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20050800305
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Aggression		Haldol	PS		INTRAMUSCULAR		
	Agitation		Sinemet	C				
	Hypersomnia		Sinemet	C				
	Stupor							

Date:08/09/05ISR Number: 4738473-7Report Type:Expedited (15-DaCompany Report #BR-JNJFOC-20050800796
Age:5 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Accidental Exposure		Haldol	PS		ORAL		
	Agitation							
	Tremor							

Date:08/10/05ISR Number: 4740735-4Report Type:Expedited (15-DaCompany Report #JP-JNJFOC-20050600327
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Death	Encephalopathy	Risperdal	PS	ORAL
	Prostration	Risperdal	SS	ORAL
	Restlessness	Haloperidol	SS	
10 mg daily				
	Ventricular Fibrillation	Haloperidol	SS	
		Haloperidol	SS	
INTRAMUSCULAR 30 mg daily				
		Haloperidol	SS	
INTRAMUSCULAR				
		Lorazepam	C	ORAL
		Biperiden Hydrochloride	C	ORAL
		Itopride Hydrochloride	C	ORAL
		Magnesium Oxide	C	ORAL
		Mianserin Hydrochloride	C	ORAL
		Nitrazepam	C	ORAL
		Flunitrazepam	C	ORAL
		Zopiclone	C	ORAL

Date:08/11/05ISR Number: 4742689-3Report Type:Expedited (15-DaCompany Report #BR-JNJFOC-20050802324
Age:50 YR Gender:Female I/FU:I

Outcome
Life-Threatening
Hospitalization -

Initial or Prolonged

	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Coma		Haldol	PS		ORAL		
	Overdose		Chlorpromazine	SS		ORAL		
	Respiratory Depression		Clonazepam	SS		ORAL		
	Suicide Attempt		Sertraline	SS		ORAL		
			Levopromazine	SS		ORAL		
			Captopril	C				

Date:08/16/05ISR Number: 4746063-5Report Type:Expedited (15-DaCompany Report #FR-JNJFOC-20050801515
Age:54 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Leukocytoclastic		Haldol	PS		ORAL	dose= drops	
Initial or Prolonged	Vasculitis		Depakote	SS		ORAL	Dose=tablet	
			Depakote	SS		ORAL		
			Loxapac	SS		ORAL		
			Seloken	C				For 15 years
			Inexium	C				For several years
			Metformine	C				For 3 years
			Movicol	C				
			Movicol	C				
			Movicol	C				
			Movicol	C				

Date:08/19/05ISR Number: 4748541-1Report Type:Expedited (15-DaCompany Report #DE-BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.-2005-
DAge:70 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Depressed Level Of Consciousness		Clonidine	PS	B.I. Pharmaceuticals,Inc.			

		Drug Ineffective			/Ridgefield	
INTRATHECAL						
		Hypoaesthesia	Morphine	SS	Roxane Laboratories,	
		Myoclonus			Inc.	
INTRATHECAL						
		Paresis	Morphine	SS	Roxane Laboratories,	
		Spinal Cord Injury			Inc.	
EPIDURAL	40 - 60 mg					
		Urinary Incontinence	Morphine	SS	Roxane Laboratories,	
					Inc.	
SUBCUTANEOUS	up to 60 mg					
			Bromazepam	SS		ORAL
			Doxepin	SS		ORAL
			Carbamazepine	SS		ORAL
			Distraneurin	SS		ORAL
			Haloperidol	SS		ORAL
			Hydromorphone	C		ORAL
			Metamizole	C		ORAL
			Diclofenac	C		ORAL

Date:08/19/05ISR Number: 4749031-2Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20050802556
Age:44 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Death	Myocardial Infarction		Haldol	PS		
	Sudden Death					

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Summary report for FOI selections:

Selection by inexact search of active ingredient: HALOPERIDOL%

Selection by inexact search of Tradename/Verbatim: HALDOL%

Total number of reports: 3,534

From: 01-NOV-1997 To: Present