FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/06/97ISR Number: 3005557-3Report Type:Direct Company Report #
Age:22 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	Health	Metoclopramide	PS			10 MG 1VP	X1
		Professional	Bicitra	C				
			Midazolam	C				

Date:11/07/97ISR Number: 3026657-8Report Type:Periodic Company Report #01780
Age:32 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dermatitis	Health	Metoclopramide	PS	Purepac	ORAL	1 TAB.	BID PO
	Hypersensitivity	Professional						
	Pruritus							

Date:11/19/97ISR Number: 3001719-XReport Type:Expedited (15-DaCompany Report #8-97233-002S
Age:36 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Aggression	Health	Reglan	PS		INTRAVENOUS	10 MG EVERY 6	HOURS IV
	Agitation	Professional						
	Alcohol Withdrawal		Demerol	SS		INTRAVENOUS	UP TO 200 MG	DAILY IV
	Syndrome							
	Confusional State		Antibiotic(S)	C		IV		
	Disorientation		Ativan	C				
	Hallucination		Valium	C				
	Psychotic Disorder							

Date:11/20/97ISR Number: 3005968-6Report Type:Direct Company Report #
Age:19 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - (PRIOR TO	Diarrhoea		Cipro	PS				
Initial or Prolonged ADMISSION	Hypovolaemia							
	Irritability							
EXACT DATES	Movement Disorder							
UNKNOWN)	Restlessness		Reglan	SS			10 MG IVP X 1	
DOSE								

Date:11/26/97ISR Number: 3002779-2Report Type:Expedited (15-DaCompany Report #8-97323-004D
Age:56 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Convulsions Local	Foreign	Parkinane	PS		ORAL	10MG DAILY	
Initial or Prolonged	Extrapyramidal Disorder	Health				ORAL		
Other	Urinary Retention	Professional	Metoclopramide	SS		ORAL	30MG DAILY	
						ORAL		
			Sertraline	SS		ORAL	50MG DAILY	
						ORAL		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/03/97ISR Number: 3004068-9Report Type:Expedited (15-DaCompany Report #8-97328-013S
Age:27 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Agranulocytosis	Foreign	Metoclopramide Hcl	PS		INTRAVENOUS	100 MG IV	
Initial or Prolonged	Pyrexia	Health	Carbamazepine	SS			400 MG/D	
	White Blood Cell Count	Professional	Fluconazole	SS			200 MG/D	
	Increased		Ketoprofen	SS		INTRAVENOUS	100 MG TWICE	A DAY
						INTRAVENOUS		
			Mianserin Hydrochloride	SS			30 MG	
			Vancomycin Hydrochloride	SS		INTRAVENOUS	125 MG IV	
			Bromazepam	C				
			Buflonedil Hydrochloride	C				
			Carbamazepine	C				
			Ciprofloxacin	C				
			Fluconazole	C				
			Fluoxetine	C				
			Hydroxyzine Hydrochloride	C				
			Ketoprofen	C		INTRAVENOUS		
			Mainserin Hydrochloride	C				
			Morphine	C				
			Nadroparin Calcium	C				
			Omeprazole	C				
			Piperacillin Sodium + Tazobactam Sodium	C				
			Propacetamol Hydrochloride	C				
			Tetrazepam	C				
			Vancomycin Hydrochloride	C		INTRAVENOUS		

			Zopiclone	C		

Date:12/03/97ISR Number: 3004108-7Report Type:Expedited (15-DaCompany Report #8-97321-010S
Age:27 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Hospitalization - Initial or Prolonged	Agranulocytosis	Foreign	Ketoprofen	PS		INTRAVENOUS 100 MG TWICE A DAY
	Leukocytosis	Health Professional				
	Neutrophil Count Increased		Carbamazepine	SS		INTRAVENOUS 400 MG/D
	Pyrexia		Fluconazole	SS		INTRAVENOUS 200 MG/D
			Metoclopramide	SS		INTRAVENOUS 100 MG IV
			Mianserin Hydrochloride	SS		30 MG
			Vancomycin Hydrochloride	SS		
			Bromazepam	C		
			Buflonedil Hydrochloride	C		
			Carbamazepine	C		
			Fluconazole	C		
			Fluoxetine	C		
			Hydroxyzine Hydrochloride	C		
			Metoclopramide	C		

Mianserin Hydrochloride	C
Morphine	C
Nadroparin Calcium	C
Omeprazole	C
Piperacillin Sodium + Tazobactrim Sodium	C
Ciprofloxacin	C
Propacetamol Hydrochloride	C
Tetrazepam	C
Vancomycin Hydrochloride	C
Zopiclone	C

Date:12/04/97ISR Number: 3033202-XReport Type:Periodic Company Report #96-210035
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Trismus	Health	Metoclopramide Hcl	PS	Faulding Pr	INTRAVENOUS	5MG IV	
		Professional	Ganciclovir	C				
			Compazine	C				
			Benadryl	C				

Date:12/05/97ISR Number: 3004379-7Report Type:Expedited (15-DaCompany Report #8-97325-005S
Age:56 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Convulsion	Foreign	Reglan	PS		ORAL	30 MG DAILY	
Other	Drug Interaction	Health						
	Extrapyramidal Disorder	Professional	Sertraline	SS				
	Urinary Retention		Trihexyphenidy	SS				
			Sertraline	C				
			Trihexyphenidyl	C				

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agranulocytosis Pyrexia	Foreign Health Professional	Vancomycin Hydrochloride	PS	Esi Lederle	INTRAVENOUS	125	
			Carbamazepine	SS		INTRAVENOUS	400 MG/D	
			Fluconazole	SS		INTRAVENOUS	200 MG/D	
			Ketoprofen	SS		INTRAVENOUS	100 MG TWICE	A DAY
			Metoclopramide	SS		INTRAVENOUS	100 MG IV	
			Mianserin Hydrochloride	SS			30 MG	
			Bromazepam	C				
			Buflonedil Hydrochloride	C				
			Carbamazepine	C				
			Ciprofloxacin	C				
			Fluconazole	C				
			Fluoxetine	C				
			Hydroxyzine					

Hydrochloride	C
Ketoprofen	C
Metoclopramide	C
Mianserin Hydrochloride	C
Morphine	C
Nadroparin Calcium	C
Omeprazole	C
Piperacillin Sodium + Tazobactam Sodium	C
Propacetamol Hydrochloride	C
Tetrazepam	C
Zopiclone	C

Date:12/09/97ISR Number: 3004867-3Report Type:Expedited (15-DaCompany Report #8-97330-005S
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Dystonia	Health Professional	Reglan	PS				

Date:12/09/97ISR Number: 3006105-4Report Type:Expedited (15-DaCompany Report #8-97328-012S
Age:27 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agranulocytosis	Foreign	.Vancomycin					
	Pyrexia	Health Professional	Hydrochlordie	PS		INTRAVENOUS	125MG	
			Carbamazepine	SS			400MG/D	
			Fluconazole	SS			200 MG/D	
			Ketoprofen	SS		INTRAVENOUS	100MG TWICE A	DAY
			Metoclopramide	SS		INTRAVENOUS	100MG IV	
			Mianserin Hydrochloride	SS			30MG	

	Bromazepam	C
	Buflonedil Hydrochloride	C
	Carbamazepine	C
400MG DAILY		
	Ciprofloxacin	C
	Fluconazole	C
200MG DAILY		
	Fluoxetine	C
	Hydroxyzine Hydrochlordie	C
	Ketoprofen	C
INTRAVENOUS 100 MF 2X/D		
	Metoclopramide	C
	Morphine	C
	Nadroparin Calcium	C
	Omeprazole	C
	Piperacillin Sodium + Tazobactam Sodium	C
	Propacetamol Hydrochloride	C
	Tetrazepam	C
	Zopiclone	C

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/10/97ISR Number: 3006348-XReport Type:Expedited (15-DaCompany Report #D0001624
Age:49 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Bradycardia	Foreign	Tracrium	PS				
	Cardiac Arrest		Propofol	SS				
	Hypertonia		Thiopentone Sodium	SS				
	Hypotonia		Ketanest	SS				
			Alfentanil Hydrochloride	SS				
			Dimethindene Maleate	SS				
			Zantac	SS				
			Euphyllin	SS				
							200 MG SINGLE	DOSE
			Metoclopramide Hcl	SS			10MG/SINGLE	DOSE
			Akrinor	SS				

Date:12/10/97ISR Number: 3006422-8Report Type:Expedited (15-DaCompany Report #D0001623
Age:73 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Bradycardia	Foreign	Tracrium	PS			UNK/ UNK	
Other	Cardiac Arrest		Zantac	SS			4MG/ UNK /	UNK
			Metoclopramide Hcl	SS			20MG/ UNK /	UNK
			Dimethindene Maleate	SS	50mg / Unk/ Unk		UNK	
			Euphyllin	SS			200MG / UNK/	UNK

			Propofol	SS		
5MG / UNK/						
UNK						
			Thiopentone Sodium	SS		
125MG / UNK/						
UNK						
			Ketanest	SS		
20MG /UNK/						
UNK						
			Alfentanil	SS		
.5 MG / FOUR						
TIMES PER DAY						

Date:12/10/97ISR Number: 3006517-9Report Type:Expedited (15-DaCompany Report #D0001623
Age:73 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Bradycardia	Foreign	Tracrium	PS			UNK/UNK	
Other	Cardiac Arrest		Zantac	SS			UNK/UNK	
			Metoclopramide Hcl	SS			20MG/UNK/UNK	
			Dimethindene Maleate	SS			50MG/UNK/UNK	
			Euphyllin	SS			200MG/UNK/UNK	
			Propofol	SS			5MG/UNK/UNK	
			Thiopentone Sodium	SS			125MG/UNK/UNK	
			Ketanest	SS			20MG/UNK/UNK	
			Alfentanil Hydrochloride	SS			5MG/FOUR	
							TIMES PER DAY	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/15/97ISR Number: 3008703-0Report Type:Expedited (15-DaCompany Report #D0001626
Age:70 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardiac Arrest	Foreign	Tracrium	PS				
	Ventricular Fibrillation		Zantac	SS				
			Metoclopramide Hcl	SS				
			Dimethindene Maleate	SS				
			Atropine	SS				
			Thiopentone Sodium	SS				
			Ketamine Hydrochloride	SS				
			Alfentanil Hydrochloride	SS				
			Propofol Infusion	SS				

Date:12/15/97ISR Number: 3008804-7Report Type:Expedited (15-DaCompany Report #B034683
Age:57 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Anxiety	Foreign	Taxol	PS				
	Coordination Abnormal	Health	Epirubicin	SS				
	Dizziness	Professional	Metoclopramide	SS		ORAL	40 MG PO	3 DAY
	Gait Disturbance		Dexamethasone	C				
	Paraesthesia		Cimetidine	C				
			Chlorpheniramine	C				
			Cytadren	C				
			Hydrocortasone	C				
			Megace	C				

Date:12/16/97ISR Number: 3007601-6Report Type:Expedited (15-DaCompany Report #049-0581-973003
Age:73 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Bradycardia	Foreign	Ketanest	PS			INTRAVENOUS	100 MG IV
	Cardiac Arrest	Health	Paspertin	SS			INTRAVENOUS	20 MG
	Coronary Artery Disease	Professional	Ranitidine	SS			INTRAVENOUS	4 MG, IV
	Haemorrhage		Fenistil	SS			INTRAVENOUS	50 MG, IV
	Hypoxia		Euphyllin	SS			INTRAVENOUS	200 MG, IV
	Oedema		Disoprivan	SS			INTRAVENOUS	SEE TEXT, IV
	Pleural Effusion		Trapanal	SS			INTRAVENOUS	225 MG, IV
	Pulmonary Oedema		Tracrium	SS			INTRAVENOUS	UNK. IV
			Rapifen	SS			INTRAVENOUS	2 MG, IV

Date:12/16/97ISR Number: 3007603-XReport Type:Expedited (15-DaCompany Report #049-0581-973002
Age:49 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Bradycardia	Foreign	Ketamine	PS			INTRAVENOUS	70 MG, IV
Life-Threatening	Cardiac Arrest	Health	Fenistil	SS			INTRAVENOUS	ONE AMPULE
	Hypertension	Professional	Sostril	SS			INTRAVENOUS	ONE AMPULE, IV
	Hypotension							
			Paspertin	SS			INTRAVENOUS	10 MG, IV
			Disoprivan	SS			INTRAVENOUS	GREATER THAN 100 MG, IV
			Trapanal	SS			INTRAVENOUS	600 MG, IV
			Tracrium	SS			INTRAVENOUS	105 MG, IV
			Rapifen	SS			INTRAVENOUS	3 MG, IV

Euphyllin SS

INTRAVENOUS 300 MG, IV

			Akrinor	SS		
INTRAVENOUS	UNK. IV					

Date:12/16/97ISR Number: 3007605-3Report Type:Expedited (15-DaCompany Report #049-0581-973001
Age:70 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Death	Cardiac Arrest	Foreign	Ketamine	PS		
INTRAVENOUS	50 MG,					
Life-Threatening	Hypertension	Health	Paspertin	SS		
INTRAVENOUS	10 MG					
	Ventricular Fibrillation	Professional	Fenistil	SS		
INTRAVENOUS	1 AMPOULE,					
			Zantic	SS		
INTRAVENOUS	50 MG					
			Atropin	SS		
INTRAVENOUS	3.5 UNKNOWN 1 DAY					
			Trapanal	SS		
INTRAVENOUS	500 MG					
			Tracrium	SS		
INTRAVENOUS	75 MG					
			Disoprivan	SS		
INTRAVENOUS	40-50 MG PER					
HOUR						

Date:12/16/97ISR Number: 3008070-2Report Type:Expedited (15-DaCompany Report #JAGER-36656
Age:70 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Death	Cardiac Arrest	Foreign	Rapifen	PS		
INTRAVENOUS	2.5 MG					
Life-Threatening	Ventricular Fibrillation					
INTRAVENOUS						
			Paspertin	SS		
INTRAVENOUS	20 MG					
INTRAVENOUS						
			Rapifen	SS		
UNKNOWN	0.5 MG FIVE					

TIMES UNKNOWN					
INTRAVENOUS	4 MG SINGLE		Fenistil	SS	
IV					
10 MG TWO			Paspertin	SS	
TIMES					
INTRAVENOUS	50 MG SINGLE		Zantic	SS	
IV					
INTRAVENOUS	0.5 MG SINGLE		Atropine	SS	
IV					
INTRAVENOUS	500 MG IV 4		Trapanal	SS	
DOSES OF 125					
MG					
INTRAVENOUS	50 MG IV		Ketanest	SS	
INTRAVENOUS	75 MG IV 3		Tracrium	SS	
DOSES					
UNKNOWN	40-50 ML		Disoprivan	SS	
UNKNOWN					

Date:12/22/97ISR Number: 3012198-0Report Type:Expedited (15-DaCompany Report #FR01-08939
Age:80 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Amnesia	Foreign	Calsyn	PS		IM		
Initial or Prolonged	Coma	Health	Primperan	SS		IM		
	Drug Interaction	Professional						
	Loss Of Consciousness							
	Malaise							
	Miosis							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/23/97ISR Number: 3011990-6Report Type:Expedited (15-DaCompany Report #JAGER-36665
Age:73 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Bradycardia	Foreign	Rapifen	PS	Janssen	INTRAVENOUS	2 MG TOTAL	
Life-Threatening	Cardiac Arrest					INTRAVENOUS		
	Cardiac Failure		Paspertin	SS		INTRAVENOUS	20 MG SINGLE	
	Peritoneal Haemorrhage					INTRAVENOUS		
	Poor Peripheral Circulation		Ranitidin	SS		4 MG SINGLE	DOSE	
	Pulmonary Oedema		Fenistil	SS		50 MG SINGLE	DOSE	
			Euphyllin	SS		200 MG SINGLE	DOSE	
			Disoprivan	SS		5 MG SINGLE	DOSE; 30 ML/HR	
			Trapanal	SS		225 MG TOTAL	(3 DOSE: 1X125MG AND 2X50MG)	
			Ketanest	SS		100 MG TOTAL	(3 DOSE: 1X20 MG, 1X30 MG AND 1X50 MG)	

			Tracrium	SS		

50 MG TOTAL

(3 DOSE: 1X30

MG AND 2X10

MG)

Date:12/29/97ISR Number: 3014162-4Report Type:Expedited (15-DaCompany Report #9727383
Age:39 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Akathisia	Foreign	Norvasc	PS		ORAL	5.00 MG	TOTAL:DAILY:O
	Excitability	Health Professional						
	Hallucination, Auditory							
	Nausea	Other	Acyclovir	SS		ORAL	400.00 MG	TOTAL:BID:ORAL
			Ciprofloxacin	SS		ORAL	500.00 MG	TOTAL:BID:ORAL
			Metoclopramid	SS		INTRAVENOUS	10.00 MG	TOTAL:DAILY:I
			Ranitidin	C		NTRAVENOUS		
			Enalaprilat	C				
			Diazepam	C				
			Phenytoin	C				
			Metoprolol	C				

Date:12/29/97ISR Number: 3014855-9Report Type:Expedited (15-DaCompany Report #8-97343-007H
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Hospitalization - 10MG EVERY 6	Extrapyramidal Disorder	Health	Reglan	PS
Initial or Prolonged HOURS IV	Facial Palsy	Professional		
Other	Headache Lethargy			

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/01/98ISR Number: 3084585-6Report Type:Direct Company Report #
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Ineffective		Reglan	PS				
			Zantac	SS				

Date:01/05/98ISR Number: 3014450-1Report Type:Expedited (15-DaCompany Report #19971200165
Age:65 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Blood Creatinine	Foreign	Prilosec	PS			20 MG QD PO	
Initial or Prolonged	Increased	Health	Primperan	SS				
	Dehydration	Professional	Theralene	C				
	Renal Failure Acute		Zerit	C				
			Epivir	C				
			Crixivan	C				
			Gaviscon	C		ORAL		

Date:01/09/98ISR Number: 3015810-5Report Type:Expedited (15-DaCompany Report #8-97181-003S
Age: Gender: I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Apnoea	Health	Reglan	PS			1 DOSE	
	Dystonia	Professional						

Date:01/13/98ISR Number: 3015126-7Report Type:Expedited (15-DaCompany Report #8-97363-003L
Age:19 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Akathisia	Foreign	Metoclopramide Hcl	PS			INTRAVENOUS	20 MG EVERY 6
	Discomfort	Literature					HOURS IV	10 DAY
	Dysarthria							

	Dyskinesia					
	Insomnia					
	Irritability					
	Muscle Rigidity					
	Parkinsonism					
	Restlessness					
	Suicide Attempt					

Date:01/13/98ISR Number: 3015666-0Report Type:Expedited (15-DaCompany Report #74253
Age:41 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Blister	Foreign	Dormicum	PS				
Hospitalization -	Cough	Health	Paspertin	SS		ORAL		
ORAL								
Initial or Prolonged	Diarrhoea	Professional	Morphin	C				
	Genital Rash		Diprivan	C				
	Nausea		Haldol	C				
	Oral Mucosal Eruption		Clexane	C				
	Pneumonia		Zinacef	C				
	Toxic Epidermal		Prednisolone	C				
	Necrolysis		Tavegil	C				
			Ibuprofen	C				
			Maaloxan	C				
			Dorithricin	C				
			Treupel	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/14/98ISR Number: 3015663-5Report Type:Expedited (15-DaCompany Report #FR01-08989
Age:54 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Alanine Aminotransferase	Foreign	Calsyn	PS		INTRAMUSCULAR	IM	
Initial or Prolonged	Increased	Health	Primperan	SS				
	Aspartate	Professional	Anafranil	SS				
	Aminotransferase		Novazam	SS				
	Increased		Zocor	SS				
	Biliary Colic		Becotide	SS				
	Blood Alkaline		Levothyrox	SS				
	Phosphatase Increased		Co-Renitec	SS				
	Blood Bilirubin Increased		Diosmine	C				
	Blood Bilirubin		Beconase	C				
	Unconjugated Increased		Transipeg	C				
	Hepatitis							
	Jaundice							

Date:01/15/98ISR Number: 3016793-4Report Type:Expedited (15-DaCompany Report #DAINJ-37021
Age:40 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Anaphylactic Reaction	Foreign	Loperamide	PS	Janssen	ORAL	3 MG DAILY	
Initial or Prolonged	Dermatitis	Health						ORAL
	Flushing	Professional	Scopolamine	SS		ORAL	60 MG DAILY	
		Other						ORAL
			Ulcermin	SS		ORAL	3 MG DAILY	
								ORAL
			Metoclopramide	SS		ORAL	1.5 MG DAILY	
								ORAL

Date:01/21/98ISR Number: 3017632-8Report Type:Expedited (15-DaCompany Report #FR01-08989
Age:54 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Alanine Aminotransferase	Foreign	Calsyn	PS	Rpr Specia			
INTRAMUSCULAR	/IM							
Initial or Prolonged	Increased	Health	Primperan	SS				
	Aspartate	Professional	Anafranil	SS				
	Aminotransferase		Novazam	SS				
	Increased		Zocor	SS				
	Biliary Colic		Becotide	SS				
	Blood Alkaline		Levothyrox	SS				
	Phosphatase Increased		Co-Renitec	SS				
	Blood Bilirubin Increased		Diosmine	C				
	Blood Bilirubin		Beconase	C				
	Unconjugated Increased		Transipeg	C				
	Cholelithiasis							
	Hepatitis							
	Jaundice							

Date:01/22/98ISR Number: 3018241-7Report Type:Direct Company Report #
Age:20 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Ineffective		Loovral	PS	Wyeth Lab Pharm Pak	ORAL		
4 TABS STAT								
PO AND 4								
TABS IN 12								
HRS								
			Metoclopramide	SS	Biocraftt Lab Pharm			

					Pak	ORAL

1 TAB PO 1/2

HR BEFORE

OTHER RX

Date:01/22/98ISR Number: 3018243-0Report Type:Direct Company Report #
Age:28 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Drug Ineffective		Lo Ovral	PS	Wyeth Lab Pharm Pak	ORAL

4 TAB PO NOW

,THEN 4 TABS

IN 12 HRS

Metoclopramide	SS	Biocraft Lab Pharm Pak	
Prozac	C		

Date:01/22/98ISR Number: 3018699-3Report Type:Direct Company Report #
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Aphasia	Health	Reglan	PS		

INTRAVENOUS 20 MG X2 IV,

	Dyspnoea	Professional		
10MG X1 IV				
	Facial Palsy		Heparin Sodium	C
	Tongue Disorder		Cimetidine	C
	Tremor		Catapres	C
			Zofran	C
			Droperidol	C
			Compazine	C
			Lisinopril	C
			Cisapride	C

Date:01/26/98ISR Number: 3086844-XReport Type:Direct Company Report #
Age:24 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Ineffective		Lo/Ovral	PS		ORAL	4 PILLS PO	
	Unintended Pregnancy						Q12H X 2	
			Metoclopramide	SS	Reglan	ORAL	10MG 1T PO Q	12H X 2

Date:02/03/98ISR Number: 3022507-4Report Type:Expedited (15-DaCompany Report #19971200165
Age:65 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Blood Creatinine	Foreign	Prilosec	PS		ORAL	20 MG QD PO	
Initial or Prolonged	Increased	Health	Primperan	SS				
	Renal Failure Acute	Professional	Gaviscon	SS				
			Crixivan	SS				
			Theralene	C				
			Zerit	C				
			Epivir	C				

Date:02/09/98ISR Number: 3026103-4Report Type:Expedited (15-DaCompany Report #980203-057010403
Age: Gender:Male I/FU:I

Outcome	PT
Congenital Anomaly	Complications Of Maternal
	Exposure To Therapeutic

Drugs
Foetal Macrosomia

			Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
			Foreign	Ofloxacin	PS		
TAB							
			Health	Ciprofloxacin			
			Professional	Hydrochloride	SS		
				Sulfamethoxazole			
				Trimethoprim	SS		
				Hyoscine			
				Butylbromide	SS		
				Metoclopramide			
				Hydrochlorise	SS		

Date:02/09/98ISR Number: 3026109-5Report Type:Expedited (15-DaCompany Report #19971200165
Age:65 YR Gender:Male I/FU:F

Outcome	PT		Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Hospitalization -	Blood Creatinine		Foreign	Prilosec	PS		ORAL
20 MG QD PO							
Initial or Prolonged	Increased		Health	Primperan	SS		
	Renal Failure Acute		Professional	Crixivan	SS		
				Gaviscon	SS	Smith Kline Beecham	
				Theralene	C		
				Zerit	C		
				Epivir	C		

Date:02/11/98ISR Number: 3030417-1Report Type:Expedited (15-DaCompany Report #8-98029-002S
Age:65 YR Gender:Male I/FU:I

Outcome	PT		Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Hospitalization -	Leukopenia		Foreign	Amiodarone	PS		
900MG DAILY							
Initial or Prolonged			Health				
IV							
			Professional	Cisapride	SS		ORAL
ORAL							
				Metoclopramide	SS		ORAL
ORAL							

			Omeprazole	SS		
INTRAVENOUS	40 MG IV					
			Cisapride	C		
			Fentanyl	C		
			Metoclopramide	C		
			Midazolam	C		
			Omeprazole	C		

Date:02/17/98ISR Number: 3032638-0Report Type:Expedited (15-DaCompany Report #D0001814
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Congenital Anomaly	Abortion Induced	Foreign	Raxar	PS		ORAL	ORAL	
	Complications Of Maternal	Health	Clarithromycin	SS		ORAL	ORAL	
	Exposure To Therapeutic	Professional	Beclovent	SS				
	Drugs		Metoclopramide	SS				
	Trisomy 21		Norfenefrine Hcl	SS				
			Bisolvon	SS				
			Clobutinol Hydrochloride	SS				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/20/98ISR Number: 3032610-0Report Type:Expedited (15-DaCompany Report #8-97328-012S
Age:27 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Unevaluable Event	Foreign Health Professional	Vancomycin Hydrochloride	PS		INTRAVENOUS	125 MG/INTRAVENOUS	
			Carbamazepine	SS			400 MG/D	
			Metoclopramide	SS		INTRAVENOUS	100 MG IV	
			Mianserin Hydrochloride	SS		INTRAVENOUS	30 MG	
			Diazepam	C				
			Boflonedil Hydrochloride	C				
			Carbamazepine	C				
			Ciprofloxacin	C				
			Fluconazole	C				
			Ketoprofen	C				
			Hydroxyzine Hyrocholoride	C				
			Metoclopramide	C				
			Mianserin Hydrochloride	C				
			Morphine	C				
			Nadroparin Calcium	C				
			Omepraole	C				
			Piperacillin Sodium + Tazobactam Sodium	C				
			N/A	C				
			Propacetamol Hydrochloride	C				
			Tetrazepam	C				
			Zopiclone	C				

Date:02/20/98ISR Number: 3032611-2Report Type:Expedited (15-DaCompany Report #8-97328-012S
Age: Gender: I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	No Adverse Drug Effect	Foreign Health Professional	Vancomycin Hydrochloride	PS		INTRAVENOUS	125 MG/INTRAVENOUS	
			Carbamazepine	SS			400 MG/D	
			Ketoprofen	SS		INTRAVENOUS	100 MG/TWICE DAY/ NTRAVENOUS	
			Mianserin Hydrochloride	SS			30 MG	
			Metoclopramide	SS		INTRAVENOUS	100 MG/IV	
			Fluconazole	C			200 MG/D	
			Bromazepam	C				
			Buflonedil Hydrochloride	C				
			Carbamazepine	C				
			Ciprofloxacin	C				
			Fluconazole	C				
			Fluoxetine	C				
			Hydroxyzine Hydrochloride	C				
			Ketoprofen	C				

				Metoclopramide	C		
				Mianserin Hydrochloride	C		
				Morphine	C		
				Nadroparin Calcium	C		
				Omeprazole	C		
				Piperacillin Sodium + Tazobactam Sodium	C		
				Propacetamol Hydrochloride	C		
				Tetrazepam	C		
				Zopiclone	C		

Date:02/23/98ISR Number: 3036675-1Report Type:Direct Company Report #
Age:59 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Chorea		Reglan	PS		INTRAVENOUS	10 G IV Q	12H
	Depressed Level Of Consciousness		Nystatin	C			POWDER	
	Disorientation		Heparin	C				
	Mental Impairment		Phoslo	C				
			Vac	C				
			Zinc	C				

Date:02/26/98ISR Number: 3041082-1Report Type:Expedited (15-DaCompany Report #8-97328-012S
Age:27 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agranulocytosis	Foreign	Vancomycin Hydrochloride	PS		INTRAVENOUS	125 MG	
	Drug Interaction	Health						
	Pyrexia	Professional					INTRAVENOUS	
			Carbamazepine	SS			400 MG/ D	
			Fluconazole	SS			200 MG/ D	

		Ketoprofen	SS
INTRAVENOUS	100MG TWICE A		
DAY			
INTRAVENOUS			
		Metoclopramide	SS
INTRAVENOUS	100 MG IV		
		Mianserin Hydrochloride	SS
30 MG			
		Bromazepam	C
		Buflonedil Hydrochloride	C
		Ciprofloxacin	C
		Fluoxetine	C
		Hydroxyzine Hydrochloride	C
		Morphine	C
		Nadroparin Calcium	C
		Omeprazole	C
		Piperacillin Sodium + Tazobactam Sodium	C
		Propacetamol Hydrochloride	C
		Tetrazepam	C
		Zopiclone	C

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/27/98ISR Number: 3040668-8Report Type:Expedited (15-DaCompany Report #8-98040-010L
Age:35 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Convulsion	Health	Reglan	PS		INTRAVENOUS	10 MG ONE	
Initial or Prolonged	Hypoglycaemia	Professional						
TIME DOSE IV								
			Pepcid	C				

Date:03/02/98ISR Number: 3039662-2Report Type:Expedited (15-DaCompany Report #8-98048-002T
Age:27 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Agranulocytosis	Foreign	Vancoled Injection	PS		INTRAVENOUS	125 MG IV	
Initial or Prolonged	Pyrexia	Health	Carbamazepine	SS			400 MG DAILY	
		Professional	Fluconazole	SS			200 MG DAILY	
			Ketoprofen	SS		INTRAVENOUS	100 MG TWICE	
DAILY IV								
			Metoclopramide	SS		INTRAVENOUS	100 MG IV	
			Mianserin Hydrochloride	SS			30 MG	
			Bromazepam	C				
			Buflonedil Hydrochloride	C				
			Ciprofloxacin	C				
			Fluoxetine	C				
			Hydroxyzine Hydrochloride	C				
			Morphine	C				
			Nadroparin Calcium	C				
			Omeprazole	C				
			Piperacillin Sodium	C				
			Tazobactam Sodium	C				
			Propacetamol Hydrochloride	C				

			Tetrazepam	C		
			Zopiclone	C		

Date:03/02/98ISR Number: 3128461-9Report Type:Periodic Company Report #A0056503
Age: Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
	Blood Pressure Decreased	Health	Zofran	PS		
	Electrocardiogram Change	Professional	Metoclopramide	SS		

Date:03/02/98ISR Number: 3133291-8Report Type:Periodic Company Report #9700032
Age:71 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Diarrhoea	Health	Zoloft	PS		
100.00 MG						
	Vomiting	Professional				
TOTAL: DAILY:						
NASOGASTRIC						
TUBE						
			Reglan	SS		
			Aspirin	C		
			Diltiazem	C		
			Isosorbide Dinitrate	C		
			Metronidazole	C		
			Acetaminophen	C		
			Albuterol	C		

				Ipratropium	C		
				Prochlorperazine	C		
				Promix	C		
				Fat Emulsion	C		
				Vitamin High Potency Liquid	C		
				Kaolin And Pectin Susp.	C		

Date:03/02/98ISR Number: 3146609-7Report Type:Periodic Company Report #9716238
Age:45 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Diarrhoea	Consumer	Zoloft Tablets	PS		ORAL	50.00MG TOTAL	
	Hyperhidrosis	Health					DAILY ORAL	
	Nausea	Professional	Reglan	SS		ORAL	ORAL	
			Imitrex	C				
			Depakote	C				
			Amitriptyline	C				
			Nadolol	C				

Date:03/04/98ISR Number: 3041230-3Report Type:Expedited (15-DaCompany Report #970904-057012912
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Congenital Anomaly	Complications Of Maternal	Foreign	Ofloxacin Tablet	PS		ORAL	400MG QD,	
	Exposure To Therapeutic	Health					ORAL	3 DAY
	Drugs	Professional	Nizatidine	SS			300 MG QD	3 DAY
	Foetal Macrosomia		Metoclopramide	SS			30 MG QD	2 DAY

Date:03/04/98ISR Number: 3041234-0Report Type:Periodic Company Report #970904-057012916
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Congenital Anomaly	Complications Of Maternal	Foreign	Ofloxacin Tablets	PS		ORAL	400 MG QD	7 DAY
	Exposure To Therapeutic	Health	Metoclopramide	SS			90 DROPS QD	14 DAY
	Drugs	Professional	Loperamide	SS			4	DAY
	Foetal Macrosomia		Acetylsalicylic Acid	SS			7	DAY
			Paracetamol	SS			7	DAY
			Caffeine	SS			7	DAY
			Sulfamethoxazole	SS			1400 MG QD	7 DAY
			Trimethoprim	SS			320 MG QD	7 DAY

Date:03/05/98ISR Number: 3041522-8Report Type:Expedited (15-DaCompany Report #8-98048-002T
Age:27 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Agranulocytosis	Foreign	Vancoled	PS		INTRAVENOUS	125MG IV	
Initial or Prolonged	Pyrexia	Health	Carbamazepine	SS			400MG DAILY	
		Professional	Fluconazole	SS			200MG DAILY	
			Ketoprofen	SS			INTRAVENOUS	100MG TWICE
							DAILY IV	
			Metoclopramide	SS			INTRAVENOUS	100MG IV
			Mianserin Hydrochloride	SS			30MG	
			Bromazepam	C				
			Buflonedil					

Hydrochloride	C
..	C
Ciprofloxacin	C
..	C
Fluoxetine	C
Hydroxyzine Hydrochloride	C
..	C
..	C
..	C
Morphine	C
Nadroparin Calcium	C
Omeprazole	C
Pipercillin Sodium + Tazobactam Sodium	C
Propacetamol Hydrochloride	C
Tetrazepam	C
Zopiclone	C

Date:03/05/98ISR Number: 3050375-3Report Type:Direct Company Report #
Age:16 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Muscle Spasms		Reglan Injection	PS		INTRAVENOUS	10MG	
			Reglan Tablets	SS		ORAL	1 PO AT AC & HS	
			Tagamet Oral	C				
			Tagamet Iv	C				
			Doxycycline	C				

Date:03/06/98ISR Number: 3157910-5Report Type:Periodic Company Report #8-97065-001S
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Torticollis	Consumer	Reglan	PS		ORAL	ORAL	

Date:03/06/98ISR Number: 3157911-7Report Type:Periodic Company Report #8-97280-002S
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Convulsion	Health Professional	Reglan	PS				

Date:03/06/98ISR Number: 3157912-9Report Type:Periodic Company Report #8-97083-011S
Age:52 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dystonia	Health Professional	Reglan	PS		ORAL	5 MG QID ORAL	

Date:03/06/98ISR Number: 3157913-0Report Type:Periodic Company Report #8-97113-005S
Age:35 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Sleep Disorder	Health Professional	Reglan	PS		ORAL	ORAL	
	Unevaluable Event	Professional	Calcium Concentrate	C				

			Compazine	C		
			Insulin	C		
			Norvasc	C		
			Vasotec	C		

Date:03/06/98ISR Number: 3157914-2Report Type:Periodic Company Report #8-97114-002S
Age:73 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Extrapyramidal Disorder	Consumer	Reglan	PS		ORAL	10-20 MG QID	ORAL
			Elavil	C				
			Propulsid	C				
			Urecholine	C				

Date:03/06/98ISR Number: 3157916-6Report Type:Periodic Company Report #8-97114-003S
Age:43 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Agitation	Consumer	Reglan	PS		ORAL	2 TABLETS/DAY	
	Anxiety							ORAL
	Insomnia		Synthroid	C				
	Neck Pain							
	Nervousness							
	Tremor							

Date:03/06/98ISR Number: 3157917-8Report Type:Periodic Company Report #8-97115-011S
Age:17 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dystonia	Health Professional	Reglan	PS		ORAL	10 MG EVERY 6 HOURS PRN	

ORAL

Prenatal Vitamins C

Date:03/06/98ISR Number: 3157918-XReport Type:Periodic Company Report #8-97121-025S
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Convulsion	Health Professional	Reglan	PS				

Date:03/06/98ISR Number: 3157919-1Report Type:Periodic Company Report #8-97143-006S
Age:67 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Muscle Twitching	Health Professional	Reglan	PS		ORAL	5-10 MG 1 HR BEFORE MEALS AND BEDTIME	
ORAL			Multiple Medications	C			2	YR

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/06/98ISR Number: 3157920-8Report Type:Periodic Company Report #8-97143-012S
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dystonia	Health Professional	Reglan	PS				

Date:03/06/98ISR Number: 3157921-XReport Type:Periodic Company Report #8-97160-003S
Age:66 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Salivary Hypersecretion	Consumer	Reglan	PS		ORAL	10 MG THREE TIMES DAILY DECREASED TO 5 MG AT LUNCH AND 10 MG AT	
	Sedation							
	Thinking Abnormal							
			Cardizem Cd	C				
			Pepcid	C				
			Premarin	C				
			Provera	C				
			Synthroid	C				
			Xanax	C				

Date:03/06/98ISR Number: 3157922-1Report Type:Periodic Company Report #8-97197-004S
Age:45 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Anxiety	Consumer	Reglan	PS		ORAL	5-7 MG THREE TIMES DAILY ORAL	
	Depression							
	Drug Interaction							
	Major Depression		Dmae (Di-Methyl-Amino-Eth					

			ylene-Bitartrate)	SS		
			Ativan	C		
			Hydrocodone	C		
			Prilosec	C		
			Tenormin	C		

Date:03/06/98ISR Number: 3157923-3Report Type:Periodic Company Report #8-97216-003S
Age:8 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Abnormal Dreams	Health	Reglan	PS		ORAL	5 MG AT ONSET	
		Professional					OF HEADACHE	
							NOT TO EXCEED	
							2 DOSES PER	
							DAY ORAL	
			Ibuprofen	C				

Date:03/06/98ISR Number: 3157924-5Report Type:Periodic Company Report #8-97280-003S
Age:59 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Extrapyramidal Disorder	Consumer	Reglan	PS		ORAL	10 MG TWICE	
	Salivary Hypersecretion						DAILY; DOSE	
							HAS VARIED	
							OVER YEARS	
							ORAL	

			Elavil	C		
			Sinequan	C		
			Trilafon	C		
			Zantac	C		

Date:03/06/98ISR Number: 3157925-7Report Type:Periodic Company Report #8-97325-003S
Age:80 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Depression	Consumer	Reglan	PS		ORAL	DAILY, ORAL	
			Coumadin	C				
			Vasotec	C				

Date:03/06/98ISR Number: 3157926-9Report Type:Periodic Company Report #8-97335-001S
Age:80 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Attention	Consumer	Reglan	PS		ORAL	ONE TABLET	
	Deficit/Hyperactivity						DAILY ORAL	
	Disorder		Coumadin	C				
	Confusional State		Vasotec	C				
	Depression							
	Nervousness							

Date:03/06/98ISR Number: 3157927-0Report Type:Periodic Company Report #8-97345-001J
Age:45 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Ineffective	Consumer	Reglan	PS		ORAL	10 MG FOUR	
	Dyspepsia						TIMES DAILY	
	Nausea						ORAL 20 MG	

FOUR TIMES

DAILY

Date:03/06/98ISR Number: 3157928-2Report Type:Periodic Company Report #8-97364-006H
Age:36 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Asthenia	Consumer	Reglan	PS		ORAL	10 MG FOUR TIMES DAILY	
	Nervousness							
	Sedation						ORAL	

Date:03/06/98ISR Number: 3157929-4Report Type:Periodic Company Report #8-98016-022L
Age:82 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Confusional State	Health Professional	Reglan	PS		ORAL	ORAL	

Date:03/09/98ISR Number: 3051588-7Report Type:Expedited (15-DaCompany Report #199810538RHF
Age:66 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agranulocytosis	Foreign	Furosemide	PS		ORAL	PO	16 DAY
		Other	Sucralfate	SS				

				Propacetamol Hydrochloride	SS			
INTRAVENOUS	IV	3	DAY					
				Metoclopramide Solution For Injection	SS			
INTRAVENOUS	IV	15	DAY					
				Ranitidine Hydrochloride Solution For Injection	SS			
INTRAVENOUS	IV	6	DAY					
				Cloxacillin Sodium	SS			ORAL
PO								
				Cefotaxime Sodium	SS			
PO								
				Pefloxacin Mesilate	SS			ORAL
PO								
				Dexchlorpheniramine Maleate	SS			ORAL
PO								
				Dopamine	SS			ORAL
PO								
				Heparin-Fraction, Calcium Salt	SS			
				Vancomycin Hydrochloride	SS			
				Valproate Sodium	C			
				Netilmicin Sulfate	C			
				Trimebutine Maleate	C			
				Ambroxol	C			

Date:03/12/98ISR Number: 3058544-3Report Type:Direct Company Report #
Age:21 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Pregnancy Test Positive		Lo-Ovral -28	PS	Wyeth Laboratories	ORAL	3 TABS STAT	
							PO & 3 TABS	
							IN 12 HR PO	
			Metoclopramide	SS	Biocraft Lab			

						Pharmpak	ORAL

1 TAB PO 1/2

HR BEFORE

EACH LO-OVRAL

DOSE

Date:03/13/98ISR Number: 3066781-7Report Type:Direct Company Report #
Age:27 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Pregnancy Test Positive		Loovral	PS		ORAL	4 PO Q12H X 2	
			Metoclopramide	SS			10MG 1T PO	Q12HX2

Date:03/16/98ISR Number: 3055304-4Report Type:Expedited (15-DaCompany Report #D0001814
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Congenital Anomaly	Abortion Induced	Foreign	Raxar	PS		ORAL	ORAL	
	Complications Of Maternal	Health	Clarithromycin	SS		ORAL	ORAL	
	Exposure To Therapeutic Drugs	Professional	Beclovent	SS				
			Metoclopramide Hcl	SS				
	Concussion		Norfenefrine Hcl	SS				
	Trisomy 21		Bisolvon	SS				
			Clobutinol Hydrochloride	SS				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/20/98ISR Number: 3057362-XReport Type:Direct Company Report #
Age:55 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Myocardial Infarction		Reglan	PS				
INTRAVENOUS							10 MG Q6H	IV
Hospitalization - Initial or Prolonged	Neuroleptic Malignant Syndrome		Albuterol	C				
			Ipatropium	C				
Required Intervention to Prevent Permanent Impairment/Damage			Cosec Protein Powder	C				
			Digitalis	C				
			Docusate	C				
			Lovenox	C				
			Insulin Drip	C				
			Iron Complex	C				
			Riopan	C				
			Acetaminophen	C				
			Ibuprofen	C				
			Lorazepam	C				
			Nipride	C				
			Propofol	C				
			Dopamine	C				
			Nitroglycerine	C				
			Tobra	C				
			Amphoteracin	C				
			Vanco	C				
			Metronidazole	C				
			Famotidine	C				

Date:03/26/98ISR Number: 3065037-6Report Type:Direct Company Report #
Age:48 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Anuria		Metoclopramide	PS				
PT ON THIS								
	Atrial Fibrillation							
PTA								
	Bradycardia		Meperidine	C				
	Cardiac Arrest		Promethazine	C				
	Hypotension		Oxycodone& Apap	C				
	Pyrexia		....	C				
	Renal Failure Acute		Furosemide	C				
	Rhabdomyolysis		Warfarin	C				
	Sepsis		Hydrocodone & Apap	C				

			Donnatal	C		

Date:03/27/98ISR Number: 3064996-5Report Type:Direct Company Report #
Age:18 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Ineffective		Lo-Oval-28#12	PS	Wyeth Laboratories	INTRAVENOUS	IV TABS STAT	

PO & IV TRABS

IN 12HR PO

			Metoclopramide	SS	Biocraft Lab	ORAL

1T TAB PO 1/2

HR WITH EWACH

LO OVRAL DOSE

Date:03/31/98ISR Number: 3063262-1Report Type:Direct Company Report #
Age:48 YR Gender:Male I/FU:I

Outcome	PT
	Cold Sweat
	Flushing

	Nausea Restlessness					
		Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
			Metoclopramide	PS		
INTRAVENOUS	10 MG IV Q 6					
HRS(12/9/97						
1200-->12/9						
1800)						
			Aspirin	C		
			Pepcid	C		
			Phenergan	C		
			Ketorolac	C		
			Morphine	C		

Date:04/01/98ISR Number: 3058726-0Report Type:Expedited (15-DaCompany Report #JAGER-37888
Age:21 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Other	Abdominal Distension	Foreign	Imodium	PS	Janssen	ORAL
30 MG ORAL						
	Intentional Misuse	Health	Mcp	SS		ORAL
150 MG ORAL						
	Suicide Attempt	Professional	Rulid	SS		ORAL
2250 MG						
	Vomiting					

Date:04/01/98ISR Number: 3058869-1Report Type:Expedited (15-DaCompany Report #8-98040-010L
Age:35 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization -	Convulsion	Health	Reglan	PS		
INTRAVENOUS	10 MG ONE					
Initial or Prolonged	Hypoglycaemia	Professional				
TIME DOSE IV						
	Insulinoma		Pepcid	C		

Date:04/01/98ISR Number: 3153113-9Report Type:Periodic Company Report #8-98041-013N
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Ineffective	Health	Lo/Ovral-28	PS		ORAL	12 TABLETS	
	Unintended Pregnancy	Professional				ORAL		
			Metoclopramide	SS		ORAL	10MG-2	
			Metoclopramide	C			TABLETS ORAL	

Date:04/01/98ISR Number: 3154067-1Report Type:Periodic Company Report #8-98016-030N
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Unintended Pregnancy	Health	Lo/Ovral	PS		ORAL	ORAL	
		Professional	Metoclopramide	SS				
			Metoclopramide	C				

Date:04/02/98ISR Number: 3060744-3Report Type:Expedited (15-DaCompany Report #8-98079-012L
Age:3 MON Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Developmental Delay	Consumer	Reglan	PS				
Other	Medication Error							
	Overdose							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/06/98ISR Number: 3060971-5Report Type:Expedited (15-DaCompany Report #JAGER-38224
Age:18 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Intestinal Functional Disorder	Foreign Health Professional	Imodium	PS	Janssen	ORAL	11 CAPSULES, SINGLE ORAL	
	Sedation		Dulcolax	SS		ORAL	SINGLE ORAL	
	Suicide Attempt		Imipramin	SS		ORAL	20 TABLETS, SINGLE ORAL	
			Paracetamol	SS		ORAL	1100 MG SINGLE ORAL	
			Kytta	SS		ORAL	SINGLE ORAL	
			Rulid	SS			SINGLE	
			Isocillin	SS			SINGLE	
			Ibuprofen	SS			SINGLE	
			Paspertin	SS			SINGLE	
			Effortil	SS			SINGLE	
			Zyrtec	SS		ORAL	3 TABLETS, SINGLE ORAL	
			Dolomo	SS			SINGLE	
			Lisino	SS		ORAL	5 TABLETS, SINGLE ORAL	
			Celestamine	SS		ORAL	12 TABLETS, SINGLE ORAL	
			Unspecified	SS			INTRAVENOUS	

Date:04/07/98ISR Number: 3154872-1Report Type:Periodic Company Report #97147
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Nausea	Distributor	Metoclopramide Hcl	PS				

Date:04/10/98ISR Number: 3155401-9Report Type:Periodic Company Report #8-97342-006H
Age:18 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dystonia	Health	Reglan	PS		INTRAVENOUS		IV
	Muscle Twitching	Professional						

Date:04/13/98ISR Number: 3079130-5Report Type:Expedited (15-DaCompany Report #1998 USA 001326
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	Health Professional	Droperidol	PS		INTRAVENOUS	0.625MG, ONCE,	
	Clonic Convulsion					INTRAVENOUS		
	Coma		Metoclopramide	SS		INTRAVENOUS	10 MG, ONCE,	
	Confusional State					INTRAVENOUS		
	Hyperhidrosis		Ketorolac	C				
	Meningitis		Vancomycin	C				
	Mental Impairment		Ceftriaxone	C				
	Muscle Rigidity		Bactrim	C				
	Pyrexia		Cimetidine	C				
	Tachycardia		Heparin	C				
	Tremor							
	Urinary Incontinence							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/15/98ISR Number: 3071726-XReport Type:Direct Company Report #
Age:27 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Blood Creatine		Droperidol	PS				
INTRAVENOUS							0.625 MG	IV,
Initial or Prolonged	Phosphokinase Increased							
ONCE								
	Clonic Convulsion		Metoclopramide	SS				
INTRAVENOUS							10 MG	IV,
	Coma							
ONCE								
	Confusional State		Vancomycin	C				
	Csf Test Abnormal		Ceftriaxone	C				
	Depressed Level Of		Bactrim	C				
	Consciousness		Cimetidine	C				
	Hyperhidrosis		Heparin	C				
	Mental Impairment							
	Muscle Rigidity							
	Pyrexia							
	Tachycardia							
	Tremor							
	Urinary Incontinence							

Date:04/17/98ISR Number: 3065266-1Report Type:Expedited (15-DaCompany Report #8-98098-002A
Age:27 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Hyperhidrosis	Health	Reglan	PS				
INTRACAVERNOUS							10 MG	IV ONCE
Initial or Prolonged	Mental Impairment	Professional						
INTRAVENOUS								
Other	Muscle Rigidity							
	Tachycardia							
	Tremor							

Date:04/21/98ISR Number: 3074861-5Report Type:Direct Company Report #
Age:29 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Other	Dyskinesia		Reglan	PS	A.H. Robins	
10 MG Q6H						
	Muscle Twitching					
IVPB						

Date:04/23/98ISR Number: 3153976-7Report Type:Periodic Company Report #8-97220-004S
Age:8 MON Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Insomnia	Consumer	Reglan	PS		ORAL
1 ML 4 TIMES						
DAILY ORAL						
			Tagamet	C		

Date:04/23/98ISR Number: 3154896-4Report Type:Periodic Company Report #8-97033-001S
Age:77 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Disability	Choreoathetosis	Consumer	Reglan	PS		ORAL
10MG BEFORE						
Other	Extrapyramidal Disorder					
MEALS AND						
BEDTIME ORAL						
			Aspirin	C		
			Bisacodyl	C		
			Digoxin	C		
			Docusate And Casant	C		
			Ensure	C		
			Ibuprofen	C		

			Jevity	C			
			Maalox	C			
			Mylanta	C			
			Nifedipine	C			
			Norfloxacin	C			
			Sucralfate	C			
			Theragran	C			

Date:04/23/98ISR Number: 3154898-8Report Type:Periodic Company Report #8-97148-002S
Age:1 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Overdose		Reglan	PS		ORAL		
			Advil	C				
			Augmentin	C				
			Cimetidine	C				
			Erythromycin	C				
			Rondec	C				

Date:04/23/98ISR Number: 3154901-5Report Type:Periodic Company Report #8-97143-009S
Age:82 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dystonia	Consumer	Reglan	PS			2 TBSP. TWICE	
	Insomnia						A DAY	G-TUBE
	Tremor		Reglan	SS		ORAL		
			Axid	C				
			Ceftin	C				
			Depakene	C				
			Diabetic Tussin	C				
			Heparin Injectable	C				
			Multivitamin	C				
			Neocalgulcan	C				
			Nph Humulin Insulin	C				
			Promod	C				
			Regular Humulin Insulin	C				

Trusopt	C
Vancomycin	C
Vitamin	C
Zinc Sulfate	C

Date:04/30/98ISR Number: 3073818-8Report Type:Direct Company Report #
Age:18 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Ineffective	Health	Lo Ovral	PS		ORAL	#8	
	Pregnancy Test Positive	Professional	Reglan	SS		ORAL	10 MG # 2	

Date:05/14/98ISR Number: 3078881-6Report Type:Expedited (15-DaCompany Report #8-98125-055A
Age:25 YR Gender:Female I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Dry Mouth
	Hallucination
	Overdose
	Sedation

	Tachycardia Tremor Vomiting	Report Source	Product	Role	Manufacturer	Route Dose Duration
		Foreign	Effexor	PS		ORAL ORAL
		Health Professional	Dothiepin Hydrochloride	SS		ORAL ORAL
			Metoclopramide	SS		
			Oxazepam	SS		
			Temazepam	SS		ORAL

Date:05/22/98ISR Number: 3082799-2Report Type:Expedited (15-DaCompany Report #B038725
Age:85 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Hospitalization - Initial or Prolonged	Agranulocytosis Leukopenia Neutropenia Pyrexia	Foreign Health Professional	Mucomyst Primperan Ticlid (Ticlopidine Hydrochloride)	PS SS SS		ORAL 600 MG QD ORAL 30 MG QD ORAL 250 MG QD
			Ciblor (Amoxicillin +Potassium Clavulan)	SS		1500 MG QD
			Tardyferon	C		
			Lasilix	C		
			Rythmol	C		
			Aspegic	C		
			Corvasal	C		
			Daonil	C		
			Tadenan	C		

Date:05/28/98ISR Number: 3083368-0Report Type:Direct Company Report #
Age:68 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration

Required	Tongue Spasm		Metoclopramide	PS	Schein	ORAL
10MG PO						
Intervention to						
QID; 10MG						
Prevent Permanent						
PO BID						
Impairment/Damage			Haldol	C		

Date:05/28/98ISR Number: 3083377-1Report Type:Direct Company Report #
Age:33 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
	Hypoaesthesia Oral		Reglan	PS		
10 MG ONCE						
	Muscle Twitching					
IVP						

Date:06/01/98ISR Number: 3087838-0Report Type:Expedited (15-DaCompany Report #B0056506
Age:30 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Sinoatrial Block	Foreign	Nimbex	PS		
INTRAVENOUS 2 MG/ML/IV						
Initial or Prolonged			Metoclopramide	SS		
INTRAVENOUS IV						
			Cisapride	C		
			Omeprazole	C		
			Metolazone	C		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/02/98ISR Number: 3088563-2Report Type:Expedited (15-DaCompany Report #98D--10331
Age:58 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Erythema Nodosum	Foreign	Ludiomil	PS		INTRAVENOUS	1 DF,DAILY,	
Hospitalization -		Health				INTRAVENOUS	5	DAY
Initial or Prolonged		Professional	Bactrim Forte	SS				
			Maalox Suspension	SS				
			Adumbran	SS				
			Fenistil Retard Slow Release	SS		ORAL	3 DF, DAILY,	
						ORAL	4	DAY
			Paspertin Drops	SS				
			Paracetamol	SS				
			Timonil	SS				
			Ludiomil	C				

Date:06/04/98ISR Number: 3090068-XReport Type:Expedited (15-DaCompany Report #9814100
Age:35 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Pyrexia	Foreign	Diflucan	PS		ORAL	DAILY: ORAL	
Initial or Prolonged		Health	Metoclopramide	SS				
		Professional	Bactrim	C				

Date:06/04/98ISR Number: 3090276-8Report Type:Direct Company Report #
Age:41 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Migraine		Metoclopramide	PS		ORAL	10 MG TID PRN	
						PO		
			Percocet	C				
			Sertraline	C				

Date:06/05/98ISR Number: 3091122-9Report Type:Expedited (15-DaCompany Report #FR02-08990
Age:81 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Pyelonephritis	Foreign	Primperan Tab	PS		ORAL PO		
	Urinary Retention	Health Professional	Athymil	SS		ORAL PO		
			Skenan	SS		ORAL PO		
			Calcitonin	SS		ORAL PO		
			Lovenox	SS		SUBCUTANEOUS SC		
			Deroxat	SS		ORAL PO		

Date:06/16/98ISR Number: 3094594-9Report Type:Expedited (15-DaCompany Report #909#5#1998-15067 (000)
Age:86 YR Gender:Male I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Asthenia
	Cardiac Failure Congestive
	Cardiac Murmur
	Chest X-Ray Abnormal
	Coordination Abnormal
	Cyanosis
	Echocardiogram Abnormal
	Gait Disturbance

	Haematuria					
	Hypoxia					
	Lethargy	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
	Lung Infiltration	Study	Cyclophosphamide	PS		
INTRAVENOUS	1500					
	Lymphangiosis					
MILLIGRAM						
	Carcinomatosa					
INTRAVENOUS	1					
	Oedema Peripheral					
CYCLE						
	Palpitations		Dppe	SS		
INTRAVENOUS	INTRAVENOUS					
	Pco2 Decreased		Ativan	SS		
UNKNOWN	UNKNOWN					
	Pericardial Effusion		Reglan	SS		
UNKNOWN	UNKNOWN					
	Pleural Effusion		Kytril	C		
	Pneumonia					
	Pneumonitis					
	Po2 Decreased					
	Pulmonary Oedema					
	Rales					
	Respiratory Disorder					
	Respiratory Failure					

Date:06/17/98ISR Number: 3095321-1Report Type:Expedited (15-DaCompany Report #8-98160-014A
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Disability	Akathisia	Consumer	Reglan	PS		ORAL
UNSPECIFIED						
	Anxiety					
DOSE THREE TO						
	Asthenia					
FOUR TIMES						
	Blindness					
DAILY ORAL						
	Decreased Activity					
	Depression					
	Disability					
	Dyspnoea					
	Dystonia					

	Eye Movement Disorder
	Eye Pain
	Fatigue
	Headache
	Insomnia
	Irritability
	Mastication Disorder
	Muscle Twitching
	Nervousness
	Respiratory Disorder
	Speech Disorder
	Suicidal Ideation
	Tardive Dyskinesia
	Tongue Disorder
	Vomiting

Date:06/23/98ISR Number: 3097677-2Report Type:Expedited (15-DaCompany Report #WAES 98060615
Age:47 YR Gender:Male I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Anuria
	Fatigue
	Glycosuria
	Hepatocellular Damage
	Jaundice
	Liver Disorder
	Liver Function Test

Abnormal
Proteinuria
Renal Failure Acute

Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Foreign	Noroxin	PS		ORAL	400 MG	4 DAY
Health Professional	Acetaminophen (+) Salicylamide	SS		ORAL	2 GM	4 DAY
	Thiaton	SS		ORAL	30 MG	4 DAY
	Antimicrobial Therapy	SS		ORAL	3 GM	4 DAY
	Primperan	SS		ORAL	15 MG	4 DAY

Date:06/25/98ISR Number: 3098510-5Report Type:Expedited (15-DaCompany Report #B0057317
Age:62 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hypotension	Foreign	Zantac	PS		ORAL	INTRAVENOUS	INTRAVENOUS
			Hetastarch	SS				
			Metoclopramide	SS				
			Temazepam	SS				
			Lisinopril	C				
			Vecuronium Bromide	C				
			Metronidazole	C				
			Fentanyl	C				
			Ephedrine	C				
			Propofol	C				
			Bupivacaine	C				
			Glycopyrronium Bromide	C				
			Fentanyl	C				
			Cephradine	C				

Date:06/25/98ISR Number: 3098534-8Report Type:Expedited (15-DaCompany Report #100819
Age:39 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Health	Midazolam	PS		INTRAVENOUS	INTRAVENOUS	
	Drug Toxicity	Professional	Fentalny	SS		INTRAVENOUS	INTRAVENOUS	
			Metoclopramide	SS		INTRAVENOUS	INTRAVENOUS	
			Caffeine	SS				

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	
	Hypokalaemia	Health					PER DAY ORAL	
	Hyponatraemia	Professional	Bactrim	SS		INTRAVENOUS	2 DOSE FORM 1	
		Other					X PER DAY	
						INTRAVENOUS		
			Atacand	SS		ORAL	16 MG 1 X	
							PER DAY ORAL	
			Anafranil	SS			25 MG 1 X PER	
							DAY	
			Haldol	SS		ORAL	2 DROP 3 X	
							PER DAY ORAL	
			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:06/30/98ISR Number: 3100018-5Report Type:Direct Company Report #
Age:52 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Agitation		Metoclopramide	PS				
INTRAVENOUS	10MG IV Q 6H							
	Anxiety							
	Extrapyramidal Disorder							
	Restlessness							
	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 &					
	Pruritus		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				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/01/98ISR Number: 3103745-9Report Type:Direct Company Report #
Age:29 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Anxiety		Daclizumab	PS		INTRAVENOUS	64MG IV	
Required	Feeling Hot		Reglan	SS		INTRAVENOUS	10MG IV	
Intervention to	Hypotension		Aspirin	SS			325MG	
Prevent Permanent Impairment/Damage	Restlessness							

Date:07/02/98ISR Number: 3101012-0Report Type:Expedited (15-DaCompany Report #9814100
Age:35 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dermatitis	Foreign	Diflucan	PS		ORAL	400.00 MG	TOTAL:DAILY:
	Dyskinesia	Professional				ORAL		
	Extrapyramidal Disorder		Metoclopramide	SS		ORAL		
	Pyrexia		Itraconazole	SS				
			Bactrim	C				
			Combivir	C				
			Nelfinavir	C				
			Alprazolam	C				
			Dexchlorpheniramine	C				
			Amphotericine B	C				

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

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Blood Creatinine	Foreign	Valium	PS		INTRAVENOUS	2.5000 MG	

	Increased	Health				
DAILY						
	Blood Lactate	Professional				
INTRAVENOUS						
	Dehydrogenase Increased	Other	Bactrim Forte	SS		ORAL
1.0000 DOSE						
	Blood Urea Increased					
FORM 2.0 X						
	Cardiac Failure					
PER DAY ORAL						
	Dermatitis		Adumbran	SS		ORAL
1.0000 DOSE						
	Dermatitis Bullous					
FORM 1.0XPER						
	Leukocytosis					
DAY ORAL						
	Mental Disorder		Heparin-Natrium	SS		
SUBCUTANEOUS	7500.0000 IU					
	Pruritus					
2.0 X PER DAY						
	Pyrexia					
SUBCUTANEOUS						
	Renal Failure Acute		Coffein	SS		ORAL
1.0000 DOSE						
	Stevens-Johnson Syndrome					
FORM 1.0 X						
	Toxic Epidermal					
PER DAY ORAL						
	Necrolysis		Paspertin	SS		ORAL
20.0000 DROP						
	Urinary Tract Infection					
DAILY ORAL						
	White Blood Cell Count		Baymyard	SS		ORAL
1.0000 DOSE						
	Increased					
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:07/06/98ISR Number: 3102041-3Report Type:Expedited (15-DaCompany Report #B0057436
Age:73 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged Disability	Dyskinesia	Foreign Health Professional	Leukeran	PS		ORAL	PER DAY ORAL
	Extrapyramidal Disorder		Metoclopramide	SS			
	Paralysis		Blood	C			
	Tremor						

Date:08/14/98ISR Number: 3117188-5Report Type:Expedited (15-DaCompany Report #081-0991-980105
Age:51 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Abdominal Pain Upper	Foreign Health Professional Company Representative	Rezulin	PS		ORAL	400 MG (DAILY), PER ORAL
	Alanine Aminotransferase Increased						
	Anorexia		Cylock	SS		ORAL	600 MG, PER ORAL
	Blood Alkaline Phosphatase Increased		Primperan	SS		ORAL	PER ORAL

	Blood Lactate		Lorelco	C	
	Dehydrogenase Increased		Meblin	C	
	Gamma-Glutamyltransferase Increased		Alosenn	C	
	Hepatic Steatosis				
	Hepatocellular Damage				
	Jaundice				
	Nasopharyngitis				
	Nausea				
	Pyrexia				

Date:08/17/98ISR Number: 3117955-8Report Type:Expedited (15-DaCompany Report #8-98223-025A
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Health Professional	Reglan	PS		ORAL	ORAL	

Date:08/21/98ISR Number: 3120405-9Report Type:Expedited (15-DaCompany Report #104244
Age:12 MON Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dental Caries	Health Professional	Rocaltrol	PS		ORAL	.5 MCG 4XPER	DAY ORAL
	Tooth Discolouration							
	Wound Infection		Minipress	SS		ORAL	1 MG 4XPER	DAY ORAL
			Lasix	SS		ORAL	8 MG 3 X PER	

DAY ORAL						
			Potassium	SS		ORAL
ORAL						
			Reglan	SS		ORAL
.8 MG 4XPER						
DAY ORAL						
			Titralac	SS		ORAL
7.5 ML 3XPER						
DAY ORAL						
			Vancomycin	SS		
			Labetalol	SS		
			Digoxin	SS		
			Keflex	SS		
			Captoril	SS		
			Fortaz	SS		
			Dicloxacillin	SS		
			Nafcillin	SS		

Date:08/21/98ISR Number: 3120461-8Report Type:Expedited (15-DaCompany Report #98D--10650
Age:72 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Dermatitis Exfoliative	Foreign	Voltaren	PS		ORAL	1 DF	DAILY
Hospitalization -	Pruritus	Health				ORAL		
Initial or Prolonged	Pyrexia	Professional	Adumbran	SS		ORAL		
ORAL								
			Corvaton	SS		ORAL		
ORAL								
			Imap	SS		ORAL		
ORAL								
			Saroten	SS		ORAL		
ORAL								
			Heparin	SS				
SUBCUTANEOUS	SUBCUTANEOUS							
			Scandicain	SS				
SUBCUTANEOUS	SUBCUTANEOUS							
			Paspertin	SS		ORAL		
ORAL								
			Atosil	SS		ORAL		
ORAL								

			Thioctacid	SS		
INTRAVENOUS	INTRAVENOUS					

Date:08/26/98ISR Number: 3121925-3Report Type:Expedited (15-DaCompany Report #199812477HPD
Age:72 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Pulmonary Embolism	Foreign	Novalgin	PS		ORAL	20 DROP BID	
Hospitalization -	Toxic Epidermal	Study					PO; DROPS	1 DAY
Initial or Prolonged	Necrolysis	Health	Lasix	SS			INTRAVENOUS	QD IV 1 DAY
		Professional	Arelix	SS			INTRAVENOUS	30 MG QD IV;
							SOLUTION FOR	
							INJECTION	1 DAY
			Corvaton	SS		ORAL	8 MG BID PO;	
							RETARD	
							CONTROLLED	6 DAY
			Tegretal	SS		ORAL	400 MG QD PO	2 DAY
			Voltaren	SS		ORAL	QD PO;	
							DISPERS	13 DAY
			Arthotec	SS		ORAL	QD PO	4 DAY
			Durazanil	SS		ORAL	3 MG QD PO	1 DAY
			Diazepam	SS		ORAL	5 MG QD PO	1 DAY
			Adumbran	SS		ORAL	HS PO	1 DAY
			Saroten	SS		ORAL	HS PO	26 DAY
			Noctamid	SS		ORAL	HS PO	8 DAY
			Heparin	SS			INTRAVENOUS	20000 IU/DAY
							IV; SOLUTION	
							FOR INJECTION	3 DAY

SUBCUTANEOUS 4 ML QD SC;

SOLUTION FOR

INJECTION 2 DAY

INTRAVENOUS QD IV;

19-Aug-2005 10:55 AM
Page: 34

Scandicain SS

Psyquil SS

SOLUTION FOR

INJECTION 1 DAY

5-0-15 DROP

PO; DROPS 6 DAY

INTRAMUSCULAR QD IM;

SOLUTION FOR

INJECTION 1 DAY

INTRAVENOUS BID IV;

SOLUTION FOR

INJECTION 3 DAY

INTRAVENOUS 600 MG QD IV;

SOLUTION FOR

INFUSION 3 DAY

20 DROP QD

PO; DROPS 1 DAY

Atosil	SS	ORAL
Imap	SS	
Bromuc	SS	
Thioctacid	SS	
Paspertin	SS	ORAL
Madopar	SS	
Heparin	C	
Madopar	C	
Calsynar	C	
Multibionta	C	
Glucoplasmal	C	
Nacl	C	
Glucose	C	
Ringer Lactat	C	
Jonosteril	C	
Caliumgluconat	C	
Bromuc Granulat	C	

Date:08/27/98ISR Number: 3121867-3Report Type:Expedited (15-DaCompany Report #9825147
Age:78 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Convulsion	Health	Cardura	PS		ORAL		
	Drug Interaction	Professional	Reglan	SS				
			Insulin	C				

Date:08/31/98ISR Number: 3124193-1Report Type:Expedited (15-DaCompany Report #9826416
Age:89 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Anaemia	Foreign	Diflucan	PS		ORAL	50.00 MG	
Life-Threatening	Anorexia	Health					TOTAL;;	
	Gastrointestinal	Professional					DAILY; ORAL	
	Candidiasis	Other	Fusidic Acid	SS		ORAL	1.50 GRAM	
	Mental Impairment						TOTAL;	
	Osteitis						DAILY; ORAL	
	Osteoarthritis		Metoclopramide	SS		ORAL	ORAL	
	Suicidal Ideation		Fluoxetine	SS		ORAL	20.00 MG	
	Thrombocytopenia						TOTAL;	
							DAILY; ORAL	
			Pristinamycine	C				
			Omeprazole	C				
			Aluminum Magnesium Hydroxyde	C				
			Sodium Docusate	C				
			Morphine Sulfate	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/31/98ISR Number: 3124696-XReport Type:Expedited (15-DaCompany Report #8-98230-060A
Age:38 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Drug Level Above	Consumer	Reglan	PS		INTRAVENOUS	10 MG	SINGLE
	Therapeutic							
							DOSE IV	
			Ambien	C				
			Duricef	C				
			Morphine	C				
			Norflex	C				
			Pepcid	C				
			Peri-Colace	C				
			Prozac	C				

Date:08/31/98ISR Number: 3124956-2Report Type:Expedited (15-DaCompany Report #19980800196
Age:89 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Anaemia	Foreign	Prilosec	PS		ORAL	20 MG QD PO	
Life-Threatening	Haemoglobin Decreased	Health	Primperan	SS				
	Thrombocytopenia	Professional	Fucidine	SS				
			Prozac	SS		ORAL		
			Triflucan	SS				
			Pyostacine	SS				
			Skenan	C				
			Jamylene	C				
			Maalox	C				

Date:09/01/98ISR Number: 3124900-8Report Type:Expedited (15-DaCompany Report #8-98230-111A
Age:46 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Haematoma	Foreign	Profenid	PS				
	Leukopenia		Clorazepate					
	Neutropenia		Dipotassium	SS			20 MG DAILY	
	Pyrexia		Lamaline	SS				

			Metoclopramide	SS		
INTRAVENOUS	30 MG DAILY					
			Nifuroxazide	SS		ORAL
			Propacetamol Hydrochloride	SS		
INTRAVENOUS	4 G DAILY					
			Ceftriaxone	C		
			Clorazepate Dipotassium	C		
			Gentamycin	C		
			...	C		

Date:09/10/98ISR Number: 3128213-XReport Type:Direct Company Report #
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Pregnancy Test Positive	Health Professional	Lo/Ovral	PS		ORAL	4PO Q 12 HRS	X 2
			Metoclopramide	SS		ORAL	1 PO Q 12HRS	X 2 1 DAY

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/21/98ISR Number: 3133035-XReport Type:Direct Company Report #
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Malaise	Health	Metoclopropamide	PS		ORAL	1 PO QID	
	Urticaria	Professional						
	Vomiting							

Date:09/23/98ISR Number: 3134133-7Report Type:Direct Company Report #
Age:62 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Nodding Of Head	Health	Cimetidine	PS				
	Tremor	Professional	Metoclopramide	SS				

Date:09/24/98ISR Number: 3134983-7Report 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	Asthenia		Reglan	PS			MORNING AND NIGHT	
	Difficulty In Walking							
	Discomfort							
	Dyskinesia							
	Formication							
	Myalgia							
	Pain							

Date:09/29/98ISR Number: 3136353-4Report Type:Expedited (15-DaCompany Report #2329/20771
Age:65 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Atrial Fibrillation	Foreign	Detrol	PS		ORAL	2 MG 1 DOSE	

Initial or Prolonged	Dysuria	Health			
ORAL					
Other		Professional	Paspertin	SS	
		Company	Metoclopramide	SS	
		Representative	Hyoscine		
			Butylbromide	C	
			Hydromorphone		
			Hydrocloride	C	
			Doxycyline	C	
			Diclofenac Sodium	C	
			Piritramide	C	

Date:10/01/98ISR Number: 3136635-6Report Type:Direct Company Report #
Age:21 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Dystonia		Metoclopramide	PS		ORAL
PO 10 MG BID						
			Compazine	C		

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

Outcome	PT
Other	Condition Aggravated
	Dyskinesia
	Dyspepsia

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

Date:10/05/98ISR Number: 3138027-2Report Type:Direct Company Report #
Age:18 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Other	Amenorrhoea		Lo-Ovral	PS		
#8						
	Pregnancy On Oral		Reglan	SS		
10 MG #2						
	Contraceptive		Na	C		
	Pregnancy Test Positive					

Date:10/06/98ISR Number: 3138820-6Report Type:Expedited (15-DaCompany Report #D/98/03712/SIM03
Age:48 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Death	Blister	Foreign	Sandimmun Optoral	PS		ORAL
350 MG; ORAL						
Required	Conjunctival Hyperaemia	Study	Lasix	SS		
INTRAVENOUS	330 MG;					
Intervention to	Dermatitis	Health				
INTRAVENOUS;						
Prevent Permanent	Diarrhoea	Professional				
INFUSION						
Impairment/Damage	Epidermolysis Bullosa		Praxiten	SS		ORAL
10 MG ORAL						

		Fungal Infection	Tazobac	SS		
INTRAVENOUS	13.5 G					
		Graft Versus Host Disease				
INTRAVENOUS;						
		Mucosal Erosion				
INFUSION						
		Mucosal Inflammation	Dilaudid	SS		
INTRAVENOUS	2 MG					
		Pruritus				
INTRAVENOUS;						
		Rash Maculo-Papular				
INFUSION						
		Renal Failure Acute	Diflucan	SS		
INTRAVENOUS	200 MG;					
		Sepsis				
INTRAVENOUS;						
		Shock				
INFUSION,						
		Toxic Epidermal				
ORAL						
		Necrolysis	Thrombocyte Concentrate	SS		
			Erythrocyte Concentrate	SS		
			Dopamin	SS		
INTRAVENOUS	250 MG;					
INTRAVENOUS						
INFUSION						
			Paspertin	SS		
INTRAVENOUS	30 MG;					
INTRAVENOUS						
INFUSION						
			Alt Insulin	SS		
100 IU						
			Vergentan	SS		
			Diazepam	SS		ORAL
ORAL						
			Meronem	SS		
INTRAVENOUS	3 G					
INTRAVENOUS						
INFUSION						
			Paracetamol	SS		
1 G						
			Presomen	SS		ORAL
0.3 MG						
ORAL						

	Folsan	SS
	Ciprobay	SS

10 MG; ORAL

INTRAVENOUS INTRAVENOUS

INFUSION,					
ORAL					
200 MG;			Sempera	SS	ORAL
ORAL					
INTRAVENOUS	2 G		Novaminsulfon	SS	
INTRAVENOUS					
INFUSION					
INTRAVENOUS	1500 MG;		Clont	SS	
INTRAVENOUS					
INTRAVENOUS	2 G		Fortum	SS	
INTRAVENOUS;					
INFUSION					
INTRAVENOUS	INTRAVENOUS		Humanalbumin	SS	
INFUSION					
INTRAVENOUS	INTRAVENOUS;		Buscopan	SS	
INJECTION					
INTRAVENOUS	96 MG;		Urbason	SS	
INTRAVENOUS					
INFUSION					
ORAL			Maaloxan	SS	ORAL
ORAL			Nizax	SS	ORAL
25 MG; ORAL			Saroten	SS	ORAL

Date:10/06/98ISR Number: 3138858-9Report Type:Expedited (15-DaCompany Report #B0056506
Age:30 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Sinoatrial Block	Foreign	Nimbex	PS		INTRAVENOUS	2 MG/ML; INTRAVENOUS INJECTION	
			Metoclopramide Injection	SS		INTRAVENOUS	INTRAVENOUS	
			Cisapride	SS		ORAL	1 MG/ML; ORAL	
			Omeprazole	C				
			Metolazone	C				

Date:10/09/98ISR Number: 3140442-8Report Type:Direct Company Report #
Age:69 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Dermatitis	Health	Metoclopramide	PS	Gensia	INTRAVENOUS	10MG IV Q6	
	Pruritus	Professional	Ranitidine	SS	Glaxo	INTRAVENOUS	50 MG IV Q8	
			Dexametasone	C				
			Trovafloxacin	C				

Date:10/13/98ISR Number: 3142055-0Report Type:Expedited (15-DaCompany Report #199812862HPD
Age:48 YR Gender:Female I/FU:I

Outcome	PT
Death	Acute Myeloid Leukaemia
Hospitalization - Initial or Prolonged	Blister
	Cardiac Failure
	Condition Aggravated
	Conjunctival Hyperaemia
	Dermatitis
	Diarrhoea
	Epidermolysis Bullosa
	Fungal Infection

		Gastroenteritis							
		Graft Versus Host Disease							
		Hyperlipidaemia		Report Source	Product	Role	Manufacturer		Route
Dose	Duration								
		Mouth Ulceration		Foreign	Urbason	PS			
INTRAVENOUS	96 MG/DAY IV								
		Pruritus		Study	Lasix	SS			
INTRAVENOUS	20 UP TO 330								
		Rash Erythematous		Health					
MG QD IV									
		Rash Macular		Professional	Praxiten	SS			ORAL
10 MG/DAY PO									
		Renal Failure			Tazobac	SS			
INTRAVENOUS	4.5 G TID IV	10	DAY						
		Sepsis			Dilaudid	SS			
INTRAVENOUS	2 MG/DAY IV	1	WK						
		Supraventricular			Diflucan	SS			
INTRAVENOUS	100 UP TO 200								
		Tachycardia							
MG QD IV	18 DAY								
		Toxic Epidermal Necrolysis			Thrombozytenkonzentrat	SS			
INTRAVENOUS	IV	3	DAY						
					Thrombozytenkonzentrat	SS			
INTRAVENOUS	IV	1	DAY						
					Erythrozytenkonzentrat	SS			
INTRAVENOUS	IV	1	DAY						
					Dopamin	SS			
INTRAVENOUS	250 MG/DAY IV	1	WK						
					Paspertin	SS			
INTRAVENOUS	10 UP TO 30								
MG QD IV	6 DAY								
					Alt-Insulin	SS			
INTRAVENOUS	100 IU/DAY IV								
					Vergentan	SS			
INTRAVENOUS	IV	15	DAY						
					Diazepam	SS			ORAL
7.5 UP TO 10									
U QD PO	2 WK								
					Meronem	SS			
INTRAVENOUS	1 G TID IV	5	DAY						
					Paracetamol	SS			ORAL
1 G/DAY PO	6 DAY								

1 U/DAY PO	1	WK		
INTRAVENOUS	15 UP TO 30			
MMOL QD IV	3	DAY		
5 UP TO 10 MG				
QD PO	4	DAY		
INTRAVENOUS	200 UP TO 600			
MG QD IV	1	DAY		
200 MG/DAY PO	2	DAY		
175 MG QD PO	1	DAY		
INTRAVENOUS	2 G/DAY IV	2	DAY	
INTRAVENOUS	500 MG TID IV	6	DAY	
INTRAVENOUS	2 G/DAY IV	9	DAY	
1	DAY			
5	DAY			
1	DAY			
200 MG/DAY PO	2	DAY		
2	DAY			
25 MG/DAY PO				

Presomen 0.3 Mite Sugar-Coated	SS		ORAL
Sodium Phosphate	SS		
Folsan 5	SS		ORAL
Ciprobay	SS		
Sempera	SS		ORAL
Sandimmun Optoral	SS		ORAL
Novaminsulfon	SS		
Clont	SS		
Fortum	SS		
Humanalbumin	SS		
Buscopan	SS		
Maaloxan	SS		
Diflucan	SS		ORAL
Nizax	SS	Lilly	
Saroten	SS		ORAL
Dolantin	C		
Lamisil	C		
Panthenol As	C		
Zyloric	C		
Frisium	C		
Ursofalk	C		
Sodium Bicarbonate	C		
Potassium Chloride	C		
Zovirax	C		
Heparin	C		
Amphotericin B	C		
Isoptin	C		
Sodium Chloride	C		
Dipeptamin	C		
Glucose	C		
Ampho-Moronal	C		

Euthyrox	C
Endoxan	C
Kevatril	C
Uromitexan	C
Magnesium Sulfate	C
Vomex A	C
Aminomix	C
Pfefferminzoel	C
Sandimmun	C
Atosil	C
Allcept	C
Comycin	C
Zofran	C
Nephrotect	C
Cernevit	C
Tracitrans	C
Lipofundin	C
Calcium Gluconate	C
Pepdul	C
Konakion	C
Aminoplamal	C
Multibionta N	C
Anithistamines For Topical Use	C
Novalgin	C

Date:10/19/98ISR Number: 3143404-XReport Type:Expedited (15-DaCompany Report #8-98160-014A
Age:58 YR Gender:Female I/FU:F

Outcome	PT
Disability	Akathisia
	Anxiety
	Arthralgia
	Asthenia
	Blindness
	Blood Cholesterol Increased
	Blood Glucose Increased
	Blood Triglycerides Increased
	Dysarthria
	Dysgraphia
	Dyskinesia
	Dyspnoea
	Dystonia

Emotional Disorder
Emphysema
Eye Pain
Facial Pain
Facial Palsy
Fatigue
Gamma-Glutamyltransferase
Increased
Haematocrit Decreased
Headache
Insomnia
Irritability
Muscle Twitching
Musculoskeletal Stiffness
Nervousness

	Parkinsonism Red Blood Cell Count Decreased	Report Source	Product	Role	Manufacturer	Route Dose Duration
	Restlessness	Consumer	Reglan	PS		ORAL 10 MG THREE
	Rhinitis					TO FOUR TIMES
	Tardive Dyskinesia					DAILY ORAL
	Vomiting		Carafate	C		
			Estrace	C		
			Pepcid	C		
			Premarin	C		

Date:10/28/98ISR Number: 3148899-3Report Type:Expedited (15-DaCompany Report #JAGER-40898
Age:48 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Death	Angiopathy	Foreign	Sempera			
Life-Threatening	Cardiac Failure	Health	(Itraconazole)	PS	Janssen	ORAL 200 MG 1
	Fungal Sepsis	Professional				DAILY ORAL
	Pruritus		Lasix (Furosemide)	SS		DAILY
	Renal Failure					INFUSION; 20
	Toxic Epidermal					TO 330 MG
	Necrolysis					DAILY
			Praxiten (Oxazepam)	SS		ORAL 10 MG 1 DAILY ORAL
			Tazobac	SS		INTRAVENOUS 4.5G AMPOULE 3 DAILY
						INTRAVENOUS 10 DAY
			Thrombozytenkonzentrat (Platelets, Human			

				Blood)	SS	
1						
DAILY/SINGLE	3	DAY				
				Dopamin (Dopamine)	SS	
INTRAVENOUS	250MG					
SINGLE/DAILY						
INTRAVENOUS						
AMPOULE	4	WK				
				Alt-Insulin (Insulin, Unspec)	SS	
UP TO 100						
UNITS/DAY						
				Diazepam (Diazepam)	SS	ORAL
DAILY ORAL						
7.5 TO 10						
MG/DAY	13	DAY				
				Paracetamol (Paracetamol)	SS	ORAL
DAILY:ORAL UP						
TO 1G/DAY	5	DAY				
				Buscopan (Hyoscine Butylbromide)	SS	
INTRAVENOUS	1 DAILY					
INTRAVENOUS						
AMPOULE	4	DAY				
				Humanalbumin (Albumin)	SS	
INTRAVENOUS	100 ML SINGLE					
INTRAVENOUS						
AMPOULE; 20%						
SOLUTION						
				Fortum (Ceftazidime)	SS	
INTRAVENOUS	2 G DAILY					
INTRAVENOUS						
AMPOULE	8	DAY				
				Clont (Metronidazole)	SS	
INTRAVENOUS	500 MG 3					

DAILY

INTRAVENOUS

AMPOULE	5	DAY				
			Novaminsulfon (Metamizole)	SS		
INTRAVENOUS	2 G DAILY					
INTRAVENOUS						
AMPOULE						
			Sandimmune Optoral (Ciclosporine)	SS		ORAL
175 MG 2						
DAILY ORAL						
			Ciprobay (Ciprofloxacin)	SS		
INTRAVENOUS	200MG 3 DAILY					
INTRAVENOUS						
AMPOULE						
			Folsan (Folic Acid)	SS		ORAL
5 TO 10						
MG/DAY						
DAILY/SINGLE						
ORAL	3	DAY				
			Presomen Mite (Estrogens Conjugated)	SS		ORAL
.3MG 1 DAILY						
ORAL	6	DAY				
			Saroten (Amitriptyline)	SS		ORAL
25MG DAILY						
ORAL						
			Nizax (Nizatidine)	SS		ORAL
1 DAILY ORAL						
CAPSULES						
			Maaloxan (Maaloxan(R))	SS		ORAL
SINGLE DOSE						

ORAL						
				Urbason (Methylprednisolone)	SS	
INTRAVENOUS	95 MG DAILY					
INTRAVENOUS						
AMPOULE						
				Meronem (Meropenem)	SS	
INTRAVENOUS	1 G 3 DAILY					
INTRAVENOUS						
AMPOULE						
				Vergantan (Alizapride)	SS	
INTRAVENOUS	1 DAILY					
INTRAVENOUS						
AMPOULE	14	DAY				
				Paspertin (Metoclopramide)	SS	
INTRAVENOUS	DAILY					
INTRAVENOUS						
10-30 MG	5	DAY				
				Erythrozytenkontenzrat (Red Blood Cells)	SS	
INTRAVENOUS	2 DAILY					
INTRAVENOUS						
				Dilaudid (Hydromorphone)	SS	
INTRAVENOUS	2 MG DAILY					
AMPOULE						
INTRAVENOUS	6	DAY				
				Diflucan (Fluconazole)	SS	ORAL
200 MG DAILY						
ORAL	4	WK				
				Diflucan (Fluconazole)	C	
INTRAVENOUS	DAILY					
INTRAVENOUS	17	DAY				
				Natriumbicarbonat	C	
				Kaliumchlorid	C	

Zovirax	C
Heparin	C
Amphotericin B	C
Isoptin	C

Nacl	C
Dipeptamin	C
Glucose	C
Ampho-Moronal	C
Euthyrox	C
Mg So4	C
Vomex	C
Pfefferminzoel	C
Sandimmun	C
Cellcept	C
Vancomycin	C
Cernevit	C
Tracitrans	C
Lipofundin	C
Calciumgluconat	C
Konakion	C
Aminoplasmal	C
Na Po4	C
Multibionta	C
Antihistaminikum	C
Novalgin	C
Vidisic	C
Ursofalk	C

Date:11/06/98ISR Number: 3153414-4Report Type:Expedited (15-DaCompany Report #1998PK45778
Age:48 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardiac Failure	Foreign	Merrem	PS		INTRAVENOUS	3 G	DAILY IV
Life-Threatening	Fungal Sepsis	Health	Lasix	SS				
Hospitalization -	Pruritus	Professional	Praxiten	SS				
Initial or Prolonged	Renal Failure	Other	Tazobec	SS		INTRAVENOUS	4.5 G	TID IV
	Shock		Dilaudid	SS		INTRAVENOUS	2 MG	DAILY IV
	Toxic Epidermal Necrolysis		Diflucan	SS				
			Thrombocyte Concentrate	SS				
			Erythrocyte Concentrate	SS				
			Dopamin	SS		INTRAVENOUS	250 MG	DAILY

IV

	Paspertin	SS	
	Insulin	SS	
	Vergentan	SS	
	Diazepam	SS	
	Paracetamol	SS	
	Presomen	SS	
	Folsan	SS	
	Ciprobay	SS	
	Sempera	SS	ORAL

200 MG DAILY

PO

	Sandimmun	SS	ORAL

350 MG DAILY

PO

	Novaminsulfon-Ratiopharm	SS	

INTRAVENOUS	2 G DAILY IV		
	Clont	SS	

INTRAVENOUS	1500 MG DAILY		

IV

	Fortum	SS	

INTRAVENOUS	2 G DAILY IV		
	Humanalbumin	SS	

INTRAVENOUS	100 ML DAILY		

IV

	Buscopan	SS	

		Urbason	SS	
INTRAVENOUS	96 MG DAILY			
IV				
		Maaloxan	SS	
		Diflucan	SS	ORAL
200 MG DAILY				
PO				
		Nizax	SS	
		Saroten	SS	ORAL
25 MG DAILY				
PO				
		Dolantin	C	
		Lamisil	C	
		Panthenol	C	
		Zyloric	C	
		Ciprobay	C	
		Frisium	C	
		Ursofalk	C	
		Sodium Bicarbonate	C	
		Potassium Chloride	C	
		Zovirax	C	
		Heparin	C	
		Amphotericin B	C	
		Isoptin	C	
		Sodium Chloride	C	
		Dipeptamin	C	
		Glucose	C	
		Ampho-Moronal	C	
		Euthyrox	C	
		Endoxan	C	
		Kevatril	C	
		Uromitexan	C	
		Mg S04	C	
		Vomex	C	
		Aminomix	C	
		Pepermint Oil	C	
		Sandimmun	C	
		Stem Cells	C	
		Atosil	C	
		Cellcept	C	
		Vancomycin	C	
		Zofran	C	
		Nephrotect	C	
		Cernevit	C	

Tracitrans	C
Lipofundin	C
Calcium Gluconate	C
Pepdul	C
Konakion	C
Aminoplasmal	C
Na Po4	C
Multibionta	C
Antihistaminic Gel	C
Novalgin	C
Zovirax	C
Vidisic	C
....	C

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/09/98ISR Number: 3154399-7Report Type:Expedited (15-DaCompany Report #8-98286-059A
Age:54 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Cerebellar Infarction	Health	Reglan	PS		INTRAVENOUS	10 MG IV X 7	
	Cerebrovascular Accident	Professional					DOSES	
	Nodding Of Head					INTRAVENOUS		
	Tremor		Flagyl	C				

Date:11/10/98ISR Number: 3155794-2Report Type:Expedited (15-DaCompany Report #1998MCL0001
Age:30 MON Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Acidosis	Consumer	Metoclopramide	PS			1.5 MG Q6H IV	
	Blood Culture Positive		Antibiotics	C				
	Blood Pressure Systolic Decreased							
	Cardiac Arrest							
	Chills							
	Cyanosis							
	Depressed Level Of Consciousness							
	Disseminated Intravascular Coagulation							
	Drug Toxicity							
	Dystonia							
	Eye Disorder							
	Hyperpyrexia							
	Lethargy							
	Livedo Reticularis							
	Miosis							
	Muscle Spasms							
	Oculogyration							
	Oxygen Saturation Decreased							
	Pulse Absent							
	Purpura							
	Respiratory Arrest							
	Sepsis							

Tachycardia

Date:11/16/98ISR Number: 3158290-1Report Type:Expedited (15-DaCompany Report #9825147
Age:78 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Convulsion	Health	Cardura	PS		ORAL	2.00 MG TOTAL	
Initial or Prolonged	Drug Interaction	Professional					DAILY ORAL	
			Reglan	SS				
			Insulin	C				
			Micronase	C				
			Pepcid	C				

Date:11/17/98ISR Number: 3158536-XReport Type:Expedited (15-DaCompany Report #1998USA 003617
Age:85 YR Gender:Female I/FU:I

Outcome	PT
Death	Conjunctival Hyperaemia
Hospitalization -	Dermatitis Bullous
Initial or Prolonged	Dizziness

	Mucosal Erosion Pyrexia					
Dose	Duration	Report Source	Product	Role	Manufacturer	Route
		Foreign	Beloc Zok	PS		ORAL
50MG, QD, PERORAL		Company				
		Representative	Bactrim Forte	SS		
			Unacid	SS		
1 DAY			Metoprolol Tartrate	SS		ORAL
50MG	18 DAY		Paspertin	SS		
8 DAY			Delix	SS		
			Amaryl	SS		
			Peritrast-Oral Ct	SS		
1 DAY			Iopental	SS		
1 DAY			Lanitop	SS		ORAL
			Acetylsalicylic Acid	SS		
			Sodium Chloride	C		
			Bepanthen	C		

Date:11/18/98ISR Number: 3159446-4Report Type:Expedited (15-DaCompany Report #8-98315-008A
Age:32 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization -	Bronchospasm	Foreign	Reglan	PS		ORAL
10 MG X 2						
Initial or Prolonged	Cyanosis	Literature				
DOSES ORAL						
Other	Dyspnoea		Albuterol Sulfate			
Required	Flushing		Aerosol	C		
Intervention to	Hypokalaemia		Amitriptyline	C		
Prevent Permanent	Laryngeal Oedema		Estrogen	C		
Impairment/Damage	Peak Expiratory Flow Rate		Fluticasone			
	Decreased		Propionate Aerosol	C		
	Po2 Decreased		Imipenem	C		
	Respiratory Alkalosis		Oxazepam	C		
	Stridor		Prednisone	C		
	Tachycardia		Ranitidine			

	Tachypnoea		Suspension	C		

Date:11/25/98ISR Number: 3163969-1Report Type:Direct Company Report #
Age:51 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hallucination		Reglan	PS				
			Silver Sulfadiazine	C				
			Nifedipine (Adalat Cc)	C				
			Metoprolol	C				
			Terazosin	C				
			Fosinopril	C				
			Insulin Reg Human	C				
			Insulin Nph Human	C				
			Aloh.Mgoh/Simeth	C				
			Promethazine	C				
			Acetaminophen	C				
			Clonidine	C				
			Nitroglycerin Transdermal Patch	C				
			Ranitidine	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/25/98ISR Number: 3287928-3Report Type:Periodic Company Report #JAUSA-34978
Age:62 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Attention Deficit/Hyperactivity Disorder	Health Professional	Propulsid (Cisapride), Janssen, Tablet	PS	Janssen			
SEE IMAGE								
			Reglan (Metoclopramide) Tablet	SS		ORAL		
ORAL								

Date:11/25/98ISR Number: 3289243-0Report Type:Periodic Company Report #JAUSA-33835
Age:50 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Therapeutic Response Decreased	Consumer	Propulsid (Cisapride),Janssen, Tablet	PS	Janssen	ORAL		
ORAL								
			Reglan (Metoclopramide) Tablet 10 Mg	SS		ORAL		
10 MG 4 DAILY								
ORAL								

Date:11/27/98ISR Number: 3163533-4Report Type:Direct Company Report #
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Congenital Limb Hyperextension		Metoclopramide	PS		ORAL	10MG PO AC & HS	
	Dyskinesia Gaze Palsy Hyperreflexia		Thiothixine	C				

Date:12/02/98ISR Number: 3165836-6Report Type:Expedited (15-DaCompany Report #WAES 96115567
Age:17 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Blister	Foreign	Primaxin	PS				
						INTRAVENOUS	IV/INJ	2 DAY
Life-Threatening	Corneal Erosion		Heparin	SS				
						INTRAVENOUS	INJ/IV	
	Mucosal Erosion		Furosemide	SS				
						INTRAVENOUS	INJ/IV	5 DAY
	Multi-Organ Failure		Diazepam	SS				
								1 DAY
	Pyrexia		Acetaminophen	SS		ORAL		
								4 DAY
	Rash Maculo-Papular		Tobramycin	SS				
						INTRAVENOUS	INJ	4 DAY
	Sepsis		Amphotericin B	SS				
						INTRAVENOUS		
	Skin Lesion		Dipyrone	SS				
						INTRAVENOUS	INJ	1 DAY
	Stevens-Johnson Syndrome		Potassium Chloride	SS		ORAL		
								3 DAY
	Toxic Epidermal		Promethazine Hcl	SS				
						INTRAVENOUS	INJ	1 DAY
	Necrolysis		Lactulose	SS		ORAL		
								2 DAY
			Cotrimoxazole	SS		ORAL		
								2 DAY
			Clemastine Fumarate	SS				
						INTRAVENOUS	INJ	4 DAY
			Meperidine	SS				
						INTRAVENOUS	INJ	3 DAY
			Vancomycin Hcl	SS				
						INTRAVENOUS	INJ	15 DAY
			Methotrimeprazine	SS				
						INTRAVENOUS	INJ	6 DAY
			Metoclopramide	SS		ORAL		
								4 DAY
			Prednisolone	SS				
						INTRAVENOUS	INJ	5 DAY
			Ciprofloxacin	SS				
						INTRAVENOUS		5 DAY
			Ranitidine Hcl	SS				
						INTRAVENOUS		5 DAY
			Ceftazidime	SS				
						INTRAVENOUS	INJ	4 DAY
			Midazolam Hcl	SS				
						INTRAVENOUS	INJ	1 DAY

					Fluconazole	SS		ORAL PO
INTRAVENOUS	INJ				Ganciclovir	SS		
INTRAVENOUS	INJ				Omeprazole	SS		
INTRAVENOUS	INJ				Teicoplanin	SS		
INTRAVENOUS	INJ	1	DAY		Protein	SS		
INTRAVENOUS	INJ	4	DAY		Piperacillin	SS		
INTRAVENOUS	INJ	2	DAY		Filgrastim	SS		
INTRAVENOUS	INJ				Meropenem	SS		
					Acyclovir	C		
					Calcium	C		
					Doxycycline	C		
					Folic Acid	C		
					Lynestrenol	C		
					Metronidazole	C		
					Prednisone	C		
					Vitamins	C		

Date:12/03/98ISR Number: 3166991-4Report Type:Expedited (15-DaCompany Report #199813209HMRI
Age:35 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Blood Ph Decreased	Health	Dolasetron (Anzemet)	PS		INTRAVENOUS	12.5 MG ONCE	
Hospitalization -	Bradycardia	Professional				IV	1	DAY
Initial or Prolonged	Cardiac Arrest		Metoclopramide	SS		INTRAVENOUS	10MG ONCE IV	1 DAY
	Cardiac Disorder		Fentanyl	C				
	Cardiac Failure		Lidocaine	C				
	Dermatitis		Propofol	C				
	Hypertension		Oxygen	C				
	Mitral Valve Incompetence		Glycopyrronium Bromide	C				
	Po2 Increased		Nitrous Oxide	C				
	Pulse Absent		Sevoflurane	C				
	Tachycardia							
	Urticaria							

Date:12/03/98ISR Number: 3167528-6Report Type:Direct Company Report #
Age:5 MON Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Dyskinesia		Metoclopramide	PS		ORAL	0.5 PO QID	3 MON
Initial or Prolonged	Joint Stiffness		Ranitidine	SS			15 MG BID	3 MON
	Musculoskeletal Stiffness							
	Oculogyration							
	Salivary Hypersecretion							
	Staring							
	Tremor							

Date:12/04/98ISR Number: 3167148-3Report Type:Expedited (15-DaCompany Report #199813632HPD
Age:72 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Angina Pectoris	Foreign	Euglucon N Tablets	PS		ORAL	3.5 MG TID PO	
Initial or Prolonged	Face Oedema	Study	Corvaton Ratard					
	Pyrexia	Health	Tablets	SS		ORAL	1 U/DAY PO	
	Stevens-Johnson Syndrome	Professional	Novodigal	SS				
	Toxic Epidermal		Tranxilium	SS				
	Necrolysis		Lactulose	SS			16 DAY	
			Isoptin Mite	SS			9 DAY	
			Kalinor	SS			9 DAY	

					Heparin	SS		
3	DAY							
					Adumbran	SS		
2	DAY							
					Ass 100	SS		
					Dytide H	SS		
					Isoket 120 Retard	SS		
					Zyloric 300	SS		
					Sab Simplex	SS		
					Dilzem Retard	SS		
12	DAY							
					Glucobay 50	SS		
1	WK							
					Dulcolax	SS		
1	WK							
					Paspertin	SS		
1	DAY							
					Nitrolingual	C		
					Corangin	C		
					Norvasc	C		
					Multibionta	C		
					Bepanthen	C		
					Paracetamol	C		
					Basal-H-Insulin	C		
					Pepdul	C		
					Rithricin (Illegible)	C		

Date:12/08/98ISR Number: 3168486-0Report Type:Expedited (15-DaCompany Report #109324
Age:16 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Multi-Organ Failure	Foreign	Dormicum	PS		INTRAVENOUS	5 MG 1 X PER	
	Pyrexia	Study					ONE DOSE	
	Sepsis	Health					INTRAVENOUS	
	Stevens-Johnson Syndrome	Professional	Diazepam	SS			5 MG DAILY	
	Toxic Epidermal		Liquemin	SS			INTRAVENOUS	9700 IU DAILY
	Necrolysis						INTRAVENOUS	

INTRAVENOUS	250 MG DAILY	Cymeven	SS	
INTRAVENOUS	400 MG 1 X PER DAY ORAL	Diflucan	SS	ORAL
INTRAVENOUS	25 MG 1 X PER DAY	Octagam	SS	
INTRAVENOUS	240 MG 2 X PER DAY ORAL	Cotrim	SS	ORAL
INTRAVENOUS	500 MG 2 X PER DAY	Vancomycin	SS	
INTRAVENOUS	2.5 GRAM 1 X PER DAY	Fortum	SS	
INTRAVENOUS	1 GRAM 1 X PER DAY ORAL	Ben-U-Ron	SS	ORAL
10 ML 1 X PER DAY ORAL		Lactulose	SS	ORAL
INTRAVENOUS	500 MG 1 X PER ONE DOSE	Novalgin	SS	
INTRAVENOUS	15 MG DAILY	Ampho B	SS	
INTRAVENOUS	25 MG 1 X PER DAY	Dolantin	SS	

INTRAVENOUS

Zienam SS

INTRAVENOUS 650 MG 1 X

PER DAY				
INTRAVENOUS				
INTRAVENOUS	1 GRAM 2 X	Meronem	SS	
PER DAY				
INTRAVENOUS				
INTRAVENOUS	20 MG 1 X PER	Lasix	SS	
DAY				
INTRAVENOUS				
INTRAVENOUS	100 MG 1 X	Solu- Decortin H	SS	
PER DAY				
INTRAVENOUS				
INTRAVENOUS	1 AMPOULE 2 X	Tavegil	SS	
PER DAY				
INTRAVENOUS				
20 DROP 1 X		Paspertin	SS	ORAL
PER DAY ORAL				
ORAL		Rekawan	SS	ORAL
		Neurocil Injektionslosung	SS	
INTRAVENOUS	8 MG DAILY			
INTRAVENOUS				
INTRAVENOUS	280 MG 3 X	Ciprobay Infusionsloesung	SS	
PER DAY				
INTRAVENOUS				
INTRAVENOUS	1 AMPULE	Zantac	SS	

DAILY			
INTRAVENOUS			
INTRAVENOUS	500 MG 1 X	Targocid	SS
PER DAY			
INTRAVENOUS			
INTRAVENOUS	80 MG 2 X PER	Gernebcin	SS
DAY			
INTRAVENOUS			
SUBCUTANEOUS	150 MG 1 X	Neupogen	SS
PER DAY			
SUBCUTANEOUS			
INTRAVENOUS	25 MG 1 X PER	Atosil	SS
DAY			
INTRAVENOUS			
INTRAVENOUS	20 MG 2 X PER	Antra	SS
DAY			
INTRAVENOUS			
INTRAVENOUS	3.5 GRAM 3 X	Piperil	SS
PER DAY			
INTRAVENOUS			
		Folsan	C
		Decortin	C
		Multibionta	C
		Zovirax	C
		Calcium Brausetabletten	C
		Orgametril	C
		Clont	C
		Doxycyclin	C

Date:12/11/98ISR Number: 3169601-5Report Type:Expedited (15-DaCompany Report #199813755HPD
Age:34 YR Gender:Female I/FU:I

Outcome	PT
Death	Blister
Life-Threatening	Blood Creatinine

Increased Blood Urea Increased Dermatitis Epidermolysis Bullosa	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Liver Function Test	Foreign	Claforan	PS				
INTRAVENOUS						2 G TID IV	5 DAY
Abnormal	Study	Novalgin	SS				
INTRAVENOUS						QD IV	1 DAY
Oral Mucosal Eruption	Health	Novalgin	SS				
INTRAVENOUS						QD IV	1 DAY
Pruritus	Professional	Lasix	SS		ORAL		
20 MG QD PO						1 DAY	
Pyrexia		Dolantin	SS				
INTRAVENOUS						25 MG/DAY IV	1 DAY
Shock		Suprarenin	SS				
INTRAVENOUS						TID IV	3 DAY
Stevens-Johnson Syndrome		Allopurinol	SS		ORAL		
300 MG/DAY PO						15 DAY	
Toxic Epidermal		Augmentin	SS				
INTRAVENOUS						2 G BID IV	5 DAY
Necrolysis		Diflucan	SS		ORAL		
200 MG BID PO						5 DAY	
White Blood Cell Count		Diflucan	SS		ORAL		
200 MG BID PO						12 DAY	
Decreased		Paracetamol	SS		ORAL		
PO						1 DAY	
		Paracetamol	SS		ORAL		
PO						2 DAY	
		Paracetamol	SS		ORAL		
PO						1 DAY	
		Paracetamol	SS		ORAL		
PO						1 DAY	
		Gentamycin	SS				
INTRAVENOUS						120 MG TID IV	1 WK
		Ciprobay	SS				
INTRAVENOUS						QD IV	1 DAY
		Dormicum	SS				
INTRAVENOUS						10 MG/H IV	2 DAY
		Antra	SS				
INTRAVENOUS						20 MG/DAY IV	6 DAY
		Antra	SS				
INTRAVENOUS						20 MG/DAY IV	2 WK
		Zofran	SS				
INTRAVENOUS						QD IV	6 DAY
		Zofran	SS				
INTRAVENOUS						QD IV	3 DAY

15 MG/DAY THE	1	DAY					
5000 MG/DAY							
IVF	1	DAY					
15 MG/DAY THE	1	DAY					
TID PO	6	DAY					
TID PO	1	DAY					
INTRAVENOUS	Q2D IV		8	DAY			
INTRAVENOUS	BID IV		2	DAY			
INTRAVENOUS	BID IV		6	DAY			
SUBCUTANEOUS	300 UG/DAY SC		12	DAY			
QD PO	3	DAY					
INTRAVENOUS	500-500-0-500						
MG IV	5	DAY					
SUBCUTANEOUS	SC		2	WK			
5 DROP QD PO	6	DAY					
5 DROP QD PO	2	DAY					
1 MG/H IVF	9	DAY					
INTRAVENOUS	QD IV		8	DAY			
0.5-0.5-0-0.5							
G IVF	9	DAY					
QD PO	1	DAY					
0-0-2-2 G IVF	5	DAY					
INTRAVENOUS	3.75 MG/DAY						
IV	4	DAY					
INTRAVENOUS	QD IV		4	DAY			
0.5 G/DAY IVF	4	DAY					

Methotrexat	SS						
Methotrexat	SS						
Methotrexat	SS						
Imodium	SS						ORAL
Imodium	SS						ORAL
Multibionta	SS						
Paspertin	SS						
Paspertin	SS						
Leucomax	SS						
Pantozol	SS						ORAL
Metronidazol	SS						
Liquemin	SS						
Opium	SS						ORAL
Opium	SS						ORAL
Mst	SS						
Vitalipid	SS						
Vancomycin	SS						
Bifiteral	SS						ORAL
Ancotil	SS						
Dipidolor	SS						
Tavegil	SS						
Meronem	SS						

SUBCUTANEOUS 50 IU/DAY SC 4 DAY

INTRAVENOUS QD IV 4 DAY

INTRAVENOUS 40 MG/DAY IV 4 DAY

SUBCUTANEOUS SC 2 DAY

400 ML/DAY

IVF 2 DAY

0.5 G/DAY IVF 1 DAY

200 MG/DAY

IVF 3 DAY

INTRAVENOUS 200 MG/DAY IV 1 DAY

INTRAVENOUS 50 MG/DAY IV 1 DAY

Actrapid SS

Psyquil SS

Amphotericin B SS

Neupogen SS

Humanalbumin SS

Zienam SS

Dopamin SS

Sobelin Solubile SS

Isoptin SS

					Solu-Decortin H	SS		
INTRAVENOUS	50 MG/DAY IV	1	DAY					
					Ampho-Moronal	C		
					Fortecortin	C		
					Uromitexan	C		
					Dexamethason	C		
					Ifosfamid	C		
					Cytosin-Arabinosid	C		
					Vindesin	C		
					Leucovortin	C		
					Nutriflex	C		
					Vm-26 Bristol	C		
					Vergentan	C		
					Riopan	C		
					Magnorbin	C		
					Lipofundin Mct	C		
					Aminomel	C		
					Aminomix	C		
					Natriumbicarbonat	C		
					Uralyt-U Granulat	C		
					G5%	C		
					Nacl	C		
					Kcl-Perfusor	C		
					Glucose	C		
					Ferrosanol Duodenal	C		
					Urbason	C		

Date:12/11/98ISR Number: 3169656-8Report Type:Expedited (15-DaCompany Report #199813765HPD
Age:41 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Ano-Rectal Ulcer	Foreign	Novalgin	PS				
INTRAVENOUS							1 G/DAY IV	2 DAY
Initial or Prolonged	Blister	Study	Lasix	SS				
INTRAVENOUS							UP TO 80 MG	
	Haemolytic Uraemic	Health						
QD IV							8	DAY
	Syndrome	Professional	Daraprim	SS		ORAL		
25 MG/DAY PO								
	Mucous Membrane Disorder		Diflucan	SS		ORAL		
100 MG/DAY PO								
	Rash Macular		Thomapyrin	SS		ORAL		
PO							4	DAY

Toxic Epidermal
PO 6 DAY
Necrolysis
RESPIRATORY
(INHALATION) 300 MG/DAY
INH 1 DAY
INTRAVENOUS IV 1 DAY
INTRAVENOUS IV 5 DAY
5 DAY
INTRAVENOUS 25 MG/DAY IV 3 DAY
SUBCUTANEOUS 10 MG/DAY SC 1 DAY
PO 1 DAY
10 MG/ DAY PO 1 DAY
150 MG/DAY PO
PO 1 DAY
PO 4 DAY
PO 1 DAY
INTRAVENOUS IV 1 DAY
PO
1-1-1 G TID
PO

Ciprobay	SS	ORAL
Pentacarinat	SS	
Catapresan	SS	
Nepresol	SS	
Brevibloc	SS	
Ebrantil	SS	
Adalat	SS	
Entero Teknosal	SS	ORAL
Tranxilium	SS	ORAL
Zantic	SS	ORAL
Paractol	SS	ORAL
Lopirin Cor	SS	ORAL
Beloc Zok	SS	ORAL
Paspertin	SS	
Xanef	SS	ORAL
Calcium Carbonate	SS	ORAL
Loperamid	C	
Epivir	C	
Zerit	C	
Hyperforat Sodium Chloride	C	

Travegil	C
Solu Decortin H	C
Lasix	C
Kalinor	C
Decortin	C
Invasil	C

Date:12/14/98ISR Number: 3170562-3Report Type:Expedited (15-DaCompany Report #199812742RHF
Age:93 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Angioneurotic Oedema	Foreign	Furosemide	PS		ORAL	40 MG QD PO	
Initial or Prolonged	Nausea	Other	Bromazepam	SS		ORAL	1 U/DAY PO	
	Vomiting		Bromhexine	SS			INTRAVENOUS	8 MG/DAY IV 1 DAY
			Hydroxyzine Hydrochloride	SS		ORAL	50 MG QD PO	
			Nifedipine	SS		ORAL	20 MG QD PO	
			Metoclopramide	SS			INTRAVENOUS	10 MG/DAY IV 1 DAY

Date:12/14/98ISR Number: 3170574-XReport Type:Expedited (15-DaCompany Report #B0057436
Age:73 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Difficulty In Walking	Foreign	Leukeran	PS		ORAL	PER DAY /	
Initial or Prolonged	Dyskinesia	Health					ORAL	
Disability	Extrapyramidal Disorder	Professional	Metoclopramide	SS		ORAL	10 MG / THREE	
	Tremor						TIMES PER DAY	
							/ ORAL	
			Blood	C				

Date:12/14/98ISR Number: 3170643-4Report Type:Expedited (15-DaCompany Report #109858
Age:34 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Blister	Foreign	Midazolam					
Life-Threatening	Blood Albumin Decreased	Study	Hydrochloride	PS			INTRAVENOUS	10 MG 1 X PER
	Constipation	Health						HOUR
	Dermatitis	Professional						INTRAVENOUS
	Diarrhoea	Other	Heparin Sodium	SS			SUBCUTANEOUS	7500 IU DAILY
	Fluid Retention							SUBCUTANEOUS
	Fungal Infection		Allopurinol	SS			ORAL	300 MG DAILY
	Gastrointestinal Disorder							ORAL
	Hyperglycaemia		Omeprazole	SS			INTRAVENOUS	20 MG DAILY
	Hypertension							INTRAVENOUS
	Hypovitaminosis		Diflucan	SS			ORAL	200 MG 2 X
	Lip Disorder							PER DAY ORAL
	Neutropenia		Zofran	SS			INTRAVENOUS	1 AMPULE 1 X
	Pain							PER DAY
	Pruritus							INTRAVENOUS
	Pyrexia		Methotrexate	SS			INTRATHECAL	15MG DAILY 1
	Restlessness							X PER ONE
	Shock							DOSE
	Stevens-Johnson Syndrome							INTRATHECAL;
	Toxic Epidermal							5000 MG DAILY
	Necrolysis		Imodium	SS			ORAL	2 DOSE FORM 3
								X PER DAY
								ORAL

Multibionta SS

INTRAVENOUS 1 AMPULE 1 X

PER 2 DAYS				
INTRAVNOUS				
		Metoclopramide Hydrochloride	SS	
INTRAVENOUS	1 AMPULE 2 X			
PER DAY				
INTRAVENOUS				
		Leucomax	SS	
SUBCUTANEOUS	300 MCG DAILY			
SUBCUTANEOUS				
		Pantoprazole	SS	ORAL
1 DOSE FORM 1				
X PER DAY				
ORAL				
		Acetaminophen	SS	ORAL
1 X PER ONE				
DOSE ORAL				
		Gentamycin	SS	
INTRAVENOUS	120 MG 3 X			
PER DAY				
INTRAVENOUS				
		Cefotaxime Sodium	SS	
INTRAVENOUS	2 GRAM 3 X			
PER DAY				
INTRAVENOUS				
		Metronidazole	SS	
INTRAVENOUS	500 MG 3 X			
PER DAY				
INTRAVENOUS				
		Opium	SS	ORAL
5 DROP 1 X				
PER DAY ORAL				

INTRAVENOUS	2 GRAM 2 X PER DAY	Augmentin	SS	
INTRAVENOUS				
INTRAVENOUS	1 MG 1 X PER HOUR	Morphine Sulfate	SS	
INTRAVENOUS				
INTRAVENOUS	1 AMPULE 1 X PER DAY	Vitalipid	SS	
INTRAVENOUS				
INTRAVENOUS	1 AMPULE 1 X PER ONE DOSE	Novalgin	SS	
INTRAVENOUS				
INTRAVENOUS	.5 GRAM 3 X PER DAY	Vancomycin	SS	
INTRAVENOUS				
1 X PER OND DOSE ORAL		Lactulose	SS	ORAL
20 MG 1 X PER ONE DOSE ORAL		Lasix	SS	ORAL
INTRAVENOUS	2 GRAM 2 X PER DAY	Ancotil	SS	
INTRAVENOUS				
INTRAVENOUS	3.75 MG DIALY	Piritramide	SS	
INTRAVENOUS				
INTRAVENOUS	1 AMPULE 1 X PER DAY	Tavegil	SS	

INTRAVENOUS

INTRAVENOUS .5 GRAM DIALY

INTRAVENOUS

SUBCUTANEOUS 50 IU DIAY

SUBCUTANEOUS

INTRAVENOUS 1 AMPULE 1 X

PER DAY

INTRAVENOUS

INTRAVENOUS 40 MG DAILY

INTRAVENOUS

SUBCUTANEOUS 1 AMPULE 1 X

PER DAY

Meropenem SS

Insulin Human SS

Trifluprомazine SS

Amphotericin B SS

Neupogen SS

SUBCUTANEOUS			
INTRAVENOUS	400 ML DAILY	Albumin Human	SS
INTRAVENOUS			
INTRAVENOUS	25 MG DAILY 1	Dolantin	SS
X PER ONE			
DOSE			
INTRAVENOUS			
INTRAVENOUS	.5 GRAM	Zienam	SS
DAILIY 1 X			
PER ONE DOSE			
INTRAVENOUS			
INTRAVENOUS	200 MG DAILY	Dopamine Hydrochloride	SS
INTRAVENOUS			
INTRAVENOUS	1 AMPULE 3 X	Epinephrine	SS
PER DAY			
INTRAVENOUS			
INTRAVENOUS	200 MG DAILY	Clindamycin	SS
1 X PER ONE			
DOSE			
INTRAVENOUS			
INTRAVENOUS	1 AMPULE 1 X	Ciprofloxacin	SS
PER ONE DOSE			
INTRAVENOUS			
		Verapamil	

		Hydrochloride	SS
INTRAVENOUS	50 MG DAILY 1		
X PER PER ONE			
DOSE			
INTRAVENOUS			
		Prednisolone	SS
INTRAVENOUS	50 MG DIALY 1		
X PER ONE			
DOSE			
INTRAVENOUS			
		Ferrosanol Duodenal (Ferrous Glycine Sulfate)	C
		Urbason (Methylprednisolone)	C
		Ampho Moronal (Amphotericin B)	C
		Fortecortin (Dexaethasone)	C
		Nahco3 (Sodium Bicarbonate)	C
		Uralyt U (Potassium Sodium Hydrogen Citrate)	C
		Glucose 5% (Glucose)	C
		Sterofundin (Intravenous Solution Nos)	C
		Uromitexan (Mesna)	C
		Dexamethason (Desamethasone)	C
		Ifosfamide (Ifosfamide)	C
		Cytosine Arabinoside (Cytarabine)	C
		Vindesin (Vindesine)	C
		Leucovorin (Leucovorin)	C
		Nacl (Sodium	

Chloride)	C
Nutriflex (Amino Acids Nos)	C
Vm 26	C
Vergentan (Alizapride Hydrochloride)	C
Riopan (Magaldrate)	C
Magnorbin (Magnesium Ascorbate)	C
Lipofundin (Intravenous Fat Emulsion)	C
Aminomel (Amino Acids Nos / Minerals Nos)	C
Kcl (Potassium Chloride)	C
Aminomix (Amino Acids Nos / Carbohydrates Nos / Electolytes Nos)	C

Date:12/23/98ISR Number: 3173638-XReport Type:Expedited (15-DaCompany Report #JADEN-42239
Age:30 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Sinoatrial Block	Foreign	Prepulsid	PS	Janssen	ORAL-		
Initial or Prolonged			Primperan	SS		INTRAVENOUS	60 MG	DAILY
			Nimbex	SS		INTRAVENOUS	2 MG/ML	
			Losec	C		INJECTION		
			Zaroxolyn	C				

Date:12/24/98ISR Number: 3173914-0Report Type:Expedited (15-DaCompany Report #199813947HPD
Age:56 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Burning Sensation Mucosal	Foreign	Trental	PS				
INTRAVENOUS							15 ML/DAY IV	5 DAY
Initial or Prolonged	Conjunctival Hyperaemia	Study	Trental	SS		ORAL		
600 MG BID PO							9	DAY
	Dysphagia	Health	Tenormin Tablets	SS		ORAL		
25-0-25 MG QD								
	Face Oedema	Professional						
PO							13	DAY
	Oral Mucosal Blistering		Lopirin Cor Tablets	SS		ORAL		
2 U/DAY PO							11	DAY
	Pruritus		Lopirin Cor Tablets	SS		ORAL		
2 U/DAY PO								
	Rash Maculo-Papular		Beloc Zoc Mite					
	Stevens-Johnson Syndrome		Tablets	SS		ORAL		
1 U/DAY PO							5	DAY
			Tramal Drops	SS		ORAL		
20								
DROP/DAY PO								
			Timonil 400	SS		ORAL		
400 MG/DAY PO							2	DAY
			Timonil 600 Retard	SS		ORAL		
600 UP TO 900								
MG QD PO								
			Paspertin Drops	SS		ORAL		
20 DROP TID								
PO								
			Antra Capsules	SS		ORAL		
20 MG QD PO							10	DAY
			Tavegil	SS				
			Lopresor Mite	C				
			Nootrop 800	C				
			Vomex A	C				
			Loperamid	C				

			Ebrantil	C		
			Akineton	C		
			Sterofundin	C		

Date:12/24/98ISR Number: 3176411-1Report Type:Expedited (15-DaCompany Report #1998PK45936
Age:34 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Blister	Foreign	Meronem	PS				
							INTRAVENOUS	500 MG DAILY
Life-Threatening	Dermatitis	Health						
							IV	
	Epidermolysis Bullosa	Professional	Allopurinol	SS		ORAL		
							300 MG DAILY	
	Lip Disorder	Other						
							PO	
	Shock		Antra	SS				
							INTRAVENOUS	20 MG DAILY
	Stevens-Johnson Syndrome							
							IV	
	Toxic Epidermal		Antra	SS				
							INTRAVENOUS	20 MG DAILY
	Necrolysis							
							IV	
			Diflucan	SS		ORAL		
							200 MG BID PO	
			Zofran	SS				
			Methotrexate	SS				
							15 MG DAILY	
							IT	
			Methotrexate	SS				
							INTRAVENOUS	5000 MG DAILY
							IV	
			Imodium	SS				
			Paspertin	SS				
			Multibionta	SS				
			Multibionta	SS				
			Multibionta	SS				
			Multibionta	SS				
			Multibionta	SS				
			Multibionta	SS				
			Multibionta	SS				

		Multibionta	SS
		Novalgin	SS
		Vitalipid	SS
		Mst	SS
INTRAVENOUS	1 MG/HR DAILY		
IV			
		Augmentan	SS
INTRAVENOUS	2 G BID IV		
		Opium	SS
		Opium	SS
		Liquemin	SS
		Metronidazol	SS
		Claforan	SS
INTRAVENOUS	2 G TID IV		
		Ciprobay	SS
		Sobelin Solubile	SS
INTRAVENOUS	200 MG DAILY		
IV			
		Suprarenin	SS
		Dopamin	SS
INTRAVENOUS	200 MG DAILY		
IV			
		Zienam	SS
INTRAVENOUS	0.5 G DAILY		
IV			
		Dolantin	SS
INTRAVENOUS	25 MG DAILY		
IV			
		Humanalbumin	SS
INTRAVENOUS	400 ML DAILY		
IV			
		Neupogen	SS
		Amphotericin B	SS
INTRAVENOUS	40 MG DAILY		
IV			
		Dormicum	SS
INTRAVENOUS	10 MG /HR		
DAILY IV			
		Solu Decortin H	SS
INTRAVENOUS	50 MG DAILY		

IV				
		Isoptin	SS	
INTRAVENOUS	50 MG DAILY			
IV				
		Psyquil	SS	
		Actrapid	SS	
INTRAVENOUS	50 U DAILY IV			
		Tavegil	SS	
		Dipidolar	SS	
INTRAVENOUS	3.75 MG DAILY			
IV				
		Lasix	SS	ORAL
20 MG QD PO				
		Bifiteral	SS	
		Vancomycin	SS	
		Novalgin	SS	
		Gentamicin	SS	
INTRAVENOUS	120 MG TID IV			
		Paracetamol	SS	
		Paracetamol	SS	
		Paracetamol	SS	
		Paracetamol	SS	
		Pantozol	SS	
		Leucomax	SS	
300 MCG DAILY				
SQ				
		Paspertin	SS	
		Imodium	SS	
		Methotrexate	SS	
15 MG DAILY				
IT				
		Zofran	SS	
		Diflucan	SS	ORAL
200 MG BID PO				
		Ferrosanol Duodenal	C	
		Uralyt-U	C	
		Sterofundin	C	
		Dexamethason	C	
		Glucose 40%	C	
		Aminomix	C	
		Potassium Chloride	C	
		Aminomel	C	
		Lipofundin	C	

		Magnorbin	C
		Riopan	C
		Vergentan	C
		Vm-26 Bristol	C
		Nutriflex	C
		Sodium Chloride	C
		Leucovorin	C
		Vindesin	C
		Cytosin	C
		Ifosfamid	C
		Urumitexan	C
		Glucose	C
		Sodium Bicarbonate	C
		Urbason	C
		Ancotil	C
INTRAVENOUS	2 G BID IV		
		Fortecortin	C
		Ampho Moronal	C

Date:12/28/98ISR Number: 3173940-1Report Type:Expedited (15-DaCompany Report #8-98351-008X
Age:17 YR Gender:Female I/FU:I

Outcome	PT
Death	Blister
Life-Threatening	Corneal Erosion
	Dermatitis
	Mucosal Erosion

		Multi-Organ Failure Pyrexia Sepsis Toxic Epidermal Necrolysis	Report Source Study Other	Product Pipracil Injection (Protocol: 910a-N/A)	Role PS	Manufacturer
Dose	Duration					
INTRAVENOUS	3.5 GRAMS THREE TIMES DAILY	4 DAY				
				Amphotericin B Injection	SS	
INTRAVENOUS	15 MG DAILY					
INTRAVENOUS				Antra Injection	SS	
				Atosil Injection	SS	
				Ben-U-Ron Tablets	SS	
				Ciprobay Injection	SS	
				Cotrim Tablets	SS	
				Cymeven Injection	SS	
				Diazepam Tablets	SS	
				Diflucan Capsules	SS	
				Dolantin Injection	SS	
				Dormicum Injection	SS	
				Fortum Injection	SS	
				Gernebcin Injection	SS	
				Lactulose Syrup	SS	
				Lasix Injection	SS	
				Liquemin Injection	SS	
				Meronem Injection	SS	
				Neupogen Injection	SS	
				Neurocil Injection	SS	
				Novalgin Injection	SS	
				Octagam Injection	SS	
				Paspertin Unknown	SS	
				Rekawan Capsules	SS	
				Sdh Injection	SS	
				Targocid Injection	SS	
				Tavegil Injection	SS	
				Vancomycin Injection	SS	
				Zantac Injection	SS	
				Zienam Injection	SS	
				Folsan	C	
				Decortin Tablets	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 - Initial or Prolonged	Alanine Aminotransferase Increased	Foreign Study	Metoclopramide	PS		ORAL	10 MG Q 6H	
	Aspartate Aminotransferase Increased	Health Professional	Haloperidol	SS		ORAL	1 MG BID; 1 CYCLE	
			Dppe	SS			231 MG	1 DAY
			Doxorubicin	SS		INTRAVENOUS	85 MG Q3W; 1 CYCLE	
	Blood Alkaline 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: 3176187-8Report Type:Expedited (15-DaCompany Report #1998PK45911
Age:17 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Blister	Foreign	Meronem	PS				
						INTRAVENOUS	1000MG	BID IV
Life-Threatening	Corneal Erosion	Health	Diflucan	SS		ORAL	400MG	DAILY
	Dermatitis	Professional						
						PO		
	Mucosal Erosion	Other	Cotrim	SS		ORAL	240MG	BID PO,
	Multi-Organ Failure							
							480MG	DAILY
	Pyrexia							
						PO		
	Sepsis		Octagam	SS				
						INTRAVENOUS	25MG	DAILY IV
	Stevens-Johnson Syndrome		Vancomycin	SS				
	Toxic Epidermal		Ben-U-Ron	SS				
	Necrolysis		Novalgin	SS				
						INTRAVENOUS	500MG	QD IV
			Dolantin	SS				
						INTRAVENOUS	25MG	QD IV
			Ganciclovir	SS				
						INTRAVENOUS	250MG	QD IV
			Ciprobay	SS				
						INTRAVENOUS	280MG	TID IV
			Midazolam	SS				
						INTRAVENOUS	280MG	TID IV
			Diazepam	SS				
							5MG	DAILY,5MG
								DAILY, 5MG
								DAILY
			Neurocil	SS				
						INTRAVENOUS	8MG	DAILY IV,
								8MG DAILY IV,
								8MG DAILY IV
			Rekawan	SS				
			Paspertin	SS				
			Tavegil	SS				

		Prednisolon	SS
INTRAVENOUS	100MG QD IV		
		Lasix	SS
		Pipril	SS
INTRAVENOUS	3.5 G TID IV		
		Antra	SS
INTRAVENOUS	20MG BID IV		
		Liquemin	SS
INTRAVENOUS	9700 U DAILY		
IV			
		Atosil	SS
INTRAVENOUS	25MG QD IV		
		Neupogen	SS OTHER
150MG QD SQ			
		Gernebcin	SS
INTRAVENOUS	80MG BID IV		
		Targocid	SS
INTRAVENOUS	500MG QD IV		
		Zantic	SS
		Zienam	SS
INTRAVENOUS	650MG QD IV		
		Ampho B	SS
INTRAVENOUS	15MG DAILY IV		
		Lactulose	SS
		Fortum	SS
		Folsan	C
		Doxycyclin	C
		Zovirax	C
		Clont	C
		Decortin	C
		Ca-Brausetabletten	C
		Orgametril	C
		Multibionta	C

Date:12/29/98ISR Number: 3178028-1Report Type:Expedited (15-DaCompany Report #303174
Age:17 YR Gender:Female I/FU:I

Outcome	PT
Death	Blister
Life-Threatening	Corneal Erosion
	Mucosal Erosion
	Mucous Membrane Disorder
	Multi-Organ Failure
	Oral Mucosal Blistering

		Pyrexia Rash Maculo-Papular Sepsis	Report Source	Product	Role	Manufacturer	Route
Dose	Duration	Stevens-Johnson Syndrome	Foreign Health Professional	Neupogen (Filgrastim)	PS		
SUBCUTANEOUS	3 MCG/KG; DAILY 2 DAY						
				Amphotericin B (Amophotericin B)	SS		
				Antra (Omeprazole)	SS	Astra Pharm	
				Atosil (Isopromethazine Hydrochloride)	SS	Bayer	
1 DAY							
				Ben-U-Ron (Paracetamol)	SS	Bene-Chemie Gmbh	
				Calcium (Calcium)	SS		
				Ciprobay (Ciprofloxacin Hydrochloride)	SS	Bayer	
5 DAY							
				Cotrim (Bactrim)	SS	Lemmon Pharm	
				Cymevan (Ganciclovir Sodium)	SS	Synthex Lab	
				Decortin (Prednisone)	SS	Merck	
				Diazepam (Diazepam)	SS		
				Diflucan (Fluconazole)	SS	Pfizer Lab	
				Dolantin (Pethidine Hydrochloride)	SS	Hoechst Pharmaceuticals, Incorporated	
3 DAY							
				Folsan (Folic Acid)	SS	Kali-Chemie Aktiengesellschaft	
				Fortum (Ceftazidime)	SS	Glaxo Lab	
4 DAY							
				Gernebcin (Tombramycin Sulfate)	SS	Lilly Eli And Company	
4 DAY							
				Hydrocortisone Hydrogen Succinate			

	(Hydrocortisone Hydrogen Succinate)	SS	
5 DAY			
	Immunoglobulin Human Normal (Immunoglobulin Human Normal)	SS	
	Lactulose (Lactulose)	SS	
	Lasix (Furosemide)	SS	Hoechst Pharmaceuticals, Incorporated
	Liquemin (Heparin)	SS	Hoffman-La Roche, Inc.
	Meronem (Meropenem)	SS	Zeneca
	Midazolam Hydrochloride (Midazolam Hydrochloride)	SS	
1 DAY			
	Multibionta (Multibionta)	SS	Merck E. Ag
	Neurocil (Levomepraomazine		

				Maleate)	SS	Bayer			
				Novlgin (Metamizole Sodium)	SS	Hoechst Pharmaceuticals, Incorporated			
				Orgaemtril (Lynestrenol)	SS	Organon, Incorporated			
				Paspertin (Metoclopromide Hydrochloride)	SS	Kali-Chemie Aktiengesllschaft			
4	DAY								
				Pipril (Piperacillin Sodium)	SS	Lederle Laboratories			
4	DAY								
				Prednisolone (Prednisolone)	SS				
5	DAY								
				Rekawan (Potassium Chloride)	SS	Gilini Gebr. Gmbh			
3	DAY								
				Targocid (Teicoplanin)	SS	Merrell			
				Tavegil (Clemastine)	SS	Sandoz Pharm			
4	DAY								
				Vancomycin (Vancomycin)	SS				
				Zantic (Rantidine Hydrochloride)	SS	Glaxo Laboratories Limited			
5	DAY								
				Zienam (Cilastatin Sodium W/Iipenem)	SS	Merck Sharp & Dohme			
2	DAY								
				Zovirax (Aciclovir)	SS	Burroughs Wellcome & Company			

Date:01/04/99ISR Number: 3175854-XReport Type:Direct Company Report #
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Binocular Eye Movement		Metoclopramide	PS		INTRAVENOUS	35MG X1 IV	
Hospitalization -	Disorder							

Initial or Prolonged	Coma
Other	Dystonia
Required	Heart Rate Increased
Intervention to	Hyperventilation
Prevent Permanent	Mental Impairment
Impairment/Damage	Muscle Rigidity
	Respiratory Rate
	Decreased
	Supraventricular
	Tachycardia

Date:01/05/99ISR Number: 3177612-9Report Type:Expedited (15-DaCompany Report #8-98160-014A
Age:58 YR Gender:Female I/FU:F

Outcome	PT
Disability	Akathisia
	Anxiety
	Blood Glucose Increased
	Cataract Subcapsular
	Dysarthria
	Dyspnoea
	Emphysema
	Eye Pain

	Facial Pain Headache Lung Infiltration	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
	Parkinsonism	Consumer	Reglan	PS		ORAL
10 MG THREE						
	Photophobia					
TO FOUR TIMES						
	Tardive Dyskinesia					
DAILY ORAL						
	Vomiting		Carafate (Sucralfate)	C		
			Estrace (Oestradiol)	C		
			Pepcid (Famotidine)	C		
			Premarin (Conguated Estrogens)	C		

Date:01/05/99ISR Number: 3190761-4Report Type:Periodic Company Report #M98-381 (1)
Age:6 MON Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Tremor	Consumer	Cipro	PS		ORAL
ORAL						
		Health	Reglan	SS		ORAL
ORAL						
		Professional	Bethanechol	C		
			Zantac	C		

Date:01/06/99ISR Number: 3179890-9Report Type:Expedited (15-DaCompany Report #303192
Age:34 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Blister	Foreign	Neupogen	PS		
2 DAY						
Life-Threatening	Dermatitis	Health	Actrapid Human			
	Epidermolysis Bullosa	Professional	(Insulin Human)	SS	Novo Industri A/S	
SUBCUTANEOUS 50 IU SC						
	Hypertension		Allopurinol	SS		ORAL
300MG PO 15 DAY						
	Lip Disorder		Amoxicillin W/			
	Shock		Potassium			

		Stevens-Johnson Syndrome				
INTRAVENOUS	4GM IV		5	DAY		
		Toxic Epidermal				
INTRAVENOUS	40MG IV					
		Necrolysis				
INTRAVENOUS	IV					
INTRAVENOUS	20MG IV					
PO	1	DAY				
INTRAVENOUS	IV		1	DAY		
INTRAVENOUS	6GM IV		5	DAY		
400MG PO	18	DAY				
INTRAVENOUS	3.75 MG IV					
INTRAVENOUS	25MG IV		1	DAY		
INTRAVENOUS	200MG IV					
INTRAVENOUS	240MG IV					
INTRAVENOUS	360MG IV		7	DAY		
INTRAVENOUS	IV		17	DAY		
PO	17	DAY				
INTRAVENOUS	50MG IV		1	DAY		

Clavulanate	SS		
Amphotericin B	SS		
Ancotil	SS	Hoffman-La Roche, Inc	
Antra	SS	Astra Pharmaceutical Products, Inc.	
Bifiteral	SS	Philips-D	ORAL
Ciprobay	SS	Bayer	
Claforan	SS	Hoeschst Pharmaceuticals Incorporated	
Diflucan	SS	Pfizer Laboratories	ORAL
Dipidolor	SS	Janssen Pharmaceticals	
Dolantin	SS	Hoechst Pharmaceuticals Incorporated	
Dopamin	SS		
Dormicum	SS	Hoffman-La Roche	
Gentamicin	SS		
Humanalbumin	SS	Biotest-Serum-Institut Gmbh	
Imodium	SS	Janssen Pharmaceuticals	ORAL
Isoptin	SS	Knoll Pharmaceutical Company	
Lasix	SS	Hoechst	

20MG PO	1	DAY	
SUBCUTANEOUS	300 MCG SC	12	DAY
SUBCUTANEOUS	7500 IU SC		
INTRAVENOUS	.5GM IV	4	DAY
INTRAMENINGEAL	IT	4	DAY
INTRAVENOUS	IV	5	DAY
INTRAVENOUS	IV	9	DAY
INTRAVENOUS	IV	15	DAY
INTRAVENOUS	IV	9	DAY
PO	12	DAY	
500MG PO	7	DAY	
INTRAVENOUS	IV		
INTRAVENOUS	IV		
INTRAVENOUS	200MG IV	1	DAY
INTRAVENOUS	50MG IV	1	DAY
INTRAVENOUS	IV		
INTRAVENOUS	IV		
INTRAVENOUS	IV		
INTRAVENOUS	IV	8	DAY

		Pharmaceticals Incorporated	ORAL
Leucomax	SS	Schering-Plough	
Liquemin	SS	Hoffman-La Roche Inc	
Meronem	SS	Zeneca	
Methotrexat	SS	Lederle Laboratories	
Metronidazole	SS		
Mst	SS	Mundipharma Gmbh Frankfurt	
Multibionta	SS	Merck E. Ag	
Novalgin	SS	Hoechst Pharmaceticals	
Opium Tincture	SS		ORAL
Paracetamol	SS		ORAL
Paspertin	SS	Kali-Chemie Aktiengesellschaft	
Psyquil	SS	Heyden Von Ag Chemische Fabrik	
Sobelin	SS	The Upjohn Company	
Solu-Decortin-H	SS	Merck E. Ag	
Suprarenin	SS	Hoechst Pharmaceuticals Incorporated	
Travegil	SS	Sandoz Pharmaceuticals	
Vancomycin	SS		
Vitalipid Novum Adult	SS	Kabi-Vitrum	

					Zienam	SS	Merck Sharp & Dohme	
INTRAVENOUS	IV	1	DAY					
					Zofran	SS	Glaxo Laboratories Limited	
INTRAVENOUS	IV	11	DAY					

Date:01/07/99ISR Number: 3179027-6Report Type:Direct Company Report #
Age:40 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Agitation		Reglan	PS				
INTRAVENOUS	10 MG IV X 1							
	Nervousness							

Date:01/14/99ISR Number: 3180748-XReport Type:Expedited (15-DaCompany Report #JAAUS-42033
Age:26 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Circulatory Collapse	Foreign	Risperidone	PS	Janssen	ORAL	3 MG 2 DAILY	
Hospitalization - Initial or Prolonged	Drug Interaction	Health Professional						
	Respiratory Depression		Methadone (Methadone) Syrup	SS		ORAL	10 MG 1 DAILY	
			Risperidone (Risperidone)	SS		ORAL	2 MG 2 DAILY	
			Metoclopramide (Metoclopramide)	SS		ORAL		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/14/99ISR Number: 3180797-1Report Type:Expedited (15-DaCompany Report #8-98030-007L
Age:25 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Blister	Study	Myambutol	PS		ORAL	1 GRAM DAILY	
Hospitalization -	Conjunctivitis							
ORAL								16 DAY
Initial or Prolonged	Dermatitis Exfoliative		Antra Injection	SS				
	Mucosal Erosion		Baypen Injection	SS				
	Toxic Epidermal		Bepanthen Injection	SS				
	Necrolysis		Fortal Injection	SS				
			Klacid	SS				
			Konakion	SS				
			Multibionat Injection	SS				
			Paracetamol Suppository	SS				
			Paspertin Injection	SS				
			Prostigmine Injection	SS				
			Rifampicin Injection	SS				
			Temegesic Injection	SS				
			Thiacetazone	SS				
			Fortral	C				
			Actrapid	C				
			..	C				
			..	C				
			Rifampicin Injection	C				
			Konakion	C				
			..	C				
			Buscopan Perfusor	C				
			Aminomix	C				
			Bvk	C				
			Clont	C				
			Doxorubicin Injection	C				
			Kalinor Brause	C				
			...	C				
			Multibionta	C				
			...	C				
			...	C				
			Pyrafat	C				
			Teldane	C				
			...	C				

Date:01/19/99ISR Number: 3182371-XReport Type:Expedited (15-DaCompany Report #JAGER-42501
Age:34 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Blister	Foreign	Imodium	PS	Janssen	ORAL	4 MG 3 DAILY	
Life-Threatening	Dermatitis	Health				ORAL		
	Epidermolysis Bullosa	Professional	Dipidolor	SS	Janssen	INTRAVENOUS	3.75 MG DAILY	
	Oral Mucosal Exfoliation					INTRAVENOUS		
	Pruritus		Allopurinol	SS				
	Shock		Antra	SS		INTRAVENOUS	20 MG DAILY	5 DAY
	Stevens-Johnson Syndrome							
	Toxic Epidermal		Diflucan	SS				
			Zofran	SS		INTRAVENOUS	1 DAILY	2 DAY
	Necrolysis		Methotrexat	SS		INTRATHECAL	15 MG DAILY	
			Multibionta	SS		INTRAVENOUS	ATL DAY	14 DAY
			Paspertin	SS		INTRAVENOUS	2 DAILY	
			Leucomax	SS		SUBCUTANEOUS	300 MCG DAILY	11 DAY
			Pantozol	SS				

				Paracetamol SS ORAL
DAILY				Gentamycin SS
INTRAVENOUS	120 MG 3			
DAILY	6	DAY		Claforan SS
INTRAVENOUS	2 G 3 DAILY	4	DAY	Metronidazol SS
INTRAVENOUS	500 MG 3			
DAILY	4	DAY		Liquemin SS
SUBCUTANEOUS	DAILY			Opium SS ORAL
1 DAILY	5	DAY		Augmentan SS
INTRAVENOUS	2 G 2 DAILY	4	DAY	Mst SS
INTRAVENOUS	1 MG/HR	8	DAY	Vitalipid SS
INTRAVENOUS	1 DAILY	7	DAY	Novalgin SS
INTRAVENOUS	SINGLE			Vancomycin SS
INTRAVENOUS	.5 G 3 DAILY			Bifiteral SS ORAL
SINGLE				Lasix SS ORAL
20 MG SINGLE				Ancotil SS
INTRAVENOUS	2 G 2 DAILY			Tavegil SS
INTRAVENOUS	1 DAILY			Meronem SS
INTRAVENOUS	.5 G DAILY			Actrapid SS
SUBCUTANEOUS	50 UNITS			
DAILY				Psyquil SS
INTRAVENOUS	1 DAILY			Amphoterecin B SS
INTRAVENOUS	40 MG 1 DAILY			Neupogen SS
SUBCUTANEOUS	1 DAILY			

				Human Albumin	SS			
INTRAVENOUS	400 ML DAILY							
				Dolantin	SS			
INTRAVENOUS	25 MG DAILY							
				Zienam	SS			
INTRAVENOUS	.5 G SINGLE							
				Dopamin	SS			
INTRAVENOUS	200 MG DAILY							
				Suprarenin	SS			
INTRAVENOUS	3 DAILY							
				Sobelin Solubile	SS			
INTRAVENOUS	200 MG SINGLE							
				Ciprobay	SS			
INTRAVENOUS	SINGLE							
				Isoptin	SS			
INTRAVENOUS	50 MG SINGLE							
				Solu-Decortin	SS			
INTRAVENOUS	50 MG SINGLE							
				Dormicum	SS			
INTRAVENOUS	10 MG/HR							
DAILY								
				Ampho-Moronal	C			
				Glucose	C			
				Fortecortin	C			
				Glucose	C			
				Sterofundin	C			
				Magnorbin	C			
				Aminomel	C			
				Kaliumchlorid	C			
				Aminomix	C			
				Glukose	C			

Date:01/19/99ISR Number: 3182816-5Report Type:Expedited (15-DaCompany Report #3789/50441
Age:34 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Blister	Foreign	Cleocin	PS				
INTRAVENOUS	IV							
Hospitalization -	Dermatitis	Consumer	Vitalipid	SS				
INTRAVENOUS	IV							
Initial or Prolonged	Lip Ulceration	Company	Allopurinol	SS		ORAL		
ORAL								
	Pruritus	Representative	Antra	SS				
	Pyrexia		Methotrexate	SS				
INTRAVENOUS	IT; IV							
	Shock		Actrapid	SS				
SUBCUTANEOUS	SC							
	Toxic Epidermal		Psyquil	SS				
INTRAVENOUS	IV							

	Necrolysis	
INTRAVENOUS	IV	
SUBCUTANEOUS	SC	
INTRAVENOUS	IV	
INTRAVENOUS	IV	

Amphotericin B	SS
Neupogen	SS
Human Albumin 20%	SS
Dolantin	SS

		Zienam	SS	
INTRAVENOUS	IV			
		Dopmain	SS	
INTRAVENOUS	IV			
		Suprarenin	SS	
INTRAVENOUS	IV			
		Ciprobay	SS	
INTRAVENOUS	IV			
		Isoptin	SS	
INTRAVENOUS	IV			
		Solu Decortin H	SS	
INTRAVENOUS	IV			
		Dormicum Perfusor	SS	
INTRAVENOUS	IV			
		Metronidazole Ratio 500	SS	
INTRAVENOUS	IV			
		Liquemin	SS	
SUBCUTANEOUS	SC			
		Opium	SS	ORAL
ORAL				
		Augmentin	SS	
INTRAVENOUS	IV			
		Mst	SS	
INTRAVENOUS	IV			
		Novalgin	SS	ORAL
ORAL				
		Vancomycin 9.5 Gr)	SS	
INTRAVENOUS	IV			
		Bifiteral	SS	ORAL
ORAL				
		Lasix	SS	ORAL
ORAL				
		Ancotil (2 Gr)	SS	
INTRAVENOUS	IV			
		Dipidolar	SS	
INTRAVENOUS	IV			
		Tavegil	SS	
INTRAVENOUS	IV			
		Meronem	SS	
INTRAVENOUS	IV			
		Pantozol	SS	ORAL
ORAL				
		Paracetamol (500 Mg)	SS	
		Leucomax (Molgramostim)	SS	
SUBCUTANEOUS	SC			

		Gentamycin	SS
INTRAVENOUS	IV		
		Claforan (Cefotaxime Na)	SS
INTRAVENOUS	IV		
		Imodium (Loperamide0	SS
ORAL			
		Multibionta (Multi-Vitamin)	SS
INTRAVENOUS	1 DOSE		
4Q1WK; IV			
		Paspertin (Metoclopramide)	SS
INTRAVENOUS	IV		
		Diflucan	SS
ORAL			
		Urbason 40	C
		Ampho Moronal	C
		Fortecortin	C
		Natrium Bicarbonate	C
		Uralyt-U Granulate	C
		G 5%	C
		Sterofundin	C
		Uromitexan	C
		Dexamethasone	C
		Ifosfamid	C
		Dexamethasone	C
		Cytosine-Arabinoside	C
		Kcl Perfusor	C
		Amino-Mix	C
		Glucose 40%	C
		Magnorbin 20%	C
		Lipofundin Mct	C
		Aminomel	C
		Ferrosanol Duodenal	C
		Zofran	C
		Vindesin	C
		Leucovorin	C
		Sodium Chloride	C
		Nutriflex	C
		Vm-26	C
		Vergentan	C

			Riopan	C		

Date:01/20/99ISR Number: 3182652-XReport Type:Expedited (15-DaCompany Report #19990100117
Age:56 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Burning Sensation	Foreign	Toprol-Xl	PS		ORAL	50 MG QD PO	
Initial or Prolonged	Conjunctival Hyperaemia	Health	Antra	SS				
	Dermatitis	Professional	Paspertin	SS				
	Dysphagia		Timonil	SS				
	Face Oedema		Tramal	SS				
	Intracranial Pressure		Lopirin Cor	SS				
	Increased		Akineton	SS			INJ	
	Lip Disorder		Trental	SS				
	Mouth Haemorrhage		Ebrantil	SS				
	Pruritus		Tenormin	SS				
	Rash Maculo-Papular		Tavegil	SS				
	Stevens-Johnson Syndrome		Vomex A "Endopharm"	SS				
			Loperamide	SS				
			Nootrop	SS				
			Mcp-Ratiopharm	SS				
			Lopressor	SS				
			Sterofundin	C				

Date:01/20/99ISR Number: 3182711-1Report Type:Expedited (15-DaCompany Report #990011
Age:34 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardiac Failure	Foreign	Morphine Sulfate	PS		INTRAVENOUS	1 MG Q1H IV	
Hospitalization -	Dermatitis	Health	Allopurinol	SS		ORAL	300 MG QD PO	
Initial or Prolonged	Dermatitis Bullous	Professional	Omeprazole	SS		INTRAVENOUS	20 MG QD IV	
	Stevens-Johnson Syndrome	Other	Diflucan	SS		ORAL	400 MG QD PO	
	Toxic Epidermal		Zofran	SS		INTRAVENOUS	1 AMP QD IV	

Necrolysis

15 MG QD IT

INTRAVENOUS 5000 MG QD IV

3 CAP BID PO

INTRAVENOUS 1 INJ QD IV

INTRAVENOUS 2 AMP QD IV

SUBCUTANEOUS 300 MCG QD SC

1 TAB QD PO

500 MG

1-3/DAY PO

INTRAVENOUS 360 MG QD IV

INTRAVENOUS 2 G TID IV

INTRAVENOUS 500 TID IV

SUBCUTANEOUS 10000 IU QD

SC

5 DROP QD PO

INTRAVENOUS 4 G QD IV

INTRAVENOUS 1 AMP QD IV

INTRAVENOUS 1 AMP QD IV

INTRAVENOUS .5 G TID IV

1 TSP QD PO

20 MG QD PO

INTRAVENOUS 2 G QD IV

INTRAVENOUS 3.75 MG QD IV

INTRAVENOUS 1 AMP QD IV

INTRAVENOUS .5 G QD IV

SUBCUTANEOUS 50 U QD SC

Methotrexate Sodium	SS	
Methotrexate Sodium	SS	
Immodium	SS	ORAL
Multibionta	SS	
Metoclopramide Hcl	SS	
Molgramostim	SS	
Pantoprazol Sodium	SS	ORAL
Paraceatmol	SS	ORAL
Gentamicin Sulfate	SS	
Cefotaxime Sodium	SS	
Metronidazole	SS	
Heparin Sodium	SS	
Opium	SS	ORAL
Augmentin	SS	
Vitalipid	SS	
Metamizol Sodium	SS	
Vancomycin Hcl	SS	
Lactulose	SS	ORAL
Lasix	SS	ORAL
Flucytosine	SS	
Piritramide	SS	
Clemastine Fumarate	SS	
Meropenem	SS	
Human Insulin	SS	

INTRAVENOUS	1 AMP QD IV	Triflupromazine Hcl	SS
INTRAVENOUS	40 MG QD IV	Amphotericin B	SS
INTRAVENOUS	1 AMP QD IV	Filgrastim	SS
INTRAVENOUS	400 ML QD IV	Plasma Protein	SS
INTRAVENOUS	25 MG QD IV	Pethidine	SS
INTRAVENOUS	3 AMP QD IV	Epinephrine Hcl	SS
INTRAVENOUS	200 MG QD IV	Clindamycin Phosphate	SS
INTRAVENOUS	.5 G QD IV	Imipenem/Cilastatin Sodium	SS
INTRAVENOUS	200 MG QD IV	Dopamine Hcl	SS
INTRAVENOUS	1 AMP QD IV	Ciprofloxacin	SS
INTRAVENOUS	50 MG QD IV	Verapamil Hcl	SS
INTRAVENOUS	50 MG QD IV	Prednisolone	SS
INTRAVENOUS	10 MG Q1H IV	Midazolam Hydrochloride	SS
		Methylprednisolone	C
		Eisen	C
		Amphotericin B	C
		Dexamethasone	C
		Sodiumhydrogencarbonate	C
		Hexanatrium Trihydrogen Pentacitrate	C
		Dexamethasonedihydrogenphosphate	C
		Cytosinarabinosid	C
		Vindesin	C
		Leucovorin Calcium	C
		Nacl	C
		Nutriflex	C
		Magnesium Ascorbate	C
		Lipofundin	C

			Aminomel	C			
			Aminomix	C			

Date:01/21/99ISR Number: 3183710-6Report Type:Expedited (15-DaCompany Report #1999PK00008
Age:56 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Burning Sensation	Foreign	Tenormin	PS		ORAL	25 MG BID PO
Initial or Prolonged	Conjunctival Hyperaemia	Health	Trental	SS		INTRAVENOUS	15 ML DAILY
	Dermatitis	Professional				IV	
	Dysphagia	Other	Trental	SS		ORAL	600 MG BID PO
	Face Oedema		Lopirin Cor	SS			
	Mouth Haemorrhage		Lopirin Cor	SS			
	Oral Mucosal Eruption		Beloc Zok	SS		ORAL	47.5 MG QD PO
	Pruritus		Tramal	SS			
	Rash Maculo-Papular		Timonil	SS		ORAL	400 MG QD PO
	Stevens-Johnson Syndrome		Timonil	SS			
			Paspertin	SS			
			Paspertin	SS			
			Antra	SS		ORAL	20 MG BID PO
			Tavegil	SS			
			Lopresor	C			
			Nootrop	C			
			Vomex A	C			
			Loperamid	C			
			Mcp-Ratiopharm	C			

			Ebrantil	C		
			Akineton	C		
			Sterofundin	C		

Date:01/26/99ISR Number: 3186057-7Report Type:Expedited (15-DaCompany Report #397/9987
Age:17 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Blister	Foreign	Prednisolone (Mfr			
Life-Threatening	Corneal Erosion	Consumer	Unk)	PS		
	Multi-Organ Failure		Neupogen			
	Pyrexia		(Filgrastim)	SS		
SUBCUTANEOUS 3 MCG/KG/DAY;						
	Rash Maculo-Papular					
SC						
	Sepsis		Amphotericin B	SS		
	Stevens-Johnson Syndrome		Antra (Omeprazole)	SS		
			Atosil (Isopromethazine Hcl)	SS		
			Ben-U-Ron (Paracetamol0	SS		
			Calcium	SS		
			Ciprobay (Ciprofloxacin Hcl)	SS		
			Cotrim (Bacrim)	SS		
			Cymevan (Ganciclovir Sodium)	SS		
			Decortin (Prednisone)	SS		
			Diazepam	SS		
			Diflucan (Fluconaole)	SS		
			Dolantin (Pethidine Hcl)	SS		
			Folsan (Floic Acid0	SS		
			Fortum (Ceftazidime0	SS		
			Gernebcin (Tobramycin Sulfate)	SS		
			Hydrocortisone Hydrogen Succinate	SS		
			Immunoglobulin Human Normal	SS		
			Lactulose	SS		

Lasix (Furosemide)	SS
Liquemin (Heparin)	SS
Meronem	SS
Midazolam	SS
Multibionta	SS
Neurocil (Levomepromazin Maleae0	SS
Novalgin (Metamizole Sodium0	SS
Orgametril (Lynestrenol)	SS
Paspertin (Metoclopramide Hcl)	SS
Pipril (Piperacillin)	SS
Rekawan (Potassium Chloride)	SS

			Targocid (Teicoplanin)	SS		
			Tavegil (Clemastine)	SS		
			Vancomycin	SS		
			Zantac (Ranitidine Hcl)	SS		
			Zienam	SS		
			Zovirax (Aciclovir)	SS		

Date:01/26/99ISR Number: 3186730-0Report Type:Direct Company Report #
Age:54 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Hospitalization -	Dizziness Hypotension	Health Professional	Prochlorperazine (Compazine)	PS		INTRAMUSCULAR	10 MG IM Q 8 Initial or Prolonged	H 2 HR
			Metodopramide (Reglan)	SS		INTRAVENOUS	10 MG IVPB AC/HS	

Date:01/26/99ISR Number: 3187552-7Report Type:Direct Company Report #
Age:10 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dyspnoea Dystonia Tachycardia Torticollis		Reglan	PS	Apothecon	ORAL	10MG QID PO	

Date:01/27/99ISR Number: 3186608-2Report Type:Expedited (15-DaCompany Report #199813209HMRI
Age:35 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Life-Threatening	Anaphylactic Reaction	Health	Dolasetron	PS
INTRAVENOUS 12.5 MG ONCE				
Hospitalization -	Atrioventricular Block	Professional		
IV 1 DAY				
Initial or Prolonged	Bradycardia		Metoclopramide	SS
INTRAVENOUS 10 MG ONCE IV 1 DAY				
	Cardiac Arrest		Fentanyl	C
	Cardiac Failure		Lidocaine	C
	Dermatitis		Propofol	C
	Mitral Valve Incompetence		Oxygen	C
	Pulse Absent		Nitrous Oxide	C
	Tachycardia		Sevoflurane	C
	Urticaria		Midazolam Hydrochloride	C

Date:01/28/99ISR Number: 3187832-5Report Type:Expedited (15-DaCompany Report #10675
Age:17 YR Gender:Female I/FU:I

Outcome	PT
Death	Blister
Life-Threatening	Corneal Erosion
	Dermatitis
	Genital Ulceration
	Multi-Organ Failure
	Oral Mucosal Blistering
	Pyrexia
	Rash Maculo-Papular

Sepsis
Stevens-Johnson Syndrome

Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Foreign	Cotrim D.S.	PS		ORAL		
Health	Neupogen	SS		SUBCUTANEOUS	3 MCG/KG/ D	
Professional				SC		
Other	Amphotericin B	SS				
	Antra	SS	Astra Pharmaceutica Products, Inc.			
	Atosil	SS	Bayer		1	DAY
	Ben-U-Ron	SS	Bene-Cheme Gmbh			
	Calcium	SS				
	Ciprobay	SS	Bayer		5	DAY
	Cymevan	SS	Syntex Labs., Inc.			
	Decortin	SS	Merck E. Ag			
	Diazepam	SS				
	Diflucan	SS	Pfizer Labs.			
	Dolantin	SS	Hoechst Pharmaceuticals, Inc.			
	Folsan	SS	Kali-Chemie Aktiengesellschaft		3	DAY
	Fortum	SS				
	Gernebcin	SS				
	Hydrocortisone Hydrogen Succinate	SS			4	DAY
	Immunoglobulin Human Normal	SS			5	DAY
	Lactulose	SS				
	Lasix	SS	Hoechst Pharmaceuticals, Inc.			
	Liquemin	SS				
	Meronem	SS	Zeneca			
	Midazolam Hcl	SS			1	DAY
	Multibionta	SS	Merck E. Ag			
	Neurocil	SS	Bayer			

		Novalgin	SS	Hoechst Pharmaceuticals, Inc.
		Orgametril	SS	Organon, Inc.
		Paspertin	SS	Kali-Chemie Aktiengesellschaft
4	DAY			
		Pipril	SS	Lederel Labs.
4	DAY			
		Predisone	SS	
5	DAY			
		Rekawan	SS	Giulin Gebr. Gmbh
		Targocid	SS	
		Tavegil	SS	Sandoz Pharmaceuticals
4	DAY			
		Vancomycin	SS	
		Zantac	SS	Glaxo Labs. Ltd.
5	DAY			
		Zienam	SS	Merck Sharpe & Dohme
2	DAY			
		Zovirax	SS	Burroughs Wellcome & Cmpy.

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/29/99ISR Number: 3188489-XReport Type:Expedited (15-DaCompany Report #112120
Age:17 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Blister	Foreign	Midazolam Hydrochloride	PS			UNKNOWN	UNKNOWN
	Corneal Erosion	Health	Liquemin	SS			UNKNOWN	UNKNOWN
	Dermatitis	Professional	Cymevan Oral	SS			UNKNOWN	UNKNOWN
	Multi-Organ Failure	Other	Diazepam	SS			UNKNOWN	UNKNOWN
	Oral Mucosal Blistering		Neupogen	SS			SUBCUTANEOUS	3 MCG/KG DAILY
	Pyrexia		Amphotericin	SS			UNKNOWN	UNKNOWN
	Sepsis		Antra	SS			UNKNOWN	UNKNOWN
	Stevens-Johnson Syndrome		Atosil	SS			UNKNOWN	UNKNOWN
			Ben-U-Ron	SS			UNKNOWN	UNKNOWN
			Calcium	SS			UNKNOWN	UNKNOWN
			Ciprobay	SS			UNKNOWN	UNKNOWN
			Cotrim	SS		ORAL	ORAL	
			Decortin	SS			UNKNOWN	UNKNOWN
			Diflucan	SS		ORAL	ORAL	
			Dolantin	SS		ORAL	ORAL	
			Folsan	SS			UNKNOWN	UNKNOWN
			Fortum	SS			UNKNOWN	UNKNOWN
			Gernebcin	SS			UNKNOWN	UNKNOWN

		Hydrocortisone	SS
UNKNOWN	UNKNOWN		
		Immunoglobulin Human Normal	SS
UNKNOWN	UNKNOWN		
		Lactulose	SS
UNKNOWN	UNKNOWN		
		Lasix	SS
UNKNOWN	UNKNOWN		
		Meronem	SS
UNKNOWN	UNKNOWN		
		Neurocil	SS
UNKNOWN	UNKNOWN		
		Novalgin	SS
UNKNOWN	UNKNOWN		
		Orgametril	SS
UNKNOWN	UNKNOWN		
		Paspertin	SS
UNKNOWN	UNKNOWN		
		Pipril	SS
UNKNOWN	UNKNOWN		
		Prednisolone	SS
UNKNOWN	UNKNOWN		
		Rekawan	SS
UNKNOWN	UNKNOWN		
		Targocid	SS
UNKNOWN	UNKNOWN		
		Tavegil	SS
UNKNOWN	UNKNOWN		
		Vancomycin	SS
UNKNOWN	UNKNOWN		
		Zantac	SS
UNKNOWN	UNKNOWN		
		Zienam	SS
UNKNOWN	UNKNOWN		
		Zovirax	SS
UNKNOWN	UNKNOWN		
		Multibionta	SS
UNKNOWN	UNKNOWN		

Date:02/01/99ISR Number: 3189178-8Report Type:Direct Company Report #
Age:84 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Coordination Abnormal		Metoclopramide	PS		ORAL	10 MG AC AND	
Required	Difficulty In Walking						HS	PO
Intervention to Prevent Permanent	Extrapyramidal Disorder							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/02/99ISR Number: 3190309-4Report Type:Expedited (15-DaCompany Report #LACT003990002
Age:34 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Blister	Foreign	Bifiteral					
Life-Threatening	Dermatitis		(Lactulose)	PS		ORAL	1X/D, PER	
	Lip Disorder						ORAL	
	Mucosal Erosion		Paspertin					
	Pruritus		(Metoclopramide					
	Pyrexia		Hydrochloride)	SS				
INTRAVENOUS	2 DOSAGE							
	Shock						FORMS IV	
	Stevens-Johnson Syndrome		Novalgin (Metamizole					
	Toxic Epidermal		Sodium)	SS				
INTRAVENOUS	1 DOSAGE							
	Necrolysis						FORMS, IV	
			Allopurinol					
			(Allopurinol)	SS		ORAL	300 MG, PER	
							ORAL	
			Augmentan					
			(Amoxicillin Sodium,					
			Clavulanate					
			Potassium)	SS				
INTRAVENOUS	4 DOSAGE							
							FORMS IV	
			Diflucan					
			(Fluconazole)	SS		ORAL	400 MG, PER	
							ORAL	
			Ciprobaby					
			(Ciprofloxacin					
			Hydrochloride)	SS				
INTRAVENOUS	1 DOSAGE							
							FORMS, IV	
			Gentamycin					
			(Gentamicin Sulfate)	SS				
INTRAVENOUS	360 MG IV							

		Dormicum Perfusor (Midazolam Hydrochloride)	SS	
INTRAVENOUS	10 MG/H, IV			
		Vancomycin (Vancomycin)	SS	
INTRAVENOUS	1.5 GM IV			
		Vitalipid (Vitamins Nos)	SS	
INTRAVENOUS	1 DOSAGE			
FORMS, IV				
		Mst (Morphine Sulfate)	SS	
INTRAVENOUS	1 MG/H, IV			
		Opium (Opium Tincture)	SS	ORAL
185 DOSAGE				
FORMS, PER				
ORAL				
		Liquemin (Heparin)	SS	
SUBCUTANEOUS	7500 - 1000 7			
IU/D				
SUBCUTANEOUS				
		Metronidazol Ratio 500 (Metronidazole)	SS	
INTRAVENOUS	3 DOSAGE			
FORMS, IV				
		Pantozol (Pantoprazole Sodium)	SS	ORAL
1 DOSAGE				
FORMS, PER				
ORAL				
		Leucomax (Molgramostim	SS	
SUBCUTANEOUS	300 MICGM,			
SUBCUTANEOUS				
		Multibionta (Ascorbic Acid, Pyridoxine		

		Hydrochloride Tocophe	SS	
INTRAVENOUS	1 DOSAGE FORMS IV			
		Antra (Omeprazole)	SS	
INTRAVENOUS	20 MG, IV			
		Solu-Decortin H (Prednisolone Sodium Succinate)	SS	
INTRAVENOUS	50 MG, IV			
		Isoptin (Verapamil Hydrochloride)	SS	
INTRAVENOUS	50 MG, IV			
		Sobelin Solubile (Clindamycin Phosphate)	SS	
INTRAVENOUS	200 MG, IV			
		Suprarenin (Epinephrine)	SS	
INTRAVENOUS	3 DOSAGE FORMS, IV			
		Dopamin (Dopamine Hydrochloride)	SS	
INTRAVENOUS	200 MG, IV			
		Zienam (Imipenem, Cilastatin Sodium)	SS	
INTRAVENOUS	.5 GM IV			
		Dolantin (Pethidine Hydrochloride)	SS	
INTRAVENOUS	25 MG, IV			
		Humanalbumin 20% (Albumin Normal Human Serum)	SS	
INTRAVENOUS	400 MILLILITERS, IV			
		Riopan (Magaldrate)	SS	ORAL
3 DOSAGE FORMS, PER ORAL				
		Riopan (Magalgrate)	SS	ORAL
2 DOSAGE				

FORMS, PER ORAL			
		Vergentan (Alizapride Hydrochloride)	SS
INTRAVENOUS	2 DOSAGE FORMS IV		
		Vm-26 Bristol (Teniposide)	SS
INTRAVENOUS	170 MG IV		
		Nutriflex (Glucose, Amino Acids Nos, Electrolytes Nos)	SS
INTRAVENOUS	1440-1920 ML/D IV		
		Aminomix (Glucose, Amino Acids Nos, Electrolytes Nos)	SS
INTRAVENOUS	1000 MILLILITERS, IV		
		Leucovorin (Folinic Acid)	SS
INTRAVENOUS	75 MG, IV		
		Vindesin (Vindesine)	SS
INTRAVENOUS	5 MG IV		
		Cytosin-Arabinosid (Cytarabine)	SS
INTRATRACHEAL	4MG, INTRATHECAL		
		Aminomel (Mineral Nos, Amino Acids Nos)	SS
INTRAVENOUS	1920 MILLILITERS IV		
		Lipofunding Mct (Soya Oil, Triglycerides)	SS
250-500			
		Magnorbin (Magnesium	

		Ascorbate)	SS	
INTRAVENOUS	2 DOSAGE FORMS IV			
		Ifosfamid (Ifosfamide)	SS	
INTRAVENOUS	1300 MG IV			
		Dexamethason (Dexamethasone)	SS	ORAL
170 MG PER ORAL, INTRATHECAL				
		Uromitexan (Mesna)	SS	
INTRAVENOUS	1200 MG IV			
		Fortecortin (Dexamethasone)	SS	ORAL
17 MG, PER ORAL				
		Ampho Moronal (Amphotericin B)	SS	ORAL
1 DOSAGE FORMS, PER ORAL				
		Imodium (Loperamide Hydrochloride)	SS	ORAL
6 DOSAGE FORMS, PER ORAL				
		Methotrexat (Methotrexate)	SS	
INTRATHECAL	15 MG, INTRATHECAL			
		Zofran (Ondansetron Hydrochloride)	SS	
INTRAVENOUS	1 DOSAGE FORMS IV			
		Neupogen (Filgrastim)	SS	
SUBCUTANEOUS	1 DOSAGE			

FORMS,

SUBCUTANEOUS

		Amphotericin B (Amphotericin B)	SS
INTRAVENOUS	40 MG IV		
		Psyquil (Triflupromazine)	SS
INTRAVENOUS	1 DOSAGE		

FORMS IV

		Actrapid (Insulin)	SS

50 IU,

		Meronem (Meropenem)	SS
INTRAVENOUS	.5 GM, IV		
		Tavegil (Clemastine)	SS
INTRAVENOUS	1 DOSAGE		

FORMS, IV

		Dipidolor (Piritramide)	SS
INTRAVENOUS	3.75 MG IV		
		Ancotil (Flucytosine)	SS
INTRAVENOUS	4 GM IV		
		Claforan (Cefotaxime Sodium)	SS
INTRAVENOUS	6 GM, IV		
		Paracetamol 500 (Paracetamol)	SS ORAL

1-3 X 1/D,

PER ORAL

20 MG , PER

ORAL

		Lasix (Furosemide)	SS ORAL
		Ferrosanol Duodenal	C
		Sterofundin	C
		Nacl	C
		Glucose	C
		Kcl Perfusor	C
		G5 (Glucose)	C
		Urbason 40	C
		Natriumbicarbonat	C
		Uralyt U	C

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/03/99ISR Number: 3191329-6Report Type:Expedited (15-DaCompany Report #990043
Age:76 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agranulocytosis	Foreign	Ms Contin 30 Mg Cr	PS		ORAL	60 MG QD PO	
		Health	Visceralgin	SS			INTRAVENOUS	3 AMP IV
		Professional	Lasix	SS			INTRAVENOUS	40 MG TID IV
		Other	Rocephin	SS			INTRAVENOUS	1 INJ BID IV
			Motilium	SS		ORAL	30 MG QD PO	
			Pro-Dafalgan	SS			INTRAVENOUS	1 G TID IV
			Mopral	SS			INTRAVENOUS	40 MG IV
			Heparine	SS			INTRAVENOUS	30000 IU QD
							IV	
			Valium	SS			INTRAVENOUS	IV
			Amlor	SS		ORAL	1 QD PO	
			Profenid	SS			3 QD	
			Gaviscon	SS		ORAL	4 QD PO	
			Tiberal	SS			INTRAVENOUS	IV
			Primperan	SS			INTRAVENOUS	3 QD IV
			Lasix	SS		ORAL	40 MG TID PO	
			Duphalac	SS		ORAL	3 QD PO	
			Sintrom	SS		ORAL	1 TAB QD PO	
			Previscan (Fluindioine)	SS		ORAL	1 TAB QD PO	

Date:02/11/99ISR Number: 3195876-2Report Type:Expedited (15-DaCompany Report #112120
Age:17 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Corneal Erosion	Foreign	Midazolam Hydrochloride (Midazolam Hydrochloride)	PS			SUBCUTANEOUS	3 MCG/KG DAILY
	Genital Ulceration	Health	Liquemin (Heparin Sodium)	SS			SUBCUTANEOUS	
	Multi-Organ Failure	Professional	Cymevan Oral (Ganciclovir)	SS			ORAL	
	Neutropenia	Other	Diazepam (Diazepam)	SS			ORAL	
	Oral Mucosal Blistering		Neupogen (Filgrastim)	SS			SUBCUTANEOUS	
	Pyrexia		Amphotericin (Amphotericin B)	SS				
	Rash Maculo-Papular		Antra (Omeprazole)	SS				
	Sepsis		Atosil (Promethazine Hydrochloride)	SS				
	Stevens-Johnson Syndrome		Ben-U-Ron (Acetaminophen)	SS				
			Calcium (Calcium Nos)	SS				
			Ciprobay (Ciprofloxacin Or Ciprofloxacin Hydrochloride Or Ciprofloxacin	SS				
			Cotrim (Sulfamethoxazole/Trimethoprim)	SS			ORAL	
			Decortin (Prednisone)	SS				

	Diflucan (Fluconazole)	SS	ORAL
ORAL			
	Dolantin (Meperidine Hydrochloride)	SS	ORAL
ORAL			
	Folsan (Folic Acid)	SS	
	Fortum (Ceftazidime)	SS	
	Gernebcin (Tobramycin Sulfate)	SS	
	Hydrocortisone (Hydrocortisone)	SS	
	Immunoglobulin Human Normal (Globulin, Immune)	SS	
	Lactulose (Lactulose)	SS	
	Lasix (Furosemide)	SS	
	Meronem (Meropenem)	SS	
	Neurocil (Methotrimeprazine)	SS	
	Novalgin (Dipyrone)	SS	
	Orgametril (Lynestrenol)	SS	
	Paspertin (Metoclopramide Hydrochloride)	SS	
	Pipril (Piperacillin Sodium)	SS	
	Prednisolone (Prednisolone)	SS	
	Rekawan (Potassium Chloride)	SS	
	Targocid (Teicoplanin)	SS	
	Tavegil (Clemastine Or Clemastine Fumarate)	SS	
	Vancomycin (Vancomycin Hydrochloride)	SS	
	Zantac (Ranitidine)	SS	
	Zienam (Cilastatin Sodium/Imipenem)	SS	
	Zovirax (Acyclovir)	SS	
	Multibionta (Ascorbic		

				Acid/Cholecalciferol /Dexpanthenol/Niacin amide/Pyridoxine	SS		

Date:02/11/99ISR Number: 3195997-4Report Type:Expedited (15-DaCompany Report #DEU001275
Age:48 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Toxic Epidermal	Foreign	Dilaudid	PS		INTRAVENOUS	2 MG DAILY	IV
Life-Threatening	Necrolysis	Health	Tazobac	SS		INTRAVENOUS	4.5 G TID	IV
Hospitalization - Initial or Prolonged		Professional	Diflucan	SS		ORAL	100 MG DAILY	PO
			Thrombozyten Concentrate Erythrozyten	SS				

		Concentrate	SS	
		Dopamin	SS	
INTRAVENOUS	250 MG DAILY			
IV				
		Paspertin	SS	
INTRAVENOUS	10 MG DAILY			
IV; 30 MG				
DAILY IV;				
		Insulin	SS	
INTRAVENOUS	100 IU DAILY			
IV				
		Vergentan	SS	
INTRAVENOUS	2 ML DAILY IV			
		Diazepam	SS	ORAL
7.5 TAB DAILY				
PO ; 10 TAB				
DAILY PO				
		Meronem	SS	
INTRAVENOUS	1 G TID IV			
		Paracetamol	SS	ORAL
1 G DAILY PO				
		Presomen	SS	ORAL
0.3 MG OD PO				
		Folsan	SS	ORAL
5 MG DAILY PO				
; 10 MG DAILY				
PO				
		Ciprobay	SS	
INTRAVENOUS	200 MG DAILY			
IV ; 600 MG				
DAILY IV				
		Sempera	SS	ORAL
200 MG OD PO				
		Sandimmun	SS	ORAL
175 MG BID PO				
		Novaminsulfon	SS	
INTRAVENOUS	2 G DAILY IV			

INTRAVENOUS	500 MG TID IV		
INTRAVENOUS	20 MG DAILY IV		
		Clont	SS
		Lasix	SS
		Praxiten	SS
		Fortum	SS
		Human Albumin	SS
		Buscopan	SS
		Urbason	SS
		Maaloxan	SS
		Diflucan	SS
		Nizax	SS
		Saroten	SS
		Aminomix	C
		Peppermint	C
		Leucozyten	C
		Atosil	C
		Cellcept	C
		Vancomycin	C
		Zofran	C
		Nephrotect	C
		Cernevit	C
		Tracitrans	C
		Lipofundin	C
		Calciumgluconat	C
		Pepdul	C
		Konakion	C
		Aminoplasmal	C
		Natrium	C
		Multibionta	C
		Dolantin	C
		Lamisil	C

IV; 330 MG DAILY IV			
10 MG OD PO			
INTRAVENOUS	2 G DAILY IV		
INTRAVENOUS	20 ML DAILY IV		
INTRAVENOUS	1 ML OD IV		
INTRAVENOUS	96 MG DAILY IV		
10 ML OD PO			
200 MG DAILY PO			
1 CAP OD PO			
25 MG DAILY PO			
		Praxiten	SS
		Maaloxan	SS
		Diflucan	SS
		Nizax	SS
		Saroten	SS

Panthenol	C
Zyloric	C

Frisium	C
Ursofalk	C
Natriumbicarbonat	C
Kaliumklorid	C
Zovirax	C
Heparin	C
Amphotericin B	C
Isoptin	C
Natriumchlorid	C
Dipeptamin	C
Glucose	C
Ampho-Moronal	C
Euthyrox	C
Endoxan	C
Antihistaminicum	C
Novalgin	C
Vidisic	C
Kevatril	C
Uromitexan	C
Magnesiumsulfat	C

Date:02/12/99ISR Number: 3198462-3Report Type:Direct Company Report #
Age:68 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Agitation	Health	Reglan	PS			10 MG AC + HS	2 DAY
	Movement Disorder	Professional	Provocol	C				
	Restlessness		Omicar	C				
			Hydrocortisone	C				
			Robitussin Ac	C				
			Spironolactone	C				
			Prilosec	C				
			Periculance	C				
			Compazine	C				
			Phenergan	C				
			Ativan	C				
			Lidocaine	C				
			Msir	C				

Date:02/18/99ISR Number: 3203246-3Report Type:Expedited (15-DaCompany Report #199710241HPD
Age:79 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Conjunctivitis	Foreign	Zinacef Powder And Solvent For Infusion	PS				
Life-Threatening	Mouth Ulceration	Study						
							INTRAVENOUS IV	1 DAY
	Oral Mucosal Eruption	Health	Lasix Tablets	SS		ORAL	PO	8 DAY
	Rash Macular	Professional	Lasix Solution For Infusion	SS				
	Shock						INTRAVENOUS IV	
	Toxic Epidermal Necrolysis		Suprarenin Perfusor Solution For Injection	SS				
							INTRAVENOUS IV	1 DAY
			Perfan Perfusor Solution For Injection	SS				
							INTRAVENOUS IV	1 DAY
			Zyloric Tablets	SS		ORAL	QD PO	
			Bactrim Forte Tablets	SS		ORAL	PO	2 DAY
			Ass 100 Tablets	SS		ORAL	100 MG QD PO	9 DAY
			Adumbran Tablets	SS		ORAL	10 MG QD PO	1 DAY

				Tramal Drops	SS	ORAL
20 DROP/DAY						
PO	1	DAY				
1.5 MG QD PO	1	DAY		Lexotanil Tablets	SS	ORAL
PRN PO				Valium Tablets	SS	ORAL
QD PO	2	DAY		Digimerck Tablets	SS	ORAL
PO	2	DAY		Digimerck Solution For Injection	SS	ORAL
PO				Acc Effervescent Granules	SS	ORAL
INTRAVENOUS	3 ML/H IV	10	DAY	Dopamin Perfusor	SS	
INTRAVENOUS	IV	1	DAY	Dormicum (Midazolam) Solution For Injection	SS	
INTRAVENOUS	IV	26	DAY	Rohypnol Solution For Injection	SS	
20 DROP TID				Paspertin Drops	SS	ORAL
PO						
PRN PO				Temgesic Tablets	SS	ORAL
HYPOTHYROIDIS				L-Thyroxin 100 Tablets	SS	
M						
PO				Ulcogant	SS	ORAL
SUBCUTANEOUS	SC	26	DAY	Heparin Solution For Injection	SS	
PO	2	DAY		Bifiteral Syrup	SS	ORAL
PO	10	DAY		Kalium Tablets	SS	ORAL
				Ringer Injlsg Solution For		

INTRAVENOUS	80	ML/H	IV	1	DAY
INTRAVENOUS			IV	3	DAY
INTRAVENOUS			IV	3	DAY
INTRAVENOUS			IV	2	DAY
INTRAVENOUS			IV	2	DAY
INTRAVENOUS			IV	1	DAY
INTRAVENOUS			IV	1	DAY
INTRAVENOUS			IV	1	DAY
RESPIRATORY					
(INHALATION)			INH	1	DAY
INTRAVENOUS			IV	3	DAY
PO					
PO				1	DAY
PO				1	DAY

Injection	SS	
Human-Albumin Solution For Infusion	SS	
Gelafundin Solution For Infusion	SS	
Alt-Insulin Perfusor	SS	
Mannitol Solution For Infusion	SS	
Dilzem Perfusor	SS	
Nitro Perfusor	SS	
Fentanyl Solution For Injection	SS	
Enfluran Solution For Inhalation	SS	
Doxutrex Solution For Infusion	SS	
Ferro Sanol Tablets	SS	ORAL
Bisolvon Liquid	SS	ORAL
Hydromedin Tablets	SS	ORAL
Adalat	C	
Cor-Tensobon	C	
Beloc Mite	C	
Isoket Perfusor	C	
Glucose	C	
Nacl	C	
Ciprobay	C	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/19/99ISR Number: 3202332-1Report Type:Direct Company Report #
Age:21 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dyskinesia		Reglan	PS	Robinss	ORAL	10MG AC & HS	
Required	Dysphagia						PO	
Intervention to Prevent Permanent Impairment/Damage	Dystonia							

Date:02/19/99ISR Number: 3202341-2Report Type:Direct Company Report #
Age:54 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Facial Palsy		Reglan	PS	Robins	ORAL	10MG X 1 PO	
	Hypertension		Sufenta	SS	Janssen		10MG X5=50MG	
	Tachycardia		Pepcid	C				

Date:02/22/99ISR Number: 3205038-8Report Type:Expedited (15-DaCompany Report #B044434
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Blister	Foreign	Amphotericin B	PS			INTRAVENOUS	40 MG IV
Life-Threatening	Dermatitis	Health	Neupogen	SS			NI	
	Epidermolysis Bullosa	Professional	Insulin Human	SS			SUBCUTANEOUS	50 IU SC
	Hyperglycaemia		Allopurinol	SS		ORAL	300 MG PO	15 DAY
	Hypertension		Amoxicillin W/Potassium Clavulanate	SS			INTRAVENOUS	4 GM IV 5 DAY
	Lip Ulceration							
	Mycosis Fungoides							
	Pain		Ancotil	SS			INTRAVENOUS	40 MG IV

	Pruritus			
INTRAVENOUS	20 MG IV			
	Pyrexia			
PO				
	Shock			
INTRAVENOUS	IV	1	DAY	
	Stevens-Johnson Syndrome			
INTRAVENOUS	6 GM IV			
	Toxic Epidermal			
400 MG PO	18 DAY			
	Necrolysis			
INTRAVENOUS	3.75 MG IV			
INTRAVENOUS	25 MG IV	1	DAY	
INTRAVENOUS	200 MG IV			
INTRAVENOUS	240 MG IV			
INTRAVENOUS	360 MG IV			
INTRAVENOUS	IV			
PO	31 DAY			
INTRAVENOUS	50 MG IV	1	DAY	
20 MG PO	1 DAY			
SUBCUTANEOUS	300 MCG SC	12	DAY	
SUBCUTANEOUS	7500 IU SC			
INTRAVENOUS	.5 GM IV			
INTRATHECAL	IT	4	DAY	
INTRAVENOUS	IV	5	DAY	
INTRAVENOUS	24 MG IV	9	DAY	
INTRAVENOUS	IV	15	DAY	
INTRAVENOUS	IV	9	DAY	
PO	13 DAY			
500 MG PO	7 DAY			
INTRAVENOUS	IV			

Antra	SS	
Bifiteral	SS	ORAL
PO		
Ciprobay	SS	
Claforan	SS	
Diflucan	SS	ORAL
400 MG PO	18 DAY	
Dipidolor	SS	
Dolantin	SS	
Dopamine	SS	
Dormicum	SS	
Gentamicin	SS	
Albumin Human	SS	
Imodium	SS	ORAL
20 MG PO	1 DAY	
Isoptin	SS	
Lasix	SS	ORAL
20 MG PO	1 DAY	
Leucomax	SS	
Liquemin	SS	
Meronem	SS	
Methotrexate	SS	
Metronidazole	SS	
Mst (Morphine Tartrate)	SS	
Multibionta (Multivitamins)	SS	
Novalgin (Dipyrone)	SS	
Opium Tincture (Opium)	SS	ORAL
Paracetamol	SS	ORAL
500 MG PO	7 DAY	
Paspertin	SS	

Psyquil	SS
Sobelin	
INTRAVENOUS	IV

				(Clindamycin)	SS
INTRAVENOUS	200 MG IV	1	DAY		
				Zofran (Ondansetron Hcl)	SS
INTRAVENOUS	IV	11	DAY		
				Zienam	SS
INTRAVENOUS	,5 GM IV	1	DAY		
				Solu-Dacortin	SS
INTRAVENOUS	50 MG IV	1	DAY		
				Suprarenin	SS
INTRAVENOUS	IV				
				Tavegil	SS
INTRAVENOUS	IV				
				Vancomycin	SS
INTRAVENOUS	IV				
				Unknown (Reporter Did Not Know)	C
INTRAVENOUS	IV	8	DAY		

Date:02/23/99ISR Number: 3205653-1Report Type:Periodic Company Report #8-98352-014A
Age:4 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Attention Deficit/Hyperactivity Disorder	Consumer	Reglan	PS		ORAL	DOSE UNSPECIFIED	
	Personality Disorder		Zantac	C		ORAL		

Date:02/23/99ISR Number: 3205655-5Report Type:Periodic Company Report #8-91104-001F
Age:50 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Disability	Extrapyramidal Disorder	Consumer	Reglan	PS		ORAL		
			Tagamet	C				
			Premarin	C				
			Carafate	C				
			Metamucil	C				
			Calcium	C				

			Maalox	C		
			Mylanta	C		
			Amphogel	C		

Date:02/23/99ISR Number: 3205657-9Report Type:Periodic Company Report #8-97065-001S
Age:53 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Torticollis	Health	Reglan	PS		ORAL	PRN ORAL	
		Professional	Aspirin	C				
			Metoprolol	C				
			Zocor	C				

Date:02/23/99ISR Number: 3205659-2Report Type:Periodic Company Report #8-97345-001J
Age:45 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Ineffective	Consumer	Reglan	PS		ORAL	10 MG FOUR	
	Dyspepsia						TIMES DAILY	
	Nausea						ORAL	

Date:02/23/99ISR Number: 3205680-4Report Type:Periodic Company Report #8-98014-004L
Age:20 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Diarrhoea	Health	Reglan	PS		ORAL	10 MG IN 24	
		Professional					HOURS ORAL	24 HR

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/23/99ISR Number: 3205681-6Report Type:Periodic Company Report #8-98268-039A
Age:83 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Extrapyramidal Disorder	Consumer	Reglan	PS		ORAL	2 TABLETS	DAILY ORAL

Date:02/23/99ISR Number: 3205682-8Report Type:Periodic Company Report #8-98289-080A
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Neuroleptic Malignant Syndrome	Health Professional	Reglan	PS		ORAL	DOSE UNSPECIFIED	ORAL

Date:02/23/99ISR Number: 3205683-XReport Type:Periodic Company Report #8-98036-011L
Age:30 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Muscle Twitching	Health	Reglan	PS		ORAL	2-3 TIMES	DAILY ORAL
	Torticollis	Professional						
			Phenergan	C				
			Prenatal Vitamins	C				

Date:02/23/99ISR Number: 3205684-1Report Type:Periodic Company Report #8-98037-011L
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hepatic Steatosis	Health	Reglan	PS		ORAL	ORAL	

	Liver Function Test Abnormal	Professional				

Date:02/23/99ISR Number: 3205685-3Report Type:Periodic Company Report #8-98068-012L
Age:24 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Oedema	Health	Reglan	PS		ORAL	30 MG DAILY	
		Professional					ORAL	

Date:02/23/99ISR Number: 3205687-7Report Type:Periodic Company Report #8-98069-004L
Age:70 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Extrapyramidal Disorder	Health	Reglan	PS		ORAL	5 MG THREE	
	Pain	Professional					TIMES DAILY	
							ORAL	
			Amlodipine	C				
			Digoxin	C				
			Isosorbide Mononitrate	C				
			Aspirin	C				
			Metoprolol	C				
			Insulin	C				
			Calcium Carbonate	C				
			Mevacor	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/23/99ISR Number: 3205689-0Report Type:Periodic Company Report #8-98077-028L
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Laboratory Test Abnormal	Health	Reglan	PS		ORAL	ORAL	
	Nonspecific Reaction	Professional						

Date:02/23/99ISR Number: 3205690-7Report Type:Periodic Company Report #8-98083-015L
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hyperpituitarism	Health	Reglan	PS		ORAL	ORAL	
		Professional						

Date:02/23/99ISR Number: 3205692-0Report Type:Periodic Company Report #8-98098-002L
Age:68 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Extrapyramidal Disorder	Health	Reglan	PS		ORAL	20 MG THREE TIMES DAILY;	
		Professional					ORAL	
			Allopurinol	C				
			Coumadin	C				
			Dolobid	C				
			Dyrenium	C				
			Inderal	C				
			Lanoxin	C				
			Lasix	C				
			Premarin	C				
			Provera	C				
			Prozac	C				
			Xanax	C				
			Zantac	C				

Date:02/23/99ISR Number: 3205694-4Report Type:Periodic Company Report #8-98132-005L
Age:31 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Breast Neoplasm	Consumer	Reglan	PS		ORAL	10 MG TWICE	
	Breast Pain						DAILY ORAL	
	Depression		Prevacid	C				
	Nervousness							
	Psychotic Disorder							
	Visual Disturbance							

Date:02/23/99ISR Number: 3205696-8Report Type:Periodic Company Report #8-98134-070A
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Akathisia	Consumer	Reglan	PS		ORAL	ORAL, 15 MG	
	Depersonalisation						THREE TIMES	
	Insomnia						DAILY	
			Unspecified Psychotropics Oral	C				
			Muscles Relaxants Oral	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/23/99ISR Number: 3205697-XReport Type:Periodic Company Report #8-98195-038A
Age:13 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Sedation	Consumer	Reglan	PS		ORAL	10 MG FOUR	TIMES DAILY
			Zantac	C		ORAL		

Date:02/23/99ISR Number: 3205699-3Report Type:Periodic Company Report #8-98286-032A
Age:54 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Anxiety	Consumer	Reglan	PS			5 MG FOUR	
	Nervousness						TIMES DAILY	
			Zantac Tablets	C				

Date:02/23/99ISR Number: 3205701-9Report Type:Periodic Company Report #8-98309-099A
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Pyrexia	Health	Reglan	PS		ORAL	DOSE	
		Professional					USPECIFIED	
						ORAL		

Date:02/23/99ISR Number: 3205702-0Report Type:Periodic Company Report #8-98309-114A
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Abnormal Labour	Health Professional	Reglan	PS		ORAL	UNSPECIFIED	

Date:02/23/99ISR Number: 3205704-4Report Type:Periodic Company Report #8-98320-050A
Age:83 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Extrapyramidal Disorder	Health Professional	Reglan	PS		ORAL	2.5 MG TWICE DAILY	
			Darvon	C				
			Dyazide	C				
			Premarin	C				
			Prozac	C				

Date:02/23/99ISR Number: 3205706-8Report Type:Periodic Company Report #8-98328-059A
Age:52 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Asthenia Dyspnoea Yawning	Health Professional	Reglan	PS		ORAL	10 MG TABLES;UNSPECIFIED	FREQUENCY
			Nortriptyline Hcl	C				
			Xalatan	C				

Zestril Tablets C

Date:02/23/99ISR Number: 3205708-1Report Type:Periodic Company Report #8-98348-084A
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Extrapyramidal Disorder	Health Professional	Reglan	PS		ORAL	USPECIFIED	DOSE ORAL

Date:02/23/99ISR Number: 3205709-3Report Type:Periodic Company Report #8-98350-082A
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Extrapyramidal Disorder	Health Professional	Reglan	PS			DOSE USPECIFIED	

Date:02/23/99ISR Number: 3411309-2Report Type:Periodic Company Report #8-98345-110A
Age:52 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Akathisia	Health Professional	Reglan	PS		ORAL	5 MG FOUR TIMES DAILY	
	Depression						ORAL	

Date:02/24/99ISR Number: 3206721-0Report Type:Expedited (15-DaCompany Report #19990200321
Age:17 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Death	Blister	Foreign	Prilosec	PS
Life-Threatening	Corneal Erosion	Health	Liquemin	SS
Hospitalization -	Genital Rash	Professional	Pipril	SS
Initial or Prolonged	Multi-Organ Failure		Neupogen	SS
SUBCUTANEOUS INJ 3 MCG/KG				
	Oral Mucosal Blistering			
QD SC				
	Pyrexia		Atosil	SS
	Rash Maculo-Papular		Targocid	SS
	Sepsis		Gernebcin	SS
	Stevens-Johnson Syndrome		Ciprobay	SS
			Zantic	SS
			Diazepam	SS
			Midazolam Hydrochloride	SS
			Neurocil	SS
			Hydrocortisone Hydrogen Succina	SS
			Paspertin	SS
			Prednisolone	SS
			Lasix	SS
			Rekawan	SS
			Tavegil	SS
			Cymevan	SS
			Meronem	SS
			Amphotericin B	SS
			Dolantin	SS
			Ben-U-Ron	SS
			Zienam	SS
			Novalgin	SS
			Lactulose	SS

Fortum	SS
Vancomycin	SS
Cotrim	SS
Calcium	SS
Zovirax	SS
Diflucan	SS
Orgametril	SS
Multibionta	SS
Immunoglobin Human Normal	SS
Folsan	SS
Decortin	SS

Date:02/24/99ISR Number: 3206798-2Report Type:Expedited (15-DaCompany Report #WAES 99020839
Age:34 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Blister	Other	Primaxin	PS		INTRAVENOUS	.5 GM/IV	
Life-Threatening	Dermatitis		Allopurinol	SS		ORAL	PO	
	Epidermolysis Bullosa		Amoxicillin/Clavulanate Potassium	SS		INTRAVENOUS	IV	
	Fungal Infection		Amphotericin B	SS		INTRAVENOUS	IV	
	Hyperglycaemia		Ancotil	SS		INTRAVENOUS	IV	
	Hypertension		Antra	SS		INTRAVENOUS	IV	
	Mycosis Fungoides		Bifiteral	SS		ORAL	PO	
	Pruritus		Ciprobay	SS		INTRAVENOUS	IV	
	Pyrexia		Claforan	SS		INTRAVENOUS	IV	
	Shock		Diflucan	SS		ORAL	PO	
	Skin Ulcer		Dipidolor	SS		INTRAVENOUS	IV	
	Stevens-Johnson Syndrome		Dolantin	SS		INTRAVENOUS	IV	
	Toxic Epidermal		Dopamine Hcl	SS		INTRAVENOUS	IV	
	Necrolysis							

INTRAVENOUS	IV	Midazolam Maleate	SS	
INTRAVENOUS	IV	Gentamicin	SS	
INTRAVENOUS	IV	Albumin	SS	
PO		Imodium	SS	ORAL
INTRAVENOUS	IV	Isoptin	SS	
PO		Lasix	SS	ORAL
		Inj Granulocyte-Macrophage Colony Stimulating Factor Preparations 300	SS	
SUBCUTANEOUS	SC	Liquemin	SS	
SUBCUTANEOUS	SC	Meronem	SS	
INTRAVENOUS	IV	Methotrexate	SS	
		Metronidazole	SS	
INTRAVENOUS	IV	Morphine	SS	
INTRAVENOUS	IV	Multibionta	SS	
INTRAVENOUS	IV	Novalgin	SS	
INTRAVENOUS	IV	Opium	SS	ORAL
PO		Acetaminophen	SS	ORAL
PO		Metoclopramide Mono Hcl Monohydrate	SS	
INTRAVENOUS	IV	Triflupromazine	SS	
INTRAVENOUS	IV	Clindamycin Hcl	SS	
INTRAVENOUS	IV	Solu-Decortin	SS	
INTRAVENOUS	IV	Suprarenin	SS	
INTRAVENOUS	IV	Tavegil	SS	
INTRAVENOUS	IV	Vancomycin	SS	
INTRAVENOUS	IV	Vitalipid	SS	
INTRAVENOUS	IV			

			Zofran	SS			
INTRAVENOUS	IV						
			Neupogen	SS			
			Actrapid	SS			
SUBCUTANEOUS	SC						

Date:02/24/99ISR Number: 3207224-XReport Type:Expedited (15-DaCompany Report #WAES 99020839
Age:34 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Blister	Other	Inj Primaxin .5 Gm	PS				
INTRAVENOUS	.5 GM/IV							
Life-Threatening	Dermatitis		Allopurinol 300 Mg	SS		ORAL		
PO								
	Hyperglycaemia		Inj Amoxicillin/Clavulan					
	Hypertension		ate Potassium 4 Gm	SS				
	Lip Ulceration							
INTRAVENOUS	IV							
	Pruritus		Inj Amphotericin B					
	Pyrexia		40 Mg	SS				
INTRAVENOUS	IV							
	Shock		Inj Ancotil	SS				
INTRAVENOUS	IV							
	Stevens-Johnson Syndrome		Antra 20 Mg	SS				
INTRAVENOUS	IV							
	Toxic Epidermal		Bifiteral	SS		ORAL		
PO								
	Necrolysis		Ciprobay	SS				
INTRAVENOUS	IV							
			Claforan 6 Gm	SS				
INTRAVENOUS	IV							
			Diflucan 400 Mg	SS		ORAL		
PO								
			Inj Dipidolor 3.75					
			Mg	SS				
INTRAVENOUS	IV							
			Colantin 25 Mg	SS				
INTRAVENOUS	IV							
			Dopamine Hcl 200 Mg	SS				
INTRAVENOUS	IV							
			Midazolam Maleate					
			240 Mg	SS				
INTRAVENOUS	IV							

		Gentamicin 360 Mg	SS	
INTRAVENOUS	IV			
		Serum Albumin	SS	
INTRAVENOUS	IV			
		Imodium	SS	ORAL
PO				
		Isoptin 50 Mg	SS	
INTRAVENOUS	IV			
		Lasix 20 Mg	SS	ORAL
PO				
		Inj Granulocyte-Macrophage Colony Stimulating Factor Preparations 300	SS	
SUBCUTANEOUS	SC			
		Inj Liquemin 7500 Iu	SS	
SUBCUTANEOUS	SC			
		Inj Meronem .5 Gm	SS	
INTRAVENOUS	IV			
		Inj Methotrexate (Methotrexate Disodium Salt)	SS	
		Inj Metronidazole	SS	
INTRAVENOUS	IV			
		Inj Morphineo4 24 Mg	SS	
INTRAVENOUS	IV			
		Inj Multibionta	SS	
INTRAVENOUS	IV			
		Inj Novalgin	SS	
INTRAVENOUS	IV			
		Liq Opium	SS	ORAL
PO				
		Acetaminophen 500 Mg	SS	ORAL
PO				
		Metoclopramide Monohcl Monohydrate	SS	
INTRAVENOUS	IV			
		Triflupromazine	SS	
INTRAVENOUS	IV			
		Inj Clindamycin Hcl Monohydrate 200 Mg	SS	
INTRAVENOUS	IV			
		Inj Solu-Decortin-H 50 Mg	SS	
INTRAVENOUS	IV			
		Inj Suprarenin	SS	
INTRAVENOUS	IV			
		Tavegil	SS	
INTRAVENOUS	IV			
		Vancomycin	SS	
INTRAVENOUS	IV			

INTRAVENOUS	IV
INTRAVENOUS	IV

Inj Vitalipid	SS
Zofran	SS

				Neupogen	SS		
				Inj Human Actrapid 50 Iu	SS		
SUBCUTANEOUS	SC						

Date:03/02/99ISR Number: 3218089-4Report Type:Periodic Company Report #JAUSA-34978
Age:62 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Other	Attention Deficit/Hyperactivity Disorder	Health Professional	Propulsid (Cisapride) Janssen, Tablet	PS	Janssen	
20 MG 2 DAILY						
NASO-GASTRIC						
			Reglan (Metoclopramide) Tablet	SS		ORAL
10 MG 3 DAILY						
ORAL						

Date:03/02/99ISR Number: 3218788-4Report Type:Direct Company Report #
Age:3 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Other	Condition Aggravated		Vincristine	PS		
	Decreased Appetite		Doxorubicin (Iv)	SS		
INTRAVENOUS						
	Deep Vein Thrombosis		Actinomycin-D (Iv)	SS		
INTRAVENOUS						
	Feeling Cold		Kytril (Iv)	SS		
INTRAVENOUS	IV					
	Vomiting		Bactrim (Po)	SS		ORAL
			Fluconazole (Iv)	SS		
INTRAVENOUS						
			Zantac (Iv)	SS		
INTRAVENOUS						
			Reglan (Iv)	SS		
INTRAVENOUS						
			Morphine Sulfate			

			(Iv)	SS			
INTRAVENOUS							
			Fentanyl (Iv)	SS			
INTRAVENOUS							

Date:03/03/99ISR Number: 3210706-8Report Type:Direct Company Report #
Age:88 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Balance Disorder		Metoclopramide	PS	Pure Pac	ORAL	10 MG BID PO	
Required Intervention to Prevent Permanent Impairment/Damage	Dementia Alzheimer'S Type Difficulty In Walking Memory Impairment Parkinson'S Disease Sedation							

Date:03/03/99ISR Number: 3211540-5Report Type:Expedited (15-DaCompany Report #DEU001275
Age:48 YR Gender:Female I/FU:F

Outcome	PT
Death	Acute Leukaemia
Life-Threatening	Cardiac Failure
Hospitalization - Initial or Prolonged	Dermatitis Mouth Ulceration Mucosal Inflammation Oral Soft Tissue Disorder Renal Failure Sepsis Shock

Toxic Epidermal Necrolysis

Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Foreign	Dilaudid	PS			INTRAVENOUS	2 MG DAILY IV
Study	Tazobac	SS			INTRAVENOUS	4.5 G TID IV
Health	Diflucan	SS		ORAL	100 MG DAILY	
Professional					PO	
Other	Thrombozyten Concentrate	SS				
	Erythrozyten Concentrate	SS				
	Dopamin	SS			INTRAVENOUS	250 MG DAILY
					IV	
	Paspertin	SS			INTRAVENOUS	10 MG DAILY
					IV; 30 MG	
					DAILY IV	
	Insulin	SS			INTRAVENOUS	100 I.U.
					DAILY IV	
	Vergentan	SS			INTRAVENOUS	2 ML DAILY IV
	Diazepam	SS		ORAL	7.5 TAB DAILY	
					PO; 10 TAB	
					DAILY PO	
	Meronem	SS			INTRAVENOUS	1 G TID IV
	Paracetamol	SS		ORAL	1 G DAILY PO	
	Presomen	SS		ORAL	0.3 MG OD PO	
	Folsan	SS		ORAL	5 MG DAILY	

PO; 10 MG DAILY PO				
INTRAVENOUS	200 MG DAILY IV; 600 MG DAILY IV			
175 MG BID PO				
2 G DAILY IV				
200MG OD PO				
INTRAVENOUS	500 MG TID IV			
INTRAVENOUS	20 MG DAILY IV; 330 MG DAILY IV			
10 MG OD PO				
INTRAVENOUS	2 G DAILY IV			
INTRAVENOUS	20 ML DAILY IV			
INTRAVENOUS	1 ML OD IV			
INTRAVENOUS	96 MG DAILY IV			
10 ML OD PO				
200 MG DAILY PO				
1 CAP OD PO				
25 MG DAILY PO				
		Ciprobay	SS	
		Sandimmun	SS	ORAL
		Novaminsulfon-Ratiopharm	SS	
		Sempera	SS	
		Clont	SS	
		Lasix	SS	
		Praxiten	SS	ORAL
		Fortum	SS	
		Humanalbumin	SS	
		Buscopan	SS	
		Urbason	SS	
		Maaloxan	SS	ORAL
		Diflucan	SS	ORAL
		Nizax	SS	ORAL
		Saroten	SS	ORAL
		Aminomix	C	
		Peppermint	C	

Sandimmun	C
Leucozyten	C
Atosil	C
Cellcept	C
Vancomycin	C
Zofran	C
Nephrotect	

(Ssoleucin, Leucin, Lysinacetat, Methionin, Phenylalanin)	C
Cernevit	C
Tracitrans (Ca-Chlorid, Ma-Chlorid, Fe-Chlorid, Zinkchlorid,	C
Lipofundin	C
Calcium Gluconat	C
Pepdul	C
Konakion	C
Aminoplasmal	C
Natrium	C
Multibionta	C
Dolantin	C
Lamisil	C
Panthenol	C
Zyloric	C
Ciprobay	C
Frisium	C
Ursofalk	C
Natriumbicarbonat	C
Kalium Klorid	C
Zovirax	C
Heparin	C
Amphotericin B	C
Isoptin	C
Natriumchlorid	C
Dipeptamin	C
Glucose	C
Ampho-Moronal	C
Euthyrox	C
Endoxan	C
Antihistaminicum	C
Novalgin	C
Zovirax	C
Vidisic	C
Kevatril	C
Uromitexan	C
Magnesiumsulfat	C

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Disability	Facial Palsy Intervertebral Disc Disorder Muscle Disorder Muscle Spasms Neck Pain Sedation Spinal X-Ray Abnormal	Health Professional	Reglan Tagamet (Cimetidine) Tablet	PS C		ORAL		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/05/99ISR Number: 3214105-4Report Type:Expedited (15-DaCompany Report #B043834
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Blister	Foreign	Amphotericin B	PS				
Life-Threatening	Corneal Erosion	Health	Neupogen (Filgrastim)	SS			3 MCG/KG QD	2 DAY
	Multi-Organ Failure	Professional	Antra (Omeprazole)	SS				
	Oral Mucosal Blistering		Atosil (Promethazine Hcl)	SS				1 DAY
	Pyrexia		Paracetamol	SS				
	Rash Maculo-Papular		Calcium	SS				
	Sepsis		Ciprobay (Ciprofloxacin Hcl)	SS				5 DAY
	Stevens-Johnson Syndrome		Cotrim (Sulfamethoxazole+Trimethroprim)	SS				
			Cymevan (Ganciclovir)	SS				
			Decortin (Prednisone)	SS				
			Diazepam	SS				
			Diflucan (Fluconazole)	SS				
			Dolantin (Meperidine Hcl)	SS				3 DAY
			Folsan (Folic Acid)	SS				
			Fortum (Ceftazidime)	SS				4 DAY
			Gernebcin (Tobramycin Sulfate)	SS				4 DAY
			Hydrocortisone	SS				5 DAY
			Immunoglobulin (As Reported)	SS				
			Lactulose	SS				5 DAY
			Lasix (Furosemide)	SS				13 DAY
			Liquemin (Heparin)	SS				
			Meronem (Meropenem)	SS				

		Midazolam (Midazolam Hcl)	SS
1	DAY		
		Multibionta (Multivitamins)	SS
		Neurocil (Methotrimeprazine)	SS
		Novalgin (Dipyrone)	SS
		Orgametril (Lynestrenol)	SS
		Paspertin (Methochlorpropamide Hcl)	SS
4	DAY		
		Pipril (Piperacillin Sodium)	SS
4	DAY		
		Prednisolone	SS
5	DAY		
		Rekawan (Potassium Chloride)	SS
3	DAY		
		Targocid (Teicoplanin)	SS
		Tavegil (Clemastine Fumarate)	SS
4	DAY		
		Vancomycin (Vancomycin Hcl)	SS
		Zantac (Ranitidine Hcl)	SS
5	DAY		

				Zienam (Imipenem + Cilastatin Sodium)	SS			
2	DAY							
				Zovirax (Acyclovir)	SS			

Date:03/08/99ISR Number: 3215223-7Report Type:Expedited (15-DaCompany Report #3800/50441
Age:34 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Blister	Foreign	Cleocin Phosphate	PS				
INTRAVENOUS	200 MG/DAY;IV							
Life-Threatening	Dermatitis	Health	Neupogen	SS				
	Hyperglycaemia	Professional	Actrapid (Human					
	Hypertension	Company	Insulin)	SS				
SUBCUTANEOUS	50 IU/DAY;SC							
	Lip Disorder	Representative	Allopurinol	SS		ORAL		
300 MG/DAY;								
	Mycosis Fungoides	Other						
ORAL								
	Neutropenia		Amoxicillin W/					
	Pain		Potassium					
	Pruritus		Clavulanate	SS				
INTRAVENOUS	4 GM/DAY;IV							
	Pyrexia		Amhpotericin B	SS				
INTRAVENOUS	40 MG/DAY;IV							
	Shock		Ancotil					
	Stevens-Johnson Syndrome		(Flucytosine)	SS				
INTRAVENOUS	IV							
			Antra (Omperazole)	SS				
INTRAVENOUS	20 MG/DAY; IV							
			Bifiteral					
			(Lactulose)	SS		ORAL		
ORAL								
			Ciprobay	SS				
INTRAVENOUS	IV							
			Claforan	SS				
INTRAVENOUS	6 GM/DAY;IV							
			Diflucan	SS		ORAL		
400								
MG/DAY;ORAL								
			Dipidolor					
			(Piritramide)	SS				
INTRAVENOUS	3.75 MG/DAY;							

IV

INTRAVENOUS 25 MG/DAY; IV

Dolantin (Pethidine Hcl)	SS
Dopamine	SS
Dormicum (Midazolam)	SS
Gentamicin	SS
Human Albumin	SS
Imodium	SS
Isoptin	SS
Lasix	SS
Leucomax (Gm-Csf)	SS
Liquemin (Heparin)	SS
Meronem (Meropenem)	SS
Methotrexate	SS
Metronidazole	SS
Mst (Morphine Sulfate)	SS
Multibionta	SS
Novalgin (Metamizole)	SS
Opium Tincture	SS
Acetaminophen	SS
Paspertin (Metoclopramide)	SS
Psyquil (Triflupromazine)	SS
Solu-Decortin-H	SS
Suprarenin (Epinephrine)	SS
Tavegil (Clemastine)	SS
Vancomycin	SS

Vitalipid Novum Adult	SS	
Zienam (Cilastatin/Imipenem)	SS	
Zofran	SS	

Date:03/09/99ISR Number: 3215446-7Report Type:Expedited (15-DaCompany Report #1999AP01161
Age:31 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Atrial Fibrillation	Foreign	Tenormin	PS		ORAL	25 MG QD PO	
Initial or Prolonged	Atrioventricular Block	Literature	Metoclopramide	SS		INTRAVENOUS	20 MG IV	
	Blood Pressure Decreased	Health	Ketotifen Fumarate	SS		ORAL	2 MG DAILY PO	
	Bradycardia	Professional	Cyproheptadine Hydrochloride	SS		ORAL	16 MG DAILY PO	
	Cardiac Arrest							
	Cardio-Respiratory Arrest							
	Dermatitis		Famotidine	SS		INTRAVENOUS	20 MG DAILY IV	
	Electrocardiogram Qt Prolonged		Thiamazole	SS		ORAL	30 MG DAILY PO	
	Electrocardiogram St Segment Depression		Carbazochrome Sodium Sulfonate	C				
	Electrocardiogram T Wave Amplitude Decreased		Potassium Chloride	C				
	Haematemesis		Fosfomycin	C				
	Hypokalaemia							
	Loss Of Consciousness							
	Overdose							
	Palpitations							
	Quadriplegia							
	Respiratory Arrest							
	Tachycardia							
	Ventricular Extrasystoles							
	Vomiting							

Date:03/11/99ISR Number: 3218585-XReport Type:Direct Company Report #
Age:84 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Aphasia		Metoclopramide	PS	A-H Robins	INTRAVENOUS	10 MG IVP	
Hospitalization - Initial or Prolonged	Bradycardia		Piroxicam	C				
	Respiratory Arrest		Levothyroxine	C				
			Enalapril Maleate	C				
			Trimaterene/ Hctz	C				

Date:03/15/99ISR Number: 3221061-1Report Type:Periodic Company Report #8-98334-129A
Age:88 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Methaemoglobinaemia	Health Professional	Reglan	PS		INTRAVENOUS	10 MG FOUR TIMES DAILY	

INTRAVENOUS

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/15/99ISR Number: 3221062-3Report Type:Periodic Company Report #8-98351-035A
Age:20 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Extrapyramidal Disorder	Health	Reglan	PS		INTRAVENOUS	10 MG ONCE	
Initial or Prolonged		Professional						DAILY
						INTRAVENOUS		
			Fentanyl Injection	C				
			Midazolam Injection	C				
			Benadryl	C				

Date:03/15/99ISR Number: 3221065-9Report Type:Periodic Company Report #8-98061-002L
Age:31 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Stomatitis	Health	Reglan	PS		INTRAVENOUS	10 MG EVERY 8	
		Professional						HOURS IV
			Zantac	C				

Date:03/15/99ISR Number: 3221068-4Report Type:Periodic Company Report #8-98140-022A
Age: Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Thrombocytopenia	Health	Reglan	PS		INTRAVENOUS	INTRAVENOUS	
		Professional						

Date:03/15/99ISR Number: 3221069-6Report Type:Periodic Company Report #8-99022-113A
Age:41 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Other Hyperhidrosis Consumer Reglan PS
INTRAVENOUS DOSE
Muscle Twitching
UNSPECIFIED
Vasodilatation
INTRAVENOUS
Visual Disturbance

Date:03/15/99ISR Number: 3221070-2Report Type:Periodic Company Report #8-98279-054A
Age: Gender:Female I/FU:I

Outcome PT Report Source Product Role Manufacturer Route
Dose Duration
Other Extrapyramidal Disorder Literature Reglan PS
SUBCUTANEOUS SC

Date:03/15/99ISR Number: 3221073-8Report Type:Periodic Company Report #8-98288-003Z
Age: Gender:Female I/FU:I

Outcome PT Report Source Product Role Manufacturer Route
Dose Duration
Other Extrapyramidal Disorder Literature Reglan PS
SUBCUTANEOUS DOSE

UNSPECIFIED

SC

Date:03/15/99ISR Number: 3221076-3Report Type:Periodic Company Report #8-98288-004Z
Age: Gender:Female I/FU:I

Outcome PT Report Source Product Role Manufacturer Route
Dose Duration
Other Extrapyramidal Disorder Literature Reglan PS
SUBCUTANEOUS SC

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/15/99ISR Number: 3221080-5Report Type:Periodic Company Report #8-98288-005Z
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Extrapyramidal Disorder	Literature	Reglan	PS		SUBCUTANEOUS	SC	

Date:03/15/99ISR Number: 3221082-9Report Type:Periodic Company Report #8-98288-006Z
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Extrapyramidal Disorder	Literature	Reglan	PS		SUBCUTANEOUS	SC	

Date:03/15/99ISR Number: 3221084-2Report Type:Periodic Company Report #8-98288-007Z
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Extrapyramidal Disorder		Reglan	PS		SUBCUTANEOUS	SC	

Date:03/15/99ISR Number: 3221086-6Report Type:Periodic Company Report #8-98288-008Z
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Extrapyramidal Disorder	Literature	Reglan	PS		SUBCUTANEOUS	SC	

Date:03/15/99ISR Number: 3221088-XReport Type:Periodic Company Report #8-98288-009Z
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Extrapyramidal Disorder	Literature	Reglan	PS		SUBCUTANEOUS	SC	

Date:03/15/99ISR Number: 3221091-XReport Type:Periodic Company Report #8-98288-010Z
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Extrapyramidal Disorder	Literature	Reglan	PS		SUBCUTANEOUS	SC	

Date:03/15/99ISR Number: 3221093-3Report Type:Periodic Company Report #8-98288-011Z
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Extrapyramidal Disorder	Literature	Reglan	PS		SUBCUTANEOUS	SC	

Date:03/15/99ISR Number: 3221095-7Report Type:Periodic Company Report #8-98288-012Z
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Extrapyramidal Disorder	Literature	Reglan	PS		SUBCUTANEOUS	SC	

Date:03/17/99ISR Number: 3223121-8Report Type:Expedited (15-DaCompany Report #8-99068-073A
Age:72 YR Gender:Male I/FU:I

Outcome
Hospitalization -
Initial or Prolonged

Other

	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Blood Creatinine Increased	Literature	Reglan	PS		ORAL	10 MG THREE TIMES DAILY	
	Haematocrit Decreased					ORAL		
	Haemoglobin Decreased		Albuterol Inhalation	C				
	Oedema Peripheral		Amlodipine Tablets	C				
	Purpura		Aspirin Tablets	C				
	Rash Papular		Beclomethasone Inhalation	C				
			Digoxin Tablets	C				
			Furosemide Tablets	C				
			Insulin (70/30) Injection	C				
			Ipratropium Bromide Inhalation	C				
			Gemfibrozil Tablets	C				

Date:03/18/99ISR Number: 3222365-9Report Type:Expedited (15-DaCompany Report #325/153
Age:29 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Amniotic Fluid Embolus	Foreign	Prostin	PS		VAGINAL	2 MG/DAY;	
	Anaphylactic Shock	Health Professional Company Representative	Maxolon	SS		I.VAG		
	Cardio-Respiratory Arrest		Morphine	SS		INTRAMUSCULAR	10 MG/DAY;IM	
			Marcaine Spinal	SS		INTRADISCAL (INTRASPINAL)	.25 GM/DAY;I.SPIN	
						INTRADISCAL (INTRASPINAL)	2.2 ML/DAY;	

I.SPIN

			Mefoxim	SS		
INTRAVENOUS	2 GM/DAY; IV					
			Salbutamol	SS		
RESPIRATORY						
(INHALATION)	INHAL					

Date:03/22/99ISR Number: 3223990-1Report Type:Expedited (15-DaCompany Report #F/99/00487/LEX
Age:53 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Convulsion		Leponex (Clozapine)	PS		ORAL	600 MG ORAL	3 YR
Initial or Prolonged	Electroencephalogram		Primperan	SS		ORAL	ORAL	
Required	Abnormal		Importal	SS		ORAL	ORAL	
Intervention to	Hypokalaemia		Loxen (Nicardipine					
Prevent Permanent	Hyponatraemia		Hydrochloride)	SS		ORAL	ORAL	
Impairment/Damage	Oesophagitis		Daflon (Diosmin)	SS		ORAL	4 OTH ORAL	
	Polydipsia Psychogenic							
	Vomiting							

Date:03/22/99ISR Number: 3224327-4Report Type:Expedited (15-DaCompany Report #1998-12-0942
Age:1 MON Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Dermatitis	Foreign	Celestene					
Initial or Prolonged	Hypotension	Health	(Betamethasone) Oral					
Other		Professional	Suspension "Like					
		Other	Celectone Syrup"	PS		ORAL	10 DROPS QD	
							ORAL	

			Speciafoldine Tablets	SS		ORAL 2.5 MG QD ORAL
			Fumafer Tablets	SS		ORAL 100 MG QD ORAL
			Primperan Oral Solution	SS		ORAL 12 DROPS QD ORAL
			Uvesterol	SS		ORAL 1 ML, QD, ORAL
			Caffeine, No Dose Form	SS		ORAL 7.5 MG QD ORAL

Date:03/23/99ISR Number: 3224612-6Report Type:Expedited (15-DaCompany Report #325/153
Age:29 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Amniotic Fluid Embolus	Foreign	Prostin E2 Gel	PS			2 MG/DAY;	
	Anaphylactic Shock	Health					I.VAG	
	Cardio-Respiratory Arrest	Professional	Maxolon	SS			INTRAMUSCULAR	10 MG/DAY; IM
		Company	Morphine	SS			0.25 GM/DAY;	
		Representative					I.SPIN	
			Marcaine Spinal	SS			2.2 ML/DAY;	
							I.SPIN	
			Mefoxim	SS			INTRAVENOUS	2 GM/DAY; IV

				Salbutamol	SS		
RESPIRATORY							
(INHALATION)	INHAL						

Date:03/30/99ISR Number: 3229929-7Report Type:Expedited (15-DaCompany Report #199813612HPD
Age:17 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Blister	Foreign	Novalgin	PS				
INTRAVENOUS	500 MG/DAY IV						1	DAY
	Corneal Erosion	Study	Novalgin	SS				
INTRAVENOUS	500 MG/DAY IV						2	DAY
	Dermatitis	Health	Novalgin	SS				
INTRAVENOUS	500 MG/DAY IV							
	Genital Disorder Female	Professional	Lasix	SS				
INTRAVENOUS	20 UP TO 30							
	Mucosal Erosion	Other						
MG QD IV							5	DAY
	Multi-Organ Failure		Lasix	SS				
INTRAVENOUS	20 UP TO 30							
	Pyrexia							
MG QD IV							1	DAY
	Shock		Dolantin	SS				
INTRAVENOUS	25 MG/DAY IV						3	DAY
	Skin Disorder		Targocid	SS				
INTRAVENOUS	500 MG/DAY IV							
	Stevens-Johnson Syndrome		Diflucan	SS		ORAL		
400 MG/DAY PO								
	Toxic Epidermal		Octagam	SS				
INTRAVENOUS	25 MG/DAY IV						1	DAY
	Necrolysis		Octagam	SS				
INTRAVENOUS	25 MG/DAY IV						1	DAY
			Octagam	SS				
INTRAVENOUS	25 MG/DAY IV						1	DAY
			Octagam	SS				
INTRAVENOUS	25 MG/DAY IV						1	DAY
			Octagam	SS				
INTRAVENOUS	25 MG/DAY IV						2	DAY
			Cotrim Tablets	SS		ORAL		
240 MG BID PO							2	DAY
			Cotrim Tablets	SS		ORAL		
240 MG BID PO							2	DAY
			Vancomycin	SS				
INTRAVENOUS	1000 UP TO							
2000 MG QD IV							15	DAY
			Vancomycin	SS				
INTRAVENOUS	1000 UP TO							

2000 MG QD IV

INTRAVENOUS 2.5 UP TO 7.5

MG QD IV 4 DAY

1 UP TO 3 G

QD PO 4 DAY

1 UP TO 3 G

Fortum SS

Ben-Uron Tablets SS ORAL

Ben-Uron Tablets SS ORAL

QD PO	1	DAY				
10 UP TO 20						
ML QD PO	2	DAY				
10 UP TO 20						
ML QD PO	2	DAY				
INTRAVENOUS	15 MG/DAY IV					
INTRAVENOUS	650 MG/DAY IV	2	DAY			
INTRAVENOUS	250 MG/DAY IV					
INTRAVENOUS	1 G BID IV	6	DAY			
INTRAVENOUS	1 G BID IV					
INTRAVENOUS	100 MG/DAY IV	5	DAY			
4	DAY					
20 DROP/DAY						
PO	4	DAY				
PO	4	DAY				
INTRAVENOUS	8 MG/DAY IV	6	DAY			
INTRAVENOUS	8 MG/DAY IV	3	DAY			
INTRAVENOUS	8 MG/DAY IV	1	DAY			
5 MG/DAY	1	DAY				
5 MG/DAY	1	DAY				
5 MG/DAY	2	DAY				
INTRAVENOUS	5 MG/DAY IV	1	DAY			
INTRAVENOUS	280 MG TID IV	5	DAY			
5	DAY					
				Lactulose Syrup	SS	ORAL
				Lactulose Syrup	SS	ORAL
				Ampho B	SS	
				Zienam	SS	
				Cymeven	SS	
				Meronem	SS	
				Meronem	SS	
				Solu-Decortin-H	SS	
				Travegil	SS	
				Paspertin Drops	SS	ORAL
				Rekawan	SS	ORAL
				Neurocil	SS	
				Neurocil	SS	
				Neurocil	SS	
				Diazepam	SS	
				Diazepam	SS	
				Diazepam	SS	
				Dormicum	SS	
				Ciprobay	SS	
				Zantic	SS	

						Gernebcin	SS	
INTRAVENOUS	80 MG BID IV	4	DAY					
						Neupogen	SS	
SUBCUTANEOUS	150 MG/DAY SC	2	DAY					
						Atosil	SS	
INTRAVENOUS	25 MG/DAY IV	1	DAY					
						Liquemin	SS	
INTRAVENOUS	9700 IU/DAY							
IV								
						Antra	SS	
INTRAVENOUS	20 MG BID IV							
						Pipril	SS	
INTRAVENOUS	3.5 MG TID IV	4	DAY					
						Folsan	C	
						Decortin	C	
						Multibionta	C	
						Zovirax	C	
						Calcium	C	
						Orgametril	C	
						Clont	C	
						Doxycyclin	C	

Date:03/31/99ISR Number: 3231131-XReport Type:Expedited (15-DaCompany Report #WAES 98121762
Age:71 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	Tab Zocor (Simvastatin)	PS		ORAL	5 MG PO	22 MON
	Dermatitis		Sodium Sulfate	SS		ORAL	1.5 GM PO	119 DAY
	Eczema		Metoclopramide	SS		ORAL	15 MG PO	118 DAY
	Gastric Cancer		Vasotec (Enalapril Maleate)	SS		ORAL	10 MG PO	22 MON
	Gastrointestinal Disorder		Diltiazem D-Cis Form Hcl	SS		ORAL	100 MG PO	22 MON
	Rash Erythematous		Amlodipine	SS		ORAL	5 MG PO	10 MON
			Aluminum Bis (Acetylsalicylate)	SS				22 MON
			[Composition Unspecified]	SS		ORAL	22.5 GM PO	111 DAY
			Betamethasone	C				
			Hydrocortisone	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/09/99ISR Number: 3236647-8Report Type:Expedited (15-DaCompany Report #199910472HPD
Age:78 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Blepharitis	Foreign	Lasix Tablets	PS		ORAL	QD PO	4 WK
Hospitalization -	Blister	Study	Zentropil Tablets	SS		ORAL	QD PO	5 WK
Initial or Prolonged	Cardiac Failure	Health	Paspertin	SS		ORAL	20 DROP/DAY	
	Conjunctivitis	Professional					PO	
	Mucosal Erosion		Paspertin	SS			INTRAVENOUS	1 U/DAY IV
	Pruritus		Fortecortin Tablets	SS		ORAL	8 MG/DAY PO	1 WK
	Rash Macular		Pantozol Tablets	SS		ORAL	40 MG/DAY PO	2 WK
	Stevens-Johnson Syndrome		Ciprobay Tablets	SS		ORAL	250 MG/DAY PO	2 WK
	Toxic Epidermal		Diazepam	SS			INTRAVENOUS	10 MG/DAY IV
	Necrolysis		Innohep	SS			SUBCUTANEOUS	0.3 ML/DAY SC 2 WK
			Valoron N	SS		ORAL	20 DROP/DAY	
							PO	
			Riopan Gel	SS		ORAL	1 U/DAY PO	
			Unacid	C				
			Zantic	C				
			Natriumchlorid 0.9%	C				
			Dipiperon	C				
			Tavegil	C				
			Resonium A	C				
			Ferro Sanol	C				
			Glucose	C				
			Calcium Brausetabletten	C				
			Calcium-Gluconat	C				
			Magnesium Diasporal	C				
			Vigantoletten	C				
			Fenistal Tropfen	C				
			Solu-Decortin H	C				

Date:04/09/99ISR Number: 3236767-8Report Type:Expedited (15-DaCompany Report #199910469HPD
Age:71 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Blister	Foreign	Lasix	PS			INTRAVENOUS	40 MG/DAY IV 2 DAY
	Dermatitis	Study	Lasix	SS			INTRAVENOUS	40 MG/DAY IV 3 DAY
	Mucosal Erosion	Health	Lasix	SS			INTRAVENOUS	40 MG/DAY IV
	Oral Soft Tissue Disorder	Professional	Lasix	SS			40 MG/DAY IV	
	Stevens-Johnson Syndrome		Lasix	SS			40 MG/DAY IV	
	Toxic Epidermal		Lasix	SS		ORAL	QD PO	3 WK
	Necrolysis		Ass 100	SS		ORAL	1 U/DAY PO	3 WK
			Noctamid	SS		ORAL	1 U/DAY PO	2 DAY
			Noctamid	SS		ORAL	1 U/DAY PO	1 WK
			Noctamid	SS		ORAL	1 U/DAY PO	2 WK
			Tramal	SS		ORAL	ONCE PO	
			Tramal	SS		ORAL	ONCE PO	
			Tramal	SS		ORAL	PO	1 WK
			Tramal	SS		ORAL	ONCE PO	1 WK
			Tramal	SS			INTRAVENOUS	I U/DAY IV
			Acc Long	SS		ORAL	1 U/DAY PO	4 WK
			Paracetamol	SS			QD	1 WK
			Paracetamol	SS			QD	2 DAY
			Paracetamol	SS			2 DAY	
			Augmentan	SS		ORAL	1 U TID PO	4 DAY
			Novodigal	SS		ORAL	PO	2 WK
			Dilzem	SS		ORAL	QD PO	4 DAY
			Dilzem	SS		ORAL	QD PO	4 DAY

Dipidolor SS

INTRAVENOUS QD IV 5 DAY

INTRAVENOUS	600 SOLUBILE					
QD IV	5	DAY				
INTRAVENOUS	QD IV	1	WK			
RESPIRATORY						
(INHALATION)	ONCE INH					
RESPIRATORY						
(INHALATION)	QD INH	2	WK			
INTRAVENOUS	250 ML/DAY IV	2	DAY			
QD PO	3	DAY				
INTRAVENOUS	2 U/DAY IV					
INTRAVENOUS	2 U/DAY IV					
QD	4	DAY				
INTRAVENOUS	2 U/DAY IV					
INTRAVENOUS	2 U/DAY IV					
INTRAVENOUS	2 U/DAY IV					
INTRAVENOUS	ONCE IV					
300 MG/DAY PO	3	WK				
INTRAVENOUS	QD IV	5	DAY			

Sobelin	SS		
Vancomycin	SS		
Sultanol	SS	Dosier	
Sultanol	SS	Dosier	
Osmosteril	SS		
Neurocil	SS		ORAL
Fresh Frozen Plasma	SS		
Fresh Frozen Plasma	SS		
Ben-U-Ron	SS		
Erythrozytenkonzentrat	SS		
Erythrozytenkonzentrat	SS		
Erythrozytenkonzentrat	SS		
Paspertin	SS		
Ranimerck	SS		ORAL
Augmentan	SS		
Emser Salt	C		
Aquaphor Tablet	C		
Kalinor-Brausetabletten	C		
Uniphyllin	C		
Amaryl	C		
Pulmicort Dosier-Aerosol	C		

Ringer-Laktat	C
Fragmin P	C
Berodual	C
Natriumchlorid	C
Rekawan	C
--Vodigal	C
Paspertin	C
Magnesiocard	C
Isoptin	C
Temesic	C
Euphylong	C
Betaisodona	C
Sufenta	C
Propofol	C
Kaliumchlorid	C
Bronchoretard	C
Tiklyd	C
Baypen	C
Digimerck	C
Insulin, Nos	C
Dopamin	C
Acc Injektion	C
Uniphyllin	C
Turixin	C
Zantic	C
Jonosteril Hd5	C
Inzolen Injektionslsg	C
Targocid	C
Digimerck	C

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/12/99ISR Number: 3325781-XReport Type:Periodic Company Report #1999UW00507
Age:13 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required	Dyspnoea	Consumer	Zomig	PS		ORAL	10 MG PO	
Intervention to	Dystonia		Reglan	SS			10 MG	
Prevent Permanent	Haemorrhage		Migranol	SS				
Impairment/Damage	Nasal Oedema							
	Oedema							
	Pharyngeal Oedema							
	Skin Discolouration							

Date:04/14/99ISR Number: 3239876-2Report Type:Expedited (15-DaCompany Report #8-99096-034A
Age:29 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Placental Disorder	Health	Reglan	PS		ORAL	ORAL	
		Professional	Prenatal Vitamins Tablets	C				

Date:04/15/99ISR Number: 3240540-4Report Type:Expedited (15-DaCompany Report #D/99/00438/LES
Age:63 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Blister	Foreign	Locol (Fluvastatin					
Initial or Prolonged	Burning Sensation	Study	Sodium)	PS		ORAL	40 MG ORAL	
Required	Conjunctival Hyperaemia	Health	Oedemase					
Intervention to	Conjunctivitis	Professional	(Furosemide)	SS		ORAL	TAB 2 ORAL	
Prevent Permanent	Dermatitis		Zyloric					
Impairment/Damage	Enanthema		(Allopurinol)	SS		ORAL	450 MG ORAL	
	Mucosal Erosion		Ass Mini					
	Oral Discomfort		(Acetylsalicylic					
	Pruritus		Acid)	SS		ORAL	50 MG ORAL	

Pyrexia
Rash Erythematous
Skin Disorder

INTRAVENOUS	250 MG	5) Aspisol (Acetylsalicylate Lysine)	SS		
INTRAVENOUS					
INTRAVENOUS	3 MG	Morphin (Morphine)	SS		
INTRAVENOUS					
DROP 20 ORAL		Novalgin (Metamizole Sodium)	SS		ORAL
INTRAVENOUS	AMP 1	Ebrantil (Urapidil)	SS		
INTRAVENOUS					
INJECTION					
SUBCUTANEOUS	INTRAVENOUS	Heparine (Heparin)	SS		
INJECTION,SUB					
CUTANEOUS					
INTRAVENOUS		Furosemid (Furosemide)	SS		ORAL
INJECTIONORAL					
INTRAVENOUS	40 MG	Lasix (Furosemide)	SS		
INTRAVENOUS					
INJECTION					
INTRAVENOUS		Nitro (Glyceryl Trinitrate)	SS		ORAL
INFUSION,					
ORAL		Mcp (Metoclopramide)	SS		ORAL
AMP 1					
INTRAVENOUS					
INJECTION,					

ORAL				
		Diazepam (Diazepam)	SS	ORAL
ORAL				
		Actrapid (Insulin Human)	SS	
INTRAVENOUS	INTRAVENOUS			
INJECTION				
		Perlinganit (Glyceryl Trinitrate)	SS	
INTRAVENOUS	50 MG			
INTRAVENOUS				
INJECTION				
		Amoxicillin (Amoxicillin)	SS	ORAL
ORAL				
		Pantozol (Pantoprazole Sodium)	SS	ORAL
TAB 1 ORAL				
		Paracetamol (Paracetamol)	SS	
RECTAL	1000 MG			
RECTAL				
		Corvaton (Molsidomine)	SS	ORAL
TAB 1 ORAL				
		Acc (Acetylcysteine)	SS	ORAL
TAB 1 ORAL				
		Isoket (Isosorbide Dinitrate)	SS	ORAL
40 MG ORAL				
		Optipect (Acetylcysteine)	SS	ORAL
DROPS 20 ORAL				
		Molsidomin (Molsidomine)	C	
		Ismn Basics (Isosorbide Mononitrate)	C	
		Insulin (Insulin)	C	
		Querto (Cardilol)	C	
		Aquaphor (Aquaphor)	C	

Date:04/19/99ISR Number: 3243189-2Report 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		Fluconazole	PS		INTRAVENOUS	200 MG IV/DAY	1 WK
Required			Metoclopramide	SS		INTRAVENOUS	20 MG IV Q 6	
Intervention to						HOURS	1	WK
Prevent Permanent			Vancomycin	C				
Impairment/Damage			Albuterol Aerosol	C				

Date:04/20/99ISR Number: 3243261-7Report Type:Expedited (15-DaCompany Report #D0002958
Age:69 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Affective Disorder	Foreign	Zantac Tablet 300 Mg	PS		ORAL	300 MG / PER	
Initial or Prolonged	Depression	Health					DAY/ ORAL	
Other	Murder	Professional	Paracetamol					
	Psychotic Disorder		(Formulation Unknown)	SS				
			Metoclopramide Hcl (Formulation Unknown)	SS				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/22/99ISR Number: 3244259-5Report Type:Direct Company Report #
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Abdominal Distension		Maxolon 10 Mg					
	Cyanosis		(Metoclopramide					
	Joint Stiffness		Hydrochloride)	PS	Smithkline Beecham			

Date:04/22/99ISR Number: 3244643-XReport Type:Direct Company Report #
Age:66 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Depression		Metoclopramide	PS		ORAL	PO	
	Extrapyramidal Disorder							

Date:04/22/99ISR Number: 3246706-1Report Type:Periodic Company Report #8-98323-107A
Age:1 MON Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Asthenia	Health	Reglan	PS		ORAL	1 TEASPOON	
	Dermatitis	Professional					FOUR TIMES	
	Overdose						DAILY ORAL	
			Zantac	C				

Date:04/22/99ISR Number: 3246708-5Report Type:Periodic Company Report #8-98324-009A
Age:9 MON Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Extrapyramidal Disorder	Consumer	Reglan	PS		ORAL	10 TIMES THE	
	Overdose						NORMAL DOSE	

ORAL

Date:04/22/99ISR Number: 3246711-5Report Type:Periodic Company Report #8-98070-015L
Age:34 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Muscle Twitching	Consumer	Reglan	PS		ORAL	ONE DOSE ORAL	
	Nausea		Oxytocin	C				
	Salivary Hypersecretion		Demerol	C				
			Cylert	C				
			Trazadone	C				

Date:04/22/99ISR Number: 3246714-0Report Type:Periodic Company Report #8-98294-082A
Age:6 MON Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Interaction	Health	Reglan	PS		ORAL	UNSPECIFIED	
	Dystonia	Professional					DOSE ORAL	
	Tremor		Cipro Tablet	SS		ORAL	UNSPECIFIED	
							DOSE ORAL	
			Bethanechol	C				
			Zantac	C				

Date:04/23/99ISR Number: 3245800-9Report Type:Expedited (15-DaCompany Report #1998-12-0942
Age:1 MON Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Dermatitis Hypotension	Foreign Health Professional	Celestene (Betamethasone)	PS		ORAL	10 DROPS QD
Other			Speciafoldine Tablets	SS		ORAL	2.5MG QD ORAL
			Fumafer Tablets	SS		ORAL	100MG QD ORAL
			Primperan	SS		ORAL	12 DROPS QD ORAL
			Uvesterol Oral Solution	SS		ORAL	1ML QD ORAL
			Caffeine No Dose Form	SS		ORAL	7.5MG QD ORAL

Date:04/26/99ISR Number: 3246047-2Report Type:Expedited (15-DaCompany Report #319278
Age:51 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Death	Bronchitis Acute Cardiac Failure Congestive	Consumer	Dantrium Capsules (Dantrolene Sodium)	PS		ORAL	4 TIMES DAILY ORAL
	Choking Chronic Obstructive Pulmonary Disease Drug Level Above Therapeutic Dyspnoea Peak Expiratory Flow Rate		Darvocet-N (Di-Gesic)	SS		ORAL	ORAL
			Reglan (Metoclopramide)	SS		ORAL	ORAL
			Baclofen	C			
			Imipramine	C			

		Decreased					
		Productive Cough					
		Respiratory Depression					
		Respiratory Failure					
		Sedation					

Date:04/28/99ISR Number: 3248992-0Report Type:Expedited (15-DaCompany Report #8-99105-060A
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hepatic Enzyme Increased	Literature	Reglan	PS		INTRAVENOUS	INTRAVENOUS	
	Hepatitis		Acetaminophen	SS		ORAL	ORAL	

Date:04/29/99ISR Number: 3249953-8Report Type:Expedited (15-DaCompany Report #8-99112-033A
Age:62 YR Gender:Male I/FU:I

Outcome	PT
Death	C-Reactive Protein Increased
	Candidiasis
	Decreased Activity
	Delirium
	Hallucination
	Pain
	Sedation
	Sepsis
	Shock
	White Blood Cell Count

Increased

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
		Foreign	Metoclopramide Hcl	PS		SUBCUTANEOUS	10 MG ONCE	DAILY SC
		Literature	Metoclopramide Hcl	SS			60 MG ONCE	DAILY
			Artificial Rehydration	C				
			Diclofenac Sodium Tablets	C				
			Flurbiprofen Injection	C				
			Morphine Sulfate	C				
			Morphine Sulfate Injection	C				

Date:04/29/99ISR Number: 3249984-8Report Type:Expedited (15-DaCompany Report #FLUV00399000009
Age:14 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Interaction	Foreign	Fluvoxamine	PS		ORAL	10 MG TID	
	Dysarthria	Literature	Metoclopramide	SS		ORAL		
	Dystonia							
	Jaw Disorder							
	Movement Disorder							
	Nystagmus							

Date:04/30/99ISR Number: 3251184-2Report Type:Direct Company Report #
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Muscle Rigidity		Reglan	PS				
	Tremor							

Date:05/03/99ISR Number: 3252773-1Report Type:Expedited (15-DaCompany Report #9913345
Age:11 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Electroencephalogram Abnormal	Foreign Health	Vistaril Parenteral Solution	PS		INTRAVENOUS	8.30 MG	
Required	Loss Of Consciousness	Professional						
TOTAL: DAILY:								
Intervention to		Company				INTRAVENOUS		
Prevent Permanent		Representative	Primperan	SS		INTRAVENOUS	10.00 MG	
Impairment/Damage								
TOTAL: DAILY:								
						INTRAVENOUS		
			Multi-Vitamin	C				
			Ascorbic Acid	C				

Date:05/10/99ISR Number: 3257877-5Report Type:Expedited (15-DaCompany Report #99D--10363
Age:58 YR Gender:Female I/FU:I

Outcome	PT
Life-Threatening	Blister
Hospitalization - Initial or Prolonged	Cough
	Dermatitis
	Lip Disorder

	Pruritus Toxic Epidermal Necrolysis	Report Source	Product	Role	Manufacturer	Route	Dose Duration
		Foreign Health	Voltaren Suppository (Diclofenac Sodium)	PS			
RECTAL							100 MG, QD,
		Professional					
RECTAL							4 DAY
		Other	Bactrim Ampoule (Bactrim)	SS			
INTRAVENOUS							2 DF, DAILY,
INTRAVENOUS							7 DAY
			Metoclopramide Hydrochloride Drops (Metoclopramide Hydrochloride)	SS		ORAL	90 DRP,
							DAILY, ORAL
			Voltaren Emulgel Emulgel (Diclofenac Diethylamine)	SS			
TOPICAL							UNK, UNK,
TOPICAL/LOCAL							
			Femara Film-Coated Tablet (Letrozole)	SS		ORAL	1 DF, DAILY ,
ORAL							

Date:05/12/99ISR Number: 3259951-6Report Type:Expedited (15-DaCompany Report #8-99125-042A
Age: Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - UNSPECIFIED	Thrombocytopenia	Health	Reglan	PS		ORAL	
Initial or Prolonged		Professional					
DOSE ORAL							

Date:05/12/99ISR Number: 3260127-7Report Type:Expedited (15-DaCompany Report #205025
Age:53 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Convulsion	Foreign	Loxen (Nicardipine Hydrochloride)	PS		ORAL		
	Diarrhoea	Other						
	Electroencephalogram Abnormal		Primperan (Metoclopramide Hydrochloride)	SS				
	Hypokalaemia		Imortal (Lactitol)	SS				
	Hyponatraemia		Daflon (Diosmin)	SS				
	Nausea		Leponex (Clozapine)	SS				
	Oesophagitis						1096	DAY
	Thirst							
	Vomiting							

Date:05/19/99ISR Number: 3265636-2Report Type:Expedited (15-DaCompany Report #199910714HPD
Age:62 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Peritonitis	Foreign	Novalgin	PS		ORAL	PO	1 DAY
Other	Stevens-Johnson Syndrome	Study	Novalgin	SS		ORAL	PO	1 DAY
		Health	Novalgin	SS		ORAL	PO	1 DAY
		Professional Other	Novalgin Solution For Injection	SS			INTRAVENOUS	IV 1 DAY
			Novalgin Solution For Injection	SS			INTRAVENOUS	IV 1 DAY
			Claforan Solution For Injection	SS			INTRAVENOUS	2 G BID IV 3 DAY
			Lasix Solution For					

				Injection	SS
INTRAVENOUS	20-40 MG QD				
IV	1	DAY			
				Urbason Solution For Injection	SS
INTRAVENOUS	80 MG BID IV	1	DAY		
				Urbason Tablets	SS ORAL
250 MG QD PO	1	WK			
				Urbason Tablets	SS ORAL
250 MG QD PO	1	DAY			
				Urbason Tablets	SS ORAL
250 MG QD PO	1	DAY			
				Tarivid Tablets	SS ORAL
QD PO	4	DAY			
				Refobacin Tablets	SS
INTRAVENOUS	160 MG QD IV	3	DAY		
				Tavegil Solution For Injection	SS
INTRAVENOUS	QD IV	1	DAY		
				Tavegil Tablets	SS ORAL
PO	1	DAY			
				Tavegil Tablets	SS ORAL
PO	1	DAY			
				Zyrtec Tablets	SS ORAL
BID PO	1	DAY			
				Mogadan Tablets	SS ORAL
QD PO	6	DAY			
				Nizax Capsules	SS ORAL
QD PO	6	DAY			
				Bepanthen Lozenges	SS ORAL
6XD PO	6	DAY			
				Myrrhetinktur	SS
1	DAY				
				Oxazepam Tablets	SS ORAL
PO	1	DAY			
				Oxazepam Tablets	SS ORAL
PO	1	DAY			
				Oxazepam Tablets	SS ORAL
PO	1	DAY			
				Paspertin	SS
INTRAVENOUS	BID IV	1	DAY		
				Ampicillin Solution For Infusion	SS
INTRAVENOUS	2 G BID IV	2	DAY		
				Staphylex Solution For Infusion	SS
INTRAVENOUS	2 G BID IV	1	DAY		

PO	3	DAY	
PO	1	DAY	
PO	1	DAY	
20 DROP IRR			
PO	3	DAY	
20 DROP IRR			
PO	1	WK	
300 MG QD PO	1	WK	
1 DAY			
1 DAY			
BID PO	3	DAY	
PO	1	DAY	
PO	1	DAY	
PO	1	DAY	
PO	1	DAY	
INTRAVENOUS	IV	1	DAY
INTRAVENOUS	IV	1	DAY

Imeson Tablets	SS	ORAL
Imeson Tablets	SS	ORAL
Imeson Tablets	SS	ORAL
Tramal	SS	ORAL
Tramal	SS	ORAL
Zyloric Tablets	SS	ORAL
Laxoberal	SS	
Laxoberal	SS	
Cotrim Forte Tablets	SS	ORAL
Combaren Tablets	SS	ORAL
Combaren Tablets	SS	ORAL
Ben-U-Ron	SS	ORAL
Ben-U-Ron	SS	ORAL
Psyquil Solution For Injection	SS	
Psyquil Solution For Injection	SS	
Volon-A-Schuettelmixtur	C	
Nacl	C	
Glucose	C	
Parenteral Nutrition	C	
Baby Oil	C	
Laceran	C	
Fosfocin	C	
Tranxilium	C	
Kalinor Brause	C	
Diazepam	C	
Pantozol	C	
Heparin	C	
Bronchoretard	C	
Serevent	C	
Flutide N125	C	
Laxans	C	

			Lasix	C		
			Spasmo Urgenin Tc	C		
			Paspertin	C		
			Azuprostat M	C		
			Lichtenstein Gelb	C		
			Ringers Solution	C		
			Acimethin	C		
			Spasmex	C		
			Betaisodona	C		
			Lactulose	C		

Date:05/19/99ISR Number: 3266566-2Report Type:Periodic Company Report #8-99081-110A
Age:42 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Chest Pain	Consumer	Effexor Xr Capsules	PS		ORAL	75 MG ONCE	
	Dizziness						DAILY	ORAL
	Dyspnoea		Carbocaine					
	Mania		(Mepivacaine)					
	Nervousness		Injection	SS				
	Tachycardia		Effexor Tablet	SS		ORAL	12.5 MG AT	
							12:30PM &	
							3:30PM	ORAL
			Reglan					
			(Metoclopramide)					
			Unspecified	SS				
			Cylert (Pemoline)					
			Tablets	C				

Date:05/24/99ISR Number: 3269558-2Report Type:Expedited (15-DaCompany Report #PRIUSA1999001594
Age:62 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Balanoposthitis	Foreign	Ofloxacin (Tablet)					
	Blister	Study	(Ofloxacin)	PS		ORAL	2 TABLE, 1 IN	

	Condition Aggravated	Health			
1 DAILY, ORAL					
	Dermatitis Epidermolysis Bullosa Peritonitis Stevens-Johnson Syndrome	Professional	Tramadol Hydrochloride (Tramadol Hydrochloride)	SS	ORAL
20 DROP, 1 IN					
1 DAILY, ORAL					
			Novalgin (Metamizole Sodium)	SS	ORAL
SEE IMAGE					
			Claforan (Cefotaxime Sodium)	SS	
INTRAVENOUS	4 G, 1 IN 1				
DAILY, IV					
			Lasix (Furosemide)	SS	
INTRAVENOUS	20 MG, 1 IN 1				
DAILY, IV					
			Urbason (Methylprednisolone)	SS	
INTRAVENOUS	SEE IMAGE				
			Refobacin (Gentamicin Sulfate)	SS	ORAL
160 MG, 1 IN					
1 DAILY, ORAL					
			Tavegil (Clemastine)	SS	ORAL
SEE IMAGE					
			Zyrtec (Cetirizine Hydrochloride)	SS	ORAL
2 TABLE, 1 IN					
1 DAILY, ORAL					
			Mogadan (Nitrazepam)	SS	ORAL
1 TABLE, 1 IN					
1 DAILY, ORAL					

			Nizax (Nizatidine)	SS	ORAL
1 CAP, 1 IN 1 DAILY, ORAL					
			Bephanthen (Dexpanthenol)	SS	ORAL
6 UNK, 1 IN 1 DAILY, ORAL					
			Myrrhetinktur (Myrrh Tincture)	SS	
			Oxazepam (Oxazepam)	SS	ORAL
SEE IMAGE					
			Paspertin (Metoclopramide Hydrochloride)	SS	
INTRAVENOUS	2 UNK, 1 IN 1 DAILY, IV				
			Ampicillin (Ampicillin)	SS	
INTRAVENOUS	4 G, 1 IN 1 DAILY, IV				
			Staphylex (Flucloxacillin Sodium)	SS	
INTRAVENOUS	4 G, 1 IN 1 DAILY, IV				
			Imeson (Nitrazepam)	SS	ORAL
SEE IMAGE					
			Zyloric (Allopurinol)	SS	ORAL
300 MG, 1 IN 1 DAILY, ORAL					
			Laxoberal (Sodium Picosulfate)	SS	ORAL
SEE IMAGE					
			Cotrim Forte	SS	ORAL
2 TABLE, 1 IN 1 DAILY, ORAL					
			Combaren (Combaren)	SS	ORAL
SEE IMAGE					
			Ben-U-Ron		

(Paracetamol)	SS	ORAL
SEE IMAGE		
Psyquil (Triflupromazine)	SS	
INTRAVENOUS	SEE IMAGE	
Volon-A-Schuettel-Mixtur	C	
Sodium Chloride	C	
Glucose	C	
Parenteral Nutrition	C	
Baby Oil	C	
Laceran	C	
Fosfocin	C	
Tranxilium	C	
Kalinor Brause	C	
Diazepam	C	
Pantozol	C	
Heparin	C	
Bronchoretard	C	
Serevent	C	
Flutide	C	
Laxans	C	
Spasmo-Urgenin Tc	C	
Paspertin	C	
Azuprostat M	C	
Lichtenstin Gelb	C	
Ringers Solution	C	
Acimethin	C	
Eugalac	C	
Rekawan	C	
Spasmex	C	
Betaisodona	C	
Lactulose	C	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/25/99ISR Number: 3270492-2Report Type:Direct Company Report #
Age:62 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Coma		Metoclopramide 10 Mg					
Hospitalization -	Hypertension		Iv	PS				
INTRAVENOUS							10MG IV	1 X
Initial or Prolonged			Insulin	C				
			Asa	C				
			Digoxin	C				
			Careria	C				
			Frosol	C				
			Kdur	C				
			Tuclid	C				
			Morphine	C				
			Heparin	C				
			Dopdomine	C				
			Tripil	C				
			Pepcid	C				

Date:05/28/99ISR Number: 3272994-1Report Type:Expedited (15-DaCompany Report #1181899A
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Haemolysis	Foreign	Loperamide 2 Mg					
Initial or Prolonged		Health	Capsules	PS				
		Professional	Metoclopramide	SS				

Date:06/10/99ISR Number: 3280293-7Report Type:Direct Company Report #
Age:83 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Agitation	Health	Reglan	PS				
QID								
	Mania	Professional						
	Paraesthesia							

Date:06/15/99ISR Number: 3284132-XReport Type:Direct Company Report #
Age:35 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Tongue Oedema	Health	Relgan	PS		INTRAVENOUS	10 MG IV	
Initial or Prolonged	Vomiting	Professional						

Q6H:NDC#

00031-6709-78

Date:06/15/99ISR Number: 3284148-3Report Type:Direct Company Report #
Age:22 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Dystonia	Health	Metoclopramide	PS		INTRAVENOUS	10 MG IV Q6H	
Initial or Prolonged	Tardive Dyskinesia	Professional						
PRN								
Required			Compazine	SS		INTRAVENOUS	10 MG IV Q6H	
Intervention to								
PRN								
Prevent Permanent								
Impairment/Damage								

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/16/99ISR Number: 3284766-2Report Type:Expedited (15-DaCompany Report #8-99160-139A
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dystonia Overdose	Foreign Literature	Reglan (Metoclopramid Hcl)	PS				

Date:06/17/99ISR Number: 3286027-4Report Type:Expedited (15-DaCompany Report #8-99162-120A
Age:1 MON Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Anaemia Anuria Medication Error Muscle Spasms Overdose	Consumer	Reglan	PS		ORAL	ONE-HALF TEASPOON ORAL	

Date:06/17/99ISR Number: 3286028-6Report Type:Expedited (15-DaCompany Report #8-99162-003A
Age:55 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Cerebral Infarction Extrapyramidal Disorder Mental Impairment	Health Professional	Reglan 776c85 Tablet	PS SS		ORAL	25 MG [13.8 MG/M(2)] DAILY FOR FIRST 28 DAYS OF EACH 5	
			Fluorouracil Tablet	SS		ORAL	2.5 MG [1.38 MG/M(2)]DAILY FOR FIRST 28	

DAYS OF EACH

5 WEEK CYCLE

..	C
..	C
Insulin Iintermediate/Long-Acting)	C
Thyroxine (Levothyroxine)	C
Insulin (Short-Acting)	C
Lisinopril	C
Conjugated Estrogens	C
Medroxyprogesterone Acetate	C
Clonidine	C
Cisapride	C
Compazine (Prochlorperazine)	C
Loperamide	C
Omerazole	C
Paroxetine	C

Date:06/21/99ISR Number: 3287998-2Report Type:Expedited (15-DaCompany Report #10018844
Age:70 YR Gender:Female I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Biopsy Skin Abnormal
	Burning Sensation

	Dermatitis Diarrhoea Face Oedema	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
	Herpes Simplex Pruritus	Foreign Health	Vasten Tabs 20 Mg (Pravastatin Sodium)	PS		ORAL
20 MILLIGRAM,						
	Pyrexia	Professional				
ORAL						
	Urticaria	Other	Efferalgan (Acetaminophen)	SS		
500 MILLIGRAM						
			Spasfon (Phloroglucinol)	SS		
80 MILLIGRAM						
			Primperan (Metoclopramide Hcl)	SS		
			Vastarel (Trimetazidine Hcl)	SS		
20 MILLIGRAM						
			Smecta (Smectite Beidellitique)	C		

Date:06/22/99ISR Number: 3288905-9Report Type:Expedited (15-DaCompany Report #VISP004990040
Age:61 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Life-Threatening	Stevens-Johnson Syndrome	Foreign Health	Visipaque 270 Mgi / Ml	PS		
INTRAVENOUS INTRAVENOUS						
		Professional	Agarol	SS		
		Other	Aminomix	SS		
			Antra	SS		
			Decadron	SS		
			Dexamethason	SS		
			Dipidolor	SS		
			Fenatyl	SS		
			Fortecortin	SS		
			Ofragmin	SS		
			Gramaxin	SS		
			Heparin	SS		
			Intramin	SS		
			Kalitrans	SS		
			Laxoberal	SS		

Liquemin	SS
Mcp	SS
Novalgin	SS
Pancuronium	SS
Pantozol	SS
Paspertin	SS
Phenhydan	SS
Propofol	SS
Rohypnol	SS
Sostril	SS
Thiopental	SS
Tramal	SS
Zentropil	SS
Biofanal	C
Dimen	C
Doretonsin	C
Kalinor	C
Maaloxan	C
Nacl	C
Rocephin	C
Sterofundin	C
Zovirax	C

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/22/99ISR Number: 3289000-5Report Type:Expedited (15-DaCompany Report #1191267A
Age:19 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Literature	Unknown Ibuprofen					
	Overdose	Health Professional	Product Metoclopramide	PS SS		ORAL ORAL		

Date:06/30/99ISR Number: 3294696-8Report 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	Lethargy		Metoclopramide 10mg Tab Levothyroxine Cisapride Lansoprazole	PS C C C		ORAL	10MG, QAC & HS, ORAL	

Date:07/01/99ISR Number: 3295435-7Report Type:Direct Company Report #
Age:15 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Interaction Dyskinesia Dystonia Muscle Spasms Muscle Twitching		Metoclopramide Prozac	PS C				

Date:07/01/99ISR Number: 3298969-4Report Type:Expedited (15-DaCompany Report #LACT00399000404
Age:62 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Balanoposthitis	Foreign	Lactulose	PS		ORAL	10 ML ONCE PO	

	Cystitis	Other	Paspertin	SS		
INTRAVENOUS	1 DF BID IV					
	Peritonitis		Zyloric 300	SS		ORAL
1 DF QD PO						
	Stevens-Johnson Syndrome		Novalgin	SS		ORAL
UNK UNK PO,						
	Urethritis					
UNK UNK IV						
INTRAVENOUS	2 G BID IV		Ampicillin	SS		
INTRAVENOUS	2 G BID IV		Staphylex	SS		
INTRAVENOUS	2 G BID IV		Claforan	SS		
INTRAVENOUS	160 MG QD IV		Refobacin	SS		
1 DF QD PO			Mogadan	SS		ORAL
INTRAVENOUS	40 MG QD IV		Lasix	SS		
UNK PO,			Oxazepam	SS		ORAL
20 DF QID PO,			Tramal	SS		ORAL
20 DF QID PO						
1 DF BID PO			Cotrim Forte	SS	Ratiopharm	ORAL
UNK PO,			Combaren	SS		ORAL
UNK, PO			Imeson	SS		ORAL
UNK PO,			Laxoberal	SS		ORAL
UNK PO,			Ben-U-Ron	SS		ORAL
2 DF QD PO			Tarivid	SS		ORAL
INTRAVENOUS	UNK IV,		Psyquil	SS		
80 MG BID IV,			Urbason	SS		ORAL
250 MG QD PO,						
250 MG ONCE						
PO, 250 MG						
ONCE PO						

		Tavegil	SS	ORAL
1 DF BID IV,				
UNK PO, UNK				
UNK PO				
		Zyrtec	SS	ORAL
1 DF BID PO				
		Nizax	SS	ORAL
1 DF QD PO				
		Bepanthen	SS	ORAL
1 DF QID PO				
		Myrrhetincture	SS	
TRANSPLACENTAL	UNK TP			
		Volon A-Schuettelmix	SS	
TRANSPLACENTAL	UNK ONCE TP			
		Baby-Oil	SS	
TRANSPLACENTAL	UNK TP			
		Laceran	SS	
TRANSPLACENTAL	UNK UNK TP			
		Pantozol	SS	ORAL
1 DF QD PO				
		Heparin	SS	
SUBCUTANEOUS	7500 IU BID			
SC				
		Bronchoretard 350 / Mite	SS	ORAL
1 DF BID PO				
		Serevent Metered Dose Aerosol	SS	
RESPIRATORY				
(INHALATION)	2 DF BID IH			
		Flutide N 125 Metered Dose Aerosol	SS	
RESPIRATORY				
(INHALATION)	2 DF TID IH			
		Glucose 5%	SS	
INTRAVENOUS	1000 MI QD IV			
		Nacl 0.9%	SS	
INTRAVENOUS	2500 MI QD IV			
		Rekawan	SS	ORAL
1 DF TID PO				
		Eugalac	SS	ORAL
1 DF QD PO				

			Ringers Solution	SS		
INTRAVENOUS	1000 M1 ONCE					
IV						
			Betaisodona	SS		
TRANSPLACENTAL	1 DF QD TP					
			Spasmex 5	SS		ORAL
2 DF TID PO						
			Acimethin	SS		ORAL
2 DF TID PO						
			Spasmo-Urgenin Tc	SS		ORAL
2 DF TID PO						
			Azuprostat M	SS		ORAL
1 DF TID PO						
			Lichtenstein Gelb	C		ORAL
1 DF QD PO						
			Parenteral	C		
INTRAVENOUS	1500 MI QD IV					
			Paspertin	C		
			Laxans	C		
			Lasix	C		

Date:07/01/99ISR Number: 3299210-9Report Type:Expedited (15-DaCompany Report #199911012HPD
Age:79 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Blood Potassium Decreased	Foreign	Lasix Tablets	PS		ORAL	1 U/DAY PO	1 WK
Life-Threatening	Blood Uric Acid Increased	Study	Lasix	SS		INTRAVENOUS	ONCE IV	
Hospitalization -	Conjunctivitis	Health	Lasix	SS		INTRAVENOUS	ONCE IV	
Initial or Prolonged	Dermatitis	Professional	Acc	SS		ORAL	1 U QD PO	16 DAY
	Infection	Other	Ferro Sanol	SS		ORAL	1 U QD PO	16 DAY
	Mucosal Erosion		Kalinor	SS		ORAL	QD PO	2 DAY
	Nausea		Kalinor	SS		ORAL	QD PO	5 DAY
	Oral Soft Tissue Disorder		Bactrim Forte	SS		ORAL	1 U QD PO	2 DAY
	Pain		Zyloric	SS		ORAL	1 U/DAY PO	9 DAY
	Pruritus		Adumbran Tablets	SS		ORAL	ONCE PO	
	Pyrexia		Zinacef	SS		INTRAVENOUS	1 U TID IV	8 DAY
	Shock		Tramal Drops	SS		ORAL	ONCE PO	

	Skin Ulcer	Lexotanil	SS		ORAL
6 U/DAY PO					
	Sleep Disorder	Paspertin Drops	SS		ORAL
QD PO	6 DAY				
	Stevens-Johnson Syndrome	Buscopan	SS		
ONCE					
	Toxic Epidermal	Rohypnol	SS		
ONCE					
	Necrolysis	L-Thyroxin	C		
		Digimerck	C		

Ulcogant	C
Cor Tensobon	C
Beloc Mite	C
Isoket	C
Heparin	C
Adalat	C
Novodigal	C
Suprarenin	C
Perfan	C
Kcl	C
Dilzem	C
Human-Albumin	C
Dopamin	C
Dulcolax	C
Solu-Decortin H	C
Tavegil	C
Ciprobay	C
Eucalyptus	C
Alt-Insulin	C
Mannitol	C
Hydromedin	C
Dipidolor	C
Calcium	C
Antithrombin Iii	C
Nitrolingual	C
?Afundin	C
Erenol	C
Pancuronium	C
Inzolen	C
Trasylol	C
Sufenta	C
Dobutrex	C

Date:07/01/99ISR Number: 3358303-8Report Type:Periodic Company Report #A0074086
Age:6 MON Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Interaction	Health	Zantac (Formulation					
	Tremor	Professional	Unknown)	PS		ORAL	ORAL	
		Other	Ciprofloxacin Hcl Tablet	SS		ORAL	ORAL	
			Mewtoclopramide Hcl					

			(Formulation Unknown)	SS		ORAL	ORAL
			Bethanechol Chloride	C			

Date:07/06/99ISR Number: 3296983-6Report Type:Direct Company Report #
Age:41 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Akathisia Dystonia Extrapyramidal Disorder		Metoclopramide 10mg/2ml-Ohmeda	PS	Ohmeda	INTRAVENOUS	10MG IV X 1	DOSE

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/09/99ISR Number: 3300389-0Report Type:Expedited (15-DaCompany Report #112424USA
Age:17 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Blister	Foreign	Sulfamethoxazole &					
Life-Threatening	Chronic Myeloid Leukaemia	Health	Trimethoprim Usp,					
	Conjunctivitis	Professional	D.S. Tablets	PS		ORAL	2 TABLET QD	
	Corneal Erosion						BY MOUTH/P.O.	
	Dermatitis		Neupogen	SS			SUBCUTANEOUS	3 MICROGRAM
	Dermatitis Bullous						QD	
	Epidermolysis Bullosa						SUBCUTANEOUS	
	Graft Versus Host Disease		Amphotericin B	SS			15 MILLIGRAM	
	Mucosal Erosion						QD	
	Multi-Organ Failure		Antra (Omeprazole)	SS			40 MILLIGRAM	
	Oral Mucosal Blistering						QD	
	Oral Mucosal Exfoliation		Atosil					
	Pemphigoid		(Isopromethazine)	SS			25 MILLIGRAM	
	Pyrexia						QD	
	Rash Maculo-Papular		Ben-U-Ron					
	Sepsis		(Paracetamol)	SS				
	Stevens-Johnson Syndrome		Calcium (Calcium)	SS			500 MILLIGRAM	
	Toxic Epidermal						QD	
	Necrolysis		Ciprobay	SS			840 MILLIGRAM	
	Visual Disturbance						QD	
			Cymevan	SS			250 MILLIGRAM	
							QD	
			Decortin	SS				
			Diazepam (Diazepam)	SS			5 MILLIGRAM	

QD	Diflucan	SS
400 MILLIGRAM QD	Dolantin	SS
25 MILLIGRAM QD	Folsan	SS
5 MILLIGRAM QD	Fortum	SS
	Gernebcin	SS
160 MILLIGRAM QD	Hydrocortisone Hydrogen Succinate (Hydrocortisone Hydrogen Succinate)	SS
100 MILLIGRAM QD	Immunoglobulin Human Normal (Immunoglobulin Human Normal)	SS
25 MILLIGRAM QD	Lactulose (Lactulose)	SS
	Lasix	SS
	Liquemin	SS
	Meronem	SS
2 GRAM QD	Midazolam Hcl (Midazolam Hcl)	SS
5 MILLIGRAM QD	Multibionta	SS
	Neurocil	SS
8 MILLIGRAM QD	Novalgin	SS
500 MILLIGRAM QD		

	Orgametril	SS

3 TABLET QD

			Paspertin	SS			
			Pipril	SS			
			Prednisolone (Prednisolone)	SS			
100 MILLIGRAM QD							
			Rekawan	SS			
			Targocid	SS			
500 MILLIGRAM QD							
			Tavegil	SS			
			Vancomycin (Vancomycin)	SS			
			Zantac	SS			
			Zienam	SS			
650 MILLIGRAM QD							
			Zovirax	SS			
1200 MILLIGRAM QD							
			Metronidazole	SS			
1125 MILLIGRAM QD							
			Doxycycline	SS			
400 MILLIGRAM QD							

Date:07/19/99ISR Number: 3306660-0Report Type:Expedited (15-DaCompany Report #199920069RHF
Age:78 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Arthralgia	Foreign	Rifampicin					
	Pain In Extremity	Other	(Rifadine)	PS		ORAL	300 MG BID PO	8 DAY
	Tendonitis		Pefloxacin Mesilate (Peflacine)	SS		ORAL	400 MG BID PO	8 DAY
			Metoclopramide					

					(Primperan)	SS			ORAL
PO	6	DAY							
					Heparin-Fraction, Sodium Salt (Innohep)	SS			
SUBCUTANEOUS	SC	8	DAY						
					Cefotaxime Sodium	C			
					Fosfomycin	C			
					Caffeine	C			
					Paracetamol	C			
					Belladonna Extract	C			
					Opium	C			
					Tincture	C			
					Omeprazole	C			
					Sertraline Hydrochloride	C			
					Zopiclone	C			
					Sodium Bicarbonate	C			
					Potassium Chloride	C			
					Sodium Chloride	C			
					Macrogol	C			

Date:07/19/99ISR Number: 3306944-6Report Type:Expedited (15-DaCompany Report #1191267A
Age:19 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Literature	Unknown Ibuprofen					
		Health Professional	Product	PS				
UNK DOSE, STARTING AT								
2300	1 DAY							
			Reglan	SS				
UNK DOSE,								

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Freedom Of Information (FOI) Report

STARTING AT

2300 1 DAY

See Attached Case Report C

Date:07/19/99ISR Number: 3307285-3Report Type:Expedited (15-DaCompany Report #209223
Age:79 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Blister	Foreign	Bactrim Forte					
Required	Blood Creatinine	Study	(Sulfamethoxazole/Tr					
Intervention to	Increased	Health	imethoprim)	PS		ORAL	1 DOSE FORM	2
Prevent Permanent	Blood Lactate	Professional					PER DAY	ORAL
Impairment/Damage	Dehydrogenase Increased		Lexotanil					
	Condition Aggravated		(Bromazepam) 6 Mg	SS		ORAL	.25 DOSE FORM	
	Conjunctivitis						1 PER DAY	
	Constipation						ORAL	
	Dermatitis		Rohypnol					
	Infection		(Flunitrazepam)	SS			INTRAVENOUS	INTRAVENOUS
	Lymphopenia		Lasix (Furosemide)	SS		ORAL	1 DOSE FORM	1
	Mucosal Erosion						PER DAY	ORAL
	Pruritus		Ferro Sanol					
	Pyrexia		(Cyanocobalamin/Ferr					
	Shock		ous Glycine					
	Skin Ulcer		Sulfate/Folic Acid)	SS		ORAL	1 DOSE FORM	2
	Toxic Epidermal						PER DAY	ORAL
	Necrolysis		Paspertin					
			(Metoclopramide					
			Hydrochloride)	SS		ORAL	ORAL	
			Lasix (Furosemide)	SS			INTRAVENOUS	INTRAVENOUS

		Adumbran (Oxazepam)	SS	ORAL
ORAL				
		Tramal Tropfen (Tramadol Hydrochloride)	SS	ORAL
ORAL				
		Zinacef (Cefuroxime Sodium)	SS	
INTRAVENOUS	1 DOSE FORM 3			
PER DAY				
INTRAVENOUS				
		Zyloric (Allopurinol)	SS	ORAL
ORAL				
		Buscopan (Scopolamine Butylbromide)	SS	
RECTAL	RECTAL			
		Kalinor-Brausetablet ten (Citric Acid/Potassium Bicarbonate/Potassiu m Citrate)	SS	ORAL
ORAL				
		Acc (Acetylcysteine)	SS	ORAL
1 DOSE FORM 3				
PER DAY ORAL				
		Heparin	C	
		Adalat	C	
		Subcutaneous Heparin	C	
		Antithrombin Iii	C	
		Calcium	C	
		Dipidolor	C	
		Hydromedin	C	
		Mannitol	C	
		Altinsulin	C	
		Eucalyptus	C	
		Ciprobay		

Filmtabletten	C
Tavegil	C
Dobutrex	C
Sufenta	C
Trasylol	C
Inzolen	C
Pancuronium	C
Arterenol	C
Gelafundin	C
Nitrolingual	C
Solu-Decortin-H	C
Dulcolax	C
Dopamin	C
Human Albumin	C
Dilzem	C
Kcl	C
Perfan	C
Suprarenin	C
Novodigal	C
Isoket	C
Digimerck	C
Ulcogant	C
Beloc Mite	C
Cor Tensobon	C
L-Thyroxin	C

Date:07/23/99ISR Number: 3309925-1Report Type:Direct Company Report #
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Medication Error		Phenytoin Inj 100mg/2ml(50mg/1ml)Ampule	PS				
			Reglan Inj 10mg/2ml (5mg/1ml)Ampule	SS				

Date:07/23/99ISR Number: 3310012-7Report Type:Expedited (15-DaCompany Report #PRIUSA1999003593
Age:47 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Diarrhoea	Foreign	Ultram (50 Mg					
Life-Threatening	Gastroenteritis	Health	Tablet) (Tramadol					

	Professional	Hydrochloride)	PS		ORAL
200 MG,					
DAILY, ORAL 2 DAY					
		Buprenorphine (Buprenorphine)	SS		ORAL
0.2 MG,					
DAILY, ORAL					
		Metoclopramide (Metoclopramide)	SS		
INTRAMUSCULAR 20 MG, IM					
		Meprobamate, Aceprometazine	SS		
		Ibuprofen (Ibuprofen)	SS		
		Loperamide (Loperamide)	SS		
		Nifuroxazide (Nifuroxazide)	C		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/30/99ISR Number: 3315886-1Report Type:Expedited (15-DaCompany Report #8-99078-019A
Age:4 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Genital Pruritus Female	Health	Reglan	PS		ORAL	7.5 MG THREE	
	Nocturia	Professional					TIMES DAILY;	
	Pollakiuria						ORAL	
			Prilosec	C				
			Flovent	C				
			Atrovent	C				
			Intal	C				

Date:07/30/99ISR Number: 3316047-2Report Type:Expedited (15-DaCompany Report #209223
Age:79 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Blood Creatinine	Foreign	Bactrim Forte					
Required	Increased	Study	(Sulfamethoxazole/Tr					
Intervention to	Blood Lactate	Health	imethoprim)	PS		ORAL	1 DOSE FORM 2	
Prevent Permanent	Dehydrogenase Increased	Professional					PER DAY ORAL	
Impairment/Damage	Cardiac Failure		Lexotanil					
	Conjunctivitis		(Bromazepam) 6 Mg	SS		ORAL	.25 DOSE FORM	
	Constipation						1 PER DAY	
	Dermatitis						ORAL	
	Lymphopenia		Rohypnol					
	Mouth Ulceration		(Flunitrazepam)	SS			INTRAVENOUS	INTRAVENOUS
	Pruritus		Valium Tablets					
	Pyrexia		(Diazepam)	SS		ORAL	1 PER PRN	
	Skin Ulcer						ORAL	
	Toxic Epidermal		Dormicum (Inj)					
	Necrolysis		(Midazolam					

		Hydrochloride)	SS	
INTRAVENOUS	INTRAVENOUS			
		Lasix (Furosemide)	SS	ORAL
1 DOSE FORM 1				
PER DAY ORAL				
		Acc (Acetylcysteine)	SS	ORAL
1 DOSE FORM 3				
PER DAY ORAL				
		Ferro Sanol (Cyanocobalamin/Ferrous Glycine Sulfate/Folic Acid)	SS	ORAL
1 DOSE FORM 2				
PER DAY ORAL				
		Kalinor-Brausetabletten (Citric Acid/Potassium Bicarbonate/Potassium Citrate)	SS	ORAL
ORAL				
		Paspertin (Metoclopramide Hydrochloride)	SS	ORAL
20 DROP 3 PER				
DAY ORAL				
		Buscopan (Scopolamine Butylbromide)	SS	
RECTAL	RECTAL			
INTRAVENOUS	120 MG DAILY	Lasix (Furosemide)	SS	
INTRAVENOUS				
		Zyloric (Allopurinol)	SS	ORAL
1 DOSE FORM				
DAILY ORAL				
		Adumbran (Oxazepam)	SS	ORAL
1 DOSE FORM				
DAILY ORAL				
		Zinacef (Cefuroxime		

		Sodium)	SS		
INTRAVENOUS	1 DOSE FORM 3				
PER DAY					
INTRAVENOUS					
		Tramal Tropfen (Tramadol Hydrochloride)	SS		ORAL
ORAL					
		Dopamine Infusion (Dopamine Hydrochloride)	SS		
INTRAVENOUS	INTRAVENOUS				
		Ass (Aspirin) 100 Mg	SS		ORAL
1 DOSE FORM					
DAILY ORAL					
		Heparin	C		
		L-Thyroxin 100	C		
		Digimerck	C		
		Ulcogant	C		
		Cor Tensobon	C		
		Beloc Mite	C		
		Isoket	C		
		Adalat	C		
		Novodigal	C		
		Subcutaneous Heparin	C		
		Suprarenin	C		
		Perfan	C		
		Kcl	C		
		Dilzem	C		
		Human Albumin	C		
		Dulcolax	C		
		Solu-Decortin-H	C		
		Tavegil	C		
		Ciprobay Filmtabletten	C		
		Eucalyptus	C		
		Altinsulin	C		
		Mannitol	C		
		Hydromedin	C		
		Dipidolor	C		
		Calcium	C		
		Antithrombin Iii	C		
		Nitrolingual	C		
		Gelafundin	C		
		Arterenol	C		

Pancuronium	C
Inzolen	C
Trasylol	C
Sufenta	C
Dobutrex	C
Bifiteral	C
Glucose 5% Solution	C
Fentanyl Infectable	C
Enfluran	C
0.9% Nacl	C
Bisolvon	C
Hydromedin	C
Temgesic	C
Kaliumchlorid	C
Ringer'S Solution	C
Glucose 20%	C
Digimerck	C

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/02/99ISR Number: 3316738-3Report Type:Expedited (15-DaCompany Report #78424
Age:81 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Anxiety	Foreign	Dormicum (Inj)					
Life-Threatening	Blister	Health	(Midazolam					
	Blood Creatinine	Professional	Hydrochloride)	PS		INTRAVENOUS	1 PER ONE	
	Increased						DOSE	
	Blood Urea Increased						INTRAVENOUS	
	Cardiac Failure		Valium (Diazepam)	SS		ORAL	1 PER PRN	
	Conjunctivitis						ORAL	
	Constipation		Rohypnol					
	Hypertension		(Flunitrazepam)	SS		INTRAVENOUS	1 PER ONE	
	Hyperuricaemia						DOSE	
	Hypokalaemia						INTRAVENOUS	
	Hyponatraemia		Bactrim Forte					
	Liver Function Test		(Sulfamethoxazole/Tr					
	Abnormal		imethoprim)	SS		ORAL	2 DOSE FORM	
	Metabolic Disorder						DAILY ORAL	
	Nausea		Lexotanil					
	Oedema		(Bromazepam)	SS		ORAL	.25 GRAM	
	Pericardial Drainage						DAILY 1 PER	
	Shock						ONE DOSE ORAL	
	Skin Ulcer		Lasix (Furosemide)	SS		ORAL	205 MG DAILY	
	Thrombosis Prophylaxis						ORAL	
	Toxic Epidermal		Digimerck (Diitoxin)	SS		ORAL	1 DOSE FORM	
	Necrolysis						DAILY ORAL	
			Acc (Acetylcysteine)	SS		ORAL	3 SACHET	

DAILY ORAL			
INTRAVENOUS	120 MG DAILY	Lasix (Furosemide)	SS
INTRAVENOUS			
INTRAVENOUS	1.5 GRAM 2	Zinacef (Cefuroxime)	SS
PER DAY			
INTRAVENOUS			
		Dopamin (Dopamine Hydrochloride)	SS
INTRAVENOUS	3 ML 1 PER		
HOUR			
INTRAVENOUS			
		Zyloric (Allopurinol)	SS ORAL
1 DOSE FORM 1			
PER DAY ORAL			
		Ass (Aspirin) 100 Mg	SS ORAL
1 DOSE FORM			
DAILY ORAL			
		Adumbran (Oxazepam)	SS ORAL
1 DOSE FORM 1			
PER ONE DOSE			
ORAL			
		Tramal (Tramadol Hydrochloride)	SS ORAL
20 DROP DAILY			
ORAL			
		Paspertin (Metoclopramide Hydrochloride)	SS ORAL
20 DROP 3 PER			
DAY ORAL			
		L-Thyroxin 100	C
		Temgesic	C
		Ulcogant	C
		Adalat	C
		Cor Tensobon	C
		Beloc Mite	C
		Heparin Natrium	C
		Bifiteral	C

Kalium	C
Ringer'S Injection	C
Human-Albumin	C
Gelafundin	C
Alt-Insulin	C
Mannitol	C
Glucose Infusion	C
Digimerck	C
Suprarenin	C
Dilzem	C
Glucose 5%	C
Perfan	C
Nitro	C
Fentanyl	C
Enfluran	C
Dobutrex	C
Nacl	C
Ferro Sanol	C
Bisolvon	C
Hydromedin	C
Tavegil	C
Ciprobay	C

Date:08/04/99ISR Number: 3319406-7Report Type:Expedited (15-DaCompany Report #8-99207-098A
Age:87 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Fall Fatigue Spinal Compression Fracture Vertigo Vomiting	Foreign Health Professional	Seresta Capsules (Oxazepam)	PS		ORAL		
			Primperan (Metoclopramide)	SS		ORAL		
			Spasfon (Phloroglucinol/Trimethylpholoroglucinol)	SS		INTRAMUSCULAR		
			Vadilex (Ifenprodil)	SS		ORAL		
			Atarax (Hydroxyzine)	C				
			Cordarone (Amiodarone)	C				
			Dacryoserum (Bortic Acid)	C				
			Indocollyre (Indometacine)	C				

Date:08/05/99ISR Number: 3324553-XReport Type:Periodic Company Report #UK F1I 012799 0006
Age:76 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	Pyrexia Vomiting	Foreign Study Other	5-Fluorouracil (Fluorouracil) Folic Acid Metoclopramide	PS SS SS		ORAL	10 MG DAILY	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/05/99ISR Number: 3324555-3Report Type:Periodic Company Report #UK F1I 012799 0006
Age:76 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Pyrexia	Foreign	Fluorouracil	PS		INTRAVENOUS	425 MG	
Hospitalization -	Sepsis	Study	Folic (Folinic) Acid	SS		INTRAVENOUS	20 MG	
Initial or Prolonged	Vomiting	Health	Metoclopramide	SS		ORAL	10 MG	
		Professional	Metoclopramide (From Ni)	C				

Date:08/05/99ISR Number: 3324570-XReport Type:Periodic Company Report #UK FLI 012799 0006
Age:76 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Sepsis	Foreign	Fluorouracil	PS		INTRAVENOUS	425 MG	NI
Initial or Prolonged	Vomiting	Study	Folic Acid	SS		INTRAVENOUS	20 MG	NI
		Health	Metoclopramide	SS		ORAL	10 MG	NI
		Professional						

Date:08/06/99ISR Number: 3321313-0Report Type:Expedited (15-DaCompany Report #10058121
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Abdominal Pain	Foreign	Videx (Didanosine)	PS		ORAL	400	MILLIGRAM, 1 DAY
	Arthralgia	Health						
	Erythema Multiforme	Professional						
	Headache		Zerit Caps (Stavudine)	SS		ORAL	80 MILLIGRAM, 1 DAY	
	Malaise							
	Myalgia							

	Pyrexia		Zerit Caps (Stavudine)	SS		ORAL 80 MILLIGRAM, 1 DAY
			Viramune (Nevirapine)	SS		ORAL 200 MILLIGRAM
			Codeine Phosphate (Codeine)	SS		AS NECESSARY
			Metoclopramide (Metoclopramide Hcl)	SS		AS NECESSARY

Date:08/09/99ISR Number: 3321782-6Report Type:Expedited (15-DaCompany Report #8-99215-021A
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Other	Accidental Overdose	Health	Reglan	PS		ORAL 7 CC (TWO
	Dystonia	Professional				DOSES) ORAL
	Medication Error					

Date:08/16/99ISR Number: 3326402-2Report Type:Direct Company Report #
Age:39 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Required Intervention to Prevent Permanent Impairment/Damage	Aphasia	Health	Metoclopramide 10mg Tab	PS		ORAL 10MG TAB PO QID
	Convulsion	Professional				
	Loss Of Control Of Legs					
			Albuterol	C		
			Amoxicillin	C		
			Beclomethasone	C		
			Gabapentin	C		

Ibuprofen	C
Lansoprazole	C
Metoclopramide Hcl	C
Mertazapine	C
Nicotine	C
Olopatadine Hcl	C
Phenytoin Na (Dilantin)	C
Salneterol	C
Trazodone	C
Zafirlukast	C

Date:08/16/99ISR Number: 3326533-7Report 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	Dyspnoea Feeling Hot Restlessness	Health Professional	Reglan 10 Mg Injection	PS		INTRAVENOUS	IV Q 6 HRS PRN	1 DAY

Date:08/18/99ISR Number: 3328621-8Report Type:Expedited (15-DaCompany Report #1222874A
Age:47 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Diarrhoea	Foreign	Loperamide	PS				1 DAY
	Gastroenteritis	Health Professional	Tramadol Hydrochloride Tablets (Slow Release)	SS		ORAL	200 MG DAILY	PO 1 DAY
			Buprenorphine	SS		ORAL	0.2 MG QD PO	
			Metoclopramide Inj	SS			INTRAMUSCULAR	20 MG ONCE IM
			Meprobamate	SS				

			Acepromet azine	SS		
			Nifuroxazide	SS		
			Ibuprofen	SS		

1600 MG QD

Date:08/19/99ISR Number: 3332312-7Report Type:Periodic Company Report #8-99081-110A
Age:42 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Breast Neoplasm	Health	Effexor Xr Capsules	PS		ORAL	75 MG ONCE	
	Breast Pain	Professional					DAILY ORAL	
	Chest Pain		Carbocaine					
	Dizziness		(Mepivacaine)					
	Dyspnoea		Injection	SS				
	Mania		Effexor Tablet	SS		ORAL	12.5 MG AT	
	Nervousness						12:30PM &	
	Tachycardia						3:30 PM ORAL	
			Reglan					
			(Metoclopramide)	SS				
			Cylert	C				
			Ambien	C				
			...	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/27/99ISR Number: 3336618-7Report Type:Expedited (15-DaCompany Report #8-99078-019A
Age:4 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Genital Pruritus Female	Health	Reglan	PS		ORAL	7.5 MG THREE	
	Ketonuria	Professional					TIMES DAILY	
	Middle Insomnia						ORAL	
	Nocturia		Propulsid	C				
	Pollakiuria		Prilosec	C				
	Vulvovaginal Discomfort		Flovent	C				
			Atrovent	C				
			Intal	C				

Date:08/31/99ISR Number: 3338094-7Report Type:Expedited (15-DaCompany Report #9936273
Age:44 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Atrioventricular Block	Foreign	Zoloft Tablets	PS		ORAL	50.00 MG	
Hospitalization -	Autonomic Neuropathy	Health					TOTAL ORAL	
Initial or Prolonged	Cardiac Arrest	Professional	Primperan	SS		ORAL	ORAL	
Required	Dehydration		Omeprazole	C				
Intervention to	Erysipelas		Oxacillin	C				
Prevent Permanent	Hyperhidrosis							
Impairment/Damage	Hyperreflexia							
	Hyperventilation							
	Hypothermia							
	Malaise							
	Renal Failure Acute							
	Respiratory Disorder							
	Salivary Gland Disorder							
	Sepsis							
	Serotonin Syndrome							
	Syncope							
	Syncope Vasovagal							
	Tachypnoea							
	Tremor							
	Ventricular Tachycardia							

Date:09/01/99ISR Number: 3338626-9Report Type:Direct Company Report #
Age:12 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Anxiety	Health	Reglan 10mg	PS		INTRAVENOUS	10MG Q	6HRS
	Oculogyration	Professional				IV		
	Opisthotonus							

Date:09/03/99ISR Number: 3342309-9Report Type:Expedited (15-DaCompany Report #USA/99/01730/DHE
Age:36 YR Gender:Female I/FU:F

Outcome	PT
Other	Bronchospasm
Required	Conjunctivitis
Intervention to	Diarrhoea
Prevent Permanent	Dyspnoea
Impairment/Damage	Eye Irritation
	Muscle Contractions
	Involuntary
	Oedema Peripheral
	Overdose

		Pain In Extremity Paraesthesia Rhinitis	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
		Thrombosis	Health Professional	D.H.E.-45 (Dihydroergotamine Mesylate)	PS		
INTRAVENOUS	1 MG THREE TIMES A DAY						
IV INJECTION							
				Reglan (Metoclopramide)	SS		
INTRAVENOUS	10 MG IRREGULAR						
USE, IV							
INJECTION							
				Nubain	SS		
INTRAMUSCULAR	IM						
				Serzone	C		
				Xanax	C		
				Benadryl	C		

Date:09/08/99ISR Number: 3343003-0Report Type:Direct Company Report #
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Required Intervention to Prevent Permanent Impairment/Damage	Back Pain Dyspnoea Flushing Heart Rate Increased	Health Professional	Metoclopramide Iv	PS		INTRAVENOUS

Date:09/09/99ISR Number: 3343558-6Report Type:Expedited (15-DaCompany Report #8-99244-125A
Age:44 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					

Hospitalization -	Depression	Health	Reglan	PS		ORAL
10 MG THREE						
Initial or Prolonged	Drug Level Above	Professional				
TIMES DAILY						
	Therapeutic					
ORAL						
	Mania					

Date:09/21/99ISR Number: 3352945-1Report Type:Direct Company Report #
Age:53 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Confusional State		Metoclopramide Au300	PS		ORAL
10MG Q 6 HRS						
Initial or Prolonged	Hallucination, Auditory					
PRN PO						
	Paranoia		Methocarbamol	SS		ORAL
1500MG Q 6						
PRN PO						
			Naproxen	C		
			Nefazidone	C		

Date:09/21/99ISR Number: 3353249-3Report Type:Expedited (15-DaCompany Report #8-99251-015A
Age:3 MON Gender:Male I/FU:I

Outcome	PT
Other	Accidental Overdose
	Medication Error
	Muscle Spasms
	Oral Intake Reduced
	Sedation
	Speech Disorder

Tremor

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
		Consumer	Reglan	PS		ORAL	2.5 CC FOUR TIMES DAILY	ORAL

Date:09/22/99ISR Number: 3355107-7Report Type:Expedited (15-DaCompany Report #8-99257-007A
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Pancytopenia	Consumer	Reglan	PS			DOSE UNKNOWN	

Date:09/27/99ISR Number: 3359740-8Report Type:Expedited (15-DaCompany Report #215346
Age:72 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Angina Pectoris Arrhythmia	Foreign Study	Valium Injectable (Diazepam)	PS			5 MG DAILY	
	Blood Creatine Phosphokinase Increased	Health Professional	Rapilysin 10 U (Retelplase) 10 Iu	SS		INTRAVENOUS	10 IU 2 PER 1 HOUR	
	Blood Creatine Phosphokinase Mb Increased					INTRAVENOUS		
	Cardiac Enzymes Increased		Aspisol (Aspirin Dl-Lysine/Glycine)	SS		INTRAVENOUS	INTRAVENOUS	
	Electrocardiogram St Segment Elevation		Heparin (Heparin Sodium)	SS			1000 IU 1 PER 1 HOUR	
	Sedation							

	Subdural Haematoma		Morphin (Morphine Hydrochloride)	SS		
10 MG DAILY						
			Mcp Drops (Metoclopramide Hydrochloride)	SS		
1 AMPULE DAILY						
			Nitroglycerin (Nitroglycerin)	SS		
2 MG 1 PER HOUR						
			Ass (Aspirin)	SS		
INTRAVENOUS	.5 GRAM DAILY					
INTRAVENOUS						

Date:09/28/99ISR Number: 3359230-2Report Type:Direct Company Report #USP 52584
Age:50 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Medication Error		Celexa	PS	Forest Pharmaceuticals			
			Metoclopramide Hydrochloride	SS				

Date:10/04/99ISR Number: 3362713-2Report Type:Direct Company Report #
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Extrapyramidal Disorder		Metoclopramide	PS		ORAL	20MG PO AC & HS	
			Promethazine	SS			25MG PR Q6H	

			Albuterol	C		
			Insulin	C		
			Cloridine	C		
			Isinopril	C		

Date:10/14/99ISR Number: 3373070-XReport Type:Expedited (15-DaCompany Report #8-99069-136A
Age:59 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Akathisia	Consumer	Reglan Tablet	PS		ORAL	10 MG 4X PER	1 DAY ORAL
	Anorexia							
	Bradykinesia		Mellaril	SS		ORAL	25 MG THREE	TIMES A DAY
	Cachexia							
	Depression							TAPERING OFF
	Extrapyramidal Disorder							THEN
	Flat Affect							DISCONTINUED,
	Hypercholesterolaemia		Xanax	C				
	Hyperglycaemia		Vitamin C	C				
	Hypertonia		Multivit	C				
	Hyporeflexia		Calcium	C				
	Immobile		Effexor	C				
	Joint Stiffness							
	Masked Facies							
	Movement Disorder							
	Muscle Rigidity							
	Myalgia							
	Oral Intake Reduced							
	Tardive Dyskinesia							
	Tremor							

Date:10/14/99ISR Number: 3373908-6Report Type:Expedited (15-DaCompany Report #10130151
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Hospitalization - Initial or Prolonged INTRAVENOUS 344 MILLIGRAM, 1/1 DAY IV INTRAVENOUS 515 MILLIGRAM, 1/1 CYCLE IV INTRAVENOUS 246 MILLIGRAM, 3/1 CYCLE IV	Leukopenia Thrombocytopenia	Foreign Study Health Professional Other	Taxol Inj (Paclitaxel) Carboplatin Etopophos For Inj(Etoposide Phosphate) Navoban(Tropisetron Hcl) Dexamethasone Metoclopramide(Metoclopramide Hcl) Neupogen (Granulocyte Csf)	PS SS SS SS SS SS	5 MILLIGRAM 4 MILLIGRAM 10 MILLIGRAM

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/14/99ISR Number: 3373912-8Report Type:Expedited (15-DaCompany Report #10058121
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Abdominal Pain	Foreign	Videx (Didanosine)	PS		ORAL	400	MILLIGRAM,1
	Arthralgia	Health						DAY ORAL
	Dermatitis	Professional						
	Erythema Multiforme	Other	Zerit Caps(Stavudine)	SS		ORAL	80 MILLIGRAM,	1 DAY ORAL
	Headache							
	Malaise							
	Myalgia		Viramune(Nevirapine)	SS		ORAL	200	MILLIGRAM,
	Pyrexia							ORAL
	Rash Erythematous							
			Codeine Phosphate(Codeine)	SS				AS NECESSARY
			Metoclopramide(Metoclopramide)	SS				AS NECESSARY
			Penicillin V (Penicillin V)	C				
			Paracetamol (Paracetamol)	C				

Date:10/15/99ISR Number: 3374051-2Report Type:Expedited (15-DaCompany Report #NUBAIN 1999-00075
Age:36 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Bronchospasm Diarrhoea Dyspnoea	Health Professional	Nubain 10 Mg Endo	PS	Endo Pharmaceuticals Inc.	INTRAVENOUS	10 MG Q4HR IV	
	Eye Irritation Muscle Spasms		D.H.E. 45 Novartis Phar	SS	Novartis			

		Oedema Peripheral				Pharmaceuticals Inc.	
INTRAVENOUS	1 MG Q8HR IV	Pain In Extremity		Reglan	SS		
10 MG		Paraesthesia		Serzone	C		
		Respiratory Disorder		Xanax	C		
				Benadryl	C		

Date:10/15/99ISR Number: 3374061-5Report Type:Expedited (15-DaCompany Report #USA/99/01730/DHE
Age:36 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Bronchospasm	Health	D.H.E.-45					
Required	Conjunctivitis	Professional	(Dihydroergotamine					
Intervention to	Diarrhoea		Mesylate)	PS				
1 MG, THREE								
Prevent Permanent	Dyspnoea							
TIMES								
Impairment/Damage	Eye Irritation		Reglan					
	Muscle Contractions		(Metoclopramide)	SS				
10 MG,								
	Involuntary							
IRREGULAR								
	Muscle Spasms		Nubain	SS				
	Oedema		Serzone (Nefazodone					
	Oedema Peripheral		Hydrochloride)	C				
	Overdose		Xanax (Alprazolam)	C				
	Pain In Extremity		Benadryl					
	Paraesthesia		(Diphenhydramine					
	Respiratory Disorder		Hydrochloride)	C				
	Rhinitis							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/20/99ISR Number: 3377052-3Report Type:Expedited (15-DaCompany Report #HQ1878311OCT1999
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Clitoral Engorgement	Consumer	Reglan Injection	PS				
	Decubitus Ulcer		Compazine	SS				
	Deep Vein Thrombosis		Dilaudid	C				
	Demyelination		Zovirax	C				
	Dermatitis Contact		Zinc Sulfate	C				
	Hypertonia		Oscal	C				
	Hypoxia		Bactrim	C				
	Neurogenic Bladder		Prednisone	C				
	Pain		Multivitamins, Plain	C				
	Pyrexia		Heparin	C				
	Rhonchi		Prilosec	C				
	Tracheostomy		Baclofen	C				
			Neurontin	C				
			Vitamin E	C				
			Ferrous Sulfate	C				
			Potassium Chloride	C				
			Actigall	C				
			Metamucil	C				
			Artane Tablet	C				
			Tylenol	C				
			Fleet Ready-To-Use Enema	C				
			Dulcolax	C				
			Hydrocortisone	C				
			Balmex Ointment	C				
			Dakin'S Solution	C				

Date:10/20/99ISR Number: 3377059-6Report Type:Expedited (15-DaCompany Report #HQ1120304OCT1999
Age:62 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Health	Zaleplon (Zaleplon)	PS		ORAL	10 MG 1 X PER 1 DAY ORAL, 1	CAPSULE ORAL 1 DAY
	Injury	Professional						
			Metoclopramide					

			(Metoclopramide)	SS		ORAL
ORAL	15 DAY					

Date:10/21/99ISR Number: 3378765-XReport Type:Expedited (15-DaCompany Report #HQ2566314OCT1999
Age:36 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Bronchospasm	Health	Reglan Injection	PS		INTRAVENOUS	10 MG,	
	Diarrhoea	Professional				IRREGULAR USE		
	Dyspnoea	Other	Dhe-45	SS		INTRAVENOUS	1 MG 1X PER	
	Eye Irritation					8HR		
	Muscle Spasms		Nubain	SS		INTRAMUSCULAR		
	Oedema Peripheral		Serzone	C				
	Pain In Extremity		Xanax	C				
	Paraesthesia		Benadryl	C				
	Pulmonary Congestion							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/22/99ISR Number: 3379421-4Report Type:Expedited (15-DaCompany Report #B0071419A
Age:61 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hepatitis	Foreign	Fortaz Injection					
	Liver Function Test	Health	(Ceftazidime Sodium)	PS		INTRAVENOUS	1 G/TWICE PER	
	Abnormal	Professional					DAY/	
	Pancytopenia	Company				INTRAVENOUS		
		Representative	Aminofluid (Formulation Unknown)	SS				
			Metoclopramide (Formulation Unknown) (Metoclopramide)	SS				

Date:10/26/99ISR Number: 3382844-0Report Type:Expedited (15-DaCompany Report #HQ1120304OCT1999
Age:62 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Health	Sonata	PS		ORAL	10 MG 1X PER	
		Professional					1 DAY ORAL	8 DAY
			Metoclopramide (Metoclopramide)	SS		ORAL	ORAL	15 DAY
			Mianserin (Mianserin)	SS		ORAL	60 MG 1X PER	
							1 DAY ORAL	140 DAY

Date:11/01/99ISR Number: 3393691-8Report Type:Periodic Company Report #01996
Age:62 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Disability	Dyskinesia	Other	Metoclopramide				
	Dyspnoea		Tablets, 10 Mg				
	Eye Pain		(Purepac)	PS	Purepac		
10 MG T.I.D.							
	Tongue Disorder		Compazine P.R.N.	C			
			Carafate	C			
			Pepcid	C			
			Prisolec	C			
			Premarin	C			
			Nitrostat	C			
			Estrace	C			
			Xanax	C			

Date:11/05/99ISR Number: 3389661-6Report Type:Expedited (15-DaCompany Report #B0071728A
Age:41 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required	Condition Aggravated	Foreign	Zantac Injection					
Intervention to	Dermatitis Bullous	Health	(Ranitidine					
Prevent Permanent	Eczema	Professional	Hydrochloride)	PS				
INTRAVENOUS							50 MG /	TWICE
Impairment/Damage	Erythema Nodosum							
PER DAY /								
	Face Oedema							
INTRAVENOUS								
	Oedema Peripheral							
INFUSION								
	Pain		Metoclopramide					
	Pruritus		(Formulation					
	Stevens-Johnson Syndrome		Unknown)					
			(Metoclopramide)	SS				
INTRAVENOUS							1 AMPOULE /	
PER DAY /								

INTRAVENOUS				Hyoscine Butylbromide (Formulation Unknown) (Hyoscine Butylbromide)	SS		
INTRAVENOUS	1 AMPOULE / TWICE PER DAY / INTRAVENOUS						
				Diazepam (Formulation Unknown) (Diazepam)	SS		
INTRAVENOUS	1.5 AMPOULE / TWICE PER DAY / INTRAVENOUS						

Date:11/05/99ISR Number: 3390441-6Report Type:Expedited (15-DaCompany Report #199921566DDC
Age:81 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Toxic Epidermal Necrolysis	Foreign Study	Ulcogant Suspension	PS			4	DAY
			Digimerck	SS			205 MG	2 DAY
		Health Professional	Valium	SS			3 G	2 DAY
			Lasix	SS			72 ML	9 DAY
		Other	Acc	SS			100 MG	8 DAY
			Zinacef	SS			1	DAY
			Dopamin	SS				
			Rohypnol	SS				
			Zyloric	SS				
			Acetylsalicylic Acid	SS				
			Adumbran	SS				
			Bactrim Forte	SS				
			Tramal	SS				
			Lexotanil	SS				

60 DRAM

Paspertin	SS
Temgesic	C
L-Thyroxin	C
Adalat	C
Cor Tensobon	C
Beloc Mite	C
Heparin	C
Bifiteral	C
Isoket	C
Kalium	C
Ringer	C
Humanalbumin	C
Gelafundin	C
Alt-Insulin	C
Mannitol	C
Glucose	C
Suprarenin	C
Dilzem	C
Dormicum	C
Perfan	C
Nitro	C
Fentanyl	C
Enflurane	C
Dobutrex	C
Sodium Chloride Injection	C
Ferro Sanol	C
///Olvon	C
Hydromedin	C

			Tavegil	C		
			Ciprobay	C		
			Digimerck	C		

Date:11/08/99ISR Number: 3391211-5Report Type:Expedited (15-DaCompany Report #B0071728A
Age:41 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Dermatitis Bullous Eczema Face Oedema Oedema Peripheral Stevens-Johnson Syndrome	Foreign Health Professional	Zantac Injection (Ranitidine Hydrochloride)	PS		INTRAVENOUS INTRAVENOUS INFUSION	50MG TWICE PER DAY	
			Metoclopramide (Forulation Unknwn) (Metoclopramide)	SS		INTRAVENOUS	1 AMPOULE PER DAY	
			Hyoscine Butylbromide (Formulation Unknown) (Hyoscine Butylbromide)	SS		INTRAVENOUS	1 AMPOULE TWICE PER DAY	
			Diazepam (For	SS		INTRAVENOUS		

Date:11/08/99ISR Number: 3391509-0Report Type:Expedited (15-DaCompany Report #199921558DDC
Age:61 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blister	Foreign	Ulcogant Suspension	PS		ORAL		
PO							2	WK
	Dermatitis	Study	Tegretal	SS		ORAL		
600 MG PO							8	DAY
	Mucosal Erosion	Health	Phenytoin	SS		ORAL		
300 MG PO								
	Staphylococcal Sepsis	Professional	Mono-Embolex	SS				
SUBCUTANEOUS							SC	
	Stevens-Johnson Syndrome	Other	Nolvadex	SS		ORAL		
PO								
			Megalac	SS		ORAL		
PO								
			Kalinor	SS		ORAL		
PO								
			Paspertin	SS		ORAL		
60 DRAM PO							4	DAY
			Unacid	SS				
INTRAVENOUS							4.5 G IV	2 DAY
			Dexamethasone	C				
			Tamoxifen Citrate	C				
			Methimazole	C				
			Sostril	C				
			Fraxiparine	C				
			Fenistil	C				
			Prednisolut	C				
			Urbason	C				

Date:11/08/99ISR Number: 3391517-XReport Type:Expedited (15-DaCompany Report #USA/99/02776/MEL
Age:59 YR Gender:Female I/FU:I

Outcome
Hospitalization -
Initial or Prolonged
Required
Intervention to

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Prevent Permanent Impairment/Damage	Akathisia Anorexia Anxiety Asthenia Attention Deficit/Hyperactivity Disorder Back Pain Condition Aggravated Depression Extrapyramidal Disorder Malaise Myalgia Nervousness Regurgitation Of Food Tardive Dyskinesia Tremor Weight Decreased	Consumer	Mellaril (Thioridazine Hydrochloride) Reglan (Metoclopramide) Effexor (Venlafaxine Hydrochloride) Xanax (Alprazolam) Vitamin C (Ascorbic Acid) Multivitamin (Multiple Vitamins) Calcium	PS SS C C C C C		ORAL	25 MG, THREE TIMES A DAY, ORA; 10 MG, FOUR TIMES A DAY, ORAL;	

Date:11/12/99ISR Number: 3396255-5Report Type:Expedited (15-DaCompany Report #A0104918A
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Hospitalization - Initial or Prolonged Other Required Intervention to Prevent Permanent Impairment/Damage	Breathing-Related Sleep Disorder Cough Cyanosis Livedo Reticularis Oxygen Saturation Decreased Respiratory Arrest	Consumer Other	Zantac (Formulation Unknown) (Ranitidine Hydrochloride) Metoclopramide Hcl (Formulation Unknown) (Metoclopramide Hcl)	PS SS			TWICE PER DAY/ SEE TEXT FOUR TIMES	

	Skin Discolouration					
PER DAY/ SEE						
	Yawning					
TEXT						

Date:11/15/99ISR Number: 3398558-7Report Type:Expedited (15-DaCompany Report #199921566DDC
Age:81 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Conjunctivitis	Foreign	Ulcogant Suspension	PS				
Life-Threatening	Rash Macular	Study	Digimerck Tablets	SS		ORAL	4	DAY
Hospitalization - Initial or Prolonged	Shock	Health Professional	Digimerck Solution For Injection	SS				
	Toxic Epidermal Necrolysis		Valium	SS				
	Ulcer		Lasix Tablets	SS		ORAL	205	MG
			Lasix Tablets	SS		ORAL	205 MG	3 DAY
			Lasix Tablets	SS		ORAL	205 MG	1 WK
			Lasix Solution For Injection	SS				
			Acc	SS		ORAL		
			Zinacef	SS				
			Dopamin	SS				
			Rohypnol	SS				
			Zyloric	SS		ORAL		
			Acetylsalicylic Acid	SS		ORAL		
			Adumbran	SS		ORAL		
			Bactrim Forte	SS		ORAL		

INTRAVENOUS	120 MG							
INTRAVENOUS	3 G	3	DAY					
INTRAVENOUS	72 ML	1	WK					
INTRAVENOUS								
100 MG	1 WK							
2 DAY								

			Tramal	SS		ORAL
			Lexotanil	SS		ORAL
			Paspertin	SS		ORAL
60 DRAM						
			Beloc Mite	C		
			Heparin	C		
			Bifiteral	C		
			Isoket	C		
			Kalium	C		
			Kalium	C		
			Ringer	C		
			Humanalbumin	C		
			Lafundin	C		
			Alt-Insulin	C		
			Mannitol	C		
			Glucose	C		
			Suprarenin	C		
			Dilzem	C		
			Dormicum	C		
			Perfan	C		
			Nitro	C		
			Fentanyl	C		
			Enflurane	C		
			Dobutrex	C		
			Sodum Chloride Injection	C		
			Ferro Sanol	C		
			Hydromedin	C		
			Tavegil	C		
			Ciprobay	C		
			Digimerck	C		

Date:11/18/99ISR Number: 3401365-XReport Type:Expedited (15-DaCompany Report #HQ5768216NOV1999
Age:41 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anxiety	Consumer	Reglan Tablet	PS		ORAL	20 MG	
	Insomnia						INCREASED TO	
	Suicidal Ideation						40 MG	
	Suicide Attempt						DECREASED TO	

30 MG FOR 3 3 MON

				Provera	C		
				Climara	C		

Date:11/19/99ISR Number: 3402827-1Report Type:Expedited (15-DaCompany Report #HQ5452112NOV1999
Age:51 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Bronchitis Acute	Consumer	Reglan Tablet	PS		ORAL	ORAL	
	Cardiac Failure		Darvocet-N	SS		ORAL	ORAL	
	Congestive		Dantrium	C				
	Drug Level Above		Baclofen	C				
	Therapeutic		Imipramine	C				
	Dyspnoea Exacerbated							
	Respiratory Depression							
	Respiratory Failure							
	Sedation							

Date:11/22/99ISR Number: 3405698-2Report Type:Expedited (15-DaCompany Report #8-99069-136A
Age:59 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Akathisia	Consumer	Reglan Tablet	PS		ORAL	10 MG 4X PER	1 DAY ORAL
	Anorexia							
	Anxiety		Mellaril	SS		ORAL	25 MG THREE	TIMES A DAY
	Aphonia							
	Asthenia							TAPERING OFF
	Balance Disorder							THEN
	Cachexia							DISCONTINUED,
	Depression		Xanax	C				
	Dry Skin		Vitamin C	C				
	Extrapyramidal Disorder		Multivit	C				
	Masked Facies		Calcium	C				
	Memory Impairment		Effexor	C				
	Movement Disorder							
	Myalgia							
	Nausea							
	Nervousness							
	Tardive Dyskinesia							
	Tremor							
	Weight Decreased							

Date:11/29/99ISR Number: 3409514-4Report Type:Direct Company Report #
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dystonia	Health	Metoclopramide	PS		INTRAVENOUS	9MG PRN IV	
	Headache	Professional						

Date:12/08/99ISR Number: 3416596-2Report Type:Expedited (15-DaCompany Report #9949646
Age:20 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anxiety Confusional State	Foreign Literature	Vistaril Parenteral Solution	PS			INTRAMUSCULAR	100.00 MG TOTAL:DAILY:I
	Dystonia Hypertension	Health Professional					NTRAMUSCULAR	1 DAY
	Muscle Rigidity		Metoclopramide	SS			INTRAVENOUS	10.00 MG TOTAL:DAILY:I
	Opisthotonus Pain Pyrexia Respiratory Disorder Restlessness Tremor						NTRAVENOUS	1 DAY

Date:12/13/99ISR Number: 3420602-9Report Type:Expedited (15-DaCompany Report #GB/99/01121/SIM03
Age:7 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Toxic Epidermal Necrolysis	Foreign Other	Sandimmun Neoral (Ciclosporin)	PS			45 MG, TWICE A DAY	
			Codeine Phosphate (Codeine Phosphate)	SS		ORAL	15 MG, ONCE A DAY, ORAL	
			Chlorpheniramine (Chlorphenamine)	SS			4 MG, AS	

NEEDED,				
		Paracetamol (Paracetamol)	SS	ORAL
360 MG, AS NEEDED, ORAL				
		Vancomycin (Vancomycin)	SS	
INTRAVENOUS	270 MG, THREE TIMES A DAY, INTRAVENOUS INJECTION			
		Ceftazidime (Ceftazidime)	SS	
INTRAVENOUS	900 MG, THREE TIMES A DAY, INTRAVENOUS INJECTION			
		Tranexamic Acid (Tranexamic Acid)	SS	ORAL
400 MG, THREE TIMES A DAY, ORAL				
		Fludarabine (Fludarabine)	SS	
INTRAVENOUS	18 MG, ONCE A DAY, INTRAVENOUS INJECTION			
		Ondansetron (Ondansetron)	SS	
4 MG, AS NEEDED				
		Cyclophosphamide		

		(Cyclophosphamide)	SS	
INTRAVENOUS	1.04 G, ONCE A DAY, INTRAVENOUS INJECTION			
		Immunoglobulin (Antithymocyte Immunoglobulin)	SS	
INTRAVENOUS	219 MG, ONCE A DAY, INTRAVENOUS INJECTION			
		Metoclopramide (Metoclopramide)	SS	
5 MG, AS NEEDED				
		Meropenem (Meropenem)	SS	
INTRAVENOUS	360 MG, THREE TIMES A DAY, INTRAVENOUS INJECTION			
		Acyclovir (Aciclovir)	SS	
INTRAVENOUS	175 MG, THREE TIMES A DAY, INTRAVENOUS INJECTION			
		Fluconazole (Fluconazole)	SS	ORAL
50 MG, ONCE A DAY, ORAL				
		Nifedipine (Nifedipine)	SS	ORAL
5 MG, AS NEEDED, ORAL				
		Sandoglobulin (Immunoglobulin		

Human Normal) SS

INTRAVENOUS 7 G, WEEKLY,

INTRAVENOUS

INJECTION

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/16/99ISR Number: 3423544-8Report Type:Expedited (15-DaCompany Report #HQ5768216NOV1999
Age:41 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anxiety	Consumer	Reglan Tablet	PS		ORAL	10 MG 4X PER	1 DAY, ORAL
	Depression							
	Galactorrhoea		Provera	C				
	Insomnia		Climara	C				
	Pain In Extremity							
	Suicidal Ideation							

Date:12/20/99ISR Number: 3425941-3Report Type:Expedited (15-DaCompany Report #B0074230A
Age:7 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Toxic Epidermal Necrolysis	Foreign	Zofran (Formulation Unknown) (Ondansetron Hydrochloride)	PS			AS REQUIRED	
			Zovirax (Formulation Unknown) (Acyclovir)	SS		INTRAVENOUS	175 MG/ THREE	TIMES PER DAY
			Fortaz (Formulation Unknonw) (Ceftazidime Sodium)	SS		INTRAVENOUS	900 MG/ THREE	TIME PER DAY
			Normal Immunoglobulin (Formulation Unknown) (Normal Immunoglobulin)	SS		INTRAVENOUS	WEEKLY/	

INTRAVENOUS			Nifedipine (Formulation Unknown) (Nifedipine)	SS	ORAL
AS REQUIRED/ ORAL			Fluconazole (Formulation Unknown) (Fluconazole)	SS	ORAL
PER DAY/ ORAL			Meropenem (Formulation Unknown) (Meropenem)	SS	
INTRAVENOUS	360 MG/ THREE				
TIMES PER DAY					
INTRAVENOUS			Metoclopramide (Formulation Unknown) (Metoclopramide)	SS	
AS REQUIRED			Normal Immunoglobulin (Formulation Unknown) (Normal Immunoglobulin)	SS	
INTRAVENOUS	PER DAY/				
INTRAVENOUS			Cyclophosphamide (Formulation Unknown)		

		(Cyclophosphamide)	SS		
INTRAVENOUS	PER DAY/				
INTRAVENOUS					
		Fludarabine Phosphate (Formulation Unknown) (Fludarabine	SS		
INTRAVENOUS	PER DAY/				
INTRAVENOUS					
		Tranexamic Acid (Formulation Unknown) (Tranexamic Acid)	SS		ORAL
400 MG/ THREE					
TIMES PER DAY					
ORAL					
		Vancomycin (Formulation Unknown) (Vancomycin)	SS		
INTRAVENOUS	270 MG/ THREE				
TIMES PER DAY					
INTRAVENOUS					
		Paracetamol (Formulation Unknown) (Acetaminophen)	SS		ORAL
PER DAY/ ORAL					
		Chlorpheniramine (Formulation Unknown) (Chlorpheniramine)	SS		
AS REQUIRED					
		Codeine Phosphate (Formulation Unknown) (Codeine Phosphate)	SS		ORAL
PER DAY/ ORAL					
		Cyclosporin (Formulation Unknown)			

			(Cyclosporine)	SS		

45 MG/ TWICE

PER DAY

Date:12/20/99ISR Number: 3438756-7Report Type:Direct Company Report #
Age:37 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Dyskinesia	Health	Reglan Iv	PS		INTRAVENOUS	IV BID	
Hospitalization -	Tongue Disorder	Professional						
X1MONTH,								
Initial or Prolonged								

RESTARTED 3

DAYS LATER

Date:12/23/99ISR Number: 3429947-XReport Type:Expedited (15-DaCompany Report #HQ9252521DEC1999
Age:3 MON Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Convulsion	Consumer	Reglan Syrup	PS		ORAL	4 TIMES	
Initial or Prolonged	Cyanosis						DAILY, ORAL	
	Feeding Disorder		Zantac	SS		ORAL	TWICE DAILY,	
	Heart Rate Decreased						ORAL	
	Livedo Reticularis							
	Oxygen Saturation Decreased							
	Respiratory Arrest							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/23/99ISR Number: 3430119-3Report Type:Expedited (15-DaCompany Report #10083624
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Atypical Mycobacterial	Foreign	Zerit Caps					
Hospitalization -	Infection	Health	(Stavudine)	PS		ORAL	80 MILLIGRAM,	
Initial or Prolonged	Blood Albumin Increased	Professional					1 DAY ORAL	
Other	Blood Cholinesterase		Sustiva (Efavirenz)	SS		ORAL	600	
	Increased						MILLIGRAM, 1	
	C-Reactive Protein						DAY ORAL	
	Increased		Lamivudine	SS		ORAL	300MILLIGRAM,	
	Coagulopathy						1 DAY ORAL	
	Gamma-Glutamyltransferase		Clindamycin	SS		ORAL	1200	
	Increased						MILLIGRAM, 1	
	Haemoglobin Decreased						DAY ORAL	
	Hepatic Failure		Calcium Folinate	SS		ORAL	15 MILLIGRAM,	
	Ileus Paralytic						1 DAY ORAL	
			Ciprofloxacin	SS		ORAL	1000	
							MILLIGRAM, 1	
							DAY ORAL	
			Clarithromycin	SS		ORAL	1000	
							MILLIGRAM, 1	
							DAY ORAL	
			Rifabutin	SS		ORAL	600	
							MILLIGRAM, 1	

DAY ORAL

			Diflucan (Fluconazole)	SS		
INTRAVENOUS	200 MILLIGRAM, 1 DAY					
IV						
			Heparin	SS		
INTRAVENOUS	15000 INTERNATIONAL UNIT, 1 DAY					
IV						
			Metamizol (Dipyrone)	SS		
INTRAVENOUS	5 GRAM, IV					
			Pyrimethamine	SS		ORAL
100 MILLIGRAM, 1 DAY ORAL						
			Metoclopramide (Metoclopramide Hcl)	SS		ORAL
ORAL						

Date:12/28/99ISR Number: 3432341-9Report Type:Direct Company Report #
Age:38 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Erythema Vein Disorder		Metoclopramide	PS				

Date:12/30/99ISR Number: 3434577-XReport Type:Expedited (15-DaCompany Report #HQ3588126OCT1999
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Atrial Fibrillation	Health Professional	Reglan Injection	PS				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/01/00ISR Number: 3434406-4Report Type:Direct Company Report #
Age:4 MON Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Convulsion	Health Professional	Metoclopramide 5yr #90ml	PS			7ML 3X DAILY	
Required Intervention to Prevent Permanent Impairment/Damage	Medication Error							
	Overdose							
	Respiratory Disorder							

Date:01/07/00ISR Number: 3440479-5Report Type:Expedited (15-DaCompany Report #HQ0166204JAN2000
Age:0 MON Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Apnoea	Consumer	Reglan Syrup	PS		ORAL	0.4 MG 4 X PER 1 DAY, ORAL	
	Bradycardia							
	Candidiasis							
	Cardiac Failure		Propulsid	SS				
	Congestive		Phenobarbitol	C				
	Condition Aggravated							
	Congenital Intestinal Malformation							
	Dyskinesia							
	Eye Movement Disorder							
	Gastrooesophageal Reflux Disease							
	Munchausen'S Syndrome							
	Opisthotonus							
	Peritonitis							
	Sleep Disorder							

Date:01/12/00ISR Number: 3443184-4Report Type:Expedited (15-DaCompany Report #10225480
Age:15 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Hospitalization - 15.5 Initial or Prolonged	Anaemia	Literature	Acetylcysteine	PS		ORAL
MILLILITER, 1/4 HOUR ORAL	Cyanosis	Health				
	Methaemoglobinaemia	Professional				
	Muscle Spasms		Metoclopramide			
	Oxygen Saturation Decreased		(Metoclopramide Hcl)	SS		
1 MG/KG, 1/4 HOUR						
	Pco2 Decreased					
	Po2 Increased					
	Prothrombin Time Prolonged					
	Sulphaemoglobinaemia					
	Vomiting					

Date:01/12/00ISR Number: 3443243-6Report Type:Expedited (15-DaCompany Report #219399
Age:19 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Grand Mal Convulsion	Foreign Other	Midazolam Hydrochloride (Midazolam Hydrochloride)	PS		
2 MG 1 PER ONE DOSE			Temazepam			

		(Temazepam)	SS
INTRAVENOUS	10 MG 1 PER		
ONE DOSE			
INTRAVENOUS			
		Metoclopramide Hydrochloride (Metoclopramide Hydrochloride)	SS
INTRAVENOUS	10 MG 1 PER		
ONE DOSE			
INTRAVENOUS			
		Propofol (Propofol)	SS
INTRAVENOUS	100 MG 1 PER		
ONE DOSE			
INTRAVENOUS			
		Pancuronium Bromide (Pancuronium Bromide)	SS
INTRAVENOUS	4 MG 1 PER		
ONE DOSE			
INTRAVENOUS			
		Isoflurane (Isoflurane)	SS
INTRAVENOUS	1 PER ONE		
DOSE			
INTRAVENOUS			
		Pethidine Hydrochloride (Meperidine Hydrochloride)	SS
INTRAVENOUS	100 MG 1 PER		
ONE DOSE			
INTRAVENOUS			

Date:01/12/00ISR Number: 3443837-8Report Type:Expedited (15-DaCompany Report #216788
Age:17 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Acidosis	Foreign	Ceftrixone Sodium					
	Blood Bilirubin Increased	Other	(Ceftriaxone Sodium)	PS				
INTRAVENOUS							2 GRAM	DAILY
	Blood Creatinine							
INTRAVENOUS								
	Increased		Methylprednisolone					
	Blood Urea Increased		(Methylprednisolone)	SS				
INTRAVENOUS							20 MG	DAILY
	Hepatitis							
INTRAVENOUS								
	Hyperkalaemia		Ranitidine					
	Liver Function Test		(Ranitidine)	SS				
INTRAVENOUS							150 MG	DAILY
	Abnormal							
INTRAVENOUS								
	Renal Failure Acute		Prednisolone					
			(Prednisolone)	SS		ORAL		
20 MG DAILY								
ORAL								
			Metoclopramide Hydrochloride (Metoclopramide Hydrochloride)	SS				
INTRAVENOUS							5 MG	DAILY
INTRAVENOUS								

Date:01/27/00ISR Number: 3447772-0Report Type:Expedited (15-DaCompany Report #10241438
Age:49 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Cerebellar Syndrome	Foreign	Amiklin Inj					
	Confusional State	Health	(Amikacin Sulfate)	PS				
INTRAVENOUS							1 GRAM,	1 DAY
	Difficulty In Walking	Professional						
IV								
	Pyrexia	Other	Aracytine					
	Rash Erythematous		(Cytarabine)	SS				
	Tremor		Idarubicin	SS				

				Zophren (Ondansetron Hcl)	SS		
PARENTERAL	2 MILLIGRAM,						
PAREN							
				Tranxene (Clorazepate Dipotassium)	SS		
				Primperan (Metoclopramide Hcl)	SS		
				Axepim Inj (Cefepime Hcl)	C		
				Flagyl (Metronidazole)	C		
				Fungizone Intravenous (Amphotericin B)	C		

Date:01/28/00ISR Number: 3447693-3Report Type:Direct Company Report #
Age:67 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Agitation		Metoclopramide	PS		INTRAVENOUS	10MG IV	Q6H
	Gastrointestinal Haemorrhage		Claforan Iv	C				
	Hyperthermia Malignant Neuroleptic Malignant Syndrome		Human Insulin	C				
	Restlessness		Aldactone	C				
	Sepsis		Carafate	C				
			Pepcid Iv	C				
			Lanoxin	C				
			Lasix	C				

Date:02/01/00ISR Number: 3450249-XReport Type:Expedited (15-DaCompany Report #HQ3588126OCT1999
Age:42 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Atrial Fibrillation	Health Professional	Reglan Injection	PS				
	Chills		Benadryl	C				
	Dizziness		Verapamil	C				
	Hyperhidrosis							
	Hyperventilation							

	Hypoaesthesia					
	Hypotension					
	Loss Of Consciousness					
	Pallor					
	Paraesthesia					
	Syncope Vasovagal					
	Vomiting					

Date:02/04/00ISR Number: 3452497-1Report Type:Expedited (15-DaCompany Report #B0076359A
Age:49 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Cerebellar Syndrome Confusional State Gait Disturbance	Foreign Other	Zofran Injection (Ondansetron Hydrochloride)	PS		INTRAVENOUS	INTRAVENOUS	
	Pyrexia Rash Erythematous Tremor		Amikacin Sulfate (Formulation Unknown) (Amikacin Sulfate)	SS		INTRAVENOUS	INTRAVENOUS	
			Idarubicin					

			(Formulation Unknown) (Idarubicin)	SS			
INTRAVENOUS	PER DAY,						
INTRAVENOUS							
			Cytarabine (Formulation Unknown) (Cytarabine)	SS			
INTRAVENOUS	PER DAY,						
INTRAVENOUS							
			Clorazepate Dipotassium (Clorazepate Dipotassium)	SS			ORAL
ORAL							
			Metoclopramide (Formulation Unknown) (Metoclopramide)	SS			
INTRAVENOUS	INTRAVENOUS						
			Cefepime	C			
			Metronidazole	C			
			Amphotericin	C			

Date:02/04/00ISR Number: 3452544-7Report Type:Expedited (15-DaCompany Report #HQ5452112NOV1999
Age:51 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardiac Failure	Consumer	Reglan Tablet	PS		ORAL	DOSE UNKNOWN,	
	Congestive							
ORAL								
	Drug Level Above		Darvocet-N	SS		ORAL	UNKNOWN, ORAL	
	Therapeutic		Dantrium	C				
	Dyspnoea		Baclofen	C				
	Respiratory Depression		Imipramine	C				
	Respiratory Failure							
	Sedation							

Date:02/07/00ISR Number: 3453513-3Report Type:Expedited (15-DaCompany Report #2000010470FR
Age:55 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hyperaesthesia Hypoaesthesia Paraesthesia	Health Professional	Solu-Medrol (Methylprednisolone) Powder, Sterile	PS			INTRAVENOUS 40 MG,	WEEKLY, IV 1 DAY
			Primperan (Metoclopramide)	SS			INTRAVENOUS 30 MG,	WEEKLY, IV 1 DAY
			Gemzar (Gemcitabine Hydrochloride)	SS			INTRAVENOUS 1000 MG,	WEEKLY, IV 1 DAY
			Di-Antalvic (Dextropropoxyphene Hydrochloride, Paracetamol)	C				
			Mopral (Omeprazole)	C				
			Creon (Pancreatin)	C				

Date:02/09/00ISR Number: 3455506-9Report Type:Expedited (15-DaCompany Report #2000010471FR
Age:49 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Cerebellar Syndrome Confusional State Difficulty In Walking	Health Professional Other	Aracytine (Cytarabine) Powder, Sterile	PS		INTRAVENOUS	365 MG, IV	
	Pyrexia Rash Erythematous Tremor		Zavedos Solution, Sterile (Idarubicin Hydrochloride)	SS		INTRAVENOUS	15 MG, IV	
			Amiklin (Amikacin)	SS		INTRAVENOUS	1 G, QD, IV	
			Zophren (Ondansetron Hydrochloride)	SS			30 MG, QD,	
			Tranxene (Clorazepate Dipotassium)	SS		ORAL		
			Primperan (Metoclopramide)	SS		INTRAVENOUS	30 MG, QD, IV	
			Azeprim	C				
			Flagyl (Metronidazole)	C				
			Furgizon	C				

Date:02/09/00ISR Number: 3455532-XReport Type:Expedited (15-DaCompany Report #HQ0941607FEB2000
Age:70 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Coma Drug Hypersensitivity	Consumer	Reglan Tablet	PS				
			Synvisc	C				

Date:02/10/00ISR Number: 3456341-8Report Type:Expedited (15-DaCompany Report #HQ0889402FEB2000
Age:10 DY Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Diarrhoea Dystonia Feeding Problem In Newborn Hypotonia Irritability Peristalsis Visible Skin Discolouration Vomiting	Consumer	Reglan Syrup Afrin	PS C		ORAL	1 CC 3X PER 1 DAY, ORAL; 10 CC OVERDOSE AMOUNT ORAL	

Date:02/15/00ISR Number: 3458107-1Report Type:Expedited (15-DaCompany Report #HQ1878311OCT1999
Age:24 YR Gender:Female I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged Disability	Amblyopia Asthenia Choreoathetosis Condition Aggravated Coordination Abnormal Copper Metabolism Disorder Decubitus Ulcer Deep Vein Thrombosis Delirium

	Demyelination					
	Diarrhoea					
	Dystonia	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
	Enlarged Clitoris	Consumer	Reglan Injection	PS		
	Faecal Incontinence		Compazine	SS		
	Fall		Ativan Unspecified	C		
	Hallucination		Colace	C		
	Head Injury		Heparin	C		
	Hypersensitivity		Lasix	C		
	Hypertonia		Prednisone	C		
	Mental Impairment		Tacrolimus	C		
	Muscle Twitching		Trazodone	C		
	Nausea		Tylenol	C		
	Neurogenic Bladder					
	Pyrexia					
	Rhonchi					
	Sedation					
	Speech Disorder					
	Tremor					
	Urinary Incontinence					

Date:02/15/00ISR Number: 3458556-1Report Type:Expedited (15-DaCompany Report #HQ1029111FEB2000
Age:56 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization -	Drug Effect Decreased	Consumer	Reglan Tablet	PS		ORAL
30 MG 4X PER						
Initial or Prolonged	Heart Rate Decreased					
1 DAY, ORAL						
	Heart Rate Increased		Albuterol	C		
	Oesophageal Disorder		Astelin	C		
	Oesophageal Pain		Atacand	C		
	Vomiting		Atenolol	C		
			Ativan	C		
			Atrovent	C		
			Calcium Carbonate	C		
			Cardizem	C		
			Claritin	C		
			Compazine	C		
			Gtn	C		
			Guaifenesin	C		
			Kenalog	C		
			Lacri-Lube	C		

Lactaid	C
Levaquin	C
Levothyroxine	C
Levsinex	C
Lidocaine	C
Maalox	C
Nasacort	C
Nasonex	C
Nitrostat	C
Pamelor	C
Premarin	C
Prevacid	C
Proctofoam	C
Provera	C
Pulmicort	C
Serevent	C
Tilade	C
Tylenol W/Codeine No. 3	C

				Vasotec	C		
				Vitamin B12	C		

Date:02/17/00ISR Number: 3459062-0Report Type:Direct Company Report #
Age:71 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Atrioventricular Block		Metoclopramide	PS		INTRAVENOUS	10 MG IV Q6 X	
Other	Bradycardia						8 DOSES	

Date:02/17/00ISR Number: 3459489-7Report Type:Expedited (15-DaCompany Report #HQ1081115FEB2000
Age:1 DY Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Congenital Anomaly	Asthenia	Consumer	Reglan Injection	PS		TRANSPLACENTAL	TRANSPLACENTA	
	Complications Of Maternal						L	4 WK
	Exposure To Therapeutic		Tpn	SS		TRANSPLACENTAL	TRANSPLACENTA	
	Drugs						L	4 MON
	Congenital Torticollis		Zofran	SS		TRANSPLACENTAL	TRANSPLACENTA	
	Dysphagia						L	4 MON
	Dystonia							
	Face Oedema							

Date:02/18/00ISR Number: 3459361-2Report Type:Direct Company Report #
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Medication Error		Phenytoin	PS	Elkins-Sinn	INJECTABLE		

100 MG/2 ML

			Reglan (Metoclopramide)	SS	A.H. Robins

INJECTABLE 10

MG/2 ML

Date:02/18/00ISR Number: 3459996-7Report Type:Periodic Company Report #8-99116-043A
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Galactorrhoea	Health	Reglan Tabelt	PS		ORAL	ORAL	
		Professional						

Date:02/18/00ISR Number: 3459998-0Report Type:Periodic Company Report #8-99116-044A
Age:39 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Extrapyramidal Disorder	Health	Reglan Tablet	PS		ORAL	10 MG 1X PER	
		Professional					1 DAY, ORAL	
			Zoloft	SS		ORAL	150 MG DAILY,	

ORAL

Date:02/18/00ISR Number: 3460001-7Report Type:Periodic Company Report #8-99125-029A
Age:34 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Anxiety	Health	Reglan Tablet	PS		ORAL	10 MG ONE	
	Depression	Professional					BEFORE MEALS,	

ORAL

			Prevacid (Lansoprazole)	C		
			Xanax (Alprazolam)	C		

Date:02/18/00ISR Number: 3460002-9Report Type:Periodic Company Report #8-99160-109A
Age:70 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Tardive Dyskinesia	Health	Reglan Tablet	PS		ORAL	ORAL	
		Professional						

Date:02/18/00ISR Number: 3460005-4Report Type:Periodic Company Report #8-99200-159A
Age:30 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Sedation	Health	Reglan Tablet	PS		ORAL	5 TO 15 MG	
		Professional					DAILY, ORAL	
			Micronor (Norethindrone)	C				
			Prenatal Vitamin (Unspecified)	C				

Date:02/18/00ISR Number: 3460006-6Report Type:Periodic Company Report #8-99210-205A
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Anxiety	Health	Reglan Tablet	PS		ORAL	ORAL	
	Parkinsonism	Professional						

Date:02/18/00ISR Number: 3460007-8Report Type:Periodic Company Report #8-99223-072A
Age:61 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dyskinesia	Consumer	Reglan Tablet	PS		ORAL		
			"Digitalis"	C				
			Zantac	C				

Date:02/18/00ISR Number: 3460009-1Report Type:Periodic Company Report #8-90318-006F
Age:41 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Anhedonia	Consumer	Reglan Tablet	PS		ORAL	10 MG 4X PER	
	Depression						1 DAY	ORAL
	Ear Pain		Norgesic Forte	C				
	Headache							
	Insomnia							
	Neck Pain							
	Nervousness							
	Pain In Jaw							
	Suicidal Ideation							
	Tardive Dyskinesia							
	Tearfulness							

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Freedom Of Information (FOI) Report

Date:02/18/00ISR Number: 3460011-XReport Type:Periodic Company Report #8-99055-119A
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Neuroleptic Malignant Syndrome	Health Professional	Reglan Tablet	PS		ORAL	10 MG 1X PER 1 DAY, ORAL
Other							

Date:02/18/00ISR Number: 3460012-1Report Type:Periodic Company Report #8-99067-090A
Age:48 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Anxiety	Health Professional	Reglan Tablet	PS		ORAL	10 MG 4X PER 1 DAY, ORAL
Other	Dizziness		Reglan Tablet	SS			
	Laryngospasm		Reglan Tablet	SS			5MG 4X PER 1 DAY
	Nasal Congestion						
	Pulmonary Congestion		Reglan Tablet	SS			12.5 MG 1X PER 1 DAY
	Tongue Oedema						
			Reglan Tablet	SS			
			Prilosec (Omeprazole)	C			
			Allergy Relief Medicine	C			

Date:02/18/00ISR Number: 3460015-7Report Type:Periodic Company Report #8-99091-075A
Age: Gender:Not SpecifiI/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Death	Suicide Attempt	Health Professional	Reglan Tablet	PS		ORAL	ORAL

Date:02/18/00ISR Number: 3460016-9Report Type:Periodic Company Report #8-99125-040A
Age: Gender:Not SpecifiI/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Neuroleptic Malignant Syndrome	Health Professional	Reglan Tablet	PS		ORAL	ORAL	

Date:02/18/00ISR Number: 3460017-0Report Type:Periodic Company Report #8-99204-115A
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Bradycardia	Health Professional	Reglan Tablet	PS		ORAL	ORAL	

Date:02/18/00ISR Number: 3460018-2Report Type:Periodic Company Report #HQ3924128OCT1999
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Depression	Consumer	Reglan Tablet	PS		ORAL	ORAL	
	Hallucination, Auditory		Flonase	C				
			Tagamet	C				
			Oral Contraceptive Nos Unspecified	C				
			Antidepressant	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/18/00ISR Number: 3460019-4Report Type:Periodic Company Report #8-97211-002L
Age:53 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dystonia	Consumer	Reglan Tablet	PS		ORAL	10 MG/DAY,	ORAL

Date:02/18/00ISR Number: 3460021-2Report Type:Periodic Company Report #8-98362-034A
Age:74 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Abdominal Pain Upper	Consumer	Reglan Tablet	PS		ORAL	10 MG 3X PER	
	Nausea						1 DAY, ORAL	
			Synthroid (Levothyroxine)	C				

Date:02/18/00ISR Number: 3460022-4Report Type:Periodic Company Report #8-99057-059A
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blood Glucose Decreased	Consumer	Reglan Tablet	PS				
			Zantac (Ranitidine Hydrochloride)	C				

Date:02/18/00ISR Number: 3460024-8Report Type:Periodic Company Report #8-99072-009A
Age:52 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Breast Tenderness	Health	Reglan Tablet	PS		ORAL	10MG 3X PER 1	
	Gynaecomastia	Professional					DAY, ORAL	

			Reglan Tablet	SS		
20 MG 4X PER 1 DAY						
			Reglan Tablet	SS		
10 MG 2X PER 1 DAY						
			Reglan Tablet	SS		
20 MG 1X PER1 DAY						
			Prevacid (Lansoprazole)	C		

Date:02/18/00ISR Number: 3460025-XReport Type:Periodic Company Report #8-99097-076A
Age:51 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Angioneurotic Oedema	Health	Reglan Tablet	PS		ORAL		
ORAL								
	Drug Interaction	Professional	Prilosec (Omeprazole)	C				
			Biaxin (Clarithromycin)	C				
			Prilosec	I		ORAL		
20 MG DAILY,								
ORAL								

Date:02/18/00ISR Number: 3460028-5Report Type:Periodic Company Report #8-99120-094A
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blood Glucose Increased	Consumer	Reglan Tablet	PS		ORAL		
ORAL								
			Citrucel	SS		ORAL		
ORAL								

			Citrucel (Methycellulose)	C		

Date:02/18/00ISR Number: 3460030-3Report Type:Periodic Company Report #8-99133-033A
Age: Gender:Not SpecifiI/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Burning Sensation	Consumer	Reglan Tablet	PS		ORAL	ORAL	
	Weight Increased		Zantac (Ranitidine)	C				
			Dyazide (Triamterene &	C				

Date:02/18/00ISR Number: 3460031-5Report Type:Periodic Company Report #8-99139-152A
Age:81 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Withdrawal Syndrome	Health	Reglan Tablet	PS		ORAL	10 MG 4X PER	
	Extrapyramidal Disorder	Professional					1 DAY, ORAL	
			Cozaar (Losartan)	C				
			Zoloft (Sertraline)	C				
			Cimetidine	C				
			Questran (Cholestyramine)	C				

Date:02/18/00ISR Number: 3460035-2Report Type:Periodic Company Report #8-99223-084A
Age:66 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dermatitis Bullous	Health	Reglan Tablet	PS		ORAL	ORAL	
		Professional	Miacalcin (Calcitonin)	C				
			Calcium Supplement	C				

Date:02/18/00ISR Number: 3460037-6Report Type:Periodic Company Report #8-99238-043A
Age:48 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Anxiety	Health	Reglan Tablet	PS		ORAL	5 MG, 3 IN 1	
	Drug Interaction	Professional					DAY, ORAL	
	Hypertension		Prilosec	SS				
	Insomnia		Propulsid	SS		ORAL	10 MG, 4 IN 1	
	Nausea						DAY, ORAL	
	Tachycardia		Dulcolax	C				

Date:02/18/00ISR Number: 3460038-8Report Type:Periodic Company Report #8-99260-064A
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Depression	Consumer	Reglan Tablet	PS		ORAL	ORAL	
	Suicidal Ideation		Anaprox	C				
			Midrin	C				

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Freedom Of Information (FOI) Report

Date:02/18/00ISR Number: 3460040-6Report Type:Periodic Company Report #8-99006-014A
Age:69 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dizziness	Consumer	Reglan Tablet	PS		ORAL	10 MG 1X PER	1 DAY, ORAL
	Parkinsonism		Reglan Tablet	SS			10 MG 1X PER	1 DAY
			Prevacid (Lansoprazole)	C				

Date:02/18/00ISR Number: 3460044-3Report Type:Periodic Company Report #8-99069-146A
Age:55 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Tardive Dyskinesia	Consumer	Reglan Tablet	PS		ORAL	10 MG FOUR	TIMES DAILY,
			Insulin Nph	C				ORAL
			Insulin Regular	C				
			Choline Magnesium Trisalicylate	C				
			(Paroxetine Hcl)	C				
			Zoloft (Sertraline Hydrochloride)	C				

Date:02/18/00ISR Number: 3460045-5Report Type:Periodic Company Report #8-99097-130A
Age:30 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Akathisia	Consumer	Reglan Tablet	PS		ORAL	5 MG 4X PER 1	

	Diarrhoea						
DAY, ORAL							
	Nausea		Paxil (Paroxetine)	C			
			Prevacid (Lansoprazole)	C			

Date:02/18/00ISR Number: 3460188-6Report Type:Expedited (15-DaCompany Report #HQ0889402FEB2000
Age:10 DY Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Diarrhoea	Health	Reglan Syrup	PS		ORAL	1 CC 3X PER 1	
Initial or Prolonged	Dystonia	Professional						
DAY, ORAL; 10								
Other	Feeding Problem In Child							
CC OVERDOSE								
	Gait Disturbance							
AMOUNT, ORAL								
	Irritability		Afrin	C				
	Peristalsis Visible							
	Skin Discolouration							
	Vomiting							

Date:02/23/00ISR Number: 3462053-7Report Type:Expedited (15-DaCompany Report #00P-056-0087027-00(0)
Age:49 YR Gender:Male I/FU:I

Outcome	PT
Hospitalization -	Cerebellar Syndrome
Initial or Prolonged	Confusional State
	Gait Disturbance
	Pyrexia
	Rash Erythematous

Tremor

Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Foreign Health Professional	Tranxene (Tranxene) (Clorazepate Dipotassium)	PS		ORAL	30 MG, 1 IN 1 D, PER ORAL	
	Amikacin (Amikacin)	SS		INTRAVENOUS	1 GM, 1 IN 1 D,	
	Cytarabine (Cytarabine)	SS		INTRAVENOUS	365 MG, 1 IN 1 D,	
	Idarubicin Hydrochloride (Idarubicin Hydrochloride)	SS		INTRAVENOUS	15 MG, 1 IN 1 D,	
	Ondansetron Hydrochloride (Ondansetron Hydrochloride)	SS		INTRAVENOUS	INTRAVENOUS	
	Metoclopramide (Metoclopramide)	SS		INTRAVENOUS	30 MG, 1 IN 1 D,	
	Cefepime Hydrochloride (Cefepime					

			Hydrochloride)	C		
			Metronidazole (Metonidazole Metronidazole)	C		

Date:02/23/00ISR Number: 3463039-9Report Type:Periodic Company Report #9935094
Age:39 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dystonia	Health	Zoloft Tablets	PS		ORAL	150.00 MG	TOTAL DAILY
	Extrapyramidal Disorder	Professional						
	Gastrointestinal Disorder					ORAL		
			Metoclopramide	SS		ORAL	10.00 MG	TOTAL DAILY

ORAL

Date:02/29/00ISR Number: 3465571-0Report Type:Expedited (15-DaCompany Report #033-0955-M0000003
Age:65 YR Gender:Female I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Abdominal Pain
	Abnormal Behaviour
	Chorea
	Drug Interaction
	Dystonia
	Electrocardiogram Qrs Complex Prolonged
	Gastroenteritis

	Hypoglycaemia Hyponatraemia Overdose	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Renal Failure Acute Speech Disorder Trismus	Foreign Health Professional	Acuilix Tablets (Hydrochlorothiazide, Quinapril)	PS		ORAL	UNK PER ORAL
			Cipralan (Cibenzoline Succinate)	SS		ORAL	260 MG DAILY PER ORAL
			Nureflex (Ibuprofen)	SS		ORAL	UNK PER ORAL
			Primperan (Metoclopramide)	SS		ORAL	UNK PER ORAL
			Kaleorid Leo (Potassium Chloride)	C			
			Kardegic (Acetylsalicylate Lysine)	C			
			Lipanthyl (Fenofibrate)	C			
			Sargenor (Arginine Aspartate)	C			
			Visceralgine Forte (Codeine, Tiemonium, Metamizole Sodium)	C			
			Rowasa (Mesalazine)	C			

Date:03/01/00ISR Number: 3467060-6Report Type:Expedited (15-DaCompany Report #FLUV00399000009
Age:14 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Drug Interaction Dysarthria	Foreign Literature	Fluvoxamine	PS		ORAL	50 MG DAILY PO
	Dystonia Extrapyramidal Disorder	Other	Metoclopramide	SS		ORAL	10 MG TIDA PO

Movement Disorder
Nystagmus
Tongue Disorder
Trismus

Date:03/01/00ISR Number: 3467295-2Report Type:Expedited (15-DaCompany Report #LACT00399000404
Age:62 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Peritonitis	Foreign	Lactulose	PS		ORAL	10 ML QD PO	
	Stevens-Johnson Syndrome	Other	Paspertin	SS			INTRAVENOUS	1 DF BID IV
			Zyloric 300	SS		ORAL	1 DF QD PO	
			Novalgin	SS			SEE IMAGE	
			Ampicillin	SS			INTRAVENOUS	2 G BID IV
			Staphylex	SS			INTRAVENOUS	2 G BID IV
			Claforan	SS			INTRAVENOUS	2 G BID IV
			Refobacin	SS			INTRAVENOUS	160 MG QD IV
			Mogadan	SS		ORAL	1 DF QD PO	
			Lasix	SS			INTRAVENOUS	40 MG QD IV
			Oxazepam	SS		ORAL	DAILY PO	
			Tramal	SS		ORAL	20 DF QID PO	
			Cotrim Forte	SS	Ratiopharm	ORAL	1 DF BID PO	
			Combaren	SS		ORAL	DAILY PO	
			Imeson	SS		ORAL	DAILY PO	

		Laxoberal	SS	ORAL
DAILY PO				
DAILY PO		Ben-U-Ron	SS	ORAL
		Tarivid	SS	ORAL
2 DF QD PO				
		Psyquil	SS	
INTRAVENOUS	DAILY IV			
		Urbason	SS	
SEE IMAGE				
		Tavegil	SS	
SEE IMAGE				
		Zyrtec	SS	ORAL
1 DF BID PO				
		Nizax	SS	ORAL
1 DF QD PO				
		Bepanthen	SS	ORAL
1 DF QID PO				
		Myrrhetincture	SS	
DAILY TP				
		Volon A-Schuettelmix	SS	
DAILY TP				
		Baby-Oil	SS	
DAILY TP				
		Laceran	SS	
DAILY TP				
		Pantozol	SS	ORAL
1 DF QD PO				
		Heparin	SS	
SUBCUTANEOUS	7500 IU BID			
SC				
		Bronchoretard 350/ Mite	SS	ORAL
1 DF BID PO				
		Serevent Metered Dose Aerosol	SS	
RESPIRATORY				
(INHALATION)	2 DF BI IH			
		Flutide N 125 Metered Dose Aerosol	SS	
RESPIRATORY				
(INHALATION)	2 DF TID IH			
		Glucose 5 %	SS	
INTRAVENOUS	1000 ML QD IV			

		Nacl 0.9 %	SS	
INTRAVENOUS	2500 ML, QD			
IV				
		Rekawan	SS	ORAL
1 DF TID PO				
		Eugalac	SS	ORAL
1 DF QD PO				
		Ringers Solution	SS	
1 DF QD TP				
		Betaisodona	SS	
1 DF QD TP				
		Spasmex 5	SS	ORAL
2 DF TID PO				
		Acimethin	SS	ORAL
2 DF TID PO				
		Spasmo-Urgenin Tc	SS	ORAL
2 DF TID PO				
		Azuprostat M	SS	ORAL
1 DF TID PO				
		Lichtenstein Gelb	C	ORAL
1 DF QD PO				
		Parenteral	C	
INTRAVENOUS	1`500 ML QD			
IV				
		Paspertin	C	
		Laxans	C	
		Lasix	C	
		Fosfocin	C	
		Tranxilum	C	
		Kalinor	C	
		Diazepam	C	

Date:03/01/00ISR Number: 3467405-7Report Type:Expedited (15-DaCompany Report #10083624
Age: Gender:Male I/FU:F

Outcome	PT
Life-Threatening	Blood Albumin Decreased
Hospitalization - Initial or Prolonged	C-Reactive Protein Increased
Other	Gastrointestinal Disorder
	Haemoglobin Decreased
	Hepatic Failure
	Hepatitis
	Hepatocellular Damage
	Ileus Paralytic
	Implant Site Infection

	Liver Function Test Abnormal Lymphoma Mental Disorder Oesophageal Candidiasis Toxoplasmosis	Report Source	Product	Role	Manufacturer	Route	Dose Duration
		Foreign Health Professional	Zerit Caps (Stavudine)	PS		ORAL	80 MILLIGRAM, 1 DAY ORAL
		Other	Sustiva (Efavirenz)	SS		ORAL	300 MILLIGRAM, 1 DAY ORAL
			Lamivudine	SS		ORAL	300 MILLIGRA, 1 DAY ORAL
			Clindamycin	SS		ORAL	1200 MILLIGRA, 1 DAY ORAL
			Calcium Folinate	SS		ORAL	15 MILLIGRAM, 1 DAY ORAL
			Ciprofloxacin	SS		ORAL	1000 MILLIGRAM, 1 DAY ORAL
			Clarithromycin	SS		ORAL	1000 MILLIGRAM, 1 DAY ORAL
			Rifabutin	SS		ORAL	300 MILLIGRAM, 1 DAY ORAL

				Diflucan (Fluconazole)	SS			
INTRAVENOUS	200 MILLIGRAM, 1 DAY IV							
				Heparin	SS			
INTRAVENOUS	15000 INTERNATIONAL UNIT, 1 DAY IV							
				Metamizol (Dipyrone)	SS			
INTRAVENOUS	5 GRAM, IV							
				Pyrimethamine	SS			ORAL
100 MILLIGRAM, 1 DAY ORAL								
				Metoclopramide (Metoclopramide Hc1)	SS			ORAL
ORAL								

Date:03/02/00ISR Number: 3466599-7Report Type:Direct Company Report #USP 52874
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Medication Error		Metoprolol Tartrate	PS	Abbott			
			Metoclopramide	SS	Abbott			

Date:03/03/00ISR Number: 3468941-XReport Type:Expedited (15-DaCompany Report #10287688
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Convulsion	Foreign	Briplatin					
Life-Threatening	Loss Of Consciousness	Literature	(Cisplatin)	PS				
INTRAVENOUS	100 MILLIGRAM							
Other		Health						
,1/1 DAY IV								
		Professional	Taxotere (Docetaxel)	SS				
INTRAVENOUS	100							
		Other						
MILLIGRAM,								

1/1 DAY IV

Primperan
(Metoclopramide Hcl) SS

INTRAVENOUS 20 MILLIGRAMS

19-Aug-2005 10:55 AM

, 1/1 DAY IV				
			Droleptan (Droperidol)	SS
INTRAVENOUS	.5 MILLIGRAM			
, 1/1 DAY IV				
			Kytril (Granisetron Hcl)	SS
INTRAVENOUS	6 MILLIGRAM			
,1/1 DAY IV				
			Decadron (Dexamethasone)	SS
INTRAVENOUS	.2 MILLIGRAMS			
, 1/1 DAY IV				
			Polaramine (Chlorpheniramine Maleate)	SS
INTRAVENOUS	10 MILLIGRAM			
,1/1 DAY IV				

Date:03/08/00ISR Number: 3471732-7Report Type:Expedited (15-DaCompany Report #AM00020002
Age:55 YR Gender:Male I/FU:F

Outcome	Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - Initial or Prolonged	INTRAVENOUS	2056.6 MG	Asthenia Blood Pressure Decreased Dizziness Dystonia Feeling Jittery Hypotension Lethargy Pallor Sedation Vomiting	Foreign Study Health Professional	Ethyol (Amifostine) Soluble Powder Maxolon Injectable Melphalan Injectable Allopurinol Tropisetron Dexamethasone	PS SS C C C C		INTRAVENOUS

Date:03/15/00ISR Number: 3475965-5Report Type:Expedited (15-DaCompany Report #HQ1081115FEB2000
Age:1 DY Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Congenital Anomaly	Asthenia	Health	Reglan Injection	PS				
TRANSPLACENTAL	TRANSPLACENTA							
	Complications Of Maternal	Professional						
L							4	MON
	Exposure To Therapeutic		Tpn	SS				
TRANSPLACENTAL	TRANSPLACENTA							
	Drugs							
L							4	MON
	Dyskinesia Neonatal		Zofran	SS				
TRANSPLACENTAL	TRANSPLACENTA							
	Dysphagia							
L							4	MON
	Dystonia							
	Face Oedema							
	Feeding Problem In Newborn							
	Muscle Contractions Involuntary							
	Nervous System Disorder							
	Torticollis							

Date:03/15/00ISR Number: 3476420-9Report Type:Direct Company Report #
Age:28 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Anxiety	Health	Reglan	PS		ORAL	10 MG PO QID	
	Flushing	Professional					PRN	
	Nervousness		Atenolol	SS			25 MG TID PRN	
			Celexa	C				
			Wellbutrin	C				

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Freedom Of Information (FOI) Report

Date:03/16/00ISR Number: 3475988-6Report Type:Direct Company Report #
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Ventricular Extrasystoles		Metoclopramide	PS				

Date:03/20/00ISR Number: 3478285-8Report Type:Expedited (15-DaCompany Report #HQ1557214MAR2000
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Aphasia	Consumer	Reglan Tablet	PS		ORAL	ORAL	
	Drug Interaction		Paxil	SS		ORAL	ORAL	
	Extrapyramidal Disorder							
	Eye Disorder							
	Laryngospasm							
	Movement Disorder							
	Muscle Twitching							
	Mydriasis							
	Photophobia							
	Photosensitivity Reaction							
	Pupillary Light Reflex							
	Tests Abnormal							
	Tremor							

Date:03/21/00ISR Number: 3479523-8Report Type:Periodic Company Report #HQ2260213OCT1999
Age:27 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Ineffective	Health Professional	Reglan Injection	PS		INTRAVENOUS	30 MG DAILY,	
			Reglan Injection	SS		INTRAVENOUS	35 MG DAILY,	

				Reglan Injection	SS		
INTRAVENOUS	DOSE UNKNOWN,						
INTRAVENOUS							
				Phenergan "Rhone -Poulenc"	C		

Date:03/21/00ISR Number: 3479524-XReport Type:Periodic Company Report #8-99208-123A
Age:8 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Depression	Health	Reglan Injection	PS				
INTRAVENOUS	DOSE UNKNOWN,							
	Hyperhidrosis	Professional						
INTRAVENOUS								
	Tremor	Company Representative						

Date:03/21/00ISR Number: 3479525-1Report Type:Periodic Company Report #8-99208-124A
Age:28 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Depression	Health	Reglan Injection	PS				
INTRAVENOUS	5 MG OR 10							
	Hyperhidrosis	Professional						
MG,								
	Tremor	Company						
INTRAVENOUS								
		Representative						

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Freedom Of Information (FOI) Report

Date:03/21/00ISR Number: 3479527-5Report Type:Periodic Company Report #8-99167-132A
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Overdose	Health	Reglan Injection	PS		INTRAVENOUS	DOSE UNKNOWN,	
		Professional				INTRAVENOUS		

Date:03/21/00ISR Number: 3479528-7Report Type:Periodic Company Report #8-98351-035A
Age:20 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Parkinsonism	Health	Reglan Injection	PS		INTRAVENOUS	10 MG AT 12:40 PM,	
Other		Professional				INTRAVENOUS		
			Fentanyl	SS		INTRAVENOUS	ONE 75 MCG DOSE,	
			Nubain	SS		INTRAVENOUS	10 MG,	
			Versed	SS		INTRAVENOUS	5 DOSES TOTALING 6.5 MGM	
			Benadryl (Diphenhydramine)	C		INTRAVENOUS		
			Fentanyl	C				
			Nubain (Nalbuphine)	C				
			Versed (Midazolam)	C				

Date:03/23/00ISR Number: 3479221-0Report Type:Expedited (15-DaCompany Report #231113
Age:41 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blood Pressure Decreased	Foreign	Rocephin					
	Discomfort	Health	(Ceftriaxone Sodium)	PS				
						INTRAVENOUS		
	Dizziness	Professional					DRIP	
							1 GRAM DAILY	
	Extrapyramidal Disorder							
						INTRAVENOUS		
	Facial Palsy							
							DRIP	
	Flushing		Scopolamine					
	Headache		Butylbromide					
	Loss Of Consciousness		(Scopolamine					
	Respiratory Rate		Butylbromide)	SS				
						INTRAVENOUS		
	Increased						DRIP	
							1 DOSE FORM	
	Shock							
							DAILY	
	White Blood Cell Count							
						INTRAVENOUS		
	Increased							
							DRIP	
			Metoclopramide					
			(Metoclopramide					
			Hydrochloride)	SS				
						INTRAVENOUS		
							DRIP	
							7 MG DAILY	
						INTRAVENOUS		
							DRIP	

Date:03/23/00ISR Number: 3479238-6Report Type:Expedited (15-DaCompany Report #WAES 00035130
Age:42 YR Gender:Female I/FU:I

Outcome	PT
Death	Gastric Haemorrhage
	Gastritis Erosive

Haematemesis

Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Foreign Health	Tab Vioxx (Rofecoxib)	PS		ORAL	12.5 MG PO	
Professional	Tab Aluminum Hydroxide/Mg Trisilicate	SS			500 MG	
	Cap Lansoprazole	SS		ORAL	30 MG PO	
	Tab Thioridazine	SS			50 MG	
	Morphine	SS		ORAL	SEE IMAGE	47 DAY
	Tab Acetaminophen/Propoxyphene Hydrochloride	SS			1-4 TABLET	
	Tab Estradiol Valerate	SS		ORAL	2 MG PO	
	Soln Lactulose	SS			3.35 MG/5 ML	
	Tab Metoclopramide	SS			GM	
	Tab Prednisolone	SS			30 PRN MG	
	Diazepam	C			2.5 MG	
	Nefazodone	C				

Date:04/10/00ISR Number: 3487246-4Report Type:Periodic Company Report #HQ0787328JAN2000
Age:4 MON Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Convulsion Dyskinesia	Health Professional	Reglan Syrup Acel-Imune Vaccine	PS SS		INTRAMUSCULAR	1 DOSE 1X PER 1 DAY,	

INTRAMUSCULAR

			Hib-Titer Vaccine	SS		
INTRAMUSCULAR	1 DOSE 1X PER 1 DAY,					
INTRAMUSCULAR			Poliomyelitis Vaccine "Merieux"	SS		
INTRAMUSCULAR	1 DOSE 1X PER 1 DAY,					

INTRAMUSCULAR

Date:04/10/00ISR Number: 3487247-6Report Type:Periodic Company Report #8-99130-131A
Age:88 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Fatigue	Consumer	Reglan Syrup	PS		ORAL	5 CC 2X PER 1	
	Weight Decreased						DAY, ORAL	
			Lasix	C				
			Nitroglycerin Patch	C				
			Plavix	C				
			Zestril	C				

Date:04/10/00ISR Number: 3487250-6Report Type:Periodic Company Report #HQ3270622OCT1999
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Constipation	Health	Reglan Syrup	PS		ORAL	0.5 ML 3X PER 1 DAY, ORAL	
	Diarrhoea	Professional						

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/14/00ISR Number: 3488453-7Report Type:Direct Company Report #
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Constipation		Metoclopromide 5mg					
	Feeling Jittery		Tid	PS			5MG TID	
	Headache							

Date:04/21/00ISR Number: 3490847-0Report Type:Direct Company Report #
Age:29 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required	Dystonia		Reglan 10 Mg Tablet	PS		ORAL	1 TAB PO Q 6	
Intervention to	Trismus							
Prevent Permanent Impairment/Damage							HOURS	1 DAY

Date:04/21/00ISR Number: 3491279-1Report Type:Expedited (15-DaCompany Report #2000CG00266
Age:71 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Cholestasis	Foreign	Diprivan	PS			INTRAVENOUS	500 MG DAILY
Initial or Prolonged	Hepatic Cirrhosis	Health					IV	
	Hepatic Fibrosis	Professional	Forene	SS			RESPIRATORY	
	Hepatic Steatosis	Other					(INHALATION)	
	Hepatitis		Sufenta	SS			INTRAVENOUS	TOTAL DAILY
	Hepatocellular Damage						DOSE: 50 MCG,	
	Hyperbilirubinaemia						INTRAVENOUS	
	Liver Function Test		Nimbex	SS			INTRAVENOUS	TOTAL DAILY

	Abnormal		
DOSE: 5 MG			
	Post Procedural		
INTRAVENOUS			
	Complication	Sermion	SS
	Prothrombin Time	Mopral	SS
	Prolonged	Morphine	SS
	Vocal Cord Paralysis	Solumedrol	SS
		Fonzylane	SS
		Tranxene	SS
		Vogalene	SS
		Primperan	SS
		Clamoxyl	SS
		Augmentin	SS
		Lovenox	SS
		Imovane	SS
		Diffu-K	SS

Date:04/24/00ISR Number: 3491686-7Report Type:Expedited (15-DaCompany Report #HQ1557214MAR2000
Age:52 YR Gender:Male I/FU:F

Outcome	PT
Disability	Akathisia
	Aphasia
	Diarrhoea
	Drug Interaction
	Dysarthria
	Dysuria
	Extrapyramidal Disorder
	Fear
	Irritability
	Laryngospasm

	Muscle Twitching Mydriasis Photophobia	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Photosensitivity Reaction	Health	Reglan Tablet	PS		ORAL	10 MG TWO
	Pupillary Reflex Impaired	Professional					TWICE DAILY,
	Restlessness						ORAL
	Throat Tightness		Cimetidine	SS			
	Tic		Paxil	SS		ORAL	20 MG AT
	Tremor						BEDTIME FOR 3 WEEKS, INCREASED TO 40 MG AT
			Paxil	SS		ORAL	ORAL

Date:04/26/00ISR Number: 3492564-XReport Type:Direct Company Report #
Age:50 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Other	Galactorrhoea		Reglan 10mg Tablets	PS		ORAL	10MG PO AC HS; 6 MONTHS PRIOR

Date:05/01/00ISR Number: 3495517-0Report Type:Expedited (15-DaCompany Report #200010890HPD
Age:60 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Death	Blister	Foreign	Novalgin Tropfen				

Life-Threatening			Dermatitis		Study	Drops	PS	ORAL
20 DROP/ DAY								
			Erythema		Health			
PO	1	DAY						
			Lip Disorder		Professional	Lasix Tablets	SS	ORAL
QAM PO	6	DAY						
			Mucosal Erosion		Other	Euglucon Tablets	SS	ORAL
QAM PO	18	DAY						
			Mucous Membrane Disorder			Euglucon Tablets	SS	ORAL
QAM PO	2	DAY						
			Pneumonia Sepsis Shock			Penicillin G Solution For Injection	SS	
INTRAVENOUS	10	MGU	BID IV	6	DAY			
			Toxic Epidermal			Ass 100 Tablets	SS	ORAL
100 MG QD PO	1	DAY						
			Necrolysis			Aquaphor Tablets	SS	ORAL
40 MG QAM PO	1	DAY						
						Aquaphor Tablets	SS	ORAL
40 MG QAM PO	1	WK						
						Unat 40 Tablets	SS	ORAL
40 MG QAM PO	23	DAY						
						Pres 5 Tabelts	SS	ORAL
5 MG AM & PM								
PO	1	WK						
						Heparin Solution For Injection	SS	
SUBCUTANEOUS	7500	IU	BID					
SC	8	DAY						
						Dilatrend Tablets	SS	ORAL
3.25 MG AM &								
PM PO	19	DAY						
						Digimerck Minor Tablets	SS	ORAL
QAM PO	4	DAY						
						Paspertin Drops	SS	ORAL
20 DROP TID								
PO	5	DAY						
						Paspertin Drops	SS	ORAL
20 DROP TID								
PO	10	DAY						
						Fragmin Forte Solution For Injection	SS	
SUBCUTANEOUS	QD	SC		12	DAY			
						Xanef 5 Tablets	SS	ORAL
5 MG AM & PM								

PO 12 DAY

Isoket Ret. 60
Tablets SS ORAL

60 MG QAM PO 5 DAY

					Vancomycin 500	SS		
INTRAVENOUS	IV	6	DAY					
					Lopirin Cor	C		
					Eryfer	C		
					Novodigal	C		
					Antra	C		
					Irenat Tropfen	C		
					Depot H Insulin	C		
					Carbimazol	C		
					Zocor	C		
					Dopamin	C		
					Bepanthen	C		
					Paspertin	C		
					Tutofusin	C		
					Kalium Duriles Ret.	C		
					Kalium Brausetabletten	C		
					Kaliumchlorid	C		
					Kalinor	C		
					Sterofundin	C		
					Sterofundin + Glucose	C		
					Glucose + Kaliumchlorid	C		
					Tavegil	C		
					Solu Decortin	C		
					See Image ... Met	C		
					Paracetamol	C		
					Sortis	C		
					Zienam	C		

Date:05/01/00ISR Number: 3495582-0Report Type:Expedited (15-DaCompany Report #WAES 00045587
Age:61 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Bacterial Infection	Foreign	Tab Vasotec					
Life-Threatening	Blister	Other	(Enalapril Maleate)	PS		ORAL	10 MG PO	
	Cardiac Failure		Glyburide	SS		ORAL	3.5 MG PO	2 DAY
	Congestive		Glyburide	SS		ORAL	3.5 MG PO	
	Condition Aggravated		Aspirin	SS		ORAL	100 MG PO	

		Lip Disorder		
40 MG PO	7	DAY		
		Sepsis		
40 MG PO				
		Shock		
20 DROPS PO	1	DAY		
		Toxic Epidermal Necrolysis		
10 MG PO	7	DAY		
SUBCUTANEOUS	15000 IU SC		8	DAY
12.50 MG PO				
0.07 MG PO				
60 DROPS PO	5	DAY		
60 DROPS PO				
SUBCUTANEOUS	5000 IU SC			
60 MG PO				
INTRAVENOUS	20 MILL IU IV		6	DAY
INTRAVENOUS	UNK IV		6	DAY
500 MG PO				

Tab Xipamide	SS	ORAL
Tab Torsemide	SS	ORAL
Orso Dipyrone	SS	ORAL
Tab Vasotec (Enalapril Maleate)	SS	ORAL
Inj Heparin	SS	
Tab Carvedilol	SS	ORAL
Tab Digitoxin	SS	ORAL
Orso Metoclopramide	SS	ORAL
Orso Metoclopramide	SS	ORAL
Inj Dalteparin Sodium Salt	SS	
Tab Isosorbide Dinitrate	SS	ORAL
Benzylpenicillin Na	SS	
Vancomycin	SS	
Tab Furosemide	SS	ORAL
Zocor	C	
Carbimazole	C	
Dexpanthenol	C	
Dopamine	C	

			Electrolytes	C		
			Glucose Preparation/Kcl	C		
			Insulin	C		
			Metoclopramide	C		
			Nutritional Supplements	C		
			Omeprazole	C		
			Potassium Chloride	C		
			Sodium Perchlorate	C		

Date:05/03/00ISR Number: 3496210-0Report Type:Direct Company Report #
Age:58 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Hypertension	Health Professional	Metoclopramide 10mg Pre-Op	PS				
	Myocardial Infarction		Zantac	C				
	Phaeochromocytoma		Diprivan/Lidocaine	C				
	Pulmonary Oedema		Versed	C				
	Renal Impairment							

Date:05/04/00ISR Number: 3495977-5Report Type:Direct Company Report #
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Heart Rate Increased		Metoclopramide	PS		INTRAVENOUS	0.12M	Q8HOURS
	Supraventricular					IV		
	Tachycardia		Caffeine Citrate	C				
			Albuterol Nebs	C				
			Ipratroptium	C				
			Epogen	C				

Date:05/05/00ISR Number: 3497421-0Report Type:Expedited (15-DaCompany Report #HQ5222103MAY2000
Age:23 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Other	Bruxism	Literature	Reglan Tablet	PS	ORAL
15 MG 4X PER					
	Dystonia				
1 DAY, ORAL					
	Ear Pain		Sertraline	SS	ORAL
50 MG DAILY,					
	Extrapyramidal Disorder				
ORAL 3 DAY					
	Major Depression				
	Muscle Spasms				
	Pain				

Date:05/08/00ISR Number: 3498511-9Report Type:Expedited (15-DaCompany Report #WAES 00041983
Age:60 YR Gender:Female I/FU:I

Outcome	PT
Death	Blister
Life-Threatening	Cardio-Respiratory Arrest
Hospitalization - Initial or Prolonged	Dermatitis
	Dyspnoea
	Erythema
	Genital Ulceration
	Lip Ulceration
	Pleural Effusion
	Sepsis

		Toxic Epidermal Necrolysis					
			Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
			Foreign	Tab Vasotec (Enalapril Maleate)	PS		ORAL
10 MG	1 WK						
				Dilatrend (Carvedilol)	SS		ORAL
				Paspertin (Metoclopramide Monohcl - Monohydrate)	SS		ORAL
PO	1 DAY						
				Unat (Torsemide)	SS		ORAL
PO							
				Digimerck Minor (Digitoxin)	SS		ORAL
PO							
				Fragmin (Tedelparin Sodium)	SS		
INTRAVENOUS	IV						
				Isoket (Isosorbide Dinitrate)	SS		ORAL
PO							
				Lasix (Furosemide)	SS		
				Euglucon (Glyburide)	SS		
				Aquaphor (Xipamide)	SS		
				Novalgin (Dipyrone)	SS		
				Heparin Ca	SS		
				Lopirin (Captopril)	SS		
				Zocor (Simvastatin)	SS		
				Penicillin (Drug)	SS		
				Penicillin G K	SS		
				Vancomycin	SS		
				Aspirin	SS		

Date:05/10/00ISR Number: 3498899-9Report Type:Expedited (15-DaCompany Report #HQ5392304MAY2000
Age: Gender:Male I/FU:I

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Other		Dystonia Movement Disorder Nervous System Disorder	Consumer	Reglan	PS	Ah Robins Co	

	Respiratory Disorder					
	Speech Disorder					

Date:05/10/00ISR Number: 3499006-9Report Type:Expedited (15-DaCompany Report #HQ5230303MAY2000
Age:14 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Interaction	Literature	Reglan	PS	Ah Robins Co	ORAL	10 MG 3X PER	1 DAY, ORAL
Other	Dysarthria							
	Dyskinesia		Fluvoxamine (Fluvoxamine)	SS		ORAL	50 MG 1X PER	1 DAY, ORAL
	Dystonia							
	Extrapyramidal Disorder							
	Movement Disorder							
	Nystagmus							
	Trismus							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/11/00ISR Number: 3498682-4Report Type:Direct Company Report #
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Medication Error		Metoclopramide Hydrochloride	PS	Abbott Labs			
			Metoprolol	SS	Abbott Labs			

Date:05/11/00ISR Number: 3498890-2Report Type:Direct Company Report #
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Constipation	Health	Reglan	PS		ORAL	10 MG PO QID	
	Decreased Appetite	Professional						
	Vomiting							

Date:05/11/00ISR Number: 3499545-0Report Type:Expedited (15-DaCompany Report #HQ1557214MAR2000
Age:52 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Aphasia	Health	Reglan Tablet	PS		ORAL	SEE IMAGE	
	Diarrhoea	Professional	Cimetidine	SS				
	Dysuria		Paxil	SS		ORAL	SEE IMAGE	
	Extrapyramidal Disorder		.....	C				
	Eye Movement Disorder		...	C				
	Irritability							
	Laryngospasm							
	Movement Disorder							
	Muscle Twitching							
	Mydriasis							
	Photophobia							
	Photosensitivity Reaction							
	Restlessness							
	Speech Disorder							
	Throat Tightness							
	Tic							
	Tremor							

Date:05/12/00ISR Number: 3499552-8Report Type:Direct Company Report #USP 53041
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Medication Error		Pitocin (Oxytocin)	PS	Amer Pharm Partner			
			Reglan					
			Metoclopramide	SS	Faulding Pharm			

Date:05/15/00ISR Number: 3500746-3Report Type:Expedited (15-DaCompany Report #HQ5724311MAY2000
Age:11 WK Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Chest X-Ray Abnormal	Consumer	Reglan	PS	Ah Robins Co	ORAL	3 ML EVERY 6	
	Hyperhidrosis						HOURS, ORAL	
	Irritability		Augmentin Oral	C				
	Lung Disorder		Prednisolone	C				
	Medication Error		Zantac	C				
	Tardive Dyskinesia							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/16/00ISR Number: 3501028-6Report Type:Expedited (15-DaCompany Report #HQ5724311MAY2000
Age:11 WK Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Chest X-Ray Abnormal	Consumer	Reglan	PS	Ah Robins Co	ORAL	3 ML EVERY 6	
	Hyperhidrosis						HOURS, ORAL	
	Irritability		Augmentin	C				
	Lung Disorder		Prednisolone	C				
	Medication Error		Zantac	C				
	Tardive Dyskinesia							
	Tongue Disorder							

Date:05/17/00ISR Number: 3503107-6Report Type:Expedited (15-DaCompany Report #234733
Age:60 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Blister	Foreign	Unat (Torsemide Or					
	Lip Ulceration	Study	Torsemide Sodium) 40					
	Nausea	Health	Mg	PS	Hoffmann La Roche			
	Rash Maculo-Papular	Professional			Inc	ORAL	40 MG 1 PER	
	Shock						DAY ORAL	
	Toxic Epidermal		Lasix	SS		ORAL	1 PER DAY	
	Necrolysis						ORAL	
			Dilatrend 6.25	SS		ORAL	6.25 MG 2 PER	
							DAY ORAL	
			Heparin-Calcium	SS				
SUBCUTANEOUS	7500 IU 2 PER							
DAY								
SUBCUTANEOUS								
			Paspertin (Metoclorpmide Hydrochloride)	SS		ORAL	20 DROP 3 PER	

DAY ORAL					
			Xanef 5 (Enalapril Maelate) 5 Mg	SS	ORAL
5 MG 2 PER					
DAY ORAL					
			Benzylpenicillin	SS	
INTRAVENOUS	10 MILLIONIU				
2 PER DAY					
INTRAVENOUS					
			Aquaphor (Cerssin/Mineral Oil/Perolatum/Cool Alcohol Or Xipamide) 40 Mg	SS	ORAL
40 MG 1 PER					
ONCE DOSE					
ORAL					
			Pres (Enalapril Maleate) 5mg	SS	ORAL
5 MG 2 PER					
DAY ORAL					
			Ass (Aspirin) 100 Mg	SS	ORAL
100 MG 1 PER					
DAY ORAL					
			Novalgin Dipyrone)	SS	ORAL
DROP 1 PER					
ONE DOSE ORAL					
			Vancomycin (Vancomycin Hydrochloride) 500 Mg	SS	
INTRAVENOUS	INTRAVENOUS				
			Isoket Retard 60 (Isosorbide Dinitrate) 60 Mg	SS	ORAL
60 MG 1 PER					
DAY ORAL					

		Fragmin P Forte (Dalteparin Sodium)	SS		
SUBCUTANEOUS	1DOSE FORM 1 PER DAY				
SUBCUTANEOUS	1 PER DAY	Digimerch	SS		ORAL
ORAL	1 DOSE FORM 1 PER DAY ORAL	Euglucon	SS		ORAL
		Lopirin Cor	C		
		(Ferrous Sulfate)	C		
		Novodigal	C		
		Entra	C		
		Irenat	C		
		Depot-Insulin	C		
		Carbimazol	C		
		Zocor	C		
		Dopmin	C		
		Paspertin	C		
		Tutofusin	C		
		Daliumchlorid	C		
		Kaliumchlorid	C		
		Klinor	C		
		Sterofunidin	C		
		Glusose 5%	C		
		Kalinor	C		
		Tavegil	C		
		Solu-Decrotin H	C		
		Tagamet Intravenous	C		
		Paracetamol	C		
		Sortis	C		
		Zienam	C		
		Bepanthen Injektionsloesung	C		

Date:05/18/00ISR Number: 3501481-8Report Type:Direct Company Report #
Age:35 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Life-Threatening	Blood Pressure Decreased	Health	Metoclopramide			
Required	Dystonia	Professional	10mg/2ml Inj	PS		
INTRAVENOUS 10MG IVP						
Intervention to	Extrapyramidal Disorder		Bupivacaine/Epi	C		
Prevent Permanent	Loss Of Consciousness		Oxytocin	C		
Impairment/Damage						

Date:05/22/00ISR Number: 3503551-7Report Type:Expedited (15-DaCompany Report #1999005153GB
Age:7 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Toxic Epidermal	Foreign	Neosar	PS	Pharmacia And Upjohn	
	Necrolysis	Health			Co	
INTRAVENOUS 1044 MG, QD,						
		Professional				
IV						
		Other	Cyclosporin A			
			(Ciclosporin)	SS		
45 MG, BID,						
UNK						
			Codeine Phosphate			
			(Cyclophosphamide)	SS		ORAL
15 MG, QD,						
ORAL						
			Chlorpheniramine			
			(Chlorphenamine)	SS		
4 MG, PRN,						

UNK				
		Paracetamol (Paracetamol)	SS	ORAL
360 MG, PRN,				
ORAL				
		Vancomycin (Vancomycin)	SS	
INTRAVENOUS	270 MG, TID,			
IV				
		Ceftazidime (Ceftazidime)	SS	
INTRAVENOUS	900 MG, TID,			
IV				
		Fludarabine (Fludarabine)	SS	
INTRAVENOUS	18 MG, QD, IV			
		Ondansetron (Ondansetron)	SS	
4 MG, PRN,				
UNK				
		Anti-Humanlymphozyte n-Globulin (Antilymphocyte Immunoglobulin (Horse))	SS	
INTRAVENOUS	219 MG, QD,			
IV				
		Metoclopramide (Metoclopramide)	SS	
5 MG, PRN,				
UNK				
		Meropenem (Meropenem)	SS	
INTRAVENOUS	360 MG, TID,			
IV				
		Acyclovir (Aciclovir)	SS	
INTRAVENOUS	175 MG, TID,			
IV				

			Fluconazole (Fluconazole)	SS		ORAL	50 MG, QD, ORAL
			Nifedipine (Nifedipine)	SS		ORAL	5 MG, PRN, ORAL
			Sandoglobulin (Immunoglobulin Human Normal)	SS		INTRAVENOUS	16.7 G, WEEKLY, IV
			Cyklokapron (Tranexamic Acid) Tablet	SS		ORAL	400 MG, TID, ORAL

Date:05/23/00ISR Number: 3503344-0Report Type:Expedited (15-DaCompany Report #HQ6101018MAY2000
Age:60 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Renal Failure Acute	Health Professional	Reglan	PS	Ah Robins Co	ORAL	30 MG BEFORE MEALS AND AT BEDTIME, ORAL	

Date:05/23/00ISR Number: 3503589-XReport Type:Expedited (15-DaCompany Report #1365245A
Age:53 YR Gender:Female I/FU:I

Outcome
Death
Life-Threatening
Hospitalization -

Initial or Prolonged

	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Dermatitis Enteritis	Foreign Health	Imodium	PS	Mcneil Consumer Healthcare	ORAL	PO	
	Gastrointestinal Motility Disorder	Professional	Xeloda	SS		ORAL	4300 MG, ONCE, PO	
	Hand-Foot-And-Mouth Disease		Primperan	SS		ORAL	10 MG, TID, PO	
	Mesenteric Vascular Insufficiency		Rivotril	SS		ORAL	PO	
			Smecta	SS		ORAL	PO	
	Mucosal Inflammation Vomiting		Vastarel	SS		ORAL	PO	

Date:05/23/00ISR Number: 3503884-4Report Type:Direct Company Report #
Age:36 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Blood Pressure Decreased Coagulopathy		Reglan (Metoclopramide)	PS		INTRAVENOUS	5MG IV Q 6 HOURS	3 DAY
	Dialysis Disseminated Intravascular Coagulation Heart Rate Increased Hyperpyrexia Meningococcal Infection Renal Failure Acute Rhabdomyolysis Sepsis							

Date:05/24/00ISR Number: 3504224-7Report 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 Disability	Confusional State Decreased Activity Depression Dysgeusia Fatigue Hyperacusis Parosmia Sedation Tremor Visual Disturbance		Reglan 10mg Sidmak Laboratories, Inc.	PS	Sidmak Laboratories, Inc.	ORAL	1 PER ORAL	

Date:05/25/00ISR Number: 3505024-4Report Type:Expedited (15-DaCompany Report #HQ6101018MAY2000
Age:60 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Renal Failure Acute	Health Professional	Reglan	PS	Ah Robins Co	ORAL	5 MG, 1/2 TABLET BEFORE MEALS AND AT BEDTIME, ORAL	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/26/00ISR Number: 3564485-5Report Type:Periodic Company Report #JRFUSA2000000827
Age:66 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Diarrhoea	Consumer	Propulsid	PS	Janssen Research Fdn Div Johnson And Johnson	ORAL		
	Nausea					ORAL		
			Reglan	SS		ORAL		

Date:05/31/00ISR Number: 3506590-5Report Type:Expedited (15-DaCompany Report #236334
Age:53 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Dermatitis	Foreign	Xeloda	PS	Hlr Technology	ORAL	4300 MG 1 PER	
Life-Threatening	Enteritis	Other						DAY ORAL
Hospitalization -	Gastrointestinal Motility		Rivotril	SS		ORAL		ORAL
Initial or Prolonged	Disorder		Imodium	SS		ORAL		ORAL
	Mucosal Inflammation		Primperan	SS		ORAL	10 MG 3 PER	
	Neuropathy Peripheral							DAY ORAL
	Palmar-Plantar		Smecta	SS		ORAL		ORAL
	Erythrodysaesthesia		Vastarel	SS		ORAL		ORAL
	Syndrome							
	Vomiting							

Date:06/01/00ISR Number: 3507382-3Report Type:Direct Company Report #
Age:59 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Circulatory Collapse		Reglan 10mg/2ml					

	Coma		Solopak	PS	Solopak	
INTRAVENOUS						
	Eye Movement Disorder					BOLUS
10 MG EVERY 6						
	Hypertension					
INTRAVENOUS						
BOLUS						
			Albuterol Extended Release	C		
			Bisacodyl	C		
			Amotidine	C		
			Glipizide	C		
			Sliding Scale Insulin	C		
			Lactulose Syrup	C		
			Oxycodone	C		
			Senokot	C		
			Theophylline Sr	C		
			Dexamethasone	C		
			Furosemide	C		
			Humibid	C		
			Primaxin	C		

Date:06/02/00ISR Number: 3507858-9Report Type:Expedited (15-DaCompany Report #JACGER2000000668
Age:41 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	Hismanal	PS	Janssen Pharmaceutica Inc	ORAL	250 MG, 1 IN
Required Intervention to Prevent Permanent Impairment/Damage	Sinus Tachycardia	Professional					1 TIME(S),
	Suicide Attempt					ORAL	
			Ambrodoxy	SS		ORAL	100 MG, 1 IN 1 TIME(S),

ORAL

	Sinupret	SS		ORAL

30 TABLE, 1

IN 1 TIME(S),

ORAL

	Gastrosil	SS		ORAL

10 TABLE, 1

IN 1 TIME(S),

ORAL

	Paracetamol	SS		ORAL

3 G, 1 IN 1

TIME(S), ORAL

Date:06/06/00ISR Number: 3508667-7Report Type:Direct Company Report #
Age:64 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Tardive Dyskinesia		Metoclopramide	PS			10 MG QID	
			Peri-Colace	C				
			Norvasc	C				
			Xalatan	C				
			Prilosec	C				
			Tylenol	C				
			Zofran	C				

Date:06/08/00ISR Number: 3509785-XReport Type:Expedited (15-DaCompany Report #HQ6101018MAY2000
Age:60 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Medication Error	Health	Reglan	PS	Ah Robins Co	ORAL	130 MG BEFORE	
	Renal Failure Acute	Professional					MEALS AND AT	

BEDTIME, ORAL

			Reglan Tablet	SS		ORAL

CHANGED TO 5

MG, 1/2

TABLET BEFORE

MEALS AND AT

BEDTIME, ORAL

Date:06/08/00ISR Number: 3510777-5Report Type:Expedited (15-DaCompany Report #HQ6882805JUN2000
Age:51 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Left Ventricular Failure Pulmonary Oedema	Health Professional	Reglan	PS	Ah Robins Co			

Date:06/13/00ISR Number: 3512697-9Report Type:Expedited (15-DaCompany Report #HQ6882805JUN2000
Age:51 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardiac Disorder Pulmonary Oedema	Health Professional	Reglan	PS	Ah Robins Co			

Date:06/13/00ISR Number: 3513527-1Report Type:Expedited (15-DaCompany Report #237926
Age:82 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Agranulocytosis Haemoglobin Decreased	Foreign Other	Demadex	PS	Hoffmann La Roche Inc	ORAL	ORAL	
			Rocephin (Ceftriaxone Sodium)					

				2 Gram	SS		
INTRAVENOUS	2 GRAM DAILY						
INTRAVENOUS							
				Marcoumar (Phenprocoumon)	SS		ORAL
PER PRN ORAL							
				Inflamac (Diclofenac Sodium) 25 Mg	SS		ORAL
ORAL							
				Raxar (Grepafloxacin Hydrochloride) 600 Mg	SS		ORAL
600 MG DAILY							
ORAL							
				Primperan (Metoclopramide Hydrochloride)	SS		ORAL
ORAL							
				Maltofer (Inron Polymaltose) 50 Mg/Ml	SS		ORAL
50 MG DAILY							
ORAL							
				Zurcal (Pantoprazole) 20 Mg	SS		ORAL
10 MG DAILY							
ORAL							

Date:06/14/00ISR Number: 3513926-8Report Type:Expedited (15-DaCompany Report #HQ6446125MAY2000
Age:35 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Asthenia	Literature	Reglan	PS	Ah Robins Co	INTRAMUSCULAR		
	Biliary Colic		Fluoxetine (Fluoxetine)	SS				
	Chills							
	Difficulty In Walking		Pethidine (Pethidine)	SS		INTRAMUSCULAR		
	Drug Interaction							
	Hyperhidrosis							
	Hypertension							

Serotonin Syndrome
Tachycardia

Date:06/14/00ISR Number: 3514850-7Report Type:Expedited (15-DaCompany Report #THQ2000Q00637
Age:38 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Bilirubin Increased Dermatitis Duodenal Ulcer Gastric Outlet Obstruction Hepatitis Leukopenia Liver Function Test Abnormal Nausea Pyrexia Thrombocytopenia Vomiting	Health Professional	Prevacid An Extract From Hemolysed Blood Of Young Cattle (Ulcer 1 Min) Metclopramide (Metclopramide) Prochlorperazine Dimethanesulfonate Scopolamine Butylbromide	PS SS SS SS	Tap Pharmaceutical Products Inc	ORAL DRIP INTRAVENOUS INTRAVENOUS INTRAMUSCULAR INTRAMUSCULAR	1.30 MG (30 MG. 1 PER ORAL; (30 MG, 1 IN 1 D) 2.4 ML INTRAVENOUS DRIP INTRAVENOUS INTRAMUSCULAR INTRAMUSCULAR	11 DAY 14 DAY

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/19/00ISR Number: 3515161-6Report Type:Direct Company Report #USP 51992
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Medication Error		Phenytoin Sodium	PS	Elkins Sinn			
			Metoclopramide Hydrochloride	SS	Elkins Sinn			

Date:06/20/00ISR Number: 3515933-8Report Type:Direct Company Report #
Age:66 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Dry Mouth		Metoclopramide	PS		ORAL	30-40 MG,	Initial or Prolonged
	Parkinsonism						10MG 3-4 ORAL	
Required Intervention to Prevent Permanent Impairment/Damage			Lansoprazole	C				
			Lovastatin	C				
			Lisinopril	C				
			Citalopram Hydrobromide	C				
			Insulin Nph Human	C				
			Insulin Reg Human	C				

Date:06/20/00ISR Number: 3516453-7Report Type:Expedited (15-DaCompany Report #HQ5392304MAY2000
Age:49 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Tolerance Decreased	Consumer	Reglan	PS	Ah Robins Co	ORAL	10 MG BEFORE	
	Dysphonia						MEALS AND AT	
	Dyspnoea						BEDTIME, ORAL	
	Dystonia		Desyrel	C				
	Flatulence		Prilosec	C				
	Movement Disorder		Prozac	C				
	Nervous System Disorder		Restoril	C				
	Speech Disorder							

Date:06/20/00ISR Number: 3516561-0Report Type:Expedited (15-DaCompany Report #HQ6882805JUN2000
Age:51 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardiac Disorder	Health	Reglan	PS	Ah Robins Co			
	Left Ventricular Failure	Professional						
	Phaeochromocytoma							
	Pulmonary Oedema							
	Sudden Death							

Date:06/23/00ISR Number: 3518544-3Report Type:Expedited (15-DaCompany Report #1365245A
Age:53 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Dermatitis	Foreign	Imodium	PS	Mcneil Consumer			
Life-Threatening	Enteritis	Health			Healthcare	ORAL	PO	
Hospitalization -	Gastrointestinal Disorder	Professional	Xeloda (R)	SS		ORAL	4300 MG,	
Initial or Prolonged	Infection						ONCE, PO	
	Mesenteric Vascular		Primperan	SS		ORAL	10 MG, TID,	
	Insufficiency						PO	
	Nausea		Rivotril	SS		ORAL	PO	
	Vomiting		Smecta	SS		ORAL	PO	
			Vastarel	SS		ORAL	PO	

Date:06/23/00ISR Number: 3518626-6Report Type:Expedited (15-DaCompany Report #HQ7388415JUN2000
Age:31 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agitation Atrial Flutter	Health Professional	Effexor	PS	Wyeth Ayerst Laboratories Inc		750 MG	
Other (OVERDOSE AMOUNT)	Blood Ph Increased Coma Drug Level Above Therapeutic Dysarthria Hyperhidrosis Hypertension Hypokalaemia International Normalised Ratio Increased Mydriasis Overdose Pneumothorax Posturing Pyrexia Tachycardia Tremor	Other	Ibuprofen (Ibuprofen) Metoclopramide (Metoclopramide) Paracetamol With Codeine (Codeine Phosphate, Paracetamol) Zoplicone (Zoplicone)	SS SS SS SS			75 MG (OVERDOSE AMUNT)	

Date:06/23/00ISR Number: 3518730-2Report Type:Expedited (15-DaCompany Report #10418598
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Hospitalization - Initial or Prolonged	Blister Cough Dermatitis	Foreign Health Professional	Capoten	PS	Bristol Myers Squibb Co	ORAL	50 MILLIGRAM, 1/1 DAY ORAL	
	Eye Inflammation Mucosal Erosion	Other	Acarbose	SS		ORAL	300 MILLIGRAM,	

	Rash Generalised				
1/1 DAY ORAL					
	Stevens-Johnson Syndrome	Metformin Hcl	SS		ORAL
850					
	Toxic Epidermal				
MILLIGRAM,					
	Necrolysis				
1/1 DAY ORAL					
	Vomiting	Xanef (Enalapril Meleate)	SS		ORAL
2.5					
MILLIGRAM,					
1/1 DAY ORAL					
		Ass 100 (Aspirin)	SS		ORAL
100					
MILLIGRAM,					
1/1 DAY ORAL					
		Novalgin (Dipyrone)	SS		
INTRAVENOUS	3.5				
MILLIGRAM,					
1/1 DAY IV					
		Psyquil (Triflupromazine Hcl)	SS		
INTRAVENOUS	10 MILLIGRAM,				
1/1 DAY IV					
		Clobutinol	SS		ORAL
60 MILLIGRAM,					
1/1 DAY ORAL					
		Isoptin (Verapamil Hcl)	SS		
INTRAVENOUS	5 MILLIGRAM,				
1/1 DAY IV					
		Paspertin (Methochlorpropamide Hcl)	SS		
INTRAVENOUS	50 MILLIGRAM,				
1/1 DAY IV					
		Buscopan			

			(Scopolammonium Br)	SS			
INTRAVENOUS	60 MILLIGRAM, 1/1 DAY IV						
			Valoron (Tilidine Hcl)	SS			ORAL
50 MILLIGRAM, 1/1 DAY ORAL							
			Acetylcysteine	SS			ORAL
600 MILLIGRAM, 1/1 DAY ORAL							
			Rulid (Roxithromycin)	SS			ORAL
300 MILLIGRAM, 1/1 DAY ORAL							
			Jonosteril	C			

Date:06/29/00ISR Number: 3522358-8Report Type:Expedited (15-DaCompany Report #8-000001389F
Age:40 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Bronchospasm	Health	Reglan	PS	Ah Robins Co			
INTRAVENOUS	10 MG, INVTRAVENOUS							
	Hypotension	Professional						
	Urticaria							

Date:06/29/00ISR Number: 3522574-5Report Type:Expedited (15-DaCompany Report #10430809
Age:87 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Erythema	Foreign	Fungizone	PS	Bristol Myers Squibb			
	Rash Maculo-Papular	Health			Co	ORAL	15	

			Professional				
MILLILITER, 1							
			Other				
DAY, ORAL							
				Primperan (Metoclopramide Hcl)	SS		
				Lovenox (Heparin)	SS		
				Ciflox (Ciprofloxacin Hcl)	SS		
				Bricanyl (Terbutaline Sulfate)	SS		
				Tazocilline (Piperacillin + Tazobactam)	SS		

Date:06/30/00ISR Number: 3522763-XReport Type:Direct Company Report #
Age:23 YR Gender:Female I/FU:I

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Other		Extrapyramidal Disorder		Reglan Iv	PS		
INTRAVENOUS	IV						
		Eye Irritation		Inapsine Iv	SS		
INTRAVENOUS	IV						
		Hyperhidrosis					
		Muscle Spasms					
		Nervousness					
		Neuroleptic Malignant Syndrome					
		Pyrexia					
		Tachycardia					

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/30/00ISR Number: 3522829-4Report Type:Direct Company Report #
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain Asthenia Extrapyramidal Disorder Fall Feeling Jittery Joint Stiffness Muscle Spasms		Reglan 10mg Po Q Ac + Q Hs	PS		ORAL	10MG PO QAC & QHS	

Date:07/03/00ISR Number: 3525228-4Report Type:Periodic Company Report #206435
Age:56 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Arthralgia Asthenia Balance Disorder Bursitis Condition Aggravated Diabetic Neuropathy Dizziness Hyperhidrosis Hypoaesthesia Movement Disorder Rash Maculo-Papular	Health Professional Other	Klonopin Reglan Cogentin Tranxene Baclofen Aspirin Insulina Nph Insulin Regular Paxil Zoloft	PS SS C C C C C C C C	Hoffmann La Roche Inc	ORAL ORAL	.5 MG 3 PER DAY ORAL 10MG 4 PER DAY ORAL	

Date:07/05/00ISR Number: 3524374-9Report Type:Expedited (15-DaCompany Report #236334
Age:53 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Death	Dermatitis	Foreign	Xeloda	PS	Hlr Technology	ORAL
4300 MG 1 PER						
Life-Threatening	Enteritis	Other				
DAY ORAL						
Hospitalization -	Gastrointestinal Motility		Rivotril			
Initial or Prolonged	Disorder		(Clonazepam)	SS		ORAL
ORAL						
	Intestinal Ischaemia		Imodium (Loperamide			
	Mucosal Inflammation		Hydrochloride)	SS		ORAL
ORAL						
	Nausea		Primperan			
	Neuropathy Peripheral		(Metoclopramide			
	Palmar-Plantar		Hydrochloride)	SS		ORAL
10 MG 3 PER						
	Erythrodysaesthesia					
DAY ORAL						
	Syndrome		Smecta (*Aluminum			
	Vomiting		Hydroxide /			
			Diosmectite/*			
			Glycyrrhiza/ *			
			Magnesium Carbonate)	SS		ORAL
ORAL						
			Vastarel			
			(Trimetazidine)	SS		ORAL
ORAL						

Date:07/06/00ISR Number: 3524527-XReport Type:Direct Company Report #
Age:36 YR Gender:Female I/FU:I

Outcome	PT
	Anxiety
	Feeling Hot
	Heart Rate Increased

	Panic Reaction						
		Report Source	Product	Role	Manufacturer	Route	Dose Duration
			Reglan	PS		ORAL	10MG PO

Date:07/10/00ISR Number: 3526841-0Report Type:Expedited (15-DaCompany Report #A022314
Age:75 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Amnesia Coordination Abnormal	Consumer	Vistaril	PS	Pfizer Laboratories Div Pfizer Inc	ORAL	50.00 MG
Required	Cough						TOTAL:
Intervention to	Eyelid Oedema						DAILY:ORAL
Prevent Permanent	Fatigue		Klonopin	SS		ORAL	2.00 MG
Impairment/Damage	Gait Disturbance						TOTAL:
	Loss Of Consciousness						DAILY:ORAL
	Medication Error		Remeron	SS		ORAL	DAILY; ORAL
	Miosis		Reglan	SS		ORAL	DAILY; ORAL
	Oxygen Saturation Decreased		Megace Claforan	C C			

Date:07/11/00ISR Number: 3527592-9Report Type:Expedited (15-DaCompany Report #JACGBR2000000359
Age:83 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Disability	Gait Disturbance Movement Disorder Muscle Disorder	Foreign Health Professional	Propulsid	PS	Janssen Research Fdn Div Johnson And Johnson	ORAL	10 MG, 3 IN 1
	Tardive Dyskinesia						DAY (S), ORAL

			Metoclopramide (Metoclopramide)	SS		ORAL
10 MG, 3 IN 1 DAY (S), ORAL						
			Stemetil (Prochlorperazine Maleate)	SS		ORAL
5 MG, 3 IN 1 DAY (S), ORAL						
			Ranitidine (Ranitidine)	SS		
			Gaviscon (Gaviscon/Old Form)	C		

Date:07/11/00ISR Number: 3527670-4Report Type:Expedited (15-DaCompany Report #200012964DDC
Age:87 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dermatitis Erythema	Foreign Other	Bricanyl	PS	Aventis Pharmaceuticals Inc		INH	1 WK
	Skin Lesion		Tazocilline	SS			2	WK
			Amphotericin B (Fungizone)	SS			2	WK
			Metoclopramide (Primperan)	SS				
			Ciprofloxacin (Ciflox)	SS	`			
			Heparin-Fraction, Sodium Salt (Levonex)	SS				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/12/00ISR Number: 3528293-3Report Type:Expedited (15-DaCompany Report #HQ8372311JUL2000
Age:13 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Acidosis	Health	Reglan	PS	Ah Robins Co	INTRAVENOUS	10 MG	
	Cardiac Disorder	Professional				INTRAVENOUS /		
	Hepatic Failure					1 DOSE		
	Neuroleptic Malignant Syndrome							

Date:07/18/00ISR Number: 3530742-1Report Type:Expedited (15-DaCompany Report #C-0156
Age:5 MON Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Eye Disorder	Health	Metoclopramide	PS	Jvl Corp			
	Joint Stiffness	Professional						
	Musculoskeletal Stiffness							

Date:07/18/00ISR Number: 3530878-5Report 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	Parkinsonism	Health	Reglan	PS				
	Tremor	Professional						

Date:07/20/00ISR Number: 3532786-2Report Type:Expedited (15-DaCompany Report #200012093HMRI
Age:41 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain	Study	Bentyl W/					
	Condition Aggravated	Health	Phenobarbital	PS	Aventis			
	Diarrhoea	Professional			Pharmaceuticals Inc	ORAL	10 MG QID PO	13 DAY
	Gastroenteritis		Ranitidine					

	Hyperglycaemia		Hydrochloride			
	Hypertriglyceridaemia		Tablets	SS		ORAL
150 MG QID PO						
	Impaired Gastric Emptying		Metoclopramide Hcl			
	Oesophagitis		Tablets	SS		ORAL
10 MG QID PO						
	Vomiting		Buspirone			
			Hydrochloride	C		
			Fexofenadine			
			Hydrochloride	C		
			Clonazepam	C		
			Semisodium Valproate	C		
			Mirtazapine	C		
			Sertraline			
			Hydrochloride	C		
			Risperidone	C		

Date:07/21/00ISR Number: 3533433-6Report Type:Expedited (15-DaCompany Report #PHBS2000JP03991
Age:51 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Anorexia	Foreign	Lamisil	PS	Novartis	
	Decreased Appetite	Health			Pharmaceuticals Corp	ORAL
125 MG, QD,						
	Nausea	Professional				
ORAL						
	Oral Intake Reduced	Other	Primperan			
	Vomiting		(Metoclopramide)	SS		
TID 4 DAY						
			Dogmatyl (Sulpiride)	C		

			Akineton (Biperiden Hydrochloride)	C		
			Rohypnol (Flunitrazepam)	C		
			Pursennid	C		

Date:07/24/00ISR Number: 3533567-6Report Type:Direct Company Report #
Age:28 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Aggression		Reglan					
Hospitalization - Initial or Prolonged	Agitation Disturbance In Attention		(Metoclopramide 10 Mg)	PS		ORAL	1T PO QC	
Disability	Dizziness		Insulin	C				
Required Intervention to Prevent Permanent Impairment/Damage	Headache Iiird Nerve Paralysis Suicidal Ideation							

Date:07/24/00ISR Number: 3534695-1Report Type:Expedited (15-DaCompany Report #FLUV00300005085
Age:82 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Electrocardiogram Qt Corrected Interval Prolonged	Foreign Health Professional	Luvox	PS	Solvay Pharmaceuticals	ORAL	50 MG DAILY	PO
	Torsade De Pointes		Adalat (Nifedipine)	SS		ORAL	20 DF DAILY	PO
			Daonil (Glibenclamide)	SS		ORAL	DAILY PO	
			Melbin (Metformin Hydrochloride)	SS		ORAL	DAILY PO	
			Primperan					

			(Metoclopramide)	SS		ORAL
DAILY PO						
			Kakkon-To (Chinese Medicine)	SS		ORAL
DAILY PO						

Date:07/26/00ISR Number: 3536664-4Report Type:Periodic Company Report #124898USA
Age:22 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Anxiety		Metoclopramide Hcl	PS	Teva Pharmaceuticals Usa Inc	ORAL	10 MILLIGRAM	
	Asthenia						TID BY	
	Convulsion						MOUTH/P.O.	
	Depression							
	Dizziness		Prevacid	C				
	Hyperacusis		Zoloft	C				
	Insomnia							
	Mydriasis							
	Parosmia							
	Visual Disturbance							
	Weight Decreased							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/27/00ISR Number: 3536318-4Report Type:Expedited (15-DaCompany Report #C-0156
Age:5 MON Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Muscle Rigidity	Health Professional	Metoclopramide	PS	Jvl Corp		0.6 EVERY 2.5 HOURS (4 TIMES DAILY)	
			Sudafed	C				
			Tylenol	C				

Date:07/31/00ISR Number: 3538882-8Report Type:Expedited (15-DaCompany Report #A0124841A
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Abnormal Sleep-Related Event	Foreign Health	Zantac	PS	Glaxo Wellcome Inc	ORAL	0.5 ML/VARIABLE DOSE/ORAL	
	Agitation	Professional						
	Convulsion		Cisapride (Cisapride)	SS			.2 MG /AT NIGHT	
	Hypotonia							
	Joint Stiffness							
	Medication Error		Metoclopramide Hcl (Metoclopramdie Hcl)	SS				
	Muscle Rigidity							
	Muscle Spasms							
	Oral Discomfort							
	Sedation							
	Visual Disturbance							

Date:08/01/00ISR Number: 3539388-2Report Type:Expedited (15-DaCompany Report #B0084746A
Age:62 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Death	Fungal Infection	Foreign	Zofran	PS	Glaxo Wellcome Inc		
INTRAVENOUS	INTRAVENOUS						
Hospitalization - Initial or Prolonged	Gastritis Mucosal Inflammation Necrosis		Calcium Folinate Injection (Calcium Folinate)	SS			
INTRAVENOUS	INTRAVENOUS						
	Oesophageal Disorder Oesophagitis Sepsis		Metoclopramide Hcl (Formulation Unknown) (Metoclopramide Hcl)	SS			ORAL
ORAL							
			Fluorouracil (Formulation Unknown) (Fluorouracil)	SS			
INTRAVENOUS	INTRAVENOUS						
			Oxaliplatin Injection (Oxaliplatin)	SS			
INTRAVENOUS	INTRAVENOUS						
			Ondansetron Hydrochloride	C			

Date:08/02/00ISR Number: 3540483-2Report Type:Expedited (15-DaCompany Report #HQ5724311MAY2000
Age:11 WK Gender:Male I/FU:F

Outcome	PT
Other	Accidental Overdose
	Agitation
	Asthma
	Bronchospasm
	Constipation
	Cough

	Dyspnoea					
	Electrolyte Imbalance					
	Haemoglobin Decreased	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
	Hypercalcaemia	Health	Reglan	PS	Ah Robins Co	ORAL
3 ML EVERY 6						
	Hyperhidrosis	Professional				
HOURS, ORAL						
	Hyperkalaemia		Augmentin Oral	C		
	Hyperphosphataemia		Prednisolone	C		
	Irritability		Zantac	C		
	Laryngeal Disorder					
	Medication Error					
	Pulmonary Oedema					
	Renal Disorder					
	Renal Tubular Acidosis					
	Respiratory Distress					
	Tardive Dyskinesia					
	Vomiting					

Date:08/04/00ISR Number: 3542526-9Report Type:Expedited (15-DaCompany Report #A026691
Age:23 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Bruxism	Literature	Zoloft	PS	Pfizer	
Initial or Prolonged	Drug Interaction	Health			Pharmaceuticals Inc	ORAL
50.00 MG						
	Dystonia	Professional				
TOTAL:DAILY:O						
	Ear Pain					
RAL						
	Extrapyramidal Disorder		Metoclopramide	SS		ORAL
60.00 MG						
	Muscle Spasms					
TOTAL:QID:ORA						
L						

Date:08/04/00ISR Number: 3542868-7Report Type:Expedited (15-DaCompany Report #M0535-2000
Age:36 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Convulsion	Foreign Consumer	Hexadrol	PS	Organon Inc Sub Akzona Inc		10 MG	
			Propopfol	SS				
			Fentanyl	SS				
			Metoclopramide	SS				
			Methylprednisolone	SS				
			Benzylpenicillin	SS				
			Metronidazole	SS				
			Sevoflurane	SS				
			Hrt Drugs	SS				

Date:08/07/00ISR Number: 3544496-6Report Type:Expedited (15-DaCompany Report #B0084845A
Age:83 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Gait Disturbance Tardive Dyskinesia	Foreign	Zantac 150	PS	Glaxo Wellcome Inc			
			Cisapride (Cisapride)	SS		ORAL	10 MG/THREE TIMES PER DAY/ORAL	
			Metoclopramide (Metoclopramide)	SS		ORAL	10 MG/THREE TIMES PER DAY/ORAL	
			Prochlorperazine					

			(Prochlorperazine)	SS		
5 MG/THREE						
TIMES PER DAY						
			Gaviscon	C		

Date:08/08/00ISR Number: 3545300-2Report Type:Expedited (15-DaCompany Report #A027165
Age:39 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Diarrhoea Tardive Dyskinesia	Health Professional	Viagra	PS	Pfizer Agricultural Div	ORAL	50.00 MG	TOTAL: PRN:ORAL
			Reglan	SS			20.00 MG	TOTAL
			Levothroid	C				
			Eskaltih Cr	C				

Date:08/09/00ISR Number: 3545090-3Report 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	Cardiac Failure Congestive Cardiomegaly Condition Aggravated Left Ventricular Failure Movement Disorder Tremor		Metoclopramide 10 Mg	PS		ORAL	10 MG QID AC	
			Propulsid 10 Mg	SS		ORAL	10 MG QD ORAL	
			Furosemide	C				
			Tessalon Pearls	C				
			Acetaminophen	C				
			Hydralazine	C				
			Cisapride	C				
			Nizatadine	C				
			Aspirin	C				
			Troglitazone	C				

Levothyroxine	C
...	C
Erythropoietin	C
Combivent Mdi	C
Droperidol	C
Docusate Sodium	C
Metamucil	C
Isosorbide Dinitrate	C

Date:08/09/00ISR Number: 3546572-0Report Type:Expedited (15-DaCompany Report #A022314
Age:75 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Amnesia	Consumer	Vistaril	PS	Pfizer Laboratories			
Hospitalization -	Cough	Health			Div Pfizer Inc	ORAL	50.00 MG	
Initial or Prolonged	Eyelid Oedema	Professional					TOTAL:DAILY:O	
Required	Fatigue					RAL		
Intervention to	Gait Disturbance		Klonopin	SS		ORAL	2.00 MG	
Prevent Permanent	Hypoxia						TOTAL:DAILY:O	
Impairment/Damage	Loss Of Consciousness					RAL		
	Medication Error		Remeron	SS		ORAL	DAILY:ORAL	
	Miosis		Reglan	SS		ORAL	DAILY:ORAL	
	Oxygen Saturation		Megace	C				
	Decreased		Claforan	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/09/00ISR Number: 3546679-8Report Type:Expedited (15-DaCompany Report #HQ5392304MAY2000
Age:49 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Tolerance Decreased	Consumer	Reglan	PS	Ah Robins Co	ORAL	10 MG BEFORE	
	Dysphonia						MEALS AND AT	
	Dystonia						BEDTIME, ORAL	
	Movement Disorder		Desyrel	C				
	Nervous System Disorder		Prilosec	C				
	Respiratory Disorder		Prozac	C				
	Speech Disorder		Restoril	C				

Date:08/09/00ISR Number: 3546854-2Report Type:Expedited (15-DaCompany Report #HQ8706319JUL2000
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Drug Level Below	Health	Reglan	PS	Ah Robins Co	ORAL	ORAL	
	Therapeutic	Professional	Acetaminophen	SS		ORAL	ORAL	
	Respiratory Depression		Oxycodone	SS		ORAL	ORAL	

Date:08/10/00ISR Number: 3548108-7Report Type:Periodic Company Report #C-0156
Age:5 MON Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Eye Rolling	Health	Metoclopramide	PS	Jvl Corp		0.6 CC EVERY 2.5 HOURS (4 TIMES DAILY)	
	Muscle Rigidity	Professional						
	Musculoskeletal Stiffness							
			Sudafed	C				
			Tylenol	C				

Date:08/10/00ISR Number: 3548109-9Report Type:Periodic Company Report #C-0156
Age:5 MON Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Muscle Rigidity Paralysis		Metoclopramide	PS	Jvl Corp			

Date:08/16/00ISR Number: 3551306-XReport Type:Expedited (15-DaCompany Report #9936273
Age:44 YR Gender:Male I/FU:F

Outcome	PT
Life-Threatening	Arthropod Bite
Hospitalization - Initial or Prolonged	Atrioventricular Block Complete
	Autonomic Neuropathy
	Bronchial Obstruction
	Bronchitis Haemophilus
	Cardiac Arrest
	Cardiac Disorder
	Cardiac Pacemaker Insertion
	Dehydration
	Depressed Level Of Consciousness
	Diarrhoea
	Erysipelas
	Hallucination, Visual
	Hyperhidrosis

	Hyperventilation						
	Hypothermia						
	Malaise	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Nausea	Foreign	Zoloft	PS	Pfizer		
	Oxygen Saturation	Literature			Pharmaceuticals Inc	ORAL	100.00 MG
	Decreased	Health					TOTAL:ORAL
	Pneumonia Haemophilus	Professional	Metoclopramide	SS		ORAL	40.00 M G
	Pulmonary Congestion						TOTAL:QID:ORA
	Pyrexia						L
	Renal Failure Acute		Omeprazole	C			
	Respiratory Disorder		Oxacillin	C			
	Syncope						
	Syncope Vasovagal						
	Tachypnoea						
	Tremor						
	Ventricular Tachycardia						
	Vomiting						

Date:08/18/00ISR Number: 3589923-3Report Type:Periodic Company Report #S00-USA-00950-01
Age:32 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Drug Interaction	Health	Celexa	PS	Forest Laboratories		
	Extrapyramidal Disorder	Professional			Inc	ORAL	20 MG QD PO
		Company Representative	Reglan (Metoclopramide)	SS			
			Klonopin (Clonazepam)	C			

Date:08/23/00ISR Number: 3555029-2Report Type:Direct Company Report #
Age:69 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration

Hospitalization - Initial or Prolonged	Clonic Convulsion Myokymia Tremor	Metoclopramide Paroxetine Labetalol Felodipine Hctz Losartan Lansoprazole	PS C C C C C C	ORAL

Date:08/28/00ISR Number: 3559562-9Report Type:Direct Company Report #
Age:35 YR Gender:Male I/FU:I

Outcome	PT
Life-Threatening	Acidosis
Hospitalization - Initial or Prolonged	Blood Creatine Increased
Required Intervention to Prevent Permanent Impairment/Damage	Blood Creatine Phosphokinase Increased
	Blood Glucose Increased
	Blood Urea Increased
	Body Temperature Increased
	Liver Function Test Abnormal
	Neuroleptic Malignant Syndrome
	White Blood Cell Count

Increased

			Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
				Metoclopramide 10 Mg Tab	PS		
10 MG GT QID	1	MON					
				Amitriptyline 150 Mg	SS		
150 MG GT HS	1	MON					

Date:08/30/00ISR Number: 3561683-1Report Type:Direct Company Report #
Age:76 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Life-Threatening	Cardio-Respiratory Arrest		Metoclopramide			
Required	Coma		10mg/2cc Baxter	PS	Baxter	
INTRAVENOUS	10MG ONCE IV					
Intervention to	Eye Rolling		Pepcid 20mg/2cc			
Prevent Permanent	Fall		Merck	SS	Merck	
INTRAVENOUS	20MG/2CC					
Impairment/Damage						
MERCK 20MG						
ONCE IV						

Date:08/30/00ISR Number: 3562133-1Report Type:Expedited (15-DaCompany Report #HQ1557214MAR2000
Age:52 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Disability	Akathisia	Health	Reglan	PS	Ah Robins Co	ORAL
SEE IMAGE						
	Aphasia	Professional	Cimetidine	SS		
	Blepharospasm		Paxil	SS		ORAL
SEE IMAGE						
	Diarrhoea					
	Drug Interaction					
	Dysuria					
	Extrapyramidal Disorder					
	Gastrooesophageal Reflux Disease					
	Irritability					

Laryngospasm
Movement Disorder
Mydriasis
Photophobia
Photosensitivity Reaction
Speech Disorder
Throat Tightness
Tic
Tremor

Date:09/08/00ISR Number: 3568805-7Report Type:Expedited (15-DaCompany Report #JRFBEL2000002173
Age:26 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Drug Interaction	Foreign	Risperdal	PS	Janssen Research Fdn Div Johnson And Johnson	ORAL	MG, DAILY,	
	Vomiting	Health Professional					ORAL	
		Other	Metoclopramide (Metoclopramide)	SS		INTRAVENOUS	IV	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/11/00ISR Number: 3568846-XReport Type:Direct Company Report #
Age:73 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required	Gingivitis	Health	Reglan	PS		ORAL	10 MG PO	
Intervention to	Oral Soft Tissue Disorder	Professional					AC/HS	
Prevent Permanent	Speech Disorder							
Impairment/Damage	Tardive Dyskinesia							

Date:09/13/00ISR Number: 3571023-XReport Type:Expedited (15-DaCompany Report #055-0981-M0000721
Age:60 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Cardiac Arrest	Foreign	Lipitor	PS	Warner Lambert			
Initial or Prolonged	Diarrhoea	Consumer			Export Ltd	ORAL	10 MG	
Other	Hypertension						(DAILY), PER	
	Myocardial Infarction						ORAL	
	Pyrexia		Metoclopramide	SS			INTRAVENOUS	INTRAVENOUS
	Viral Infection		Amlodipine	C				
	Vomiting							

Date:09/13/00ISR Number: 3571152-0Report Type:Expedited (15-DaCompany Report #9936273
Age:44 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Atrioventricular Block	Foreign	Zoloft	PS	Pfizer			
Hospitalization -	Complete	Literature			Pharmaceuticals Inc	ORAL	100.00 MG	
Initial or Prolonged	Bronchial Obstruction	Health					TOTAL: ORAL	
	Bronchitis	Professional	Metoclopramide	SS		ORAL	40.00 MG	
	C-Reactive Protein						TOTAL: QID:	

	Increased		
ORAL			
	Cardiac Arrest	Omeprazole	C
	Cardiac Disorder	Oxacillin	C
	Dehydration		
	Depressed Level Of Consciousness		
	Diarrhoea		
	Erysipelas		
	Haemophilus Infection		
	Hallucination, Visual		
	Hyperhidrosis		
	Hyperreflexia		
	Hypertonia		
	Hyperventilation		
	Hypothermia		
	Inflammation		
	Malaise		
	Nausea		
	Pulmonary Congestion		
	Pyrexia		
	Renal Failure Acute		
	Respiratory Disorder		
	Serotonin Syndrome		
	Syncope		
	Syncope Vasovagal		
	Tachypnoea		
	Tremor		
	Ventricular Tachycardia		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/18/00ISR Number: 3573095-5Report Type:Direct Company Report #
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Developmental Coordination Disorder Sedation		Metoclorpramide	PS	Roxane Labs			

Date:09/18/00ISR Number: 3575003-XReport Type:Expedited (15-DaCompany Report #HQ0908112SEP2000
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Grand Mal Convulsion	Health	Reglan	PS	Ah Robins Co	ORAL	5 ML 4 X PER	
	Medication Error	Professional					1 DAY, ORAL	
			Zantac	C				

Date:09/22/00ISR Number: 3576989-XReport Type:Direct Company Report #
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Developmental Coordination Disorder		Metoclorpramide	PS	Roxane Lab			

Date:09/25/00ISR Number: 3578070-2Report Type:Expedited (15-DaCompany Report #245128
Age:15 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Extrapyramidal Disorder		Primperan	PS			1	DAY
	Gastrooesophageal Reflux		Lariam Tablets	SS	Roche		63	DAY
	Disease Nervousness Throat Tightness Tremor							

Date:09/25/00ISR Number: 3578162-8Report Type:Expedited (15-DaCompany Report #245128
Age:15 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Extrapyramidal Disorder		Primperan	PS			1	DAY
	Gastrooesophageal Reflux		Lariam Tablets	SS	Roche		63	DAY
	Disease							
	Nervousness							
	Throat Tightness							
	Tremor							

Date:09/25/00ISR Number: 3578203-8Report Type:Expedited (15-DaCompany Report #245128
Age:15 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Extrapyramidal Disorder		Lariam Tablets	PS	Roche		63	DAY
	Gastrooesophageal Reflux		Primperan	SS			1	DAY
	Disease							
	Nervousness							
	Tremor							

Date:09/25/00ISR Number: 3579511-7Report Type:Expedited (15-DaCompany Report #245128
Age:15 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Other	Extrapyramidal Disorder	Foreign	Lariam	PS	Hoffmann La Roche		
	Gastrooesophageal Reflux	Health			Inc	ORAL	1 DOSE FORM 1
	Disease	Professional					PER WEEK ORAL
	Nervousness		Primperan	SS		ORAL	1 DOSE FORM 2
	Throat Tightness						PER DAY ORAL
	Tremor						

Date:09/26/00ISR Number: 3580507-XReport Type:Expedited (15-DaCompany Report #HQ1071415SEP2000
Age:20 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Eclampsia	Consumer	Reglan	PS	Ah Robins Co		
	Intra-Uterine Death		Lasix (Furosemide, , 0)	SS			
			Mylanta (Aluminium Hydroxide Gel, Dried/Dimeticone, Activated/	SS		ORAL	ORAL
			Vitamins (Vitamins)	C			

Date:09/29/00ISR Number: 3584586-5Report Type:Expedited (15-DaCompany Report #JRFBEL2000002226
Age:2 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Life-Threatening	Agitation	Foreign	Propulsid	PS	Janssen Research Fdn		
Hospitalization - Initial or Prolonged	Congenital Limb Hyperextension	Health Professional			Div Johnson And Johnson	ORAL	DAILY ORAL
	Depressed Level Of		Metoclopramide	SS		ORAL	1 TIME (S)

	Consciousness					
ORAL						
	Difficulty In Walking					
	Dyskinesia					
	Dystonia					
	Encephalitis					
	Encephalopathy					
	Extrapyramidal Disorder					
	Hypertonia					
	Tremor					

Date:10/04/00ISR Number: 3587582-7Report Type:Expedited (15-DaCompany Report #HQ0908112SEP2000
Age:0 MON Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Medication Error	Health	Reglan	PS	Ah Robins Co	ORAL	5 ML 4X PER 1
		Professional					DAY, ORAL
			Zantac	C			

Date:10/04/00ISR Number: 3587681-XReport Type:Expedited (15-DaCompany Report #A032804
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	Hyperhidrosis	Consumer	Procardia Xl	PS	Pfizer Laboratories Div Pfizer Inc	ORAL	30.00 MG TOTAL, DAILY, ORAL
	Oedema Peripheral						

				Zoloft	SS		ORAL
25.00 MG							
TOTAL, DAILY,							
ORAL							
				Reglan	SS		
				Prilosec	SS		
				Prevacid	C		
				Buspar	C		

Date:10/10/00ISR Number: 3590421-1Report Type:Expedited (15-DaCompany Report #246352
Age:32 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Chest Discomfort		Pethidine					
	Chest Pain		Hydrochloride	PS				
1 DAY								
	Dermatitis		Maxolon	SS				
3 DAY								
	Dyspnoea		Morphine Sulphate	SS				
2 DAY								
			Panadol	SS				
			Rocephin	SS	Roche			
1 DAY								

Date:10/10/00ISR Number: 3592078-2Report Type:Expedited (15-DaCompany Report #THQ2000A01157
Age:28 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain		Prevacid	PS	Tap Pharmaceutical Products Inc	ORAL	GASTRO-RESIST	
	Anaemia						ANT CAPSULES,	
	Blood Creatinine Increased						ORAL	6 DAY
	Blood Urea Increased		Motilium					
	Crohn'S Disease		(Domperidone)	SS		ORAL	ORAL	6 DAY
	Diarrhoea		Primperan					

		Erythropenia	(Metoclopramide)	SS			ORAL
ORAL	6 DAY						
		Faeces Discoloured	Ricridene				
		Haemolytic Uraemic	(Nifurzide)	SS			ORAL
ORAL	6 DAY						
		Syndrome	Imurel				
		Jaundice	(Azathioprine)	SS			ORAL
ORAL							
		Leukopenia	Pentasa 500 Mg				
		Pallor	(Mesalazine)	SS			ORAL
4000 MG							
		Pyrexia					
TABLETS, ORAL	2 YR						
		Renal Failure Acute	Levothyrox				
		Tachycardia	(Levothyroxine				
		Thrombocytopenia	Sodium)	C			
		Vomiting	Prozac (Fluoxetine				
			Hydrochloride)	C			
			Minidril				
			(Ethinylestradiol,				
			Levonorgestrel)	C			
			Pepsane				
			(Guaiazulene,				
			Dimeticone)	C			

Date:10/11/00ISR Number: 3592465-2Report Type:Expedited (15-DaCompany Report #246352
Age:32 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Other	Chest Discomfort	Foreign	Rocephin	PS		
INTRAVENOUS	2 GRAM DAILY					
	Chest Pain	Other				
IV						
	Dermatitis		Maxolon			
	Dyspnoea		(Metoclopramide			

				Hydrochloride)	SS			
INTRAVENOUS	10 MG 1 PER							
ONE DOSE IV								
				Pethidine Hydrochloride (Meperidine Hydrochloride)	SS			
INTRAVENOUS	100 MG 1 PER							
ONE DOSE IV								
				Morphine Sulphate (Morphine Sulfate)	SS			
INTRAVENOUS	2.5 MG DAILY							
IV								
				Panadol (Acetaminophen)	SS			ORAL
1 GRAM DAILY								
PO								

Date:10/12/00ISR Number: 3594772-6Report Type:Expedited (15-DaCompany Report #THQ2000A01157
Age:28 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain Anaemia	Foreign Health	Prevacid	PS	Tap Pharmaceutical Products Inc	ORAL	GASTRO-RESISTANT CAPSULES	
	Crohn'S Disease	Professional						
	Diarrhoea	Other						
ORAL							6	DAY
	Faeces Discoloured Gastrointestinal Disorder		Motilium (Domperidone)	SS		ORAL		
ORAL							6	DAY
	Haemolytic Uraemic Syndrome		Primperan (Metoclopramide)	SS		ORAL		
ORAL							6	DAY
	Jaundice Leukopenia		Ricridene (Nifurzide)	SS		ORAL		
ORAL							6	DAY
	Pallor Pyrexia		Imurel (Azathioprine)	SS		ORAL		
ORAL								

	Red Blood Cell Count Decreased Renal Failure		Pentasa 500 Mg (Mesalazine)	SS		ORAL	4000 MG TABLETS ORAL	834 DAY
	Renal Failure Acute Tachycardia Thrombocytopenia Vomiting		Levothyrox (Levothyroxine Sodium) Prozac (Fluoxetine Hydrochloride)	C C				

Date:10/16/00ISR Number: 3596200-3Report Type:Expedited (15-DaCompany Report #10536696
Age:51 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Toxicity	Foreign	Platinol	PS			INTRAVENOUS	IV
	Lung Disorder	Health	Bleomycin Sulfate	SS	Bristol Myers Co		INTRAVENOUS	IV
	Lung Infiltration	Professional	Etoposide	SS			INTRAVENOUS	IV
	Pulmonary Function Test Abnormal	Other	Zofran (Odansetron Hcl) G-Csf (Granulocyte Csf) Metoclopramide Hcl	SS SS SS				

Date:10/18/00ISR Number: 3597639-2Report Type:Expedited (15-DaCompany Report #HQ0626805SEP2000
Age:25 YR Gender:Male I/FU:I

Outcome	PT
Disability	Depression
	Dyskinesia
	Paranoia

	Sedation Suicidal Ideation						
		Report Source	Product	Role	Manufacturer	Route	
Dose	Duration						
20 MG TWICE DAILY, ORAL		Health Professional	Reglan	PS	Ah Robins Co	ORAL	
			Zyrtec (Cetirizine Hydrochloride)	C			

Date:10/19/00ISR Number: 3598415-7Report Type:Direct Company Report #
Age:30 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other 10MG QID GT 1 MON	Convulsion		Reglan	PS		
			Tegretol	C		
			Robinul	C		

Date:10/23/00ISR Number: 3600286-7Report Type:Expedited (15-DaCompany Report #JRFUSA2000008280
Age:47 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged 40 MG, 4 IN 1 DAY(S), ORAL	Alopecia Convulsion Pancreatitis	Consumer	Propulsid	PS	Janssen Research Fdn Div Johnson And Johnson	ORAL
			Reglan (Metoclopramide)	SS		
			Nubain (Nalbuphine Hydrochloride)	C		
			Lorcet (Vicodin)	C		
			Xanax (Alprazolam)	C		
			Carafate (Sucralfate)	C		
			Paxil (Paroxetine Hydrochloride)	C		
			Unspecified			

			(Unspecified)	C		

Date:10/25/00ISR Number: 3601362-5Report Type:Expedited (15-DaCompany Report #800#3#2000-03884 (000)
Age:7 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Toxic Epidermal Necrolysis	Health Professional	Cyclophosphamide	PS	Asta Medica Inc	INTRAVENOUS	1,044 GRAM IV	
			Cyclosporin A (Ciclosporin)	SS			90 MG	
			Codeine Phosphate	SS		ORAL	15 MG PO	
			Paracetamol (Paracetamol)	SS		ORAL	360 MG PO	
			Vancomycin (Vancomycin)	SS		INTRAVENOUS	810 MG IV	
			Ceftazidime (Ceftazidime)	SS		INTRAVENOUS	2700 MG IV	
			Tranexamic Acid (Tranexamic Acid)	SS		ORAL	1200 MG PO	
			Fludarabine (Fludarabine)	SS		INTRAVENOUS	18 MG IV	
			Ondansetron (Ondansetron)	SS			4 MG	
			Antihuman Lymphocyte					

				Immunoglobulin (Antilymphocyte Immunoglobulin Horse)	SS		
INTRAVENOUS	219 MG IV						
				Metoclopramide (Metoclopramide)	SS		
5 MG							
				Meropenem (Meropenem)	SS		
INTRAVENOUS	1080 MG IV						
				Acyclovir (Acyclovir)	SS		
INTRAVENOUS	525 MG IV						
				Fluconazole (Fluconazole)	SS		ORAL
50 MG PO							
				Nifedipine (Nifedipine)	SS		ORAL
5 MG PO							
				Sandoglobulin (Immunoglobulin Human Normal)	SS		
INTRAVENOUS	7 G IV						
				Chlorpheniramine	C		

Date:10/25/00ISR Number: 3601369-8Report Type:Expedited (15-DaCompany Report #THQ2000A01157
Age:28 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain Anaemia		Prevacid	PS	Tap Pharmaceutical Products Inc	ORAL		
GASTRO-RESIST ANT CAPSULES	Colitis Ulcerative Crohn'S Disease							
ORAL							6	DAY
	Dialysis Diarrhoea		Motilium (Domperidone)	SS		ORAL		
ORAL							6	DAY
	Faeces Discoloured Gastrointestinal		Primperan (Metoclopramide)	SS		ORAL		
ORAL							6	DAY
	Haemorrhage		Pentasa 500 Mg					

		General Physical Health	(Mesalazine)	SS			ORAL
4000 MG		Deterioration					
TABLETS ORAL	852 DAY	Haemolytic Uraemic	Imurel				
		Syndrome	(Azathioprine)	SS			ORAL
ORAL		Haptoglobin Decreased	Ricridene				
		Heart Rate Increased	(Nifurazide)	C			ORAL
ORAL	6 DAY	Jaundice	Levothyrox	C			
		Melaena	Prozac	C			
		Pallor	Minidril	C			
		Pyrexia	Pepsane	C			
		Red Blood Cell					
		Schistocytes Present					
		Renal Failure Acute					
		Thrombocytopenia					
		Vomiting					

Date:10/31/00ISR Number: 3606786-8Report Type:Periodic Company Report #C-0156
Age:5 MON Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Joint Stiffness		Metoclopramide	PS	Jvl Corp			
	Musculoskeletal Stiffness							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/31/00ISR Number: 3606787-XReport Type:Periodic Company Report #C-0156
Age:5 MON Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Unevaluable Event	Health Professional	Metoclopramide	PS	Jvl Corp		0.6 CC EVERY 2.5 HOURS(4 TIMES DAILY)	
			Sudafed	C				
			Tylenol	C				

Date:11/01/00ISR Number: 3604031-0Report Type:Expedited (15-DaCompany Report #B0090145A
Age:26 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Cardio-Respiratory Arrest		Sumatriptan Succinate	PS	Glaxo Wellcome	SUBCUTANEOUS	3MG PER DAY	1 DAY
	Cyanosis							
	Depressed Level Of Consciousness		Metoclopramide	SS		INTRAVENOUS	200MG PER DAY	1 DAY
	Gaze Palsy							
	Joint Stiffness							
	Urinary Incontinence							

Date:11/02/00ISR Number: 3606627-9Report Type:Periodic Company Report #02052
Age:32 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Muscle Twitching	Consumer	Metoclopramide Hcl	PS	Purepac Pharmaceutical Co Div Purepac Inc			
			Synthroid	C				
			Minocycline	C				

Date:11/02/00ISR Number: 3606630-9Report Type:Periodic Company Report #02068
Age:52 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dyskinesia	Consumer	Metoclopramide Hcl	PS	Purepac Pharmaceutical Co Div Purepac Inc		10 MG Q.I.D.	
	Dyspepsia							
	Dysphagia							
	Dyspnoea		Paxil	SS	Smithkline Beecham		20 MG DAILY	
	Laryngospasm						RE-INTRODUCED	
	Mydriasis						IN 2/00	
	Nausea		Cogentin	C				
	Nervousness		Benadryl	C				
	Photophobia		Prilosec	C				
	Photosensitivity Reaction							
	Tic							
	Tremor							

Date:11/02/00ISR Number: 3606634-6Report Type:Periodic Company Report #02073
Age: Gender:Female I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Akathisia
	Amnesia
Disability	Depression
	Extrapyramidal Disorder
	Movement Disorder

		Myalgia Tardive Dyskinesia Tremor	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
			Other	Metoclopramide Hcl	PS	Purepac Pharmaceutical Co Div Purepac Inc	

Date:11/02/00ISR Number: 3606636-XReport Type:Periodic Company Report #02118
Age: Gender:Male I/FU:I

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Disability		Dystonia Movement Disorder Nervous System Disorder	Other	Metoclopramide Hcl	PS	Purepac Pharmaceutical Co Div Purepac Inc	
4	YR						
		Respiratory Disorder Speech Disorder Tardive Dyskinesia					

Date:11/03/00ISR Number: 3605736-8Report Type:Expedited (15-DaCompany Report #245128
Age:15 YR Gender:Female I/FU:F

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Other		Anxiety		Primperan	PS		
1	DAY						
		Extrapyramidal Disorder		Lariam Tablets	SS	Roche	
63	DAY						
		Gastrooesophageal Reflux Disease Throat Tightness Tremor					

Date:11/06/00ISR Number: 3607167-3Report Type:Expedited (15-DaCompany Report #B0090145A
Age:26 YR Gender:Female I/FU:I

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						

Life-Threatening		Cardio-Respiratory Arrest	Foreign	Imitrex	PS	Glaxo Wellcome Inc	
SUBCUTANEOUS	3 MG / PER						
		Cyanosis	Health				
DAY /							
		Gaze Palsy	Professional				
SUBCUTANEOUS							
		Joint Stiffness		Metoclopramide			
		Respiratory Arrest		Injection			
		Urinary Incontinence		(Metoclopramide)	SS		
INTRAVENOUS	200 MG / PER						
DAY /							
INTRAVENOUS							

Date:11/06/00ISR Number: 3608144-9Report Type:Expedited (15-DaCompany Report #245128
Age:15 YR Gender:Female I/FU:F

Outcome	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Dose							
Other		Extrapyramidal Disorder	Foreign	Lariam	PS	Hoffmann La Roche	
		Gastrooesophageal Reflux	Health			Inc	ORAL
1 DOSE FORM							
		Disease	Professional				
1 PER WEEK							
		Nervousness					
ORAL							
		Tremor		Primperan			
				(Metoclopramide			
				Hydrochloride)	SS		ORAL
1 DOSE FORM							
2 PER DAY							
ORAL							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/08/00ISR Number: 3608882-8Report Type:Direct Company Report #
Age:45 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Convulsion Difficulty In Walking Movement Disorder		Reglan (Metaclorpropamide) (Sidmak)	PS	Sidmak	ORAL	10 MG PO QID	
	Syncope		Zantac	C				

Date:11/09/00ISR Number: 3609487-5Report Type:Direct Company Report #
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Medication Error		Robinul -Glycopyrrolate- / 1 Ml Single Use Vials /Package / A.H. Robins	PS	Ah Robins			
			Reglan-Metocopramide -2ml Single Use Vials /Package Ah Robins	SS	Ah Robins			

Date:11/13/00ISR Number: 3610774-5Report Type:Expedited (15-DaCompany Report #HQ3396208NOV2000
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Overdose	Health Professional	Reglan	PS	Ah Robins Co			
			Phenergan (Promethazine Hydrochloride)	SS				

Date:11/14/00ISR Number: 3611410-4Report Type:Expedited (15-DaCompany Report #HQ3376208NOV2000
Age:55 DY Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Hospitalization - .8 MG	Anxiety	Consumer	Reglan	PS	Ah Robins Co	ORAL
Initial or Prolonged (FREQUENCY	Breast Engorgement					
UNKNOWN),	Feeding Problem In Newborn					
ORAL						
	Muscle Spasms		Pepcid (Famotidine)	C		
	Pain		Zantac (Ranitidine Hydrochloride)	C		
	Screaming					
	Sensory Disturbance					

Date:11/15/00ISR Number: 3612578-6Report Type:Expedited (15-DaCompany Report #JAGER42501
Age:34 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Blister	Foreign	Protostat	PS	Rw Johnson	
Life-Threatening	Lip Ulceration	Health			Pharmaceutical	
	Pruritus	Professional			Research Institute	
	Shock				Div Ortho Pharm	
INTRAVENOUS 500 MG, 3 IN	Stevens-Johnson Syndrome					
1 DAY(S), IV						
	Toxic Epidermal		Imodium (2 Mg			
	Necrolysis		Capsule) (Loperamide Hydrochloride)	SS		ORAL
4 MG, 3 IN 1						
DAY(S), ORAL						

		Allopurinol(Allopurinol)	SS	ORAL
	MG, DAILY, ORAL			
		Dipidolor(7.5 Mg/Ml Injection) (Piritramide)	SS	
INTRAVENOUS	MG, DAILY, IV			
		Antra(Ampoule) (Omeprazole)	SS	
INTRAVENOUS	MG, DAILY, IV; 20 MG, DAILY, IV			
		Zofran (Ondansetron)	SS	
INTRAVENOUS	1 IN 1 DAY(S), IV			
		Multibionta(Multibionta)	SS	
INTRAVENOUS	ALT DAY, IV			
		Leucomax(Molgramostim)	SS	
SUBCUTANEOUS	MCG, DAILY, SUBCU (DAILY 05-AUG-96): 1-3 (SEE IMAGE)			
		Paracetamol(Paracetamol)	SS	
		Vancomycin(Ampoule) (Vancomycin)	SS	
INTRAVENOUS	0.5 G, 3 IN 1 DAY(S), IV			
		Novalgin(Ampoule) (Metamizole)	SS	
INTRAVENOUS	1 IN 1 TIME (S), IV			

INTRAVENOUS DAY(S), IV	1 IN 1	Vitalipid(Vitalipid)	SS
INTRAVENOUS	1 MG/HR, IV	Mst(Morphine)	SS
INTRAVENOUS DAY(S), IV (1 DAILY 07-AUG-96): 5 DROPS/DAY	2 G, 2 IN 1	Augmentan(Clavulanic Acid)	SS
		Opium(Opium)	SS
(DAILY 06-AUG-96): 7500 - 10000 I.E.		Liquemin(Ampoule) (Heparin)	SS
INTRAVENOUS DAY(S), IV	2 G, 3 IN 1	Claforan(Cefotaxime)	SS
INTRAVENOUS 1 DAY(S), IV	120 MG, 3 IN	Gentamycin(Gentamicin)	SS
INTRAVENOUS TIME(S), IV	50 MG, 1 IN 1	Isoptin(Verapamil)	SS
INTRAVENOUS TIME(S), IV	1 IN 1	Ciprobay(Ciprofloxacin)	SS
INTRAVENOUS 1 TIME(S), IV	200 MG, 1 IN	Sobelin Solubile(Clindamycin)	SS
INTRAVENOUS	3 IN 1	Suprarenin(Ampoule) (Epinephrine)	SS

DAY(S), IV

Dopamin(Ampoule)
(Dopamine) SS

INTRAVENOUS MG, DAILY, IV

		Zienam(Imipenem)	SS
INTRAVENOUS	0.5 G, 1 IN 1 TIME(S), IV		
		Dolantin(Pethidine)	SS
INTRAVENOUS	MG, DAILY, IV		
		Human Albumin 20 %(Human Albumin)	SS
INTRAVENOUS	ML, DAILY, IV		
		Neupogen(Filgrastim)	SS
SUBCUTANEOUS	1 IN 1 DAY(S), SUBCU		
		Dormicum(Ampoule) (Midazolam)	SS
INTRAVENOUS	10 MG/HR, DAILY, IV		
		Solu-Decortin(Predni solone)	SS
INTRAVENOUS	50 MG, 1 IN 1 TIME(S), IV		
		Amphoterecin B(Ampoule) (Amphotericin B)	SS
INTRAVENOUS	40 MG, 1 IN 1 DAY(S), IV		
		Psyquil(Ampoule) (Trifluprom azine)	SS
INTRAVENOUS	1 IN 1 DAY(S), IV		
		Actrapid(Ampoule) (Insulin Rapid Act.)	SS
SUBCUTANEOUS	U, DAILY, SUBCU		
		Meronem(Ampoule) (Meropenem)	SS
INTRAVENOUS	G, DAILY, IV		
		Tavegil(Ampoule) (Clemastine)	SS
INTRAVENOUS	1 IN 1 DAY(S), IV		

		Ancotil(Ampoule 2 G) (Flucytosine)	SS	
INTRAVENOUS	2 G, 2 IN 1 DAY(S), IV			
		Lasix(Furosemide)	SS	ORAL
	20 MG, 1 IN 1 TIME(S), ORAL			
		Bifiteral(Lactulose)	SS	ORAL
	1 IN 1 TIME(S), ORAL			
		Pantozol(Pantoprazole)	SS	ORAL
	1 IN 1 DAY(S), ORAL			
		Paspertin(Ampoule) (Metoclopramide)	SS	
INTRAVENOUS	2 IN 1 DAY(S), IV			
		Methotrexat (Methotrexate)	SS	
INTRAVENOUS	MG, DAILY, THECAL (SEE IMAGE)			
		Diflucan	SS	ORAL
	200 MG, 2 IN 1 DAY(S), ORAL			
		Ampho-Moronal	C	
		Aminomel	C	
		Aminomix	C	
		Glukose 40%	C	
		Kaliumchlorid	C	
		Lipofundin Mct 10%	C	
		Fortecortin	C	
		Sterofundin	C	
		Magnorbin 20%	C	
		Glucose	C	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/17/00ISR Number: 3613264-9Report Type:Direct Company Report #
Age:40 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Dyskinesia		Reglan	PS			DAILY	
	Movement Disorder						(LIQUID)	
	Oral Intake Reduced		Thorazine	SS			DAILY TABS	
	Tongue Disorder		Ambien	C				
			Herceptin	C				
			Prochloperazine	C				
			Cipro	C				
			Prednisone	C				
			Metoclopramide	C				
			Senokot-S	C				
			Hydromorphone	C				
			Oramorph Sr	C				
			Generlac	C				
			Roxanol	C				
			Phenazopyridine	C				
			Cpt 11	C				

Date:11/22/00ISR Number: 3615523-2Report Type:Direct Company Report #
Age:14 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Crying		Reglan 10mg	PS		ORAL	10MG PO	
	Depression		Metachlopromide	C				
	Extrapyramidal Disorder							
	Muscle Twitching							
	Suicidal Ideation							
	Tardive Dyskinesia							

Date:11/22/00ISR Number: 3617827-6Report Type:Expedited (15-DaCompany Report #HQ3746815NOV2000
Age:34 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Death	Completed Suicide	Literature	Reglan	PS	Ah Robins Co	ORAL
ORAL						
			Amitriptyline	SS		ORAL
ORAL						
			Paroxetine	SS		ORAL
ORAL						

Date:11/24/00ISR Number: 3617383-2Report Type:Expedited (15-DaCompany Report #033-0955-M0000003
Age:65 YR Gender:Female I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Abdominal Pain
	Abnormal Behaviour
	Blood Creatinine Increased
	Chorea
	Creatinine Renal Clearance Decreased
	Drug Interaction
	Drug Level Above Therapeutic
	Dystonia
	Electrocardiogram Qrs Complex Prolonged
	Gastroenteritis
	Hypoglycaemia

	Hyponatraemia Overdose Renal Failure Acute	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Speech Disorder	Foreign	Accuretic	PS	Parke Davis	ORAL	PER ORAL
	Trismus	Health Professional	Cipralan(Cibenzoline Succinate)	SS		ORAL	260 MG (DAILY), PER ORAL
			Nureflex(Ibuprofen)	SS		ORAL	PER ORAL
			Primperan(Metoclopramide)	SS		ORAL	PER ORAL
			Kaleorid Leo (Potassium Chloride)	C			
			Kardegic (Acetylsalicylate Lysine)	C			
			Lipanthyl(Fenofibrate)	C			
			Sargenor(Arginine Aspartate)	C			
			Visceralgine Forte(Codeine, Tiemonium, Metamizole Sodium)	C			
			Rowasa(Mesalazine)	C			

Date:11/27/00ISR Number: 3616317-4Report Type:Direct Company Report #
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Other	Rash Erythematous		Reglan	PS			10MG TID
	Rash Papular		70/30	C			
			Prilosec	C			
			Trazodone	C			
			Neurontin	C			
			Zocor	C			

Date:11/28/00ISR Number: 3619041-7Report Type:Expedited (15-DaCompany Report #HQ0908112SEP2000
Age:0 MON Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Accidental Overdose	Health	Reglan	PS	Ah Robins Co	ORAL	5 ML 4X PER 1	
	Grand Mal Convulsion	Professional					DAY, ORAL;	
	Medication Error						DOSE UNKNOWN,	
	Tremor Neonatal						ORAL	
			Zantac (Ranitidine Hydrochloride)	C				

Date:11/29/00ISR Number: 3618736-9Report Type:Direct Company Report #
Age:72 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Extrapyramidal Disorder		Darvocet Prn Generic	PS				
	Respiratory Rate Decreased		Reglan 10mg Q6hrs (Generic)	SS			10MG Q6HRS	
	Tic							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/05/00ISR Number: 3622846-XReport Type:Direct Company Report #
Age:61 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required	Burning Sensation		Toradol	PS			30MG	
Intervention to	Oral Pain		Reglan	SS			10MG	
Prevent Permanent	Pain		Levaquin	C				
Impairment/Damage			Versed	C				

Date:12/06/00ISR Number: 3623913-7Report Type:Expedited (15-DaCompany Report #HQ0908112SEP2000
Age:0 MON Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Clonic Convulsion	Health	Reglan	PS	Ah Robins Co	ORAL	5 ML 4X PER 1	
	Medication Error	Professional					DAY ORAL	
			Reglan (Metoclopramide Hydrochloride, Syrup)	SS		ORAL	ORAL	
			Zantac (Ranitidine Hydrochloride)	C				

Date:12/07/00ISR Number: 3623701-1Report Type:Expedited (15-DaCompany Report #A0133437A
Age:68 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Anorexia		Navelbine	PS	Glaxo Wellcome		INTRAVENOUS	
Initial or Prolonged	Convulsion		Sulpiride	SS				
	Dysgeusia		Cisplatin	SS				
	Malaise		Metoclopramide	SS				
	Neutropenia		Harnal	C				
			Ubretid	C				
			Aprindine	C				
			Nizatidine	C				

			Radiation Therapy	C		

Date:12/07/00ISR Number: 3624504-4Report Type:Expedited (15-DaCompany Report #HQ4462405DEC2000
Age:54 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Macular Cyst	Health	Reglan	PS	Ah Robins Co	ORAL		
ORAL							1	MON
	Visual Disturbance	Professional	Synthroid (Levothyroxine Sodium)	C				

Date:12/08/00ISR Number: 3625535-0Report Type:Expedited (15-DaCompany Report #A0133437A
Age:68 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Anorexia	Foreign	Navelbine	PS	Glaxo Wellcome Inc			
INTRAVENOUS							30 MG /	
Initial or Prolonged	Condition Aggravated	Health						
INTRAVENOUS								
	Convulsion	Professional	Sulpiride (Formulation Unknown) (Sulpiride)	SS				
	Depression	Other						
	Dysgeusia		Cisplatin (Formulation Unknown) (Cisplatin)	SS				
	Malaise							
	Neutropenia		Metoclopramide					

			(Formulation Unknown)			
			(Metoclopramide)	SS		
			Tamsulosin Hcl	C		
			Distigmine Bromide	C		
			Aprindine	C		
			Nizatidine	C		
			Radiotherapy	C		

Date:12/11/00ISR Number: 3626777-0Report Type:Expedited (15-DaCompany Report #HQ1071415SEP2000
Age:20 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Pressure Increased	Health Professional	Reglan	PS	Ah Robins Co			
			Lasix (Furosemide)	SS				
			Mylanta (Aluminum Hydroxide Gel, Drued/Dimeticone, Activated/Magnesium Hydroxide,)	SS		ORAL	ORAL	
			Vitamins (Vitamins)	C				

Date:12/12/00ISR Number: 3627603-6Report Type:Expedited (15-DaCompany Report #HQ4502206DEC2000
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Torsade De Pointes	Health Professional	Reglan	PS	Ah Robins Co	ORAL	10 MG, 3-4 TIMES DAILY, Other ORAL	

Date:12/12/00ISR Number: 3627683-8Report Type:Expedited (15-DaCompany Report #HQ4578307DEC2000
Age:21 WK Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Death	Abortion Missed	Health	Reglan	PS	Ah Robins Co
TRANSPLACENTAL	TRANSPLACENTA				
	Anoxia	Professional			
L					
	Chorioamnionitis		Lasix (Furosemide)	SS	
TRANSPLACENTAL	TRANSPLACENTA				
	Complications Of Maternal				
L					
	Exposure To Therapeutic		Mylanta (Aluminum		
	Drugs		Hydroxide Gel,		
	Foetal Disorder		Dried/Dimeticone,		
	Hydrops Foetalis		Activated/Magnesium		
	Induced Labour		Hydroxide,)	SS	
TRANSPLACENTAL	TRANSPLACENTA				
	Infection				
L					
	Inflammation		Vitamins	C	
	Intra-Uterine Death				
	Necrosis				
	Oedema				
	Oedema Peripheral				
	Placental Disorder				
	Placental Necrosis				
	Pre-Eclampsia				
	Skin Disorder				
	Skin Exfoliation				
	Thrombosis				
	Umbilical Cord				
	Abnormality				

Date:12/12/00ISR Number: 3628830-4Report Type:Expedited (15-DaCompany Report #WAES 00112460
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain Lower	Consumer	Vioxx	PS	Merck Research Laboratories Div Merck Co Inc	ORAL	PO	
	Asthenia							
	Balance Disorder							
	Blood Pressure Increased		Reglan	SS				
	Bronchitis		Dyazide	C				
	Condition Aggravated		Evista	C				
	Dizziness		Lomotil	C				
	Fall		Pepcid Ac	C				
	Fatigue		Prevacid	C				
	Gastrooesophageal Reflux Disease		Tigan	C				
	Haematochezia		Ventolin	C				
	Headache							
	Hyponatraemia							
	Laceration							
	Nausea							
	Oedema Peripheral							
	Pleural Infection							
	Pruritus							
	Rectal Haemorrhage							
	Tinnitus							
	Vomiting							

Date:12/14/00ISR Number: 3630197-2Report Type:Expedited (15-DaCompany Report #HQ0908112SEP2000
Age:22 DY Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Clonic Convulsion	Health	Reglan	PS	Ah Robins Co	ORAL	5 ML 4X PER 1	
	Medication Error	Professional					DAY, ORAL; .5	
	Neonatal Disorder						ML THREE TO	
							FOUR TIMES	
							DAILY, ORAL	
			Zantac (Ranitidine					

			Hydrochloride)	C		

Date:12/18/00ISR Number: 3631746-0Report Type:Direct Company Report #USP 53530
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
	Medication Error		Robinul	PS	A H Robins	
			Reglan (Metoclopramide)	SS	A H Robins	

Date:12/18/00ISR Number: 3633626-3Report Type:Direct Company Report #
Age:18 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Hypertonia		Reglan 10mg Po	PS		ORAL
10 MG PO X 1						
Initial or Prolonged	Hyperventilation		Droperidol	SS		OTHER
INFUSION 1						
Required	Muscle Spasms					
MG/HR						
Intervention to	Tachycardia					
Prevent Permanent	Tremor					
Impairment/Damage						

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/21/00ISR Number: 3635743-0Report Type:Expedited (15-DaCompany Report #200090100BFR
Age:90 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Abdominal Pain	Foreign	Cipro	PS	Bayer Corp	ORAL	500 MG	ONCE
Hospitalization -	Cholecystitis Acute	Other				ORAL		
Initial or Prolonged	Convulsion		Cordarone	SS		ORAL	200 MG	ONCE
	Cyanosis					ORAL		
	Endocarditis		Primperan	SS		RECTAL	10 MG	ONCE
	Malaise					RECTAL		
	Nausea		Rocephin	SS				
	Sepsis		Zestril	SS		40 MG		
	Syncope		Hemigoxine Nativelle	SS		ORAL	0.125 MG	ONCE
	Torsade De Pointes					ORAL		

Date:12/21/00ISR Number: 3635872-1Report Type:Expedited (15-DaCompany Report #2000UW04938
Age:55 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Agitation	Foreign	Sensorcaine	PS	Astrazeneca Lp		3 ML	DAILY
	Confusional State	Literature	Metoclopramide	SS		INTRAVENOUS	10 MG	DAILY
	Hypercapnia	Health				IV		
	Methaemoglobinaemia	Professional	Morphine	C				
	Normochromic Normocytic Anaemia	Other	Fentanyl	C				
			Midazolam	C				
	Oxygen Saturation Decreased		Enoxaparin	C				
			Oxygen	C				
	Respiratory Depression		Cephazoline	C				

Date:12/21/00ISR Number: 3636224-0Report Type:Expedited (15-DaCompany Report #06134-030
Age:40 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Drug Level Above Therapeutic	Foreign Health	Dolophine Hcl	PS	Roxane Laboratories Inc	ORAL	29MG DAILY PO	
	Drug Toxicity	Professional	Effexor	SS			UNKNOWN	UNKNOWN
	Ecchymosis	Other	Metoclopramide	SS			UNKNOWN	UNKNOWN
	Electrocardiogram Qt Prolonged							
	Toxicologic Test Abnormal							

Date:12/22/00ISR Number: 3636126-XReport Type:Expedited (15-DaCompany Report #2000CG00866
Age:90 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Arrhythmia	Foreign Health	Zestril	PS	Astrazeneca Pharmaceuticals Lp	ORAL	40 MG DAILY PO	
	Cholecystitis							
	Convulsion	Professional						
	Endocarditis	Other	Cordarone	SS		ORAL	200 MG DAILY PO	
	Sepsis							
	Syncope		Primperan	SS			10 MG DAILY RC	
	Torsade De Pointes							
			Ciflox	SS				
			Rocephine	SS				
			Hemigoxine Nativelle	SS		ORAL	0.125 MG QD PO	
			Lasilix	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/26/00ISR Number: 3639865-XReport Type:Periodic Company Report #02160
Age:50 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dry Skin	Consumer	Metoclopramide Hcl	PS	Quad Pharmaceuticals Inc		0.1 MG T.I.D.	
	Keratoconjunctivitis							
	Sicca							PAST 7
	Skin Disorder							MONTHS
	Skin Irritation		Synthroid	C				7 MON
	Skin Odour Abnormal		Premarin	C				

Date:12/26/00ISR Number: 3640089-0Report Type:Expedited (15-DaCompany Report #244321
Age:90 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Blood Potassium Abnormal	Foreign	Rocehpin/Xylocaine					
Hospitalization -	Cardiac Arrest	Health	Kit	PS	Hlr Technology		INTRAMUSCULAR	1 GRAM DAILY
Initial or Prolonged	Cardiomyopathy	Professional					INTRAMUSCULAR	
	Endocarditis	Other	Ciflox					
	Malaise		(Ciprofloxacin)	SS		ORAL	1 DOSE FORM	
	Pyrexia						1 PER DAY	
	Syncope						ORAL	
	Torsade De Pointes		Cordarone					
	Ventricular Arrhythmia		(Amiodarone) 200 Mg	SS		ORAL	200 MG DAILY	
							ORAL	
			Primperan (Metoclopramide Hydrochloride)	SS			RECTAL	10 MG 1 PER
							ONE DOSE	
							RECTAL	

			Zestril (Lisinopril)	SS		ORAL
40 MG DAILY ORAL						
			Hemigoxine Nativelle (Digoxin) 0.125 Mg	SS		ORAL
0.125 MG DAILY ORAL						
			Lasilix (Furosemide	C		
			Kardegic (Aspirin Dl-Lysine)	C		
			Nitriderm (Nitroglycerin)	C		

Date:12/29/00ISR Number: 3639753-9Report Type:Expedited (15-DaCompany Report #2000SE01079
Age:50 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Rash Papular	Foreign	Prilosec	PS	Astrazeneca Lp	ORAL	20 MG DAILY PO	
	Renal Failure Acute	Health Professional	Bactrim Ds	SS		ORAL	1 DF DAILY PO	
		Other	Leustatin	SS		INTRAVENOUS	7.2 MG DAILY IV	
			Lexomil	SS		ORAL	1.5 MG DAILY PO	
			Primperan	SS		ORAL	10 MG TID PO	
			Zophren	SS		INTRAVENOUS	8 MG BID IV	
			Gaviscon	C				
			No Match	C				
			Topalgic "Nippon"	C				
			Visceralgine Forte					

Tablets C

Date:01/03/01ISR Number: 3641260-4Report Type:Expedited (15-DaCompany Report #HQ5370129DEC2000
Age:90 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain Convulsion Cyanosis Endocarditis Malaise Nausea Sepsis Syncope Torsade De Pointes	Health Professional Other	Cordarone	PS	Wyeth Ayerst Laboratories	ORAL	200 MG 1X PER 1 DAY	ORAL
			Ciflox (Ciprofloxacin)	SS		ORAL	DOSE UNSPECIFIED	ORAL
			Digoxin (Digoxin)	SS		ORAL	0.125 MG 1X PER 1 DAY	ORAL
			Primperan (Metoclopramide)	SS		ORAL	10 MG 1X PER 1 DAY	ORAL
			Rocephin (Ceftriaxone Sodium)	SS		ORAL	DOSE UNSPECIFIED	ORAL
			Zestril (Lisinopril)	SS		ORAL	40 MG 1X PER 1 DAY	ORAL

Date:01/03/01ISR Number: 3641520-7Report Type:Expedited (15-DaCompany Report #A040398
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain Movement Disorder	Foreign Other	Zithromax	PS	Pfizer Chemicals Div Pfizer Inc	ORAL	ORAL	
	Tremor		Paspertin	SS				

Date:01/03/01ISR Number: 3641743-7Report Type:Expedited (15-DaCompany Report #A031873
Age:19 MON Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Cough	Consumer	Zyrtec	PS	Pfizer Inc	ORAL	ORAL	
	Dehydration	Health Professional	Metoclopramide	SS				
	Gastroenteritis Viral		Lansoprazole Over The Counter "Drug"	SS C				

Date:01/09/01ISR Number: 3644651-0Report Type:Expedited (15-DaCompany Report #200090100BFR
Age:90 YR Gender:Male I/FU:F

Outcome	PT
Death	Abdominal Pain
Hospitalization - Initial or Prolonged	Cardio-Respiratory Arrest
	Chills
	Cholecystitis Acute
	Convulsion
	Cyanosis
	Electrocardiogram Qt Prolonged
	Endocarditis
	Haemoglobin Decreased

	Headache						
	Implant Site Infection						
	Nausea	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Platelet Count Decreased	Foreign	Cipro	PS	Bayer Corp	ORAL	500 MG ONCE
	Prothrombin Time	Other					ORAL
	Prolonged		Ciflox	SS			INTRAVENOUS 200 MG ONCE
	Pulmonary Fibrosis						INTRAVENOUS
	Sedation		Cordarone	SS		ORAL	200 MG ONCE
	Sepsis						ORAL
	Staphylococcal Infection		Primperan	SS			RECTAL 10 MG ONCE
	Streptococcal Infection						RECTAL
	Syncope		Rocephin	SS			INTRAMUSCULAR 1 G ONCE
	Torsade De Pointes						INTRAMUSCULAR
	Ventricular Fibrillation		Zestril	SS			40 MG
	Vertigo		Hemigoxine Nativelle	SS		ORAL	0.125 MG ONCE
							ORAL
			Lasilix	C			

Date:01/10/01ISR Number: 3644687-XReport Type:Direct Company Report #
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Medication Error		Reglan (Metoclopramide Hydrochloride)	PS	Robins		

Date:01/10/01ISR Number: 3645443-9Report Type:Direct Company Report #
Age:72 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drooling Dysphagia Extrapyramidal Disorder		Reglan	PS			10MG QID	

Date:01/16/01ISR Number: 3648199-9Report Type:Expedited (15-DaCompany Report #10672145
Age:21 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abscess Proteus Infection Thrombocytopenia	Foreign Health Professional Other	Amikin	PS	Apothecon Inc Div Bristol Myers Squibb		600 MILLIGRAM, 1 DAY	
			Pro-Dafalgan(Propacetamol Hcl)	SS			INTRAVENOUS	6 GRAM, 1 DAY IV
			Zantac (Ranitidine Hcl)	SS			INTRAMUSCULAR	IM
			Morphine Chlorhydrate(Morphine Hcl)	SS			SUBCUTANEOUS	30 MILLIGRAM, 1 DAY SC
			Lovenox (Heparin)	SS			SUBCUTANEOUS	20 MILLIGRAM, 1 DAY SC
			Tazocilline (Piperacillin + Tazobactam)	SS			INTRAVENOUS	12 GRAM, 1 DAY IV
			Spasfon(Phloroglucin					

olol)	SS
Primperan(Metoclopramide Hcl)	SS
Stilnox (Zolpidem Tartrate)	C
Lasilix (Furosemide)	C

Date:01/17/01ISR Number: 3649435-5Report Type:Expedited (15-DaCompany Report #HQ4432504DEC2000
Age:51 DY Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Convulsion	Health	Reglan	PS	Ah Robins Co	ORAL	SEE IMAGE	
	Dyskinesia	Professional	Zantac	C				

Date:01/22/01ISR Number: 3652873-8Report Type:Expedited (15-DaCompany Report #02301
Age:34 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide Intentional Misuse	Literature	Metoclopramide Hcl	PS	Purepac Pharmaceutical Co Div Purepac Inc	ORAL ORAL		
			Amitripytline	SS		ORAL ORAL		
			Paroxetine	SS		ORAL ORAL		

Date:01/25/01ISR Number: 3655161-9Report Type:Expedited (15-DaCompany Report #001-0991-991713
Age:58 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death Hospitalization - Initial or Prolonged Other	Abdominal Pain Upper Biliary Tract Disorder Blood Thyroid Stimulating Hormone Increased	Health Professional Company Representative	Rezulin	PS	Parke Davis Pharmaceuticals Ltd	ORAL	400 MG (DAILY), PER ORAL; 600 MG	

Required	Cholestasis		
(300 MG, TWO			
Intervention to	Condition Aggravated		
TABS WITH			
Prevent Permanent	Cystitis	Norvasc(Amlodipine	
Impairment/Damage	Dialysis	Besilate)	SS
10 MG			
	Fungal Infection	Synthroid(Levothyrox	
	Haematuria	ine Sodium)	SS
0.2 MG			
	Hepatic Failure		
(DAILY)			
	Hepatic Fibrosis	Lopressor(Metoprolol	
	Hepatic Necrosis	Tartrate)	SS
100 MG (BID)			
	Hepatic Steatosis	Procardia	
	Hypoglycaemia	Xl(Nifedipine)	SS
90 MG (BID)			
	Jaundice	Diflucan(Fluconazole	
	Obesity	)	SS
	Oedema	Reglan(Metoclopramid	
	Pain	e)	SS
	Proteinuria	Catapress Tts-	
	Pyrexia	Iii(Clonidine	
	Renal Failure	Hydrochloride)	SS
2 PATCH			
	Tenderness		
(WEEKLY)			
	Thyroxine Increased	Capoten(Captopril)	C
	Urine Analysis Abnormal	Insulin Human	
	Weight Decreased	Injection, Isophane,	
		Insulin Human Zinc	
		Suspension	C
		Paracetamol,	
		Hydrocodone	
		Bitartrate	C

Glynase(Glibenclamide)	C
Cozaar(Losartan Potassium)	C
Avapro(Irbesartan)	C
Prandin(Repaglinide)	C
Nph Insulin(Insulin Injection, Isophane)	C
Demadex(Torasemide)	C
Levaquin(Levofloxacin)	C
Glyburide(Glibenclamide)	C
Tylenol(Paracetamol)	C
Cardura(Doxazosin Mesilate)	C

Date:01/30/01ISR Number: 3658330-7Report Type:Expedited (15-DaCompany Report #WAES 00112460
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain	Consumer	Vioxx	PS	Merck Research Laboratories Div Merck Co Inc	ORAL	PO	
	Balance Disorder							
	Blood Pressure Increased							
	Bronchitis		Reglan	SS				
	Chest Pain		Beconase	C				
	Condition Aggravated		Dyazide	C				
	Diarrhoea		Evista	C				
	Dizziness		Lomotil	C				
	Fall		Pepcid Ac	C				
	Fatigue		Prevacid	C				
	Gastrooesophageal Reflux		Tigan	C				
	Disease		Ventolin	C				
	Haematochezia		[Therapy					
	Headache		Unspecified]	C				
	Nausea							
	Oedema Peripheral							
	Pleural Infection							
	Pruritus							
	Tinnitus							
	Vomiting							

Date:02/02/01ISR Number: 3658993-6Report Type:Expedited (15-DaCompany Report #B0090145A
Age:26 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Cardio-Respiratory Arrest		Sumatriptan Succinate	PS	Glaxo Wellcome	SUBCUTANEOUS	3MG Per day	1 DAY
	Coma							
	Cyanosis		Metoclopramide	SS		INTRAVENOUS	20MG Per day	1 DAY
	Respiratory Arrest							

Date:02/05/01ISR Number: 3663081-9Report Type:Expedited (15-DaCompany Report #B0090145A
Age:26 YR Gender:Female I/FU:F

Outcome	PT
Life-Threatening	Cardio-Respiratory Arrest
	Cyanosis
	Gaze Palsy

		Joint Stiffness Respiratory Arrest Urinary Incontinence	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
			Foreign	Imitrex	PS	Glaxo Wellcome Inc	
SUBCUTANEOUS	3 MG/ PER						
			Health				
DAY/							
			Professional				
SUBCUTANEOUS							
				Metocloprmaide Injection (Metoclopramide)	SS		
INTRAVENOUS	20 MG/ PER						
DAY/							
INTRAVENOUS							

Date:02/09/01ISR Number: 3663779-2Report Type:Expedited (15-DaCompany Report #WAES 01012379
Age:24 YR Gender:Female I/FU:I

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Death		Hepatitis	Foreign	Pepcid	PS	Merck Research	
Hospitalization -		Hepatitis Fulminant	Literature			Laboratories Div	
Initial or Prolonged		Juvenile Arthritis	Health			Merck Co Inc	ORAL
PO							
		Liver Disorder	Professional	Prednisolone	SS		
				Methylprednisolone	SS		
				Ranitidine	SS		
				Teprenone	SS		
				Metoclopramide	SS		
				Loxoprofen	SS		

Date:02/09/01ISR Number: 3664390-XReport Type:Expedited (15-DaCompany Report #JRFUSA2000008280
Age:47 YR Gender:Female I/FU:F

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Hospitalization -		Alopecia	Consumer	Propulsid	PS	Janssen Research Fdn	
Initial or Prolonged		Convulsion	Health			Div Johnson And	

	Pancreatitis Chronic	Professional			Johnson	ORAL

40 MG, 4 IN 1

DAY(S), ORAL

Reglan (Metoclopramide)	SS
Nubain (Nalbuphine Hydrochloride)	C
Lorcet (Vicodin)	C
Xanax (Alprazolam)	C
Carafate (Sucralfate)	C
Paxil (Paroxetine Hydrochloride)	C
Unspecified (Unspecified)	C

Date:02/12/01ISR Number: 3664273-5Report Type:Expedited (15-DaCompany Report #2001043238JP
Age:24 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Hepatic Failure Hepatitis	Foreign Health Professional Other	Solu-Medrol (Methylprednisolone) Powder, Sterile	PS	Pharmacia And Upjohn Co			
			Prednisolone (Prednisolone)	SS		ORAL	ORAL	
			Zantac (Ranitidine					

			Hydrochloride)	SS		
			Famotidine (Famotidine)	SS		
			Teprenone (Teprenone)	SS		
			Metoclopramide (Metoclopramide)	SS		
			Loxoprofen Sodium (Loxoprofen Sodium)	SS		

Date:02/13/01ISR Number: 3664980-4Report Type:Expedited (15-DaCompany Report #A102418
Age: Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Congenital Anomaly	Cleft Palate	Foreign	Atarax	PS	Roerig Div Pfizer Inc			
	Complications Of Maternal Exposure To Therapeutic Drugs	Consumer	Metoclopramide	SS				
			Unspecified Medications	SS				

Date:02/13/01ISR Number: 3665050-1Report Type:Expedited (15-DaCompany Report #2001043238JP
Age:24 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Erythema	Foreign	Solu-Medrol	PS	Pharmacia And Upjohn Co			
	Hepatic Failure	Health Professional	Prednisolone(Prednisolone)	SS		ORAL	ORAL	
	Hepatic Function Abnormal	Other	Zantac(Ranitidine Hydrochloride)	SS				
	Hepatitis		Famotidine(Famotidine)	SS				
	Pyrexia		Teprenone(Teprenone)	SS				
			Metoclopramide(Metoclopramide)	SS				
			Loxoprofen Sodium (Loxoprofen Sodium)	SS				

Date:02/16/01ISR Number: 3666721-3Report Type:Direct Company Report #
Age:30 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product			Role	Manufacturer	Route	Dose	Duration
Disability	Body Temperature		Reglan	10 Mg	R	PS		INTRAVENOUS	10 MG X	IV
	Increased							INTRAVENOUS		
	Dizziness		Reglan	5mg		SS		ORAL	5 MG	Q 8H
	Headache							PO	ORAL	
	Muscle Rigidity									
	Nervous System Disorder									
	Oculogyration									
	Pollakiuria									
	Vision Blurred									

Date:02/16/01ISR Number: 3667512-XReport Type:Expedited (15-DaCompany Report #WAES 00112460
Age:70 YR Gender:Female I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Abdominal Pain
	Balance Disorder

		Blood Sodium Decreased					
		Bronchitis					
		Condition Aggravated	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
		Coordination Abnormal	Consumer	Tab Vioxx	PS		ORAL
25							
		Diarrhoea	Health				
MG/DAILY/PO							
		Discomfort	Professional	Reglan	SS		ORAL
20							
		Dizziness					
MG/DAILY/PO							
		Ecchymosis		Beconase	C		
		Fall		Dyazide	C		
		Fatigue		Elavil	C		
		Gastrooesophageal Reflux		Evista	C		
		Disease		Lomotil	C		
		Haematochezia		Lortab	C		
		Headache		Pepcid Ac	C		
		Hypertension		Prevacid	C		
		Medication Error		Ventolin	C		
		Nausea		Therapy Unspecified	C		
		Oedema Peripheral					
		Pruritus					
		Tinnitus					
		Vomiting					

Date:02/16/01ISR Number: 3668097-4Report Type:Expedited (15-DaCompany Report #10707842
Age:15 YR Gender:Female I/FU:I

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Life-Threatening		Coagulopathy	Foreign	Maxipime	PS	Bristol Myers Squibb	
Hospitalization -		Leukocytoclastic	Health			Co Pharmaceutical	
Initial or Prolonged		Vasculitis	Professional			Research Institute	
INTRAVENOUS	300						
			Other				
MILLIGRAM, 1							
DAY IV							
				Amikin Inj (Amikacin Sulfate)	SS		
INTRAVENOUS	750						
MILLIGRAM,1							

DAY IV					
		Maxipime	SS	Bristol Myers Squibb Co Pharmaceutical Research Institute	
SUBCUTANEOUS	SC				
		Primperan (Metoclopramide Hcl)	SS		
INTRAVENOUS	10 MILLIGRAM,				
1 DAY IV					
		Termalgin (Acetaminophen)	SS		ORAL
500					
MILLIGRAM, AS					
NECESSARY					
ORAL					
		Propylthiouracil	SS		ORAL
450					
MILLIGRAM,1					
DAY ORAL					
		Levofloxacin (Levofloxacin)	C		
		Vancomycin (Vancomycin Hcl)	C		
		Propanolol Hcl (Propranolol Hcl)	C		
		Levothroid (As Reported)	C		
		Orfidal (Lorazepam)	C		
		Largactil (Chloropromazine)	C		

			Zantac (Ranitidine Hcl)	C		
			Almax (Almagate)	C		
			Motilium (Domperide)	C		

Date:02/21/01ISR Number: 3669188-4Report Type:Periodic Company Report #HQ3617013NOV2000
Age:50 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Interaction Tremor	Health Professional	Protonix	PS	Wyeth Ayerst Laboratories			
			Metoclopramide (Metoclopramide Hydrochloride)	SS		ORAL	10 MG FOUR TIMES DAILY,	
			Amitriptyline (Amitriptyline)	C		ORAL		
			Insulin (Insulin)	C				
			Temazepam (Temazepam)	C				
			Spironolactone (Spironolactone)	C				
			Gemfibrozil (Gemfibrozil)	C				
			Fosamax (Alendronate Sodium)	C				
			Verapamil (Verapamil)	C				
			Morphine (Morphine)	C				
			Soma (Carisoprodol)	C				
			Furosemide (Fuurosemide)	C				
			Buspar (Buspirone Hydrochloride)	C				

Date:02/21/01ISR Number: 3669816-3Report Type:Expedited (15-DaCompany Report #2001SE00236
Age:31 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Clonic Convulsion Partial Seizures	Foreign Health Professional Other	Prilosec Serc Tanganil Effexor Primperan	PS SS SS SS SS	Astrazeneca Lp	ORAL ORAL ORAL ORAL	20 MG DAILY 8 MG TID PO 25 MG BID PO 10 MG DAILY PO	

Date:02/22/01ISR Number: 3669131-8Report Type:Periodic Company Report #HQ0862202FEB2000
Age:69 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Confusional State	Health Professional	Reglan Lasix (Furosemide) Normodyne (Labetalol Hydrochloride) Haldol (Haloperidol)	PS C C C	Ah Robins Co	ORAL	5 MG 4X [ER 1 DAY, ORAL	

			Nph Insulin (Insulin Injection, Isophane)	C		
			Slow-K (Potassium Chloride)	C		
			Atarax (Hydroxyzine Hydrochloride)	C		
			Nitrostat (Glyceryl Trinitrate)	C		

Date:02/22/01ISR Number: 3669132-XReport Type:Periodic Company Report #HQ1192719SEP2000
Age: Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Health Professional	Reglan	PS	Ah Robins Co	ORAL	ORAL	

Date:02/22/01ISR Number: 3669133-1Report Type:Periodic Company Report #HQ1289029FEB2000
Age:80 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Health	Reglan	PS	Ah Robins Co	ORAL	10 MG THREE TIMES DAILY BEFORE MEALS,	
	Coordination Abnormal	Professional						
	Feeling Jittery							
			Ativan (Lorazepam, Tablet)	SS		ORAL	ORAL	
			Lasix (Furosemide)	C				
			Calcium Acetate (Calcium Acetate)	C				
			Vicodin (Hydrocodone Bitartrate/Paracetamol)	C				
			...	C				

Date:02/22/01ISR Number: 3669134-3Report Type:Periodic Company Report #HQ2065311OCT2000
Age:65 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Anxiety	Consumer	Reglan	PS	Ah Robins Co	ORAL	10 MG 4X PER	
Initial or Prolonged	Bradykinesia						1 DAY, ORAL	
	Decreased Activity		Xanax (Alprazolam)	C				
	Depression							
	Fatigue							
	Hallucination							
	Hypertension							
	Insomnia							
	Mydriasis							
	Restlessness							
	Sedation							
	Visual Disturbance							
	Weight Decreased							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/22/01ISR Number: 3669135-5Report Type:Periodic Company Report #HQ7570620JUN2000
Age:50 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Depression	Health	Reglan	PS	Ah Robins Co	ORAL	10 MG 4X PER	
		Professional						1 DAY, ORAL
			Claritin (Loratadine)	C				
			Ativan (Lorazepam)	C				
			Prozac (Fluoxetine Hydrochloride)	C				
			Ambien (Zolpidem Tartrate)	C				

Date:02/22/01ISR Number: 3669137-9Report Type:Periodic Company Report #HQ8108305JUL2000
Age:34 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Convulsion	Health	Reglan	PS	Ah Robins Co	ORAL	ORAL	
	Pregnancy	Professional	Zofran (Ondansetron Hydrochloride)	C				

Date:02/22/01ISR Number: 3669138-0Report Type:Periodic Company Report #HQ8542214JUL2000
Age:46 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Depression	Health	Reglan	PS	Ah Robins Co	ORAL	20 MG 4X 1	
		Professional						DAY, ORAL
			Pancrease (Pancrelipase)	C				

Date:02/22/01ISR Number: 3669140-9Report Type:Periodic Company Report #HQ9557008AUG2000
Age:45 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Testosterone Decreased Depression Extrapyramidal Disorder Nervousness Paraesthesia Restlessness Suicidal Ideation Tardive Dyskinesia	Consumer	Reglan Ambien (Zolpidem Tartrate) Prilosec (Omeprazole) Prozac (Fluoxetine Hydrochloride) Ritalin (Methylphenidate Hydrochloride)	PS C C C C	Ah Robins Co	ORAL	10 MG 4X PER	1 DAY, ORAL

Date:02/26/01ISR Number: 3675503-8Report Type:Periodic Company Report #2000029
Age:65 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Effect Decreased	Health Professional	Metoclopramide Hcl	PS	Sidmak Laboratories Inc	ORAL	1 PO QID	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/28/01ISR Number: 3677632-1Report Type:Periodic Company Report #A027471
Age:56 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Convulsion Extrapyramidal Disorder Urinary Retention	Other	Zoloft	PS	Pfizer Pharmaceuticals Inc	ORAL	50.00 MG TOTAL DAILY ORAL	
			Metoclopramide	SS		ORAL	30.00 MG TOTAL DAILY ORAL	
			Trihexphenidyl	SS		ORAL	10.00 MG TOTAL DAILY ORAL	

Date:03/05/01ISR Number: 3674165-3Report Type:Expedited (15-DaCompany Report #PHBS2001JP02145
Age:54 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Depressed Level Of Consciousness Overdose Suicide Attempt	Foreign Health Professional Other	Lescol	PS	Novartis Pharmaceuticals Corp	ORAL	SEE IMAGE	
			Lendormin(Brotizolam)	SS			126 DAY	
			Terperan (Metoclopramide Hydrochloride)	SS			126 DAY	
			Magnesium Oxide	C				
			Urso	C				
			Phenlase-S (Enzymes Nos)	C				
			Tinelac (Senoside					

			A+B)	C		
			Sedes (Caffeine, Apronal)	C		

Date:03/07/01ISR Number: 3675476-8Report Type:Expedited (15-DaCompany Report #HQ7970705MAR2001
Age:55 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anxiety Nervousness	Consumer	Reglan	PS	Ah Robins Co			

Date:03/09/01ISR Number: 3676424-7Report Type:Direct Company Report #USP 081389
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Medication Error		Reglan	PS	Mgp			
			Alupent	SS	Mgp			

Date:03/12/01ISR Number: 3681699-4Report Type:Expedited (15-DaCompany Report #PHBS2001JP02145
Age:54 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Depressed Level Of Consciousness Intentional Misuse Sedation Suicide Attempt	Foreign Health Professional Other	Lescol	PS	Novartis Pharmaceuticals Corp	ORAL	30 MG/D, ORAL; 420 MG, ONCE/SINGLE, ORAL	

				Lendormin (Brotizolam)	SS		
126 DAY							
				Terperan (Metoclopramide Hydrochloride)	SS		
126 DAY							
				Magnesium Oxide	C		
				Urso	C		
				Phenlase-S (Enzymes Nos)	C		
				Tinelac (Sennoside A+B)	C		
				Sedes G (Caffeine , Apronal)	C		

Date:03/13/01ISR Number: 3679907-9Report Type:Direct Company Report #
Age:41 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Injection Site Induration		Metoclopramide (For Inj)	PS		SUBCUTANEOUS	30 MG/DAY	CONT. SQ

Date:03/14/01ISR Number: 3681095-XReport Type:Expedited (15-DaCompany Report #HQ5718909JAN2001
Age:58 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Depersonalisation	Health	Reglan	PS	Ah Robins Co	ORAL	TWO TABLETS	FOUR TIMES
	Depression	Professional						DAILY, ORAL
	Eye Movement Disorder							
	Nodding Of Head		Prilosec (Omeprazole)	C				
	Paranoia		Premarin (Conjugated Estrogens)	C				
	Parkinsonism							
	Tremor							

Date:03/15/01ISR Number: 3681605-2Report Type:Direct Company Report #
Age:47 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Depression		Metoclopramide 5mg	PS		ORAL	4 DAY	ORAL
	Dyspnoea		Metoclopramide 10mg	SS		ORAL	4 DAY	ORAL

Date:03/16/01ISR Number: 3683086-1Report Type:Expedited (15-DaCompany Report #HQ5452112N0V1999
Age:51 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Bronchitis Acute	Consumer	Reglan	PS	Ah Robins Co	ORAL	ORAL	
	Cardiac Failure Congestive		Baclofen	SS				
	Collapse Of Lung		Dantrium (Dantrolene Sodium)	SS		ORAL	FOUR TIMES	
	Drug Interaction						DAILY, ORAL	
	Drug Level Above Therapeutic		Darvocet-N (Dextropropoxyphene/					
	Dyspnoea		Paracetamol)	SS		ORAL	ORAL	
	Respiratory Depression		Imipramine	SS				
	Respiratory Failure							
	Sedation							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/16/01ISR Number: 3683631-6Report Type:Expedited (15-DaCompany Report #200090100BFR
Age:90 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Abdominal Pain	Foreign	Cipro	PS	Bayer Corp	ORAL	500 MG	ONCE
Hospitalization - Initial or Prolonged	Cholecystitis Acute	Other				ORAL		
	Cyanosis		Ciflox	SS		INTRAVENOUS	200 MG	ONCE
	Endocarditis					INTRAVENOUS		
	Implant Site Infection		Cordarone	SS		ORAL	200 MG	ONCE
	Malaise					ORAL		
	Nausea		Primperan	SS		RECTAL	10 MG	ONCE
	Sepsis					RECTAL		
	Syncope		Rocephin	SS		INTRAMUSCULAR	1 G	ONCE
	Torsade De Pointes					INTRAMUSCULAR		
	Ventricular Arrhythmia		Zestril	SS		40 MG		
			Hemigoxine Nativelle	SS		ORAL	0.125 MG	ONCE
			Lasilix	C		ORAL		

Date:03/20/01ISR Number: 3685181-XReport Type:Direct Company Report #
Age:79 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Angioneurotic Oedema		Clonidine	PS				
	Bradycardia		Metoclopramide	SS				
	Dyspnoea		Ticlid	SS				
	Hyperhidrosis		Digoxin	C				
	Hypotension		Furosemide	C				
	Respiratory Arrest							
	Tongue Oedema							

Vomiting

Date:03/26/01ISR Number: 3692624-4Report Type:Periodic Company Report #HQ1414207MAR2000
Age:53 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Methaemoglobinaemia	Health Professional	Reglan	PS	Ah Robins Co	INTRAVENOUS	10 MG ON THREE OCCASSIONS, INTRAVENOUS "RECENTLY"	

Date:03/28/01ISR Number: 3691206-8Report Type:Expedited (15-DaCompany Report #HQ5884612JAN2001
Age:56 YR Gender:Female I/FU:I

Outcome	PT
Disability	Agitation
	Balance Disorder
	Chest Discomfort
	Depression
	Disturbance In Attention
	Dysarthria
	Dysphagia
	Dysphonia
	Dyspnoea
	Eye Pain
	Fatigue
	Feeling Jittery
	Formication

	Heart Rate Increased Insomnia Irritability	Report Source	Product	Role	Manufacturer	Route Dose Duration
	Mental Impairment	Health	Reglan	PS	Ah Robins Co	ORAL 10 MG FOUR TO
	Mood Swings	Professional				FIVE TIMES
	Muscle Rigidity					DAILY, ORAL
	Nausea Parkinsonian Gait Restlessness Tremor		Pamelor (Nortriptyline Hydrochloride) Cytotec (Misoprostol) Prilosec (Omeprazole) Norpramin (Desipramine Hydrochloride) Papaverin (Papverine Hydrochloride) Pepcid (Famotidine) Aciphex (Aciphex) Carafate (Sucralfate) Imodium (Loperamide Hydrochloride) Premarin (Conjugates Estrogens) Multivitamin And Mineral Supplement (Minerals Nos/Vitamins Nos)	C C C C C C C C C C		

Date:03/29/01ISR Number: 3692470-1Report Type:Expedited (15-DaCompany Report #HQ8033806MAR2001
Age:58 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Other	Abdominal Distension	Health	Reglan	PS	Ah Robins Co	ORAL 5 MG 3X PER
	Abdominal Pain Upper	Professional				DAY ORAL
	Flatulence		Valium (Diazepam)	C		

	Gastrointestinal Disorder					
	Gastrooesophageal Reflux Disease					
	Hypertension					
	Nervousness					
	Sensation Of Pressure					
	Stress					

Date:03/29/01ISR Number: 3692623-2Report Type:Expedited (15-DaCompany Report #1527813A
Age:30 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dehydration Dyskinesia	Health Professional	Imodium	PS	Mcneil Consumer Healthcare	ORAL	2 MG BID PO	
Other	Muscle Spasms Paraesthesia Oral Paralysis		Primeperan (Metoclopramide Hdyrochloride) Suppository	SS		RECTAL	1 SUPP TID	RECTALLY
			Effexor (Venlafaxine Hdyrochloride)	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/30/01ISR Number: 3693053-XReport Type:Direct Company Report #
Age:42 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Blood Pressure Increased		Metoclopramide Hcl					
Disability	Decreased Appetite		(Reglan) (10mg Tab)	PS		ORAL	10 QID PO;	
	Depression						INCREASED TO	
	Headache						50MG QD PO	
	Insomnia		Trazadone (Desyrel)					
	Psychotic Disorder		(50mg Tab)	SS		ORAL	60MG PO Q	
	Tachycardia						HS (X 1D	
	Weight Decreased						ONLY)	

Date:04/02/01ISR Number: 3693487-3Report Type:Expedited (15-DaCompany Report #244321
Age:90 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Endocarditis	Foreign	Rocephine	PS	Roche		1	DAY
Hospitalization -	Syncope	Health	Ciflox	SS			1	DAY
Initial or Prolonged	Torsade De Pointes	Professional	Cordarone	SS				
			Primperan	SS			1	DAY
			Zestril	SS				
			Hemigoxine Nativelle	SS				
			Lasilix	C				
			Kardegic	C				
			Nitriderm	C				

Date:04/02/01ISR Number: 3693540-4Report Type:Direct Company Report #USP 53833
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

	Medication Error		Reglan	PS	Robins Pharmaceuticals	

Date:04/03/01ISR Number: 3696572-5Report Type:Expedited (15-DaCompany Report #244321
Age:90 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Cardiac Arrest	Foreign	Rocephine			
Hospitalization -	Endocarditis	Health	(Ceftriaxone Sodium)	PS	Hlr Technology	
INTRAMUSCULAR 1 GRAM	DAILY					
Initial or Prolonged	Malaise	Professional				
INTRAMUSCULAR						
	Syncope	Other	Ciflox			
	Torsade De Pointes		(Ciprofloxacin)	SS		ORAL
1 DOSE FORM						
1 PER DAY,						
ORAL						
			Primperan (Metoclopramide Hydrochloride)	SS		
RECTAL 10 MG 1 PER						
DOSE, RECTAL						
			Cordarone (Amiodarone) 200 Mg	SS		ORAL
200 MG,						
DAILY, ORAL						
			Zestril (Lisinopril)	SS		ORAL
40 MG, DAILY,						
ORAL						
			Hemigoxine Nativelle (Digoxin) 0.125 Mg	SS		ORAL
0.125 MG						
DAILY ORAL						
			Lasilix (Furosemide)	C		
			Kardegic (Aspirin			

			Dl-Lysine)	C		
			Nitriderm (Nitroglycerin)	C		

Date:04/04/01ISR Number: 3697940-8Report Type:Expedited (15-DaCompany Report #2001CG00303
Age:78 YR Gender:Not SpecifiI/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hepatitis Hepatocellular Damage Prothrombin Time Prolonged	Foreign Health Professional Other	Diprivan Mefoxin Acupan Pro-Dafalgan	PS SS SS SS	Astrazeneca Uk Ltd	INTRAVENOUS INTRAVENOUS IV	2 DAILY IV 30 MG DAILY	
			Tracrium	SS				
			Isoflurane Ephedrine	SS SS			9 MG DAILY	
			Ultiva Augmentin	SS SS			1500 MG DAILY	
			Augmentin	SS			1000 MG DAILY	
			Fraxiparine Fraxiparine Dafalgan	SS SS SS			DAILY 6000 MG DAILY	
			Primperan Ciflox	SS SS				

Date:04/05/01ISR Number: 3697075-4Report Type:Expedited (15-DaCompany Report #244321
Age:90 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Endocarditis		Rocephine	PS	Roche		1	DAY
Hospitalization -	Syncope		Ciflox	SS			1	DAY

Initial or Prolonged	Torsade De Pointes		Cordarone	SS		
			Primperan	SS		
1 DAY						
			Zestril	SS		
			Hemigoxine Nativelle	SS		
			Lasilix	C		
			Kardegic	C		
			Nitriderm	C		

Date:04/06/01ISR Number: 3700204-7Report Type:Expedited (15-DaCompany Report #HQ9252104APR2001
Age:2 MON Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Apnoea	Consumer	Reglan	PS	Ah Robins Co	ORAL	UNKNOWN, ORAL	
Initial or Prolonged	Asthenia							
	Back Disorder							
	Constipation							
	Dermatitis							
	Developmental Delay							
	Diarrhoea							
	Electroencephalogram Abnormal							
	Movement Disorder							
	Mydriasis							
	Posturing							
	Psychomotor Hyperactivity							
	Pupillary Reflex Impaired							
	Restlessness							

Date:04/06/01ISR Number: 3700341-7Report Type:Expedited (15-DaCompany Report #244321
Age:90 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Abdominal Pain	Foreign	Rocephin Kit	PS	Hlr Technology	INTRAMUSCULAR	1 GRAM	DAILY
Hospitalization -	Atrioventricular Block	Health				INTRAMUSCULAR		
Initial or Prolonged	Complete	Professional	Ciflox					
	Cardiac Arrest	Other	(Ciprofloxacin)	SS		ORAL	1 DOSE FORM	1 PER DAY
	Cholecystitis					ORAL		
	Cyanosis		Cordarone					
	Endocarditis		(Amiodarone) 200 Mg	SS		ORAL	200 MG	DAILY
	Malaise					ORAL		
	Pyrexia		Primperan					
	Sepsis		(Metoclopramide					
	Syncope		Hydrochloride)	SS		RECTAL	10 MG	1 PER
	Torsade De Pointes					ONE DOSE		
	Vomiting					RECTAL		
			Zestril (Lisinopril)	SS		ORAL	40 MG	DAILY
						ORAL		
			Hemigoxine Nativelle					
			(Digoxin) 0.125 Mg	SS		ORAL	0.125 MG	
						DAILY ORAL		
			Lasilix (Furosemide)	C				
			Kardegic (Aspirin					
			Dl-Lysine)	C				
			Nitriderm					
			(Nitroglycerin)	C				

Date:04/06/01ISR Number: 3700902-5Report Type:Periodic Company Report #HQ2136612OCT2000
Age:22 MON Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Convulsion	Consumer	Reglan	PS	Ah Robins Co	ORAL	1.1 ML 4 X	
	Dyskinesia						PER 1 DAY,	
	Failure To Thrive						ORAL	
	Gastrointestinal Haemorrhage		Phenobarbital (Phenobarbital)	C				

Date:04/06/01ISR Number: 3700904-9Report Type:Periodic Company Report #HQ8128205JUL2000
Age:7 WK Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Convulsion	Health	Reglan	PS	Ah Robins Co	ORAL	0.5 ML FOUR	
	Dystonia	Professional					TIMES A DAY	
	Lethargy						(5MG/5ML)	
	Movement Disorder						ORAL	
	Sedation		Zantac (Ranitidine Hydrochloride)	C				
	Torticollis							
	Tremor							

Date:04/10/01ISR Number: 3702703-0Report Type:Expedited (15-DaCompany Report #2000CG00866
Age:90 YR Gender:Male I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Abdominal Pain
	Cyanosis
	Endocarditis
	Implant Site Infection
	Malaise

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Nausea							
	Sepsis							
	Syncope	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Torsade De Pointes	Foreign	Zestril	PS	Astrazeneca Uk Ltd	ORAL	40 MG DAILY	PO
		Health						
		Professional	Cordarone	SS		ORAL	200 MG DAILY	PO
		Other						
			Primperan	SS		RECTAL	10 MG DAILY	RC
			Ciflox	SS				
			Rocephine	SS				
			Hemigoxine Nativelle	SS		ORAL	0.125 MG QD	PO
			Lasilix	C				

Date:04/11/01ISR Number: 3711936-9Report Type:Periodic Company Report #2001-BP-00027
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Dry Mouth	Consumer	Flomax	PS	Boehringer Ingelheim Pharmaceuticals Inc	ORAL	0.4 MG/ 1	CAPSULE/ QD/
								PO
			Zocor	SS				
			Prilosec	SS				
			Buspar	SS				
			Reglan	SS				

Date:04/12/01ISR Number: 3703888-2Report Type:Direct Company Report #
Age:31 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Chest Discomfort Dyspnoea		Metoclopramide (10mg In D5lr 1000ml) (Ndc 61703-0210-11 Lot 0052-54-8/02)	PS			HYDRATION	@125ML/HR X 16 HRS

Date:04/13/01ISR Number: 3704613-1Report Type:Expedited (15-DaCompany Report #PHBS2001JP00880
Age:72 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dermatitis Haemorrhagic Diathesis	Foreign Health	Lescol	PS	Novartis Pharmaceuticals Corp	ORAL	20 MG/DAY, ORAL	
	Liver Disorder	Professional						
	Malaise Pancytopenia Rash	Other	Panaldine (Ticlopidine Hydrochloride) Sermion (Nicergoline) Nivadil (Nilvadipine) Strong Neo-Minophagen C (Cysteine, Aminoacetic Acid, Glycyrrhizic Acid)	SS SS SS		ORAL	ORAL	

	Tathion (Glutathione)	SS
	Primperan (Metoclopramide)	SS
	Protecadin (Lafutidine)	SS
	Epadel (Ethyl Icosapentate)	SS
	Neo-Lotan (Losartan Potassium)	SS
	Maintate (Bisoprolol Fumarate)	SS
	Norvasc (Amlodipine Besilate)	SS
	Gaster (Famotidine)	SS
	Atp / Jpn (Adenosine Triphosphate, Disodium Salt)	SS
	Solcoseryl (Blood, Calf, Deprot., Lmw Portion)	SS
	Neurotropin (Organ Lysate, Standardized)	SS
	Transamin (Tranexamic Acid)	SS
	Saxizon (Hydrocortisone Sodium Succinate)	SS

100 MG/DAY

Date:04/16/01ISR Number: 3705860-5Report Type:Expedited (15-DaCompany Report #HQ9342705APR2001
Age:37 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Agitation	Literature	Reglan	PS	Ah Robins Co	INTRAVENOUS	SEE IMAGE	2 DAY
Initial or Prolonged	Akathisia		Vitamins Nos					
	Anxiety		(Vitamins Nos)	C				
	Condition Aggravated							
	Decreased Appetite							
	Disturbance In Attention							
	Fatigue							
	Fear							

	Feeling Jittery
	Nausea
	Restlessness
	Sleep Disorder
	Vomiting
	Weight Decreased

Date:04/16/01ISR Number: 3705863-0Report Type:Expedited (15-DaCompany Report #HQ2065311OCT2000
Age:65 YR Gender:Female I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Anxiety
	Cognitive Disorder
	Decreased Activity
	Decreased Appetite
	Depression
	Fatigue

	Hallucination Hypertension Insomnia	Report Source	Product	Role	Manufacturer	Route	
Dose	Duration						
	Memory Impairment	Health	Reglan	PS	Ah Robins Co	ORAL	
SEE IMAGE							
	Restlessness Sedation Visual Disturbance Weight Decreased	Professional	Hydrochlorothiazide (Hydrochlorothiazide)	C			
			Premarin (Conjugated Estrogens)	C			
			Provera (Medroxyprogesterone Acetate)	C			
			Prilosec (Omeprazole)	C			
			Benadryl (Diphenhydramine Hydrochloride)	C			
			Perdiem (Psyllium Hydrophilic Mucilloid/Senna Fruit)	C			

Date:04/17/01ISR Number: 3707180-1Report Type:Expedited (15-DaCompany Report #HQ7035009FEB2001
Age:30 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Other	Dizziness	Health	Reglan	PS	Ah Robins Co	ORAL
10 MG THREE						
	Neuroleptic Malignant Syndrome	Professional				
TIMES DAILY						
(TOOK						
	Visual Disturbance					
APPROXIMATELY						
3 TO 4						
			Darvocet-N (Dextropropoxyphene/ Paracetamol)	C		
			Toradol (Ketorolac Tromethamine)	C		

Date:04/18/01ISR Number: 3706398-1Report Type:Expedited (15-DaCompany Report #B0103701A
Age:33 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Anaemia		Suxamethonium					
	Blood Cholinesterase		Chloride	PS	Glaxo Wellcome	INTRAVENOUS		
	Decreased		Labetalol	SS	Glaxo Wellcome	UNKNOWN		
	Hypermagnesaemia		Magnesium Sulphate	SS				
	Hypoproteinaemia		Metoclopramide	SS				
	Respiratory Disorder		Thiopentone	C				
			Nitrous Oxide	C				
			Isoflurane	C				
			Rocuronium	C				
			Fentanyl	C				

Date:04/18/01ISR Number: 3707272-7Report Type:Expedited (15-DaCompany Report #HQ9714816APR2001
Age:1 MON Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - "BELIEVES"	Convulsion	Health	Reglan	PS	Ah Robins Co	ORAL		
Initial or Prolonged	Overdose	Professional						

DOSE WAS 5 CC

(5MG), ORAL				Pepcid (Famotidine)	C		
				Mylanta (Aluminum Hydroxide Gel, Dried/Dimeticone, Activated/Magnesium Hydroxide)	C		

Date:04/18/01ISR Number: 3707457-XReport Type:Expedited (15-DaCompany Report #2001CG00303
Age:78 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Alanine Aminotransferase Increased	Foreign	Diprivan	PS	Astrazeneca Uk Ltd			
	Aspartate Aminotransferase Increased	Health Professional Other	Mefoxin	SS				
			Acupan	SS				
			Pro-Dafalgan	SS		INTRAVENOUS	2 G DAILY	IV
			Tracrium	SS		INTRAVENOUS	30 MG DAILY	IV
	Blood Bilirubin Increased							
	C-Reactive Protein Increased		Isoflurane	SS				
			Ephedrine	SS			9 MG DAILY	
	Hepatic Enzyme Increased		Primperan	SS				
	Hepatitis		Ciflox	SS				
	Liver Disorder		Ultiva	SS				
	Prothrombin Level Increased		Augmentin	SS			1500 MG DAILY	
			Augmentin	SS			1000 MG DAILY	
	Pyrexia		Fraxiparine	SS				
			Fraxiparine	SS				
			Dafalgan	C			6000 MG DAILY	

Date:04/18/01ISR Number: 3708036-0Report Type:Expedited (15-DaCompany Report #HQ8248907JUL2000
Age:26 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Caesarean Section	Health	Effexor	PS	Wyeth Ayerst			

Initial or Prolonged	Complications Of Maternal	Professional			Laboratories	ORAL
37.5 MG 2X						
	Exposure To Therapeutic					
PER 1 DAY 46 DAY						
	Drugs		Diazepam (Diazepam,			
	Drug Withdrawal Syndrome		)	SS		ORAL
10 MG 3X PER						
	Neonatal					
1 DAY						
	Hypospadias		Methadone			
	Pregnancy		(Methadone,)	SS		ORAL
	Premature Separation Of		Reglan			
	Placenta		(Metoclopramide			
			Hydrochloride,			
			Unspec)	SS		ORAL
5 TO 10 MG						
THREE TIMES						
DAILY						

Date:04/20/01ISR Number: 3708680-0Report Type:Expedited (15-DaCompany Report #WAES 01040483
Age:72 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Dermatitis	Foreign	Pepcid	PS	Merck Research	
Initial or Prolonged	Malaise	Health			Laboratories Div	
	Mouth Haemorrhage	Professional			Merck Co Inc	
INTRAVENOUS SEE IMAGE 1 DAY						
	Pancytopenia		Cilostazol	SS		ORAL
50 MG PO 78 DAY						
	Pyrexia		Ethyl			
			Eicosapentaenoate	SS		ORAL
900 MG PO 78 DAY						
			Tab Cozaar (Losartan			

				Potassium)	SS		ORAL
50 MG PO	60	DAY					
				Maintate (Bisoprolol Fumarate)	SS		ORAL
5 MG PO	52	DAY					
				Norvasc (Amlodipine Besylate)	SS		ORAL
5 MG PO	23	DAY					
				[Composition Unspecified]	SS		ORAL
10 MG PO	13	DAY					
				Primperan (Metoclopramide Hydrochloride)	SS		
INTRAVENOUS	IV	1	DAY				

Date:04/23/01ISR Number: 3709148-8Report Type:Expedited (15-DaCompany Report #B0103701A
Age:33 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Other	Drug Interaction	Foreign	Anectine	PS	Glaxo Wellcome Inc	
INTRAVENOUS	INTRAVENOUS					
		Literature	Trandate (Labetalol			
		Health	Hydrochloride)	SS		
		Professional	Magnesium Sulfate (Magnesium Sulfate)	SS		
			Metoclopramide (Metoclopramide)	SS		
			Thiopentone Sodium	C		
			Nitrous Oxide	C		
			Isoflurane	C		
			Rocuronium Bromide	C		
			Fentanyl	C		

Date:04/24/01ISR Number: 3710700-4Report Type:Expedited (15-DaCompany Report #HQ9756417APR2001
Age:4 MON Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization -	Convulsion	Consumer	Reglan	PS	Ah Robins Co	ORAL
3.75 MG 2X						
Initial or Prolonged	Lethargy					
PER 1 DAY,						

ORAL

Date:04/27/01ISR Number: 3713712-XReport Type:Expedited (15-DaCompany Report #WAES 01040483
Age:72 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dermatitis Malaise Mouth Haemorrhage	Foreign Health Professional	Pepcid	PS	Merck Research Laboratories Div Merck Co Inc			
						INTRAVENOUS	20MG/DAILY	1 DAY
	Pancytopenia		Cilostazol	SS		ORAL	50 MG	78 DAY
	Pyrexia		Cozaar (Losartan Potassium)	SS		ORAL	50 MG	70 DAY
			Maintate (Bisoprolol Fumarate)	SS		ORAL	5 MG	40 DAY
			Ethyl Eicosapnetaenoate	SS		ORAL	900 MG	78 DAY
			Norvasc (Amlodipine Besylate)	SS		ORAL	5 MG	25 DAY
			Primperan (Metoclopramide Hydrochloride)	SS				
						INTRAVENOUS		1 DAY
			[Composition Unspecified]	SS		ORAL	10 MG	
			Solcoseryl	C				
			Fluvastatin Sodium	C				

Nilvadipine	C
Ticlopidine Hydrochloride	C
Tranexamic Acid	C
Hydrocortisone Sodium Succinate	C
Nicergoline	C

Date:04/30/01ISR Number: 3715060-0Report Type:Expedited (15-DaCompany Report #PHBS2001JP00880
Age:72 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Dermatitis	Foreign	Lescol	PS	Novartis Pharmaceuticals Corp	ORAL	20 MG/DAY, ORAL
	Haemorrhagic Diathesis	Health Professional					
	Liver Disorder						
	Malaise	Other	Panaldine (Ticlopidine Hydrochloride)	SS		ORAL	ORAL
	Pancytopenia						
	Rash						
			Sermion (Nicergoline)	SS			
			Nivaldil (Nilvadipine)	SS			
			Primperan (Metoclopramide)	SS			
			Protecadin (Lafutidine)	SS			
			Epadel (Ethyl Icosapentate)	SS			
			Neo-Lotan (Losartan Potassium)	SS			
			Maintate (Bisoprolol Fumarate)	SS			
			Norvasc (Amlodipine Besilate)	SS			
			Gaster (Famotidine)	SS			
			Atp /Jpn/ (Adenosine Triphosphate, Disodium Salt)	SS			
			Solcoseryl (Blood, Calf, Deprot, Lmw Portion)	SS			

				Neurotropin (Organ Lysate, Standardized)	SS		
				Transamin (Tranexamic Acid)	SS		
				Saxizon (Hydrocortisone Sodium Succinate)	SS		

100 MG/DAY

Date:05/02/01ISR Number: 3715706-7Report Type:Expedited (15-DaCompany Report #HQ0057524APR2001
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Granulomatous Liver Disease	Health Professional	Reglan	PS	Ah Robins Co	ORAL	ORAL	

Date:05/02/01ISR Number: 3715710-9Report Type:Expedited (15-DaCompany Report #HQ2065311OCT2000
Age:65 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Anxiety	Health	Reglan	PS	Ah Robins Co	ORAL	5 MG 4X PER 1 DAY, ORAL; 10 MG 4X PER 1 DAY, ORAL
	Cognitive Disorder	Professional					
	Depression						
	Fatigue						
	Hallucination		Hydrochlorothiazide	C			
	Hypertension		Premarin (Conjugated Estrogens)	C			
	Insomnia		Provera (Medroxyprogesterone Acetate)	C			
	Memory Impairment		Prilosec (Omeprazole)	C			
	Movement Disorder		Benadryl (Diphenhydramine Hydrochloride)	C			
	Mydriasis		Perdiem (Psyllium Hydrophilic Mucilloid/Senna Fruit)	C			
	Restlessness						
	Sedation						
	Visual Disturbance						
	Weight Decreased						

Date:05/09/01ISR Number: 3720927-3Report Type:Expedited (15-DaCompany Report #HQ7035009FEB2001
Age:30 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Other	Blepharospasm	Health	Reglan	PS	Ah Robins Co	ORAL	10 MG THREE TIMES DAILY (TOOK APPROXIMATELY 3 TO 4
	Dizziness	Professional					
	Headache						
	Muscle Rigidity						
	Muscle Spasms						
	Neuroleptic Malignant		Phenergan				

	Syndrome		(Promethazine			
	Nystagmus		Hydrochloride,			
	Pyrexia		Unspec)	SS		
	Throat Tightness		Darvocet-N			
	Tremor		(Dextropropoxyphene/			
	Vision Blurred		Paracetamol)	C		
	Visual Acuity Reduced		Toradol (Ketorolac			
	Visual Disturbance		Tromethamine)	C		

Date:05/09/01ISR Number: 3720932-7Report Type:Expedited (15-DaCompany Report #HQ0475003MAY2001
Age:72 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Electrocardiogram Qt	Health	Reglan	PS	Ah Robins Co	
	Prolonged	Professional	Zofran (Ondansetron			
	Gastrointestinal		Hydrochloride)	SS		
	Haemorrhage					

Date:05/11/01ISR Number: 3721943-8Report Type:Expedited (15-DaCompany Report #HQ0620608MAY2001
Age:56 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Blood Prolactin Increased	Health	Metoclopramide Hcl	PS	Lederle Laboratories	
		Professional			Div American	
					Cyanamid Co	ORAL

10 MG 4X PER

1 DAY, ORAL						
			Synthroid (Levothyroxine Sodium)	C		
			Protonix (Pantoprazole)	C		
			Duratuss G (Guaifenesin)	C		
			Estrace (Estradiol)	C		
			Celebrex (Celecoxib)	C		

Date:05/14/01ISR Number: 3723751-0Report Type:Expedited (15-DaCompany Report #001-0981-M0103353
Age:61 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dermatitis Erythema Multiforme Muscle Twitching Systemic Lupus Erythematosus		Lipitor	PS	Pfizer Ireland Pharmaceuticals, Tablet Plant	ORAL	10 MG (DAILY), PER ORAL	
			Reglan (Metoclopramide)	SS				
			Prevacid (Lansoprazole)	C				
			(B-Complex Vitamins)	C				
			Protegra (Ascorbic Acid, Tocopheryl Acetate, Betacarotene, Manganese, Copper,	C				
			(Calcium)	C				
			(Allergy Shots)	C				

Date:05/16/01ISR Number: 3725172-3Report Type:Expedited (15-DaCompany Report #WAES 01049946
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Delirium	Foreign	Vioxx	PS	Merck Research			

Initial or Prolonged	Vomiting	Health Professional			Laboratories Div Merck Co Inc	ORAL
25 MG/DAILY	2 DAY					
			Metoclopramide Hydrochloride	SS		
1 DAY						
			Aspirin	C		
			Lisinopril	C		
			Metoprolol Succinate	C		

Date:05/17/01ISR Number: 3724368-4Report Type:Direct Company Report #USP 54006
Age:6.5 WK Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Other	Medication Error		Metoclopramide Hydrochloride	PS		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/18/01ISR Number: 3724581-6Report 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	Pancreatitis		Erythromycin Lansoprazole Sorbitol Dulcolax Nutrem Metoclopramide	PS C C C C I			UNKNOWN	UNKNOWN

Date:05/21/01ISR Number: 3725709-4Report Type:Expedited (15-DaCompany Report #236334
Age:53 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death Life-Threatening Hospitalization - Initial or Prolonged	Condition Aggravated Dermatitis Enteritis Gastrointestinal Motility Disorder Mucosal Inflammation Nausea Neuropathy Peripheral Palmar-Plantar Erythrodysaesthesia Syndrome Vomiting		Xeloda Rivotril Imodium Primperan Smecta Vastarel	PS SS SS SS SS SS	Roche Roche		16	DAY

Date:05/21/01ISR Number: 3725719-7Report Type:Expedited (15-DaCompany Report #227577
Age:54 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death Life-Threatening Hospitalization - Initial or Prolonged	Alopecia Balance Disorder Condition Aggravated Dermatitis Enteritis		Xeloda Rivotril Imodium Primperan Smecta	PS SS SS SS SS	Roche Roche		16	DAY

	Gastrointestinal Motility Disorder Intestinal Infarction Mucosal Inflammation Nausea Neuropathy Peripheral Palmar-Plantar Erythrodysaesthesia Syndrome		Vastarel	SS	

Date:05/23/01ISR Number: 3727798-XReport Type:Direct Company Report #
Age:11 DY Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Hospitalization - Initial or Prolonged Disability	Body Temperature Decreased Convulsion Crying Intraventricular Haemorrhage Perinatal Brain Damage		Reglan Syrup	PS			2 TIMES	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/23/01ISR Number: 3727827-3Report Type:Expedited (15-DaCompany Report #236334
Age:53 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Death	Asthenia	Foreign	Xeloda	PS	Hlr Technology	ORAL	4300 MG 1 PER
Life-Threatening	Condition Aggravated	Other					DAY ORAL
Hospitalization - Initial or Prolonged	Dermatitis Enteritis		Rivotril (Clonazepam)	SS		ORAL	ORAL
	Gastrointestinal Motility Disorder		Imodium (Loperamide Hydrochloride)	SS		ORAL	ORAL
	Intestinal Ischaemia Mucosal Inflammation Neuropathy Peripheral		Primperan (Metoclopramine Hydrochloride)	SS		ORAL	10 MG 3 PER
	Palmar-Plantar Erythrodysaesthesia Syndrome Vomiting		Smecta (*Aluminium Hydroxide / Diosmectite/* Glycyrrhiza/* Magnesium Carbonate)	SS		ORAL	DAY ORAL
			Vastarel (Trimetazidine)	SS		ORAL	ORAL

Date:05/23/01ISR Number: 3727831-5Report Type:Expedited (15-DaCompany Report #227577
Age:54 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Death	Alopecia	Foreign	Xeloda	PS	Hlr Technology	ORAL	2500 MG /M2
Life-Threatening	Asthenia	Health					DAILY ORAL
Hospitalization - Initial or Prolonged	Balance Disorder Condition Aggravated	Professional Other	Rivotril (Clonazepam)	SS		ORAL	ORAL
	Enteritis		Imodium (Loperamide				

	Gastrointestinal Motility		Hydrochloride)	SS		ORAL
ORAL						
	Disorder		Primperan			
	Intestinal Infarction		(Metoclopramide			
	Intestinal Ischaemia		Hydrochloride)	SS		ORAL
10 MG 3 PER						
	Mucosal Inflammation					
DAY ORAL						
	Neuropathy Peripheral		Smecta (*Aluminium			
	Palmar-Plantar		Hydroxide /			
	Erythrodysaesthesia		Diosmectite /			
	Syndrome		*Glycyrrhiza / *			
			Magnesium Carbonate)	SS		ORAL
ORAL						
			Vastarel			
			(Trimetazidine)	SS		ORAL
ORAL						

Date:05/23/01ISR Number: 3728019-4Report Type:Expedited (15-DaCompany Report #2001CG00489
Age:22 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Eosinophilia	Foreign	Cefotan	PS	Astrazeneca	
Initial or Prolonged	Hepatic Enzyme Increased	Health			Pharmaceuticals Lp	
INTRAVENOUS 2 G ONCE IV						
	Rash Pustular	Professional	Mopral	SS		
		Other	Diprivan	SS		
			Lovenox	SS		
			Nubain "Dupont			
			Pharma"	SS		
			Primperan	SS		
			Pro-Dafalgan	SS		
			Acupan	SS		
			Topalgic "Houde"	SS		
			Tracrium	SS		

			Sevoflurane	SS		
			Fentanyl	SS		
			Atarax	SS		

Date:05/25/01ISR Number: 3728941-9Report Type:Expedited (15-DaCompany Report #HQ0998117MAY2001
Age:78 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dyskinesia	Consumer	Reglan	PS	Ah Robins Co	ORAL	5 MG 4X PER 1	
	Movement Disorder						DAY, ORAL	
			Reglan (Metoclopramide Ydrochloride, Tablet)	SS		ORAL	5 MG 1X PER 1	
							DAY, ORAL	
			Coumadin (Warfarin Sodium)	C				
			Dyazide (Hydrochlorothiazide /Triamterene)	C				
			Vioxx (Rofecoxib)	C				
			Synthroid (Levothyroxine Sodium)	C				

Date:05/25/01ISR Number: 3729334-0Report Type:Expedited (15-DaCompany Report #B0107324A
Age:70 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Hypertension	Foreign	Zantac 150	PS	Glaxo Wellcome Inc	INTRAVENOUS	50 MG/	TWICE
Hospitalization -	Hypokalaemia						PER DAY/	
Initial or Prolonged	Nausea						INTRAVENOUS	
	Pancreatitis		Frusemide (Formulation					

		Unknown) (Furosemide)	SS
INTRAVENOUS	VARIABLE DOSE/ INTRAVENOUS		
		Heparin (Formulation Unknown) (Heparin)	SS
INTRAVENOUS	17500 UNIT/ PER DAY/ INTRAVENOUS		
		Papertin (Formulation Unknown)	SS
INTRAVENOUS	20 MG/ PER DAY/ INTRAVENOUS		
		Paracetamol	C
		Amlodipine	C
		Nadroparine Calcium	C
		Fentanyl	C
		Propacetamol Hcl	C
		Potassium Chloride	C
		Magnesium Sulfate	C

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/25/01ISR Number: 3729402-3Report Type:Expedited (15-DaCompany Report #B0103701A
Age:33 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Apnoea	Foreign	Anectine	PS	Glaxo Wellcome Inc	INTRAVENOUS	INTRAVENOUS	
	Blood Cholinesterase Decreased	Literature Health	Trandate (Labetalol Hydrochloride)	SS		UNKNOWN		
	Caesarean Section	Professional	Magnesium Sulfate (Magnesium Sulfate)	SS		UNKNOWN		
	Drug Interaction							
	Haemoglobin Decreased		Metoclopramide (Metoclopramide)	SS		UNKNOWN		
	Haemolysis							
	Hypoproteinaemia		Rocuronium Bromide (Rocuronium Bromide)	SS		UNKNOWN		
	Liver Function Test							
	Abnormal		Thiopentone Sodium	C				
	Platelet Count Decreased		Nitrous Oxide	C				
			Isoflurane	C				
			Fentanyl	C				
			Cefuroxime Sodium	C				
			Oxytocin	C				
			Ranitidine Hydrochloride	C				
			Sodium Citrate	C				

Date:05/29/01ISR Number: 3728999-7Report Type:Direct Company Report #
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Diarrhoea		Reglan Syrup	PS		ORAL		
	Irritability					SOLUTION-UNIT		
	Lethargy					DOSE BOTTLE;		
	Medication Error							
	Overdose							

Date:05/29/01ISR Number: 3730810-5Report Type:Expedited (15-DaCompany Report #10838803
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agranulocytosis Leukopenia	Foreign Health Professional Other	Zerit	PS	Bristol Myers Squibb Co Pharmaceutical Research Institute			
			Fungizone (Amphotericin B)	SS		INTRAVENOUS	50 MILLIGRAM,	IV
			Ancotil (Flucytosine)	SS		INTRAVENOUS	IV	
			Fluconazole	SS			200 MILLIGRAM,	2/1 DAY
			Gabapentin	SS			300 MILLIGRAM	
			Lamivudine + Zidovudine	SS				
			Metoclopramide (Metoclopramide Hcl)	SS				
			Paracetamol	SS				
			Trimethoprim + Sulfamethaxazole (Trimethoprim + Sulfam	SS				
			Didanosine (Didanosine)	C				

Thiamin (Thiamine)	C
Kalii Chloridum (Potassium Chloride)	C
Magnesium (Magnesium)	C
Clonazepam (Clonazepam)	C
Paracetamol + Codeine (Paracetamol + Codeine)	C
Filgrastim (Granulocyte Csf)	C
Nelfinavir (Nelfinavir Mesylate)	C
Guaifenesin (Guaifenesin)	C
3tc (Lamivudine)	C

Date:05/30/01ISR Number: 3729380-7Report Type:Expedited (15-DaCompany Report #B0108323A
Age:39 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Abdominal Pain		Trizivir	PS	Glaxo Wellcome	ORAL	2UNIT per day	9 DAY
Initial or Prolonged	Cholecystitis		Kaletra	SS		ORAL	6UNIT per day	
	Diarrhoea		Disulone	SS		ORAL	.25UNIT per day	
	Drug Hypersensitivity							
	Hepatitis		Paromomycin	SS		ORAL	2UNIT per day	20 DAY
	Hepatomegaly		Potassium Chloride	SS		ORAL	600MG per day	24 DAY
	Pyrexia		Metoclopramide	SS		ORAL	23 DAY	
			Didanosine	C		ORAL		
			Nevirapine	C		ORAL		
			Stavudine	C		ORAL		
			Azithromycin	C		ORAL	8 DAY	

Date:05/30/01ISR Number: 3731175-5Report Type:Expedited (15-DaCompany Report #HQ0906115MAY2001
Age:43 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Fracture	Study	Protonix Iv	PS	Wyeth Ayerst			
Hospitalization -	Haemophilus Infection				Laboratories			
						INTRAVENOUS	40 MG 1 X PER	
Initial or Prolonged	Neuroleptic Malignant							1 DAY,
Disability	Syndrome					INTRAVENOUS		
	Pneumonia		Reglan					
	Quadriplegia		(Metoclopramide					
	Rib Fracture		Hydrochloride,					
	Road Traffic Accident		Injection)	SS				
						INTRAVENOUS	10 MG 1 X PER	
	Spinal Fracture							1 DAY,
	Staphylococcal Infection					INTRAVENOUS		
			Acetaminophen					
			(Paracetamol)	C				
			Ibuprofen					
			(Ibuprofen)	C				
			Levaquin					
			(Levofloxacin)	C				
			Vancomycin					
			(Vancomycin)	C				
			Clindamycin					
			(Clindamycin)	C				

			Unasyn (Ampicillin Sodium/Sulbactam Sodium)	C		
			Famotidine (Famotidine)	C		
			Diazepam (Diazepam)	C		
			Morphine (Morphine)	C		
			Mild Of Magnesia (Magnesium Hydroxide)	C		
			Bisacodyl (Bisacodyl)	C		

Date:05/30/01ISR Number: 3731187-1Report Type:Expedited (15-DaCompany Report #2773
Age:4 MON Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Culture Urine Positive Klebsiella Infection Muscle Rigidity Musculoskeletal Stiffness Pupil Fixed	Literature Health Professional	Metoclopramide Vitamin D	PS C		ORAL	15 ML; PO	12 HR

Date:05/31/01ISR Number: 3731808-3Report Type:Expedited (15-DaCompany Report #HQ1246123MAY2001
Age:84 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Blood Alkaline Phosphatase Increased C-Reactive Protein Increased Candidiasis Culture Urine Positive Escherichia Infection Gamma-Glutamyltransferase Increased Lymphopenia	Health Professional Other	Suprax Anafranil (Clomipramine Hydrochloride) Donormyl (Doxylamine Succinate/Sodium Bromide/Sodium Phosphate	PS SS	Lederle Laboratories Div American Cyanamid Co	ORAL	ORAL	22 DAY 1 MON

	Pyrexia		Dibasic/Sodium	SS		ORAL
ORAL 1 MON						
	Toxocariasis		Primperan (Metoclopramide)	SS		
22 DAY						
			Lovenox (Heparin-Fraction, Sodium Salt)	C		

Date:06/01/01ISR Number: 3732199-4Report Type:Expedited (15-DaCompany Report #HQ7035009FEB2001
Age:30 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Eyelid Function Disorder	Health	Reglan	PS	Ah Robins Co	ORAL
10 MG THREE						
	Headache	Professional				
TIMES DAILY						
	Neuroleptic Malignant					
(TOOK						
	Syndrome					
APPROXIMATELY						
	Nystagmus					
3 TO 4 DOSES,						
	Photophobia		Phenergan (Promethazine Hydrochloride, Unspec)	SS		
	Visual Acuity Reduced		Darvocet-N			

			(Dextropropoxyphene/ Paracetamol)	C		
			Toradol (Ketorolac Tromethamine)	C		

Date:06/04/01ISR Number: 3733120-5Report Type:Expedited (15-DaCompany Report #2001CG00489
Age:22 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dermatitis Eosinophilia	Foreign Health	Cefotan	PS	Astrazeneca Pharmaceuticals Lp	INTRAVENOUS	2 G ONCE IV	
	Hepatic Enzyme Increased	Professional	Mopral	SS				
	Rash Pustular	Other	Diprivan	SS				
			Lovenox	SS				
			Nubain "Dupont Pharma"	SS				
			Primperan	SS				
			Pro-Dafalgan	SS				
			Acupan	SS				
			Topalgic "Houde"	SS				
			Tracrium	SS				
			Sevoflurane	SS				
			Fentanyl	SS				

Date:06/04/01ISR Number: 3733178-3Report Type:Expedited (15-DaCompany Report #B0108323A
Age:39 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain Body Temperature Increased Cholecystitis Diarrhoea Hepatomegaly Hypersensitivity Pyrexia	Foreign	Trizivir	PS	Glaxo Wellcome Inc	ORAL	TWICE PER DAY	/ ORAL
			Kaletra Capsule (Kaletra)	SS		ORAL	TWICE PER DAY	/ ORAL
			Disulone Tablet (Disulone)	SS		ORAL	ORAL	
			Paromycin					

			(Paromomycin Sulfate)	SS		ORAL
TWICE PER DAY						
/ ORAL						
			Potassium Chloride Capsule (Potassium Chloride)	SS		ORAL
ORAL						
			Metoclopramide Solution (Metoclopramide)	SS		ORAL
10 MG / ORAL						
			Didanosine	C		
			Nevirapine	C		
			Stavudine	C		
			Azithromycin	C		

Date:06/05/01ISR Number: 3732760-7Report Type:Expedited (15-DaCompany Report #WAES 01051191
Age:73 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Rhabdomyolysis		Noroxin	PS	Merck & Co., Inc	ORAL	2	DAY
Initial or Prolonged			Nu-Lotan	SS		ORAL		
			Primperan	SS		ORAL	2	DAY
			Cough, Cold, And Flu Therapies					

			(Unspecified)	C		ORAL
			Cefzon	C		ORAL
3 DAY						
			Gaster	C		ORAL
3 DAY						
			Asverin	C		ORAL
2 DAY						
			Ambroxol Hydrochloride	C		ORAL

Date:06/07/01ISR Number: 3735966-6Report Type:Expedited (15-DaCompany Report #HQ0475003MAY2001
Age:72 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Electrocardiogram Qt	Health	Reglan	PS	Ah Robins Co	
INTRAVENOUS INTRAVENOUS						
	Prolonged Gastrointestinal Haemorrhage	Professional	Zofran (Ondansetron Hydrochloride)	SS		
	Ventricular Tachycardia					

Date:06/07/01ISR Number: 3735975-7Report Type:Expedited (15-DaCompany Report #HQ1539001JUN2001
Age:6 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Aggression	Consumer	Reglan	PS	Ah Robins Co	ORAL
1) UNKNOWN						
	Dermatitis					
DOSE FOUR						
	Diarrhoea					
TIMES DAILY,						
	Mood Swings					
ORAL; 2)						
	Petit Mal Epilepsy					
UNKNOWN DOSE						
	Pollakiuria		Carafate (Sucralfate)	C		
			Aciphex (Aciphex)	C		

Date:06/08/01ISR Number: 3736853-XReport Type:Expedited (15-DaCompany Report #WAES 01051191
Age:73 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Rhabdomyolysis	Foreign Health Professional	Noroxin	PS	Merck Research Laboratories Div Merck Co Inc	ORAL	600 MG PO	2 DAY
			Nu-Lotan (Losartan Potassium)	SS		ORAL	50 MG PO	
			Primperan (Metoclopramide Hydrochloride)	SS		ORAL	15 MG PO	2 DAY
			Asverin	C				
			Cefzon	C				
			Gaster	C				
			Ambroxol Hydrochloride	C				
			Cough, Cold, And Flu Therapies	C				

Date:06/11/01ISR Number: 3736321-5Report Type:Expedited (15-DaCompany Report #261263
Age:83 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Confusional State		Bactrim Forte	PS	Roche			6 DAY
Initial or Prolonged	Hyponatraemia		Primperan	SS				3 DAY
			Aprovel	SS				218 DAY
			Levothyrox	C				

			Vastarel	C		
			Gaviscon	C		
			Previscan	C		
			Flixotide	C		
			Foradil	C		

Date:06/11/01ISR Number: 3737907-4Report Type:Expedited (15-DaCompany Report #HQ0620608MAY2001
Age:56 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blood Prolactin Increased	Health Professional	Reglan	PS	Ah Robins Co	ORAL	10 MG 4X PER 1 DAY, ORAL	
			Synthroid (Levothyroxine Sodium)	C				
			Protonix (Pantoprazole)	C				
			Duratuss G (Guaifenesin)	C				
			Estrace (Estradiol)	C				
			Celebrex (Celecoxib)	C				

Date:06/13/01ISR Number: 3738154-2Report Type:Direct Company Report #
Age:21 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Apnoea Grand Mal Convulsion		Demerol Pca	PS		INTRAVENOUS	20MG IV Q 15MIN WITH 80MG/HR/ LIMIT	
			Reglan	SS		INTRAVENOUS	15MG IVPB Q	

6HR

Date:06/13/01ISR Number: 3738932-XReport Type:Expedited (15-DaCompany Report #261263
Age:83 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Confusional State Hyponatraemia	Foreign Other	Bactrim	PS	Hoffmann La Roche Inc	ORAL	1 DOSE FORM 2 PER DAY ORAL	
			Primperan (Metoclopramide Hydrochloride)	SS		ORAL		
			Levothyrox (Levothyroxine Sodium)	C				
			Vastarel (Trimethoprim)	C				
			Previscan (Fluindione)	C				
			Foradil (Formoterol)	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/13/01ISR Number: 3739222-1Report Type:Expedited (15-DaCompany Report #HQ0998117MAY2001
Age:78 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Dyskinesia	Health	Reglan	PS	Ah Robins Co	ORAL	5 MG 4X PER 1	
	Tardive Dyskinesia	Professional					DAY, ORAL	
			Coumadin (Warfarin Sodium)	C				
			Dyazide (Hydrochlorothiazide /Triamterene)	C				
			Vioxx (Rofecoxib)	C				
			Synthroid (Levothyroxine Sodium)	C				

Date:06/13/01ISR Number: 3739909-0Report Type:Direct Company Report #
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Medication Error		Metoclopramide Hydrochloride	PS	Faulding			
			Oxytocin	SS	American Pharmaceutical Partners			

Date:06/15/01ISR Number: 3741780-8Report Type:Periodic Company Report #2000AU04773
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Chest Pain	Consumer	Prilosec	PS	Astrazeneca Lp	ORAL	1 DF QD PO	
	Drug Ineffective		Reglan	SS				
	Dyspnoea		Propulsid	C				

Date:06/21/01ISR Number: 3743457-1Report Type:Expedited (15-DaCompany Report #A0148770A
Age:39 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Abnormal Behaviour		Lamictal	PS	Glaxo Wellcome	ORAL	25MG Per day	3 DAY
	Condition Aggravated		Reglan	SS		ORAL	10MG Three times per day	35 DAY
			Synthroid	C	Glaxo Wellcome	ORAL	175MCG Per day	
			Buspar	C		ORAL	20MG Three times per day	
			Colace	C		ORAL	1TAB At night	
			Ortho Tri Cyclen	C		ORAL	1TAB At night	
			Naprosyn	C		ORAL	375MG As required	
			Paxil	C	Glaxo Wellcome	ORAL	20MG Per day	
			Tums	C		ORAL	1TAB Three times per day	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/22/01ISR Number: 3745667-6Report Type:Expedited (15-DaCompany Report #HQ5018219DEC2000
Age:4 MON Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Accidental Overdose	Health	Reglan	PS	Ah Robins Co	ORAL		
Initial or Prolonged	Convulsion	Professional	Unspecified Vaccine					
Other	Dystonia		(Unspecified					
	Haematocrit Decreased		Vaccine, Unspec)	SS				
	Haemoglobin Decreased		Zantac (Ranitidine					
	Heart Rate Increased		Hydrochloride)	C				
	Medication Error		Pan-Mist					
	Pyrexia		(Guaifenesin/Pseudoe					
	Respiratory Distress		phedrine)	C				
	Sedation							

Date:06/25/01ISR Number: 3747202-5Report Type:Expedited (15-DaCompany Report #A0148770A
Age:39 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required	Abnormal Behaviour	Health	Lamictal	PS	Glaxo Wellcome Inc	ORAL	25 MG/ PER	
Intervention to	Condition Aggravated	Professional					DAY/ ORAL	
Prevent Permanent			Metoclopramide Hcl	SS		ORAL	10 MG/ THREE	
Impairment/Damage							TIMES PER	
							DAY/ ORAL	
			Thyroxine Sodium	C				
			Buspirone					
			Hydrochloride	C				
			Docusate Sodium	C				
			Ortho Tri-Cyclen	C				
			Naproxen	C				
			Paroxetine					
			Hydrochloride	C				
			Calcium Carbonate	C				

Date:06/28/01ISR Number: 3749177-1Report 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	Asthenia Confusional State Difficulty In Walking		Metoclopramide 5mg Tab Teva	PS	Teva	ORAL	5 MG PO QID	

Date:07/02/01ISR Number: 3751176-0Report Type:Direct Company Report #
Age:62 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Agitation		Clonidine	PS			0.1MG -1DAILY	
Other	Anxiety		Metoclopramide	SS			10MG -4 TIME	
	Asthenia						DAILY	
	Constipation							
	Depression							
	Fatigue							
	Feeling Abnormal							
	Insomnia							
	Muscle Disorder							
	Nervousness							

Date:07/05/01ISR Number: 3753555-4Report Type:Expedited (15-DaCompany Report #2001062421US
Age: Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Creatinine Increased	Study Health	Camptosar	PS	Pharmacia And Upjohn Co	INTRAVENOUS	130.2 MG, WEEKLY, IV	
	Blood Urea Increased	Professional						
	Dehydration		Spironolactone					
	Haematocrit Decreased		(Spironolactone)	SS		ORAL	50 MG, QD, ORAL	
	Haemoglobin Decreased							
	Hepatic Neoplasm Malignant		Hydrocodone (Hydrocodone)	SS		ORAL	SEE IMAGE	
	Hyponatraemia		Reglan					
	Platelet Count Decreased		(Metoclopramide)	SS		ORAL	10 MG, PRN, ORAL	
	Upper Gastrointestinal Haemorrhage							
	Varices Oesophageal							

Date:07/06/01ISR Number: 3753798-XReport Type:Expedited (15-DaCompany Report #HQ5018219DEC2000
Age:4 MON Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Convulsion	Health	Reglan	PS	Ah Robins Co	ORAL	ORAL	
Other	Cough	Professional	Vaccine (Vaccine)	SS				
	Dystonia		Zantac (Ranitidine Hydrochloride)	C		ORAL		
	Haematocrit Decreased							
	Haemoglobin Decreased		Pan-Mist (Quaifenesin/Pseudoephedrine)	C		ORAL		
	Heart Rate Increased							
	Lymphocyte Count Increased							
	Medication Error							
	Nasal Congestion							
	Neutrophil Count Decreased							
	Overdose							

Oxygen Saturation
Decreased
Posturing
Pyrexia
Respiratory Distress
Sedation
Tachypnoea
Thrombocythaemia

Date:07/06/01ISR Number: 3753814-5Report Type:Expedited (15-DaCompany Report #101034ISR
Age:18 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Hospitalization -	Anaphylactic Reaction	Health Professional	Metoclopramide (Batch #: Unk)	PS		ORAL	1 TABLET	Initial or Prolonged
							QD/BID/PRN	3 DAY
			Metronidazole	C				

Date:07/06/01ISR Number: 3753967-9Report Type:Expedited (15-DaCompany Report #HQ0906115MAY2001
Age:43 YR Gender:Female I/FU:F

Outcome
Life-Threatening Hospitalization -

Initial or Prolonged
Disability

PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Bacterial Infection Fracture	Study	Protonix Iv	PS	Wyeth Ayerst Laboratories	INTRAVENOUS	40 MG 1X 1 DAY,	
Haemophilus Infection Injury Neuroleptic Malignant Syndrome Pneumonia Quadriplegia		Reglan (Metoclopramide Hydrochloride, Injection)	SS		INTRAVENOUS	10 MG 1X PER 1 DAY,	
Road Traffic Accident		Hydrocodone W/Acetaminophen (Hydrocodone Bitartrate/Paracetamol)	C		INTRAVENOUS		
		Acetaminophen (Paracetamol)	C				
		Ibuprofen (Ibuprofen)	C				
		Levaquin (Levofloxacin)	C				
		Vancomycin (Vancomycin)	C				
		Clindamycin (Clindamycin)	C				
		Unasyn (Ampicillin Sodium/Sulbactam Sodium)	C				
		Famotidine (Famotidine)	C				
		Diazepam (Diazepam)	C				
		Morphine (Morphine)	C				
		Milk Of Magnesia (Magnesium Hydroxide)	C				
		Bisacodyl (Bisacodyl)	C				

Date:07/09/01ISR Number: 3755320-0Report Type:Expedited (15-DaCompany Report #JAFRA10250
Age:72 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Sudden Death	Foreign	Droperidol (Ampoule)	PS			INTRAMUSCULAR	25 MG, 1 IN 1 TIME(S), IM
		Health Professional	Cortancyl (Tablet 5 Mg) (Corticosteroids)	SS			INTRAMUSCULAR	5 MG, 1 IN 1 TIME(S), IM
			Theophylline (Solution)	SS			ON PUMP	
			Salbutamol	SS				
			Metoclopramide	SS				
			Amoxicillin	SS				
			Aldactazine	SS				
			Digoxine (Digoxin)	SS				
			Euphylline (Aminophylline)	SS				

			Ventoline (Salbutamol)	SS		
			Hemisuccinate D'Hydrocortisone (Hydrocortisone)	SS		
			Tagamet (Cimetidine)	SS		
			Maalox	SS		

Date:07/09/01ISR Number: 3755410-2Report Type:Expedited (15-DaCompany Report #HQ2632828JUN2001
Age:72 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Body Temperature Increased	Health Professional	Zebeta	PS	Lederle Laboratories Div American			
	Malaise	Other			Cyanamid Co	ORAL	5 MG 1X PER 1 DAY	
	Mouth Haemorrhage							
	Pancytopenia		Cilostazol (Cilostazol)	SS		ORAL	19 DAY	
			Ethyl Icosapentate (Ethyl Icosapentate,)	SS		ORAL	900 MG 1X PER 1 DAY	78 DAY
			Gaster (Famotidine, Gas)	SS		INTRAVENOUS		
			Losartan Potassium (Losartan Potassium,)	SS		ORAL	60 DAY	
			Norvasc (Amlodipine Besilate,)	SS		ORAL		
			Primperan (Metoclopramide,)	SS		INTRAVENOUS	10 MG 1X PER 1 DAY	
			Solcoseryl (Blood, Calf, Deprot., Lmw					

			Portion,)	SS		
INTRAVENOUS						
			Elcitonin (Elcatonin)	C		

Date:07/09/01ISR Number: 3755569-7Report Type:Expedited (15-DaCompany Report #2001062654FR
Age:51 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Anaemia Neutropenia	Foreign Health	Medrol	PS	Pharmacia And Upjohn Co	ORAL
8 MG, QD,						
Other	Thrombocytopenia	Professional				
ORAL 13 DAY						
		Other	Foscavir (Foscarnet Sodium)	SS		
INTRAVENOUS 7.5 G, BID,						
IV						
			Crixivan (Indinavir Sulfate)	SS		ORAL
800 MG, BID,						
ORAL						
			Norvir (Ritonavir)	SS		ORAL
100 MG, BID,						
ORAL						
			Epivir (Lamivudine)	SS		ORAL
150 MG, BID,						
ORAL						
			Ziagen (Abacavir)	SS		ORAL
300 MG, BID,						
ORAL						
			Smecta (Liquorice, Aluminium			

				Hydroxide-Magnesium Carbonate Gel, Aluminium Magnesium	SS			ORAL	UNK, UNK, ORAL
				Primperan (Metoclopramide)	SS				
				Bricanyl(Terbutaline Sulfate)	SS				13 DAY
				Serevent (Salmeterol Xinafoate)	SS				13 DAY
				Pulmicort (Budesonide)	SS				
				Imodium (Loperamide Hydrochloride)	SS			ORAL	UNK, UNK, ORAL
				Rulid(Roxithromycin)	SS			ORAL	13 DAY UNK, UNK, ORAL
				Toplexil(Sodium Benzoate, Oxomemazine)	SS			ORAL	UNK, UNK, ORAL

Date:07/10/01ISR Number: 3756108-7Report Type:Expedited (15-DaCompany Report #132218USA
Age:74 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Electrocardiogram Qt Prolonged	Health Professional	Pimozide	PS		ORAL	1 MILLIGRAM QD BY MOUTH/P.O.	10 WK
	Haemodialysis							
	Ventricular Tachycardia		Amlodipine	C				
			Allopurinol	C				
			Senna Leaf	C				

Date:07/11/01ISR Number: 3755916-6Report Type:Direct Company Report #
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
	Feeling Jittery Medication Error		Reglan Syrup (Metoclopramide Oral Solution Usp)	PS	Wyeth-Ayerst Laboratories	

Date:07/11/01ISR Number: 3756799-0Report Type:Expedited (15-DaCompany Report #HQ0906115MAY2001
Age:43 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Life-Threatening Hospitalization -	Bacteria Sputum Identified	Study	Protonix Iv	PS	Wyeth Ayerst Laboratories	
INTRAVENOUS 40 MG 1X PER						
Initial or Prolonged 1 DAY,	Blood Culture Positive					
Disability INTRAVENOUS	Haemophilus Infection					
	Neuroleptic Malignant Syndrome Pneumonia Pyrexia		Reglan (Metoclopramide Hydrochloride, Injection)	SS		
INTRAVENOUS 10 MG 1X PER 1 DAY, INTRAVENOUS						
			Hydrocodone W/Acetaminophen (Hydrocodone			

Bitartrate/Paracetamol)	C
Acetaminophen (Paracetamol)	C
Ibuprofen	C
Levaquin (Levofloxacin)	C
Vancomycin	C
Clindamycin	C
Unasyn (Ampicillin Sodium/Sulbactam Sodium)	C
Famotidine	C
Diazepam	C
Morphine	C
Milk Of Magnesia (Magnesium Hydroxide)	C
Bisacodyl	C

Date:07/11/01ISR Number: 3758681-1Report Type:Periodic Company Report #2001UW03861
Age:59 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Fatigue	Consumer	Nexium	PS	Astrazeneca Lp	ORAL	40 MG DAILY	
	Muscle Twitching						PO	
			Reglan	SS				

Date:07/12/01ISR Number: 3757488-9Report Type:Expedited (15-DaCompany Report #HQ2632828JUN2001
Age:72 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Body Temperature Increased	Health Professional	Zebeta	PS	Lederle Laboratories Div American			
	Malaise	Other			Cyanamid Co	ORAL	58 MG 1X PER	
	Mouth Haemorrhage						1 DAY, ORAL	40 DAY
	Pancytopenia		Cilostazol					

ORAL	19	DAY					
900 MG 1X PER							
1 DAY, ORAL	78	DAY					
INTRAVENOUS		INTRAVENOUS					
ORAL	60	DAY					
ORAL	25	DAY					
INTRAVENOUS		10 MG 1X PER					
1 DAY,							
INTRAVENOUS							
INTRAVENOUS		INTRAVENOUS					

(Cilostazol)	SS	ORAL
Ethyl Icosapentate (Ethyl Icosapentate)	SS	ORAL
Gaster (Famotidine, Gas)	SS	
Losartan Potassium (Losartan Potassium)	SS	ORAL
Norvasc (Amlodipine Besilate)	SS	ORAL
Primperan (Metoclopramide)	SS	
Solcoseryl (Blood, Calf, Deprot., Lmw Portion)	SS	
Elcitonin (Elcatonin)	C	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/16/01ISR Number: 3759489-3Report Type:Expedited (15-DaCompany Report #HQ2734302JUL2001
Age:2 MON Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Diarrhoea	Health	Reglan	PS	Ah Robins Co	ORAL		
	Pyrexia	Professional						

Date:07/16/01ISR Number: 3759900-8Report Type:Expedited (15-DaCompany Report #2001062421US
Age: Gender: I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Dehydration	Study	Camptosar	PS	Pharmacia And Upjohn Co			
Hospitalization - Initial or Prolonged	Haematocrit Decreased	Health				INTRAVENOUS	130.2 MG,	WEEKLY,IV
	Haemoglobin Decreased	Professional						
	Hyponatraemia		Spironolactone(Spironolactone)	SS		ORAL	50 MG,QD,	
	Multi-Organ Failure							
	Oesophageal Varices							
	Haemorrhage		Hydrocodone (Hydrocodone)	SS		ORAL	5 MG, QD PRN,	
	Pneumonia							
	Renal Impairment							
	Respiratory Distress							
	Upper Gastrointestinal Haemorrhage		Reglan (Metoclopramide)	SS		ORAL	10 MG, PRN,	

Date:07/18/01ISR Number: 3761047-1Report Type:Direct Company Report #
Age:2 MON Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Other	Abdominal Pain		Reglan 5mg/5ml	PS		ORAL
0.5ML 4 PER						
Required	Feeding Disorder					
DAY ORAL						
Intervention to	Irritability					
Prevent Permanent	Listless					
Impairment/Damage	Muscle Twitching					
	Muscular Weakness					

Date:07/18/01ISR Number: 3761058-6Report Type:Expedited (15-DaCompany Report #HQ3175112JUL2001
Age:39 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Abnormal Behaviour	Health	Reglan	PS	Ah Robins Co	ORAL	10 MG 3X PER	
	Condition Aggravated	Professional					1 DAY, ORAL	
			Lamictal (Lamotrigine,)	SS		ORAL	25 MG 1X PER	
							1 DAY, ORAL	
			Thyroxine Sodium (Levothyroxine Sodium)	C				
			Buspirone Hydrochloride	C				
			Docusate Sodium	C				
			Ortho Tri-Cyclen (Ethinylestradiol/Norgestimate)	C				
			Naproxen	C				
			Paroxetine Hydrochloride	C				
			Calcium Carbonate	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/24/01ISR Number: 3764227-4Report Type:Expedited (15-DaCompany Report #2001PK00636
Age:61 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Asthenia	Foreign	Nexium	PS	Astrazeneca Lp	ORAL	20 MG QD PO
Initial or Prolonged	Difficulty In Walking	Study	Nexium	SS		ORAL	20 MG BID PO
	Dysphonia	Health	Mcp "Isis"	SS		ORAL	30 GTT TID PO
	Hypokinesia	Professional	Clindastad	C			
	Movement Disorder	Other	Agopton	C			
	Paraesthesia						
	Parkinson'S Disease						

Date:07/25/01ISR Number: 3765866-7Report Type:Direct Company Report #
Age:61 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Life-Threatening	Biopsy Bone Marrow		Metoclopramide 10mg				
Hospitalization -	Abnormal		Po	PS		ORAL	PO AC AND HS
Initial or Prolonged	Epiglottitis						
	Gastrooesophageal Reflux						
	Disease						
	Meningitis Streptococcal						
	Neutropenia						
	White Blood Cell Count						
	Decreased						

Date:07/27/01ISR Number: 3767263-7Report Type:Periodic Company Report #132221USA
Age:45 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Dyspnoea	Consumer	Metoclopramide	PS	Teva Pharmaceuticals		
Initial or Prolonged	Hypoglycaemia				Usa Inc	ORAL	20 MILLIGRAM
	Parkinsonism						

AC BY

	Vision Blurred					
MOUTH/P.O.						

Date:07/27/01ISR Number: 3767298-4Report Type:Expedited (15-DaCompany Report #WAES 01071136
Age:73 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Blood Lactate Dehydrogenase Increased	Foreign	Pepcid	PS	Merck Research Laboratories Div		
	Dermatitis Exfoliative				Merck Co Inc	ORAL	
	Drug Hypersensitivity		Nifedipine	SS		ORAL	
	Erythema		Ticlopidine Hydrochloride	SS		ORAL	
	Pruritus		Metoclopramide	SS		ORAL	
			Imipramine Pamoate	SS		ORAL	

Date:08/01/01ISR Number: 3769237-9Report Type:Expedited (15-DaCompany Report #2001CG00852
Age:80 YR Gender:Female I/FU:I

Outcome	PT
Death	Abdominal Pain
	Anaemia
	Hepatic Failure
	Hepatic Steatosis
	Hepatocellular Damage
	Metabolic Acidosis

		Pancreatitis					
		Renal Failure Acute					
		Shock	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
		Thrombocytopenia	Foreign	Sensorcaine	PS	Astrazeneca Lp	
			Health	Cefacidal	SS		
			Professional	Primperan	SS		
			Other	Temgesic	SS		
				Profenid	SS		
				Novatrex	SS		
				Lederfolin	C		
				Aldactone	C		
				Doliprane	C		
				Zocor	C		
				Orocal	C		
				Vastarel	C		
				Didronel	C		
				Lubentyl	C		
				Temesta	C		
				Aldomet	C		
				Cortancyl	C		

Date:08/03/01ISR Number: 3771282-4Report Type:Expedited (15-DaCompany Report #WAES 01071136
Age:73 YR Gender:Male I/FU:F

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Hospitalization -		Antinuclear Antibody	Foreign	Pepcid	PS	Merck Research	
Initial or Prolonged		Positive	Literature			Laboratories Div	
		Blood Lactate	Health			Merck Co Inc	ORAL
		Dehydrogenase Increased	Professional	Nifedipine	SS		ORAL
		Dermatitis	Other	Ticlopidine			
		Dermatitis Exfoliative		Hydrochloride	SS		ORAL
		Drug Hypersensitivity		Metoclopramide	SS		ORAL
		Eosinophil Count		Imipramine Pamoate	C		ORAL
		Increased					
		Erythema					
		Pruritus					
		White Blood Cell Count					
		Increased					

Date:08/06/01ISR Number: 3771986-3Report Type:Expedited (15-DaCompany Report #HQ2734302JUL2001
Age:2 MON Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Clostridium Colitis	Health Professional	Reglan	PS	Ah Robins Co	ORAL	UNKNOWN, ORAL	

Date:08/07/01ISR Number: 3771441-0Report Type:Expedited (15-DaCompany Report #B0115186A
Age:51 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anaemia		Epivir	PS	Glaxo Wellcome	ORAL	150MG Twice per day	13 DAY
	Neutropenia							
	Thrombocytopenia		Ziagen	SS	Glaxo Wellcome	ORAL	300MG Twice per day	
	White Blood Cell Count Decreased		Serevent	SS	Glaxo Wellcome		RESPIRATORY (INHALATION)	
			Medrol	SS		ORAL	8MG Per day	
			Foscavir	SS			INTRAVENOUS	7.5G Twice

per day

				Primperan	SS		
UNKNOWN	9	DAY					
				Pulmicort	SS		
RESPIRATORY							
(INHALATION)							
				Imodium	SS		ORAL
				Toplexil	SS		ORAL
				Rulid	SS		ORAL
4 DAY							
				Smecta	SS		ORAL
7 DAY							
				Crixivan	SS		ORAL
800MG Twice							
per day							
				Norvir	SS		ORAL
100MG Twice							
per day							
				Bricanyl	SS		
UNKNOWN							
				Rocephine	C		
UNKNOWN							

Date:08/09/01ISR Number: 3774253-7Report Type:Expedited (15-DaCompany Report #B0115186A
Age:51 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Anaemia	Foreign	Ziagen	PS	Glaxo Wellcome Inc	ORAL	300 MG/ TWICE	
Initial or Prolonged	Neutropenia						PER DAY/ORAL	
	Thrombocytopenia		Epivir (Lamivudine)	SS		ORAL	150 MG/ TWICE	
							PER DAY/ ORAL	
			Serevent (Salmeterol Xinafoate)	SS				
RESPIRATORY								
(INHALATION)	INHALED							

		Medrol (Medrol)	SS	ORAL
8 MG PER DAY/ORAL				
		Foscarnet Sodium Solution (Foscarnet Sodium)	SS	
INTRAVENOUS	7.5 G/ TWICE PER DAY/ INTRAVENOUS			
		Metoclopramide Hc1 (Metoclopramide Hc1)	SS	
		Budesonide (Budesonide)	SS	
RESPIRATORY (INHALATION)	INHALED			
		Loperamide Hydrochloride (Loperamide Hydrochloride)	SS	ORAL
ORAL		Toplexil Syrup (Toplexil)	SS	ORAL
ORAL		Roxithromycin (Roxithromycin)	SS	ORAL
ORAL		Diosmectite Powder (Diosmectite)	SS	ORAL
800 MG/ TWICE PER DAY/ ORAL		Indinavir Sulfate (Indinavir Sulfate)	SS	ORAL
		Ritonavir Capsule (Ritonavir)	SS	ORAL
100 MG/ TWICE PER DAY/ ORAL				
		Terbutaline Sulphate (Terbutaline Sulphate)	SS	
		Ceftriaxone Sodium	C	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/13/01ISR Number: 3776411-4Report Type:Expedited (15-DaCompany Report #2001062421US
Age: Gender: I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Blood Urea Increased	Study	Camptosar	PS	Pharmacia And Upjohn Co	INTRAVENOUS	130.2 MG,	
Hospitalization - Initial or Prolonged	Dehydration	Health Professional						WEEKLY, IV
	Hyponatraemia							
	Multi-Organ Failure		Spironolactone (Spironolactone)	SS		ORAL	50 MG, QD,	
	Pneumonia							ORAL
	Respiratory Distress							
	Upper Gastrointestinal Haemorrhage		Hydrocodone (Hydrocodone)	SS		ORAL	5 MG, QD PRN,	
	Varices Oesophageal							ORAL, 500 MG,
								PRN, ORAL
			Reglan (Metoclopramide)	SS		ORAL	10 MG, PRN,	
								ORAL

Date:08/14/01ISR Number: 3777309-8Report Type:Direct Company Report #
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Anxiety		Reglan	PS				DAILY
Required Intervention to Prevent Permanent Impairment/Damage	Depression							
	Insomnia							
	Tremor							

Date:08/14/01ISR Number: 3777459-6Report Type:Expedited (15-DaCompany Report #8-97148-001S
Age:8 MON Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Brain Damage	Consumer	Reglan	PS	Ah Robins Co	ORAL	SEE IMAGE	
Other	Clumsiness		Tylenol Pen (Tylenol Pen)	C				
	Cognitive Disorder		Antibiotics Prn (Antibiotics Prn)	C				
	Convulsion							
	Developmental Delay							
	Hypotonia							
	Neurotoxicity							
	Overdose							

Date:08/15/01ISR Number: 3778564-0Report Type:Expedited (15-DaCompany Report #HQ4308307AUG2001
Age:80 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Fall	Foreign	Methotrexate Sodium	PS	Lederle Laboratories			
Hospitalization - Initial or Prolonged	Femoral Neck Fracture	Health			Div American Cyanamid Co	ORAL	15 MG 1X PER	1 WK ORAL
	Hepatic Failure	Professional						
	Leukocytosis	Other						
	Macrocytosis		Cefacidal (Cefazolin Sodium)	SS				
	Pancreatitis						INTRAVENOUS	INTRAVENOUS 1 DAY
	Renal Failure Acute		Marcaine (Bupivacaine)	SS				
	Shock						INTRATHECAL	INTRATHECAL 1 DAY
	Thrombocytopenia		Primperan (Metoclopramide)	SS				
							INTRAVENOUS	INTRAVENOUS 1 DAY
			Profenid (Ketoprofen)	SS				
							INTRAVENOUS	INTRAVENOUS
			Temgesic (Buprenorphine)	SS				
							INTRAVENOUS	INTRAVENOUS 1 DAY

Atropine (Atropine)	C
Propacetemol (Propacetamol)	C
Cortancyl (Prednisone)	C
Lederfoline (Leucovorin Calcium)	C
Doliprane (Paracetamol)	C
Aldactone (Spironolactone)	C
Aldomet (Methyldopa)	C
Efferalgan (Paracetamol)	C
Codeine (Codeine)	C
Zocor (Simvastatin)	C
Orocal (Calcium Carbonate)	C
Vastarel (Trimetazidine Hydrochloride)	C
Didroneal (Etidronate Sodium)	C
Lubentyl (Parafin, Liquid)	C
Temesta (Lorazepam)	C

Date:08/17/01ISR Number: 3781180-8Report Type:Expedited (15-DaCompany Report #1827430-00-087
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Dyspnoea	Health	Entrokit	PS				
Required Intervention to Prevent Permanent Impairment/Damage	Fluid Overload	Professional	Entrobar	SS				
	Pulmonary Oedema	User Facility	Methylcellulose	SS				

Date:08/20/01ISR Number: 3779856-1Report Type:Direct Company Report #USP 54267
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

	Medication Error		Metoclopramide Hydrochloride	PS	Abbott
			Zemplar	SS	Abbott

Date:08/20/01ISR Number: 3779862-7Report Type:Direct Company Report #USP 54277
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Medication Error		Metoclopramide Hydrochloride	PS	Udl			
			Metoprolol Tartrate	SS	Udl			

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/22/01ISR Number: 3782188-9Report Type:Expedited (15-DaCompany Report #2927
Age:10 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Dystonia	Health	Metoclopramide	PS		ORAL	30 MG PO	1 DAY
Hospitalization - Initial or Prolonged	Respiratory Distress Stridor	Professional						

Date:08/22/01ISR Number: 3782294-9Report Type:Expedited (15-DaCompany Report #2001062421US
Age: Gender:Unknown I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Dehydration	Study	Camptosar (Irinotecan) Solution, Sterile	PS			INTRAVENOUS	130.2 MG, WEEKLY, IV
Hospitalization - Initial or Prolonged	Hyponatraemia	Health						
	Lobar Pneumonia	Professional						
	Multi-Organ Failure							
	Renal Impairment		Spironolactone (Spironolactone)	SS		ORAL	50 MG, QD, ORAL	
	Respiratory Distress							
	Upper Gastrointestinal Haemorrhage		Hydrocodone (Hydrocodone)	SS		ORAL	5 MG, QD PRN, ORAL (SEE IMAGE)	
			Reglan (Metoclopramide)	SS		ORAL	10 MG, PRN, ORAL	

Date:08/24/01ISR Number: 3783109-5Report Type:Expedited (15-DaCompany Report #HQ4308307AUG2001
Age:80 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Blood Ph Decreased	Health	Novatrex					
Hospitalization -	Drug Toxicity	Professional	(Methotrexate,					
Initial or Prolonged	Fall	Other	Tablet)	PS		ORAL	15 MG 1X PER	1 WK
	Femoral Neck Fracture							
	Haemoglobin Decreased		Cefacidal (Cefazolin					
	Hepatic Failure		Sodium)	SS				
INTRAVENOUS							1	DAY
	Hepatic Steatosis		Lederfoline					
	Leukocytosis		(Leucovorin Calcium)	SS				
	Macrocytosis		Marcaine					
	Pancreatitis		(Bupivacaine)	SS				
INTRATHECAL							1	DAY
	Pco2 Decreased		Primperan					
	Po2 Increased		(Metoclopramide)	SS				
INTRAVENOUS								
	Prothrombin Time Ratio		Profenid					
	Decreased		(Ketoprofen)	SS				
INTRAVENOUS							1	DAY
	Renal Failure Acute		Temesta (Lorazepam)	SS				
	Shock		Temgesic					
	Tachypnoea		(Buprenorphine)	SS				
INTRAVENOUS							1	DAY
	Thrombocytopenia		Atropine	C				
			Propacetamol	C				
			Cortancyl					
			(Prednisone)	C				
			Doliprane					
			(Paracetamol)	C				
			Aldactone					
			(Spironolactone)	C				
			Aldomet (Methyldopa)	C				
			Efferalgan					
			(Paracetamol)	C				
			Codeine	C				

				Zocor (Simvastatin)	C		
				Orocal (Calcium Carbonate)	C		
				Vastarel (Trimetazidine Hydrochloride)	C		
				Didronel (Etidronate Disodium)	C		
				Lubentyl (Paraffin, Liquid)	C		

Date:08/27/01ISR Number: 3783579-2Report Type:Expedited (15-DaCompany Report #10948867
Age:80 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Abdominal Pain	Foreign	Cefacidal Inj 1 G					
Other	Anaemia	Health	(Cefazolin)	PS				
PARENTERAL	PAREN							
	Anuria	Professional	Primperan					
	Cardiovascular Disorder	Company	(Metoclopramide Hcl)	SS				
	Hepatic Failure	Representative	Profenid					
	Hypotension	Other	(Ketoprofen)	SS				
PARENTERAL	300							
	Metabolic Acidosis							
MILLIGRAM, 1								
	Pancreatitis							
DAY PAREN								
	Pco2 Decreased		Temgesic					
	Renal Failure Acute		(Buprenorphine Hcl)	SS				
	Shock		Marcaine					
	Tachypnoea		(Bupivacaine)	SS				
	Thrombocytopenia		Novatrex					
			(Methotrexate)	SS				
2.5								
MILLIGRAM,								
			Efferalgan Codeine (Acetaminophen + Codeine Phosphate)	C				
			Pro-Dafalgan (Propacetamol Hcl)	C				
			Doliprane (Paracetamol)	C				

Date:08/27/01ISR Number: 3783853-XReport Type:Expedited (15-DaCompany Report #1622401A
Age:34 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Shock	Foreign	Imodium 2mg					
Life-Threatening	Stevens-Johnson Syndrome	Health	(Loperamide					
	Toxic Epidermal	Professional	Hydrochloride)					
	Necrolysis		Capsule	PS		ORAL	4 MG 3 IN 1	DAY PO 6 DAY
			Dipidolor 7.5 Mg/Ml					
			Injection	SS				
			Allopurinol	SS				
			Antra	SS				
			Multlibionta	SS				
			Bifiteral	SS				
			Ancotil	SS				
			Meronem	SS				
			Psyquil	SS				
			Solubile	SS				
			Sobelin	SS				
			Suprarenin	SS				

INTRAVENOUS MG, DAILY IV

Dopamine	SS
Zienam	SS
Dolantin	SS
Human Albumin 20%	SS
Neupogen	SS
Amphoterecin B	SS
Paspertin	SS
Dormicum	SS
Solu-Decortin	SS
Isoptin	SS
Ciprobay	SS
Actrapid	SS
Tavegil	SS
Lasix	SS
Vancomycin	SS
Novalgin	SS
Vitalipid	SS
Morphine	SS
Augmentin	SS
Opium	SS
Liquemin	SS
Metronidazole	SS
Claforan	SS
Gentamycin	SS
Paracetamol	SS
Pantozol	SS
Leucomax	SS
Methotrexate	SS
Diflucan	SS
Zofran	C
Ampho-Moronal	C
Fortecortin	C
Glucose	C
Sterofundin	C
Magnorbin	C
Lipofundin Mct	C
Aminomel	C
Kaliumchlorid	C
Aminomix	C
Glukose 40%	C

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Anxiety		Reglan 10mg	PS		ORAL	10MG AC AND	
	Depression						HS ORAL	
	Dystonia							

Date:08/28/01ISR Number: 3784145-5Report Type:Periodic Company Report #HQ3617013NOV2000
Age:50 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Interaction	Health Professional	Protonix (Pantoprazole, Tablet, Delayed Release)	PS				
	Tremor		Reglan (Metoclopramide					

			Hydrochloride, Tablet)	SS		ORAL
10 MG 4X PER 1 DAY, ORAL "LONG TIME"						
			Amitriptyline (Amitriptyline)	C		
			Insulin (Insulin)	C		
			Temazepam (Temazepam)	C		
			Spironolactone (Spironolactone)	C		
			Isosorbide (Isosorbide)	C		
			Gemfibrozil (Gemfibrozil)	C		
			Fosamax (Alendronate Sodium)	C		
			Verapamil (Verapamil)	C		
			Morphine (Morphine)	C		
			Warfarin (Warfarin)	C		
			Soma (Carisoprodol)	C		
			Furosemide (Furosemide)	C		
			Buspar (Buspirone Hydrochloride)	C		

Date:08/29/01ISR Number: 3785022-6Report Type:Expedited (15-DaCompany Report #HQ5154524AUG2001
Age:4 MON Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Abnormal Behaviour Accidental Overdose Arrhythmia Blood Creatinine Increased Hepatic Function Abnormal Hyperkalaemia Laboratory Test Abnormal	Health Professional	Reglan (Metoclopramide Hydrochloride, Syrup)	PS		
"10 TIMES THE NORMAL DOSE OF REGLAN",						
			Potassim Chloride (Potassium Chloride)	C		

			K-Phos (Potassium Phosphate Monobasic)	C		

Date:08/29/01ISR Number: 3785219-5Report Type:Direct Company Report #
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Disturbance In Attention		Reglan 10mg Tablets	PS		ORAL	10MG 3 TIMES	
	Feeling Abnormal					ORAL		
	Restlessness							

Date:09/05/01ISR Number: 3788719-7Report Type:Direct Company Report #
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Medication Error		Zemlar 5 Mcg/Ml Vial (Abbott)	PS	Abbott	5MCG/ML VIAL		
						INJECTABLE		
			Metoclopramide 5mg/Ml Vial (					

				Abbott)	SS	Abbott	
5MG/ML VIAL							
INJECTABLE							

Date:09/07/01ISR Number: 3789598-4Report Type:Expedited (15-DaCompany Report #HQ5440931AUG2001
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Burning Sensation	Health	Reglan	PS		ORAL
ORAL						
	Muscle Spasms	Professional				
	Trismus					

Date:09/07/01ISR Number: 3791363-9Report Type:Expedited (15-DaCompany Report #2001-07-1637
Age:80 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Hepatic Failure	Health	Cefacidal Injectable	PS		
1 DAY						
	Pancreatitis Acute	Professional	Primperan	SS		
1 DAY						
	Renal Failure Acute	Other	Temgesic			
	Shock		(Buprenorphine Hcl)			
			Injectable	SS		
1 DAY						
			Profenid Injectable	SS		
INTRAVENOUS 300 MG						
INTRAVENOUS 1 DAY						
			Marcain Spinal			
			Injectable	SS		
INTRADISCAL						
(INTRASPINAL) INTRASPINAL						
			Novatrex			
			(Methotrexate)			
			Tablets	SS		ORAL
15 MG ORAL						
			Atropine	C		
			Pro-Dafalgan			
			Intravenous	C		

Cortancyl	C
Lederfolin	C
Aldactone	C
Doliprane	C
Aldomet	C
Efferalgan Codeine	C
Zocor	C
Orocal (Calcium Carbonate)	C
Vastarel	C
Didronel	C
Lubentyl	C
Temesta	C

Date:09/10/01ISR Number: 3790075-5Report Type:Direct Company Report #
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Arrhythmia	Health Professional	Reglan Syrup (Metoclopramide Oral Solution,Usp)	PS		ORAL	ORAL; 5 MG; 1	
	Blood Creatinine Increased						PINT BOTTLE	
	Blood Phosphorus Increased							
	Hyperkalaemia							
	Liver Function Test Abnormal							
	Neonatal Disorder							
	Overdose							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/12/01ISR Number: 3792451-3Report Type:Direct Company Report #
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Dermatitis		Metoclopramide 10mg	PS		ORAL	10MG ONE TIME	
Initial or Prolonged	Pruritus						ORAL	
	Urticaria		Famotidine 20mg	SS		ORAL	20MG ONE TIME	
							ORAL	

Date:09/13/01ISR Number: 3792098-9Report Type:Expedited (15-DaCompany Report #B0103701A
Age:33 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Apnoea		Labetalol	PS	Glaxo Wellcome		UNKNOWN	
	Blood Cholinesterase Decreased		Suxamethonium Chloride	SS	Glaxo Wellcome		INTRAVENOUS	
	Caesarean Section		Magnesium Sulphate	SS				
	Drug Interaction		Metoclopramide	SS				
	Haemolysis		Rocuronium	SS				
	Hypoproteinaemia		Thiopentone	C				
	Liver Function Test Abnormal		Nitrous Oxide	C				
	Platelet Count Decreased		Isoflurane	C				
			Fentanyl	C				
			Cefuroxime	C	Glaxo Wellcome			
			Oxytocin	C				
			Ranitidine	C	Glaxo Wellcome			
			Sodium Citrate	C				

Date:09/13/01ISR Number: 3792751-7Report Type:Direct Company Report #
Age:55 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Extrapyramidal Disorder		Metoclopramide	PS		ORAL	PO	

Date:09/17/01ISR Number: 3794137-8Report Type:Direct Company Report #
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Dizziness		Metoclopramide	PS				
INTRAVENOUS							10MG IV Q8H	4 DAY
	Hallucination							

Date:09/17/01ISR Number: 3794414-0Report Type:Expedited (15-DaCompany Report #B0103701A
Age:33 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Apnoea	Foreign	Suxamethonium					
	Caesarean Section	Literature	Injection (Generic)					
	Depressed Level Of	Health	(Succinylcholine					
	Consciousness	Professional	Chloride)	PS				
INTRAVENOUS	INTRAVENOUS							
	Drug Interaction		Trandate (Labetalol					
	Enzyme Abnormality		Hydrochloride)	SS				
	Hypoproteinaemia		Magnesium Sulfate					
			(Magnesium Sulfate)	SS				
			Metoclopramide					
			(Metoclopramide)	SS				
			Rocuronium Bromide					
			(Rocuronium Bromide)	SS				
			Thiopentone Sodium	C				

Nitrous Oxide	C
Isoflurane	C
Fentanyl	C
Cefuroxime Sodium	C
Oxytocin	C
Ranitidine Hydrochloride	C
Sodium Citrate	C

Date:09/17/01ISR Number: 3794624-2Report Type:Expedited (15-DaCompany Report #WAES 01071136
Age:73 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dermatitis Exfoliative Type Iv Hypersensitivity Reaction	Foreign Literature Other	Tab Pepcid (Famotidine)	PS	Merck Sharp & Dohme	ORAL	PO	
			Nifedipine	SS		ORAL	PO	
			Ticlopidine Hydrochloride	SS		ORAL	PO	
			Metoclopramide	SS		ORAL	PO	
			Imipramine Pamoate	SS		ORAL	PO	

Date:09/20/01ISR Number: 3796884-0Report Type:Expedited (15-DaCompany Report #HQ6106318SEP2001
Age:21 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Anaphylactic Reaction	Health Professional	Reglan (Metoclopramide Hydrochloride, Unspec)	PS				

Date:09/26/01ISR Number: 3798693-5Report Type:Direct Company Report #
Age:73 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Orthostatic Hypotension		Amlodipine	PS		
2.5 ML QD						
			Metoclopramide	SS		
			Lactulose	C		
			Ferrous Sulfate	C		
			Fentanyl	C		
			Morphine	C		
			Isocal	C		

Date:09/26/01ISR Number: 3800269-8Report Type:Direct Company Report #
Age:23 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Vision Blurred		Metoclopramide 10 Mg/2 Ml Vial (Faulding)	PS	Faulding	
INTRAVENOUS 10 MG/2ML IV						
PUSH BID						
			D5 1/2 Ns + Kcl	C		
			Multivitamin (Cernevit)	C		
			Zofran	C		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/27/01ISR Number: 3801797-1Report Type:Direct Company Report #
Age:71 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Breast Tenderness		Metoclopramide 10 Mg Tab	PS			10 MG QID AC & HS	

Date:09/28/01ISR Number: 3802884-4Report Type:Periodic Company Report #2000UW04635
Age:65 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Bradycardia	Health	Seroquel "Zeneca"	PS	Zeneca	ORAL	25 MG BID PO	
	Hypothermia	Professional	Olanzapine	SS				
			Gabapentin	SS				
			Reglan	SS				

Date:09/28/01ISR Number: 3807419-8Report Type:Expedited (15-DaCompany Report #2001PL000016
Age:33 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Required	Anaesthetic Complication	Foreign	Trandate	PS				
	Pulmonary Apnoea	Literature Health	Succinylcholine Injection	SS			INTRAVENOUS	100 MG;
Intervention to Prevent Permanent Impairment/Damage	Caesarean Section	Professional					INTRAVENOUS	
	Delayed Recovery From Anaesthesia		Magnesium Sulfate	SS			INTRAVENOUS	INTRAVENOUS
			Metoclopramide	SS			INTRAVENOUS	10 MG;
	Drug Interaction						INTRAVENOUS	
	Laboratory Test Abnormal		Rocuronium Bromide	SS			INTRAVENOUS	10 MG;
							INTRAVENOUS	

			Thiopentone Sodium	C			
			Nitrous Oxide/Oxygen	C			
			Isoflurane	C			
			Fentanyl	C			
			Cefuroxime	C			
			Oxytocin	C			
			Ranitidine	C			
			Sodium Citrate	C			

Date:10/01/01ISR Number: 3802527-XReport Type:Expedited (15-DaCompany Report #HQ7035009FEB2001
Age:30 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Blepharospasm	Health	Reglan					
Other	Dizziness	Professional	(Metoclopramide					
	Headache		Hydrochloride,					
	Neuroleptic Malignant		Tablet)	PS		ORAL	10 MG THREE	
	Syndrome						TIMES DAILY	
	Nystagmus						(TOOK	
	Photosensitivity Reaction						APPROXIMATELY	
	Visual Acuity Reduced						3 TO 4	
	Visual Disturbance		Phenergan					
			(Promethazine					
			Hydrochloride,					
			Unspec)	SS				
			Darvocet-N					
			(Dextropropoxyphene					
			/ Paracetamol)	C				
			Toradol (Ketorolac					

			Tromethamine)	C		

Date:10/01/01ISR Number: 3802533-5Report Type:Expedited (15-DaCompany Report #HQ6270121SEP2001
Age:8 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Body Temperature Decreased Dyskinesia Dystonia	Health Professional	Reglan (Metoclopramide Hydrochloride, Tablet)	PS		ORAL
SEE IMAGE						
	Medication Error Psychomotor Hyperactivity Tremor		Keflex (Cefalexin Monohydrate)	C		
			Prilosec (Omeprazole)	C		

Date:10/02/01ISR Number: 3803398-8Report Type:Direct Company Report #
Age:68 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Musculoskeletal Stiffness Neck Pain		Metoclopramide (10mg)	PS		ORAL
10MG 1T PO						
QID 2 WK						

Date:10/03/01ISR Number: 3803997-3Report 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	Muscle Rigidity		Metoclopramide	PS		
5 MG Q AC AND HS						

Date:10/03/01ISR Number: 3806799-7Report Type:Expedited (15-DaCompany Report #EMADSS2001003862
Age:68 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Anaphylactic Shock	Foreign	Tramadol Hydrochloride Sr	PS				
Hospitalization -	Angioneurotic Oedema	Health						
Initial or Prolonged	Bradycardia	Professional						
	Bronchospasm		Rapifen (Alfentanil Hydrochloride)	SS				
	Face Oedema							
	Haematoma							
	Hypersensitivity		Primperan (Metoclopramide)	SS				
	Laryngeal Oedema							
	Localised Oedema							
	Macroglossia		Odrik (Trandolapril)	SS		ORAL		
	Tongue Disorder		Propacetamol (Propacetamol)	SS				
			Profenid (Ketoprofen)	SS				
			Morphine (Morphine)	SS				
			Loxen (Nicardipine Hydrochloride)	SS		ORAL		
			Norcuron (Vecuronium Bromide)	SS				

INTRAVENOUS 100 MG, 1 IN 1 TIME(S), IV

INTRAVENOUS 10 MG , 1 IN 1 TIME(S), IV

INTRAVENOUS 2 G, 1 IN 1 TIME(S), IV

INTRAVENOUS 100 MG, 1 IN 1 TIME(S), IV

3 MG, 1 IN 1 TIME(S)

20, 1 IN 1 TIME(S), ORAL

5 MG, 1 IN 1 TIME(S)

			Droperidol (Droperidol)	SS			
1.25 MG, 1 IN 1 TIME(S)							
			Fonzylane (Buflomedil Hydrochloride)	SS			
40 MG, 1 IN 1 TIME(S)							
			Propofol (Propofol)	SS			
			Atropine (Atropine)	C			
			Hypnovel (Midazolam Hydrochloride)	C			
			Cefazolin (Cefazolin)	C			
			Solumedrol (Methylprednisolone Sodium Succinate)	C			
			Urapidil (Urapidil)	C			
			Aldalix (Osyrol-Lasix)	C			
			Cirkan (Cirkan)	C			
			Atarax (Hydroxyzine Hydrochloride)	C			
			Xylocaine (Lidocaine Hydrochloride)	C			
			Celebrex (Celecoxib)	C			

Date:10/04/01ISR Number: 3805440-7Report Type:Expedited (15-DaCompany Report #HQ3356517JUL2001
Age:71 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Confusional State	Health Professional	Reglan (Metoclopramide Hydrochloride, Tablet)	PS		ORAL	10 MG 3X PER 1 DAY, ORAL	
	Depression							
	Eye Disorder							
	Fatigue							
	Herpes Zoster							
	Mental Impairment		Vioxx (Rofecoxib)	C				
	Parkinsonian Gait		Plendil (Felodipine)	C				
	Personality Change		Lescol (Fflucastatin					

	Sedation		Sodium)	C	
	Social Avoidant Behaviour		Calcitonin		
	Tremor		(Calcitonin)	C	
			Nexium		
			(Esomeprazole)	C	
			Aricept (Donepezil		
			Hydrochloride)	C	

Date:10/05/01ISR Number: 3805371-2Report Type:Direct Company Report #
Age:61 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Asthenia		Reglan -10mg	PS			10MG SEE	
	Parkinsonian Gait						IMAGE	
	Posture Abnormal		Elavil-50mg	SS			50MG 1 PER	
	Weight Decreased						DAY	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/05/01ISR Number: 3805482-1Report Type:Direct Company Report #USP 54406
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Medication Error		Reglan	PS	Robins			
			Regitine	SS	Novartis			

Date:10/05/01ISR Number: 3807500-3Report Type:Expedited (15-DaCompany Report #PHHO2001AU07677
Age:23 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain Blood Creatinine Increased Procedural Site Reaction Renal Artery Thrombosis Renal Infarct Transplant Rejection Ureteric Obstruction	Foreign Study Health Professional Other	Neoral (Ciclosporin) Capsule	PS		ORAL	SEE IMAGE	
			Fty720a Vs Mycophenolate Mofetil (Fty 720 Fty+Cap)	SS		ORAL	2 CAPSULES	DAILY, ORAL
			Methylprednisolone (Methylprednisolone)	SS		INTRAVENOUS	1 G/DAY,	INTRAVENOUS
			Prednisone (Prednisone)	SS		ORAL	25 MG/DAY,	ORAL
			Irbesartan (Irbesartan)	SS				
			Zantac (Ranitidine Hydrochloride)	SS				
			Lasix (Furosemide)	SS				
			Actrapid Insulin (Insulin)	SS				
			Diltiazem (Diltiazem)	SS				
			Amphotericin B (Amphotericin B)	SS				
			Mycostatin					

(Nystatin)	SS
Mylanta (Aluminium Hydroxide Gel, Dried, Simeticone)	SS
Maxolon (Metoclopramide Hydrochloride)	SS
Panadol (Paracetamol)	SS
Morphine (Morphine)	SS
Pethidine (Pethidine)	SS
Resonium (Sodium Polystyrene Sulfonate)	SS
Aspirin (Acetylsalicylic Acid)	SS
Trimethoprim (Trimethoprim)	SS
Ferrous Sulphate (Terrous Sulfate)	SS
Temazepam (Temazepam)	SS
Midazolam	

(Midazolam)	SS
Propofol (Propofol)	SS
Atracurium (Atracurium)	SS
Flucloxacilline (Flucloxacillin)	SS
Ephedrine (Ephedrine)	SS
Dextrose (Glucose)	SS
Isoflurane (Isoflurane)	SS
Neostigmine (Neostigmine)	SS
Atropine (Atropine)	SS

Date:10/08/01ISR Number: 3807690-2Report Type:Expedited (15-DaCompany Report #2010439
Age:41 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardiac Failure	Study	Oxycontin Cr					
	Cardiomegaly	Health	Tablets, 80 Mg					
	Coronary Artery	Professional	(Oxycodone					
	Atherosclerosis	Other	Hydrochloride)	PS		ORAL	160 MG BID PO	
	Echinococciasis		Metoclopramide	SS				
	Hepatic Steatosis		Promethazine Hcl	SS				
	Oedema		Alprazolam	SS				
	Pulmonary Congestion		Acetaminophen	SS				
	Ventricular Hypertrophy		Zanaflex (Tizanidine Hydrochloride)	C				

Date:10/10/01ISR Number: 3808164-5Report Type:Expedited (15-DaCompany Report #HQ0906115MAY2001
Age:43 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Bacterial Infection	Study	Protonix					
Hospitalization - Initial or Prolonged	Blood Culture Positive		(Pantoprazole, Injection)	PS		INTRAVENOUS	40 MG 1X PER 1 DAY,	
Disability	Injury							

Other		Neuroleptic Malignant		
INTRAVENOUS				
		Syndrome	Reglan	
		Pneumonia	(Metoclopramide	
		Pyrexia	Hydrochloride,	
		Quadriplegia	Injection)	SS
INTRAVENOUS	10 MG 1X PER			
		Rib Fracture		
1 DAY,				
		Road Traffic Accident		
INTRAVENOUS				
		Spinal Fracture	Hydrocodone	
		Staphylococcal Infection	W/Acetaminophen	
			(Hydrocodone	
			Bitartrate/Paracetam	
			ol)	C
			Acetaminophen	
			(Paracetamol)	C
			Ibuprofen	
			(Ibuprofen)	C
			Levaquin	
			(Levofloxacin)	C
			Vancomycin	
			(Vancomycin)	C
			Clindamycin	
			(Clindamycin)	C

Unasyn (Ampicillin Sodium/Sulbactam Sodium)	C
Famotidine (Famotidine)	C
Diazepam (Diazepam)	C
Morphine (Morphine)	C
Milk Of Magnesia (Magnesium Hydroxide)	C
Bisacodyl (Bisacodyl)	C
Prozac (Fluoxetine Hydrochloride)	C
Zoloft (Sertraline Hydrochloride)	C
Tetanus And Diphtheria Toxoids Adsorbed, Ultrafined (See Image)	C
Solu-Medrol (Methylprednisolone Sodium Succinate)	C
Vecuronium (Vecuronium)	C
Midazolam (Midazolam)	C
Lidocaine (Lidocaine)	C
Succinylcholine Chloride (Suxamethonium Chloride)	C
Potassium Chloride (Potassium Chloride)	C
Calcium Chloride Dihydrate (Calcium Chloride Dihydrate)	C
Magnesium (Magnesium)	C
Phosphorous (Phosphorous)	C
Phenylephrine Hydrochloride (Phenylephrine Hydrochloride)	C
Artificial Tears	

(Artificial Tears)	C
Insulin (Insulin)	C
Propofol (Propofol)	C
Bacitracin (Bacitracin)	C
Albuterol (Salbutamol)	C
Atrovent (Ipratropium Bromide)	C
Peri-Colace (Casanthranol/Docusate Sodium)	C
Magnesium Oxide	

(Magnesium Oxide)	C
Afrin (Aminoacetic Acid/Benzalkonium Chloride/Oxymetazoline Hydrochloride/Phenyl	C
Primaxin (Cilastatin Sodium/Imipenem)	C
Amikacin (Amikacin)	C
Cortrosyn (Tetracosactide)	C

Date:10/11/01ISR Number: 3806961-3Report Type:Expedited (15-DaCompany Report #WAES 01101340
Age:38 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Abdominal Pain	Health	Pepcid	PS	Merck & Co., Inc	INTRAVENOUS		1 DAY
	Circulatory Collapse	Professional	Primperan	SS		INTRAVENOUS		1 DAY
	Coronary Artery Disease							
	Myocardial Infarction							
	Pharyngolaryngeal Pain							
	Vomiting							

Date:10/16/01ISR Number: 3810066-5Report Type:Expedited (15-DaCompany Report #PHBS2001JP09787
Age:74 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Blister	Foreign	Voltaren (Diclofenac Sodium) Suppository	PS		RECTAL	25 MG,	ONCE/SINGLE,
	Cardiac Arrest	Health				RECTAL		
	Disseminated	Professional						
	Intravascular Coagulation	Other						
	Erythema		Piperacillin Sodium (Piperacillin Sodium)	SS		INTRAVENOUS	4000 MG/DAY,	
	Faeces Discoloured							
	Infection							
	Melaena					INTRAVENOUS		

		Multi-Organ Failure Pleural Effusion	Loxonin (Loxoprofen Sodium)	SS		ORAL 180 MG/DAY,
		Prurigo				ORAL
		Pulmonary Oedema	Selbex (Teprenone)	SS		ORAL 150 MG/DAY,
		Pyrexia				ORAL
		Renal Failure Shock	Primperan (Metoclopramide)	SS	INTRAVENOUS	2 DF/DAY,
		Skin Ulcer				INTRAVENOUS
		Ventricular Tachycardia White Blood Cell Count Decreased	Vitamedin Intravenous (Thiamine Disulfide)	SS	INTRAVENOUS	1 DF,
						INTRAVENOUS
			Gaster (Famotidine) Ampoule	SS	INTRAVENOUS	2 DF/DAY,
						INTRAVENOUS
			Gaster (Famotidine)	SS		ORAL 2 DF/DAY,
						ORAL
			Maalox (Aluminium Hydroxide Gel)	SS		ORAL 2 DF/DAY,
						ORAL
			Modacin (Ceftazidime)	SS	INTRAVENOUS	2000 MG/DAY,
						INTRAVENOUS

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/18/01ISR Number: 3811252-0Report Type:Expedited (15-DaCompany Report #WAES 01101340
Age:38 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Circulatory Collapse	Foreign	Inj Pepcid					
	Coronary Artery Disease	Other	(Famotidine)	PS				
INTRAVENOUS	IV						1	DAY
	Myocardial Infarction		Primperan (Metoclopramide Hydrochloride)	SS				
INTRAVENOUS	IV						1	DAY

Date:10/22/01ISR Number: 3812051-6Report Type:Direct Company Report #
Age:25 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Muscle Spasms		Reglan	PS		ORAL		
PO								
	Tremor		Darvocet	C				
	Trismus							

Date:10/23/01ISR Number: 3813869-6Report Type:Expedited (15-DaCompany Report #WAES 01101340
Age:38 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Circulatory Collapse		Pepcid	PS	Merck & Co., Inc			
INTRAVENOUS							1	DAY
Other	Coronary Artery Disease		Primperan	SS				
INTRAVENOUS							1	DAY
	Myocardial Infarction							
	Ventricular Tachycardia							

Date:10/26/01ISR Number: 3815845-6Report Type:Expedited (15-DaCompany Report #WAES 01101340
Age:38 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Death		Circulatory Collapse	Foreign	Pepecid (Famotidine)	PS			
INTRAVENOUS	IV	1 DAY						
Other		Coronary Artery Disease	Health	Primperan				
		Myocardial Infarction	Professional	(Metoclopramide				
		Ventricular Tachycardia	Other	Hydrochloride)	SS			
INTRAVENOUS	IV	1 DAY						

Date:10/26/01ISR Number: 3816279-0Report Type:Expedited (15-DaCompany Report #HQ7176816OCT2001
Age:58 YR Gender:Female I/FU:I

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Death		Abdominal Pain	Health	Reglan			
Other		Bone Marrow Depression	Professional	(Metoclopramide			
		Disseminated		Hydrochloride,			
		Intravascular Coagulation		Injection)	PS		
INTRAVENOUS	2 DOSES, 10						
		Flushing					
MG,							
		Haemorrhage					
INTRAVENOUS							
		Hepatic Failure					
		Hypotension					
		Malignant Histiocytosis					
		Renal Failure					
		Thrombocytopenia					

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/26/01ISR Number: 3816311-4Report Type:Expedited (15-DaCompany Report #HQ7250417OCT2001
Age:30 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Bradycardia Foetal Caesarean Section Complications Of Maternal Exposure To Therapeutic Drugs Convulsion Dystonia Heart Rate Decreased Respiratory Arrest	Health Professional	Reglan (Metoclopramide Hydrochloride, Injection) Pepcid (Famotidine,)	PS SS		INTRAVENOUS	10 MG REGLAN WITH 20 MG PEPCID IV PUSH 20 MG PEPCID IV PUSH WITH 10 MG, REGLAN IV	
			Ancef	C				

Date:11/02/01ISR Number: 3819839-6Report Type:Expedited (15-DaCompany Report #HQ7035009FEB2001
Age:30 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability Other	Dehydration Dermatitis Dizziness Dry Mouth Fatigue Headache Hypersensitivity Liver Function Test	Health Professional	Reglan (Metoclopramide Hydrochloride, Tablet)	PS		ORAL	10 MG THREE TIMES DAILY(TOOK APPROXIMATELY 3 TO 4	

	Abnormal Neuroleptic Malignant Syndrome Salivary Hypersecretion Thirst		Phenergan (Promethazine Hydrochloride, Unspec) Darvocet-N (Dextropropoxyphene/ Paracetamol) Toradol (Ketorolac Tromethamine)	SS C C			

Date:11/05/01ISR Number: 3820588-9Report Type:Expedited (15-DaCompany Report #HQ7886301NOV2001
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Cardiac Arrest	Consumer	Reglan (Metoclopramide Hydrochloride, Unspec)	PS				

Date:11/05/01ISR Number: 3820698-6Report Type:Expedited (15-DaCompany Report #02655
Age:70 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Literature	Metoclopramide	PS				
	Intentional Misuse		Activated Charcoal	SS				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/07/01ISR Number: 3823415-9Report Type:Expedited (15-DaCompany Report #PHHO2001AU07677
Age:23 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Creatinine Increased	Foreign Study	Neoral (Ciclosporin) Capsule	PS		ORAL	SEE IMAGE	
	Complications Of Transplant Surgery Renal Artery Thrombosis Renal Infarct	Health Professional Other	Fty720a Vs Mycophenolate Mofetil (Fty 720 Fty + Cap) Capsule	SS		ORAL	2 CAPSULES	DAILY, ORAL
	Transplant Rejection							
	Ureteric Obstruction		Methylprednisolone (Methylprednisolone)	SS		INTRAVENOUS	1 G/DAY,	
						INTRAVENOUS		
			Prednisone (Prednisone)	SS		ORAL	25 MG/DAY,	
						ORAL		
			Irbesartan (Irbesartan)	SS				
			...	SS		ORAL	25 MG/DAY,	
						ORAL		
			Irbesartan (Irbesartan)	SS				
			Zantac (Ranitidine Hyrochloride)	SS				
			Lasix (Furosemide)	SS				
			Actrapid Insulin (Insulin)	SS				
			Diltiazem (Diltiazem)	SS				
			Amphotericin B (Amphotericin B)	SS				
			Mycostatin (Nystatin)	SS				
			Mylanta (Aluminium Hydroxide Gel, Dried, Simeticone)	SS				

Maxolon (Metoclopramide Hydrochloride)	SS
Panadol (Paracetamol)	SS
Morphine	SS
Pethidine (Pethidine)	SS
Resonium (Sodium Polystyrene Sulfonate)	SS
Aspirin (Acetylsalicylic Acid)	SS
Trimethoprim (Trimethoprim)	SS
Ferrous Sulphate (Ferrous Sulfate)	SS
Temazepam (Temazepam)	SS
Midazolam (Midazolam)	SS
Propofol (Propofol)	SS
Atracurium (Atracurium)	SS

			Flucloxacillin (Flucloxacillin)	SS			
			Ephedrine (Ephedrine)	SS			
			Dextrose (Glucose)	SS			
			Isoflurane (Isoflurane)	SS			
			Neostigmine (Neostigmine)	SS			
			Atropine (Atropine)	SS			

Date:11/07/01ISR Number: 3824329-0Report Type:Expedited (15-DaCompany Report #HQ7886301NOV2001
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Cardiac Arrest	Consumer	Reglan (Metoclopramide Hydrochloride)	PS				

Date:11/12/01ISR Number: 3823724-3Report Type:Expedited (15-DaCompany Report #2014616
Age:50 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Pain	Health Professional Company Representative	Oxycontin Cr Tablets, 10 Mg (Oxycodone Hydrochloride)	PS		ORAL	400 MG QD PO	
	Psychomotor Hyperactivity							
	Tic							
	Trismus							
	Weight Decreased		Reglan (Metoclopramide)	SS		ORAL	10 MG QID PO	
			Roxicodone (Oxycodone)	SS				
			Insulin	C				

Date:11/16/01ISR Number: 3827498-1Report Type:Expedited (15-DaCompany Report #2001-11-0163
Age:17 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Back Pain Blood Creatinine Increased Suicide Attempt	Foreign Health Professional	Lisino (Loratadine) Tablets Paracetamol Tablets Paspertin Oral Suspension Amoxicillin Tablets Acetylcystiene Effervescent Tablets	PS SS SS SS SS		ORAL ORAL ORAL ORAL ORAL	800 MG 7 G 2 TABS 6 TAB	

Date:11/19/01ISR Number: 3827246-5Report Type:Expedited (15-DaCompany Report #HQ8400113NOV2001
Age:74 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardiogenic Shock Gastrointestinal Haemorrhage International Normalised Ratio Increased Mallory-Weiss Syndrome Shock	Health Professional Other	Metoclopramide (Metoclopramide Hydrochloride, Talbet) Omeprazole(Omeprazole)	PS SS		ORAL INTRAVENOUS	10 MG 3X PER 1 DAY 80 MG 1X PER	

1 DAY	63 DAY						
			Sucralfate (Sucralfate)	SS			ORAL
2 MG 21X PER							
1 DAY							
			Warfarin (Warfarin)	C			
			Digoxin (Digoxin)	C			
			Aspirin (Acetylsalicylic Acid)	C			
			Atenolol (Atenolol)	C			
			Dialtiazem (Dialtiazem)	C			
			Co-Amilofruse (Amiloride Hydrochloride/Furose mide)	C			

Date:11/21/01ISR Number: 3827141-1Report Type:Expedited (15-DaCompany Report #US-BRISTOL-MYERS SQUIBB COMPANY-11535317
Age:72 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Constipation Hypotension		Carboplatin	PS	Bristol-Myers Squibb Company	INTRAVENOUS	AUC 5.	
Other	Syncope Urinary Retention		Atenolol	SS	Apothecon			
			Metoclopramide	SS				
			Bms247550	C		INTRAVENOUS		
			Aspirin	C				
			Omeprazole	C				
			Dexamethasone	C				

Date:11/23/01ISR Number: 3829238-9Report Type:Expedited (15-DaCompany Report #11535317
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Constipation Hypotension	Foreign Study	Carboplatin Bms247550	PS		INTRAVENOUS	1/3 WEEK IV	

Other		Syncope Urinary Retention	Health Professional Company Representative	(Bms247550-Investiga tional)	SS		
INTRAVENOUS	40 MILLIGRAM/SQ. METER, 1/3 WEEK IV						
				Atenolol	SS		
	25 MILLIGRAMS						
				Metoclopramide (Metoclopramide Hcl)	SS		
	20 MILLIGRAM						
				Aspirin (Acetylsalicyclic Acid)	C		
				Omeprazole (Omeprazole)	C		
				Dexamethasone (Dexamethasone)	C		

Date:11/26/01ISR Number: 3829207-9Report Type:Direct Company Report #USP 54610
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
	Medication Error		Metoclopramide Hydrochloride	PS	Faulding	
			Oxytocin	SS	American	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Pharmaceutical Partners

Date:11/26/01ISR Number: 3829557-6Report Type:Direct Company Report #
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other Required Intervention to Prevent Permanent Impairment/Damage	Tardive Dyskinesia		Metoclopramide Tab Usp (Sidmak Labs Inc) (10mg)	PS	Sidmak Labs Inc		10MG 1 TAB, 3 TIMES DAILY	
			Vaseretic	C				
			Stool Softeners	C				
			Centrum Silver Vitamins	C				
			Cephalexin	C				
			Capteva	C				

Date:11/29/01ISR Number: 3832098-3Report Type:Expedited (15-DaCompany Report #PHBS2001IT11603
Age:38 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Arterial Occlusive Disease	Foreign Health Professional	Sandimmun Neoral (Ciclosporin)	PS		ORAL	350 MG/D,	ORAL
	Asthenia	Other	Valium (Diazepam) Drops	SS		ORAL	30 DROPS/D,	ORAL
	Dyspnoea							
	Excitability							
	Nausea							
	Respiratory Disorder		Plasil (Metoclopramide Hydrochloride)	SS		INTRAVENOUS	10 MG/D,	INTRAVENOUS

Date:12/04/01ISR Number: 3834749-6Report Type:Expedited (15-DaCompany Report #HQ8915128NOV2001
Age:4 MON Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dystonia Medication Error	Health Professional	Reglan (Metoclopramide Hydrochloride), Syrup	PS		ORAL	6 ML OVERDOSE	AMOUNT, ORAL

Date:12/04/01ISR Number: 3834851-9Report Type:Expedited (15-DaCompany Report #2014616
Age:50 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Effect Decreased Drug Tolerance Increased Joint Stiffness Psychomotor Hyperactivity	Health Professional Company Representative	Oxycontin Cr Tablets, 10 Mg (Oxycodone Hydrochloride)	PS		ORAL	400 MG QD PO	
	Tic Weight Decreased		Reglan (Metoclopramide)	SS		ORAL	10 MG QID PO	
			Roxicodone (Oxycodone)	SS				
			Insulin	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/11/01ISR Number: 3837313-8Report Type:Direct Company Report #
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Dystonia		Metoclopramide Oral Solution (Flaglan Syrup)	PS		ORAL	ORAL SOLUTION -UNIT DOSE BOTTLE 5MG	
	Medication Error							
	Overdose							

Date:12/11/01ISR Number: 3838358-4Report Type:Expedited (15-DaCompany Report #GBR003253
Age:54 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blood Pressure Increased	Health	Meridia	PS		ORAL	10 MG QD PO	
	Cystitis	Professional	Hydrocodone/Apap	SS			OTHER OTHER	
	Diabetes Mellitus	Other	Soma	SS			1 TAB QOD	
	Nausea		Neurontin	SS		ORAL	600 MG TID PO	
	Sinusitis		Reglan	SS				
	Vomiting		Quinine Sulfate	SS		ORAL	260 MG NOCTE PO	
			Mobic	SS		ORAL	1 TAB QD PO	
			Advil	SS				

Date:12/11/01ISR Number: 3838868-XReport Type:Expedited (15-DaCompany Report #HQ9177706DEC2001
Age:0 MON Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Apgar Score Low	Foreign	Efexor Xr (Venlafaxine					
	Foetal Distress Syndrome	Health						

Maternal Drugs Affecting Foetus
Vacuum Extractor Delivery

Professional

Hydrochloride, Capsule, Extended Release) PS

TRANSPLACENTAL 225 MG 1X PER

1 DAY

TRANSPLACENTA

L

Maxolon (Metoclopramide (Hydrochloride) SS

TRANSPLACENTAL 10 MG 2X PER

1 DAY

TRANSPLACENTA

L

Date:12/12/01ISR Number: 3840007-6Report Type:Expedited (15-DaCompany Report #HQ7035009FEB2001
Age:30 YR Gender:Female I/FU:F

Outcome	PT
Disability	Arthropathy
Other	Dehydration
	Dizziness
	Dry Mouth
	Fatigue
	Headache
	Insomnia
	Muscle Spasms
	Neuroleptic Malignant
	Syndrome
	Nystagmus
	Pain

		Reading Disorder Restless Legs Syndrome Salivary Hypersecretion	Report Source	Product	Role	Manufacturer	Route	Dose Duration
		Thirst Throat Tightness Vision Blurred	Health Professional	Reglan (Metoclopramide Hydrochloride, Tablet)	PS		ORAL	10 MG THREE TIMES DAILY (TOOK APPROXIMATELY 3 TO 4
				Phenergan (Promethazine Hydrochloride, Unspec)	SS			
				Darvocet-N (Dextropropoxyphene / Paracetamol)	C			
				Toradol (Ketorolac Tromethamine)	C			

Date:12/24/01ISR Number: 3844428-7Report Type:Expedited (15-DaCompany Report #HQ7035009FEB2001
Age:30 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Disability Other	Arthropathy Blepharospasm Confusional State Disorientation Disturbance In Attention Dizziness Dry Mouth Extrapyramidal Disorder	Health Professional	Reglan (Metoclopramide Hydrochloride, Tablet)	PS		ORAL	10 MG THREE TIMES DAILY (TOOK 1.1 APPROXIMATELY 3 TO 4

Fatigue	Phenergan		
Headache	(Promethazine		
Insomnia	Hydrochloride,		
Liver Function Test	Unspec)	SS	
Abnormal	Darvocet-N		
Neuroleptic Malignant	(Dextropropoxyphene/		
Syndrome	Paracetamol)	C	
Nystagmus	Toradol (Ketorolac		
Oscillopsia	Tromethamine)	C	
Pain			
Photosensitivity Reaction			
Reading Disorder			
Salivary Hypersecretion			
Thirst			
Throat Tightness			
Vision Blurred			
Visual Acuity Reduced			

Date:12/26/01ISR Number: 3844290-2Report Type:Direct Company Report #
Age:41 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Muscle Spasms Myocardial Infarction		Metoclopramide (Reglan)	PS		INTRAVENOUS	10 MG IV	
			Ketorolac (Toradol)	SS		INTRAVENOUS	30 MG IV	
			Vitamins	C				

Date:12/26/01ISR Number: 3844899-6Report Type:Expedited (15-DaCompany Report #2015259
Age:50 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Coronary Artery Atherosclerosis Haemorrhage Haemosiderosis	Health Professional Other	Oxycodone Hydrochloride (Similar To Nda 20-553)	PS		ORAL	PO	
	Head Injury Liver Disorder Nephritis Interstitial Pleural Adhesion Sickle Cell Anaemia Subarachnoid Haemorrhage		Promethazine Hcl Metoclopramide Sertraline Hydrochloride Meperidine Hcl	SS SS SS SS				

Date:12/26/01ISR Number: 3845331-9Report Type:Expedited (15-DaCompany Report #HQ8796226NOV2001
Age:72 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anaemia Confusional State Encephalitis Viral Thrombocytopenia	Health Professional Other	Eupantol (Pantoprazole, Tablet, Delayed Release)	PS		ORAL	15	DAY
			Mopral (Omeprazole)	SS				
INTRAVENOUS							5	DAY
			Primperan (Metoclopramide)	SS				

Date:12/27/01ISR Number: 3845785-8Report Type:Expedited (15-DaCompany Report #2015269
Age:59 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Abscess Bacterial Depressed Level Of Consciousness Fall Hip Fracture Hypotension	Health Professional Other	Oxycodone Hydrochloride (Similar To Nda 20-553) Morphine Sulfate (Similar To Nda	PS				

	Intervertebral Disc		19-516)	SS		
	Disorder		Morphine Sulfate			
	Necrosis		(Similar To Ands			
	Osteomyelitis		74-769 And 74-769			
	Staphylococcal Sepsis		And 74-862)	SS		
			Metoclopramide	SS		ORAL
PO						
			Lidocaine Hcl	SS		ORAL
PO						
			Promethazine	SS		

Date:12/27/01ISR Number: 3845895-5Report Type:Expedited (15-DaCompany Report #200112630BVD
Age:73 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Cardiac Failure	Foreign	Ciprobay			
	Stevens-Johnson Syndrome	Health	(Ciprofloxacin			
	Toxic Epidermal	Professional	Hydrochloride)	PS		ORAL
1000 MG DAILY						
	Necrolysis	Other				
ORAL						
			Ciprobay			
			(Ciprofloxacin			
			Hydrochloride)	SS		
			Clont			
			(Metronidazole)	SS		ORAL
400 MG BID						

ORAL				
		Clont (Metronidazole)	SS	
INTRAVENOUS	1000 MG DAILY			
INTRAVENOUS				
		Baypen (Mezlocillin Sodium)	SS	
INTRAVENOUS	2 G TID			
INTRAVENOUS				
		Pantozol (Pantoprazole Sodium)	SS	ORAL
20 MG DAILY				
ORAL				
		Antra (Omeprazole)	SS	
		Heparin	SS	
SUBCUTANEOUS	15000 IU			
DAILY				
SUBCUTANEOUS				
		Loperamid (Loperamide)	SS	
		Fortral (Pentazocine)	SS	
INTRAVENOUS	30 MG DAILY			
INTRAVENOUS				
		Vomex A (Dimenhydrinate)	SS	
		Etilefrin (Etilefrine)	SS	ORAL
30 GTT DAILY				
ORAL				
		Mcp	SS	ORAL
20 GTT DAILY				
ORAL				
		Cholspasmin (Hymecromone)	SS	
		Fenistil (Dimetindene Maleate)	SS	

			Solu-Decortin	SS		
INTRAVENOUS	100 MG DAILY					
INTRAVENOUS						

Date:12/28/01ISR Number: 3846956-7Report Type:Expedited (15-DaCompany Report #PHNU2001DE02940
Age:21 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Life-Threatening	Stevens-Johnson Syndrome	Foreign	Hydergin			
Hospitalization - Initial or Prolonged		Study	(Co-Dergocrine Mesylate)	PS		
INTRAVENOUS	SEE IMAGE					
		Health Professional	Heparin (Heparin Sodium) Ampoule	SS		
INTRAVENOUS	SEE IMAGE	Other				
			Fenistil (Dimetindene Maleate) Solution For Injection	SS		
INTRAVENOUS	SEE IMAGE					
			Insulin Human (Insulin Human) Solution For Injection	SS		
INTRAVENOUS	SEE IMAGE					
			Combactam (Sulbactam Sodium) Solution For Injection	SS		
INTRAVENOUS	1 G, TID,					
INTRAVENOUS						
			Dormicum For Injection (Midazolam Hydrochloride) Solution For Injection	SS		
INTRAVENOUS	SEE IMAGE					

		Cordanum Sugar-Coated Tablet (Talinolol)	SS		ORAL
SEE IMAGE					
		Fentanyl (Fentanyl) Solution For Injection	SS		
INTRAVENOUS	1.5MG/DAY,				
INTRAVENOUS					
		Konakion (Phytomenadione) Solution For Injection	SS		
INTRAVENOUS	1 DF, QD,				
INTRAVENOUS					
		Paracefan (Clonidine Hydrochloride) Solution For Injection	SS		ORAL
1.05 MG/DAY,					
ORAL					
		Aminoplasmal (Amino Acids Nos) Solution For Injection	SS		
INTRAVENOUS	1 DF, QD,				
INTRAVENOUS					
		Pavulon (Pancuronium Bromide)	SS		
INTRAVENOUS	SEE IMAGE				
		Kalymin "Asta Medica Awd" (Pyridostigmine Bromide) Solution For Injection	SS	Asta Medica	
INTRAVENOUS	30 MG, QD,				
INTRAVENOUS					
		Furesis Comp (Furosemide, Triamterene) Tablet	SS		ORAL
SEE IMAGE					
		Ampho-Moronal (Amphotericin B)			

			Suspension	SS	ORAL
2 ML, 6QD,					
ORAL					
			Paracetamol (Paracetamol) Tablet	SS	ORAL
1 G,					
ONCE/SINGE,					
ORAL					
			Espumisan (Dimeticone) Emulsion	SS	ORAL
2 ML, 6QD,					
ORAL					
			Dopacard (Dopexamine Hydrochloride) Solution For Injection	SS	
INTRAVENOUS	100 MG, QD,				
INTRAVENOUS					
			Berlosin S (Metamizole Sodium) Solution For Injection	SS	
INTRAVENOUS	1 DF,				
ONCE/SINGLE,					
INTRAVENOUS					
			Sinophenin (Promazine Phosphate)	SS	
INTRAVENOUS	3 DF/DAY,				
INTRAVENOUS					
			Diflucan (Fluconazole)	SS	ORAL
80 MG/DAY,					
ORAL					

		Aspisol (Acetylsalicylate Lysine) Solution For Injection	SS		
INTRAVENOUS	1 DF, QD,				
INTRAVENOUS					
		Pipril S (Piperacillin Sodium) Solution For Injection, 3g	SS		
INTRAVENOUS	3 G, BID,				
INTRAVENOUS					
		Prednisolut (Prednisolone Sodium Succinate) Solution For Injection	SS		
INTRAVENOUS	25 MG, BID,				
INTRAVENOUS					
		Intralipid (Soya Oil, Lecithin) Solution For Infusion	SS		
INTRAVENOUS	1 DF, QD,				
INTRAVENOUS					
		Panthenol (Panthenol) Solution	SS		
INTRAVENOUS	4 DF, QID,				
INTRAVENOUS					
		Ulcogant Suspension (Sucralfate)	SS		ORAL
5 ML, 6QD,					
ORAL					
		Cerucal (Metoclopramide Hydrochloride) Solution For Injection	SS		
INTRAVENOUS	1 DF, TID,				
INTRAVENOUS					

		Inzolen	SS		
INTRAVENOUS	1 DF, QD,				
INTRAVENOUS					
		Aminophylline (Aminophylline) Tablet	SS		ORAL
SEE IMAGE					
		Vitalipid Solution (Vitamins Nos)	SS		
INTRAVENOUS	1 DF, QD,				
INTRAVENOUS					
		Soluvit (Vitamins Nos)	SS		
INTRAVENOUS	1 DF, QD,				
INTRAVENOUS					
		Vioxx Tablet, 12.5mg	SS		ORAL
SEE IMAGE					
		Nimotop (Nimodipine) Solution	SS		
INTRAVENOUS	1 DF, QD,				
INTRAVENOUS					
		Ketanest (Ketamine) Solution	SS		
INTRAVENOUS	3 G, QD,				
INTRAVENOUS					
		Bifiteral "Solvay Arzneimittel" (Lactulose) Syrup	SS	Solvay	ORAL
.5 ML, TID,					
ORAL					
		Furesis (Furosemide) Solution	SS		
INTRAVENOUS	SEE IMAGE				
		Mucosolvan (Ambroxol Hydrochloride) Solution For Injection	SS		
INTRAVENOUS	3 G, QD,				
INTRAVENOUS					

				Luminal (Phenobarbital) Soluti	SS			
INTRAVENOUS	SEE IMAGE							
				Osmofundin (Sodium Acetate Trihydrate)	C			
				Eufibron Suppository	C			
				Arterenol (Norepinephrine Hydrochloride) Solution For Injection	C			
				Addel N (Zinc Chloride, Selenide Sodium, Manganese Chloride, Ferrous Chloride, Copper	C			
				Theophylline Tablet	C			
				Glucose Solution For Infusion	C			
				Indometacin Tablet	C			
				....	C			
				Normabrain Solution For Infusion	C			
				Calcium Solution For Injection	C			
				Tregor (Amantadine Sulfate) Solution For Infusion	C			

Date:01/04/02ISR Number: 3848726-2Report Type:Direct Company Report #CTU 158387
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dyskinesia		Paroxetine	PS			PAROXETINE 20	
	Muscle Spasms						MG	
			Promethazine	SS			PAROXETINE 25	
							MG	
			Metoclopramide 10					

Mg SS

10 MG

Date:01/04/02ISR Number: 3849119-4Report Type:Expedited (15-DaCompany Report #HQ7176816OCT2001
Age:58 YR Gender:Female I/FU:F

Outcome	PT
Death	Abdominal Pain
Other	Blood Bilirubin Increased
	Bone Marrow Depression
	Disseminated
	Intravascular Coagulation
	Flushing
	Haematoma
	Haemorrhage
	Hepatic Failure
	Histiocytosis
	Haematophagic
	Hypotension
	Intestinal Ischaemia
	Malignant Histiocytosis
	Multi-Organ Failure

		Petechiae Pulmonary Haemorrhage Renal Failure	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
		Sepsis Subarachnoid Haemorrhage Thrombocytopenia White Blood Cell Count Increased	Health Professional	Reglan (Metoclopramide Hydrochloride, Injection)	PS		
INTRAVENOUS	2 DOSES, 10 MG,						
INTRAVENOUS							

Date:01/11/02ISR Number: 3852105-1Report Type:Direct Company Report #CTU 158971
Age:49 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Life-Threatening	Cardio-Respiratory Arrest		Reglan (10mg)	PS		
INTRAVENOUS	10MG IV Q 6 H					
Hospitalization - Initial or Prolonged	Depressed Level Of Consciousness Laryngospasm Tremor		Prinivil Paxil Percocet Reglan	C C C C		

Date:01/14/02ISR Number: 3852422-5Report Type:Periodic Company Report #265690
Age:21 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Other	Anaphylactic Reaction	Health Professional	Versed (Midazolam Hydrochloride) 1.5 Mg	PS		
INTRAVENOUS	2 MG 1 PER ONE DOSE					
INTRAVENOUS						
			Decadron (Dexamethasone)	SS		
INTRAVENOUS	8MG 1 PER ONE					

DOSE

INTRAVENOUS

		Reglan (Metoclopramide Hydrochloride)	SS
INTRAVENOUS	10 MG 1 PER		

ONE DOSE

INTRAVENOUS

		Birth Control Pill (Oral Contraceptive Nos)	C

Date:01/14/02ISR Number: 3852885-5Report Type:Direct Company Report #CTU 159154
Age:56 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Neuroleptic Malignant		Metoclopramide 10mg	PS			10MG TID HS	
Hospitalization - Initial or Prolonged	Syndrome		Fosinopril	C				
			Amlodipine	C				
			Simvastatin	C				
			Quinine	C				
			Aspirin	C				
			Metoprolol	C				
			Furosemide	C				
			Sertraline	C				
			Clonazepam	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/16/02ISR Number: 3853587-1Report Type:Expedited (15-DaCompany Report #HQ9780007JAN2002
Age:46 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dehydration Hyponatraemia Rash Renal Impairment	Health Professional	Reglan (Metoclopramide Hydrochloride, Injection)	PS		INTRAVENOUS	INTRAVENOUS	

Date:01/17/02ISR Number: 3855133-5Report Type:Expedited (15-DaCompany Report #3209
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cyanosis	Literature	Metoclopramide	PS		INTRAVENOUS	10 MG; IV	2 DAY
	Depressed Level Of Consciousness Dyspnoea Haemolysis Methaemoglobinaemia	Health Professional						

Date:01/21/02ISR Number: 3854416-2Report Type:Expedited (15-DaCompany Report #304687
Age:21 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Stevens-Johnson Syndrome	Foreign	Dormicum	PS	Roche	START DATE		
						PRIOR TO 27 NOV 2000.		
			Konakion	SS	Roche	START DATE		
						PRIOR TO 27 NOV 2000.		
			Panthenol	SS	Roche	START DATE		

PRIOR TO 27 NOV 2000.			
ONGOING ON 25 DEC 2000.			
	Heparin	SS	Roche
	Arterenol	SS	
1 DAY			
	Osmofundin	SS	
1 DAY			
	Theophyllin	SS	
START DATE PRIOR TO 27 NOV 2000.			
	Indometacin	SS	
START DATE PRIOR TO 27 NOV 2000.			
	Eufibron	SS	
START DATE PRIOR TO 27 NOV 2000.			
	Dopacard	SS	
START DATE PRIOR TO 27 NOV 2000.			
	Nutritional Supplement	SS	
START DATE PRIOR TO 27 NOV 2000.			
	Nimotop	SS	
START DATE PRIOR TO 27 NOV 2000.			
	Fentanyl	SS	Roche
START DATE			

PRIOR TO 27

NOV 2000.

START DATE PRIOR TO 27 NOV 2000.	Luminal	SS
START DATE PRIOR TO 27 NOV 2000.	Ketanest	SS
START DATE PRIOR TO 27 NOV 2000.	Cordanum	SS
START DATE PRIOR TO 27 NOV 2000.	Bifiteral	SS
START DATE PRIOR TO 27 NOV 2000.	Pipril	SS
START DATE PRIOR TO 27 NOV 2000.	Combactam	SS
START DATE PRIOR TO 27 NOV 2000.	Human Insulin	SS
START DATE PRIOR TO 27 NOV 2000. ONGOING ON 25 DEC 2000.		

START DATE PRIOR TO 27 NOV 2000.	Mucosolvan	SS
START DATE PRIOR TO 27 NOV 2000.	Prednisolut	SS
START DATE PRIOR TO 27 NOV 2000.	Hydergin	SS
START DATE PRIOR TO 27 NOV 2000.	Intralipid	SS
START DATE PRIOR TO 27 NOV 2000.	Ulcogant	SS
START DATE PRIOR TO 27 NOV 2000. ONGOING ON 25 DEC 2000.	Cerucal	SS
START DATE PRIOR TO 27 NOV 2000.	Addel	SS
START DATE PRIOR TO 27 NOV 2000.	Osmotan	SS
START DATE PRIOR TO 27 NOV 2000.	Furesis	SS

	Inzolen	SS	
	Aminophyllin	SS	
25 DAY			
	Vitalipid	SS	
	Soluvit	SS	
	Vioxx	SS	
25 DAY			
	Multivitamin	SS	Roche
23 DAY			
	Paracefan	SS	
	Aminoplasmal	SS	
	Pavulon	SS	
4 DAY			
	Pyridostigmine Bromide	SS	Roche
13 DAY			

				Furesis Comp	SS	
19 DAY						
				Ampho Moronal	SS	
12 DAY						
				Paracetamol	SS	Roche
16 DAY						
				Fenistil	SS	
				Espumisan	SS	
ONGOING ON 25						
DEC 2000.						
				Sinophenin	SS	
1 DAY						
				Berlosin	SS	
1 DAY						
				Diflucan	SS	
6 DAY						
				Aspisol	SS	
1 DAY						

Date:01/22/02ISR Number: 3855221-3Report Type:Expedited (15-DaCompany Report #304844
Age:38 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization -	Hepatitis		Kytril	PS	Roche	
1 DAY						
Initial or Prolonged			Endoxan	SS		
500 MG/M2.						
FIRST COURSE. 29 DAY						
			Farmorubicine	SS		
FIRST COURSE. 29 DAY						
			Zophren	SS		
5 DAY						
			Fluorouracil	SS		
500 MG/M2.						
FIRST COURSE. 29 DAY						
			Primperan	SS		
1 DAY						
			Motilium	C		

Date:01/23/02ISR Number: 3856134-3Report Type:Expedited (15-DaCompany Report #US-BRISTOL-MYERS SQUIBB COMPANY-11674629
Age:38 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hepatitis		Endoxan Inj	PS	Bristol-Myers Squibb Company	INTRAVENOUS		
			Farmorubicin	SS		INTRAVENOUS		
			5-Fu	SS		INTRAVENOUS		
			Kytril	SS		INTRAVENOUS		
			Zophren	SS		ORAL		
			Primperan	SS		INTRAVENOUS		
			Motilium	C				

Date:01/23/02ISR Number: 3857779-7Report Type:Expedited (15-DaCompany Report #HQ9922615JAN2002
Age:55 YR Gender:Male I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Agitation
	Blood Bicarbonate Increased
	Blood Gases Abnormal
	Blood Ph Decreased
	Confusional State
	Haemoglobin Decreased
	Hypercapnia
	Hypoxia
	Methaemoglobinaemia
	Normochromic Normocytic Anaemia
	Oxygen Saturation Decreased
	Pco2 Decreased
	Po2 Increased

Respiratory Depression

Dose	Duration	Report Source	Product	Role	Manufacturer	Route
		Literature	Reglan (Metoclopramide Hydrochloride, Injection)	PS		
INTRAVENOUS	10 MG 1X PER 1 DAY					
			Bupivacaine (Bupivacaine,)	SS		
INTRADISCAL (INTRASPINAL)	3 ML OF 0.5% 1 DAY					
			Morphine Sulfate (Morphine Sulfate)	C		
			Morphine (Morphine)	C		
			Cefazolin (Cefazolin)	C		
			Fentanyl Citrate (Fentanyl Citrate)	C		
			Midazolam (Midazolam)	C		
			Enoxaparin Sodium (Heparin-Fraction, Sodium Salt)	C		

Date:01/23/02ISR Number: 3859452-8Report Type:Expedited (15-DaCompany Report #HQ9922715JAN2002
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Other	Confusional State Cyanosis Lethargy Methaemoglobinaemia Oxygen Saturation Decreased	Literature	Reglan (Metoclopramide Hydrochloride, Unspec)	PS		

Date:01/23/02ISR Number: 3859633-3Report Type:Expedited (15-DaCompany Report #2002088573FR
Age:38 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hepatic Lesion Hepatitis	Foreign Health Professional Other	Farmorubicin(Epirubicin Hydrochloride)Powder, Sterile	PS			INTRAVENOUS	160 MG, CYCLIC, IV
			Endoxan(Cyclophosphamide)	SS			INTRAVENOUS	800 MG, CYCLIC, IV
			Fluorouracil(Fluorouracil)	SS			INTRAVENOUS	800 MG, CYCLIC, IV
			Primperan(Metoclopramide)	SS			INTRAVENOUS	IV
			Zophren(Ondansetron Hydrochloride)	SS			ORAL	
			Kytril (Granisetron)	SS			INTRAVENOUS	IV
			Motilium (Domperidone)	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/23/02ISR Number: 3860168-2Report Type:Expedited (15-DaCompany Report #A200735
Age:72 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	Cerebral Ischaemia	Foreign	Zoloft Tablets	PS			100.00 MG	
	Drug Interaction	Literature						TOTAL DAILY
	Extrapyramidal Disorder	Health	Metoclopramide	SS		INTRAVENOUS	10.00 MG	
	Medication Error	Professional						TOTAL
	Serotonin Syndrome					INTRAVENOUS		
	Tibia Fracture		Celecoxib	C				
			Hydrocortisone	C				
			Acetaminophen	C				
			Morphine Sulfate	C				

Date:01/24/02ISR Number: 3858555-1Report Type:Direct Company Report #CTU 160028
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	Agitation		Metoclopramide	PS		ORAL	10MG PO QID	
	Akathisia		Magnesium Oxide	C				
			Fluoxetine Hcl	C				
			Lisinopril	C				
			Potassium Chloride	C				
			Beclomethasone Nasal Pockethl	C				
			Sodium Chloride Soln Nasal Spray	C				

Date:01/24/02ISR Number: 3860256-0Report Type:Expedited (15-DaCompany Report #304844
Age:38 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hepatitis	Foreign	Kytril (Granisetron)	PS		INTRAVENOUS	INTRAVENOUS	

Initial or Prolonged		Other	Endoxan (Cyclophosphamide)	SS		
INTRAVENOUS	800 MG 1 PER					
ONE DOSE						
INTRAVENOUS						
			Farmorubicine (Epirubicin Hydrochloride)	SS		
INTRAVENOUS	160 MG 1 PER					
ONE DOSE						
INTRAVENOUS						
			Zophren (Ondansetron Hydrochloride)	SS		ORAL
ORAL						
			Fluorouracil (Fluorouracil)	SS		
INTRAVENOUS	800 MG 1 PER					
ONE DOSE						
INTRAVENOUS						
			Primperan (Metoclopramide Hydrochloride)	SS		
INTRAVENOUS	INTRAVENOUS					
			Motilium (Domperidone)	C		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/28/02ISR Number: 3861442-6Report Type:Expedited (15-DaCompany Report #801#3#2002-18783 (000)
Age:38 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Toxicity Hepatitis	Health Professional	Endoxan (Cyclophosphamide)	PS		INTRAVENOUS	800 MILLIGRAM	
			Farmorubicin (Epirubicin)	SS		INTRAVENOUS	160 MG I.V.	
			Fluorouracil (Fluorouracil)	SS		INTRAVENOUS	800 MG I.V.	
			Kytril (Granisetron)	SS		INTRAVENOUS	I.V.	
			Zophren (Ondansetron Hydrochloride)	SS		ORAL	P.O.	
			Primperan (Metoclopramide)	SS		INTRAVENOUS	I.V.	
			Motilium (Domperidone)	C				

Date:01/29/02ISR Number: 3860872-6Report Type:Expedited (15-DaCompany Report #B0133033A
Age:47 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Alanine Aminotransferase Increased		Zophren	PS	Glaxo Wellcome	INTRAVENOUS	24MG per day	1 DAY
			Solumedrol	SS		INTRAVENOUS		1 DAY
	Aspartate Aminotransferase Increased		Cisplatin	SS		INTRAVENOUS	80MGM2 per day	1 DAY
			Metoclopramide	SS		INTRAVENOUS	60MG per day	1 DAY
	Blood Alkaline		Kytril	SS	Glaxo Wellcome	ORAL	4MG per day	5 DAY

	Phosphatase Increased		Cetornan	C			
UNKNOWN							
	Gamma-Glutamyltransferase		Di-Antalvic	C			
UNKNOWN							
	Increased		Eprex	C			
UNKNOWN	4285.7IU per						
	Infectious Mononucleosis						
day							
	Liver Function Test		Forlax	C			
UNKNOWN							
	Abnormal		Gemzar	C			
INTRAVENOUS	1250MGM2 per						
day	9 DAY						
			Iskedyl	C			
UNKNOWN							
			Miniphase	C			
UNKNOWN							
			Morphine	C			
UNKNOWN	60MG per day						
			Taxotere	C			
UNKNOWN							
			Xanax	C			ORAL
.5MG Twice							
per day							
			Sodium Fluoride	C	Glaxo Wellcome		
UNKNOWN							

Date:01/29/02ISR Number: 3860875-1Report Type:Expedited (15-DaCompany Report #B0133246A
Age:38 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization -	Hepatitis		Zophren	PS	Glaxo Wellcome	ORAL
5 DAY						
Initial or Prolonged			Primperan	SS	Glaxo Wellcome	
INTRAVENOUS	1 DAY					
			Farmorubicine	SS		
INTRAVENOUS	1 DAY					
			Kytril	SS	Glaxo Wellcome	
INTRAVENOUS	1 DAY					
			Endoxan	SS		
INTRAVENOUS	1 DAY					
			Fluorouracil	SS		
INTRAVENOUS						
			Domperidone	C		
UNKNOWN						

Date:01/31/02ISR Number: 3863160-7Report Type:Expedited (15-DaCompany Report #PHBS2002IT01280
Age:47 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Rhabdomyolysis	Foreign Health Professional	Torecan (Thiethylperazine Maleate) Unknown	PS		ORAL	6 MG, PRN,	
		Other	Plasil (Metoclopramide Hydrochloride)	SS		INTRAMUSCULAR	1	ADMINISTRATION, ONCE/SINGLE, INTRAMUSCULAR

Date:02/05/02ISR Number: 3865181-7Report Type:Expedited (15-DaCompany Report #B0133009A
Age:60 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Aplasia Biopsy Bone Marrow Abnormal Myeloid Maturation Arrest Neutropenia	Foreign	Valaciclovir Hydrochlorid Tablet (Non-Us Product)	PS		ORAL		ORAL
			Tramadol Hydrochloride (Tramadol Hydrochloride)	SS		ORAL		ORAL
			Metoclopramide (Metoclopramide)	SS		ORAL		ORAL
			Morphine Sulphate (Morphine Sulfate)	SS		ORAL		ORAL
			Cyclophosphamide					

				(Cyclophosphamide)	SS		
INTRAVENOUS							
							BOLUS
INTRAVENOUS							
BOLUS							
				Caelyx (Caelyx)	SS		
INTRAVENOUS							
							BOLUS
INTRAVENOUS							
BOLUS							
				Vincristine	C		
				Prednisolone	C		
				Lactulose	C		

Date:02/05/02ISR Number: 3865330-0Report Type:Direct Company Report #CTU 160856
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Medication Error		Metoclopramide	PS		
			Sodium Chloride 0.9%	SS		

Date:02/07/02ISR Number: 3867438-2Report Type:Expedited (15-DaCompany Report #EMADSS2002000590
Age:60 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Aplastic Anaemia	Foreign Health Professional	Tramadol (Unspecified)			
	Neutropenia		(Tramadol Hydrochloride)	PS		
			Primperan (Metoclopramide)	SS		

			Skenan (Morphine Sulfate)	SS			ORAL
ORAL							
			Vincristine (Vincristine)	C			
			Endoxan (Cyclophosphamide)	C			
			Zelitrex (Valaciclovir)	C			
			Caelyx (Doxorubicin Hydrochloride)	C			
			Solupred (Prednisolone Sodium Sulfobenzoate)	C			
			Lactulose (Lactulose)	C			

Date:02/12/02ISR Number: 3866840-2Report Type:Expedited (15-DaCompany Report #306562
Age:13 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Extrapyramidal Disorder		Tamiflu	PS	Roche			3 DAY
Initial or Prolonged			Primperan	SS				
			Cimetidine	C				

Date:02/12/02ISR Number: 3866841-4Report Type:Expedited (15-DaCompany Report #306409
Age:29 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Anaphylactic Reaction	Health	Tamiflu	PS	Roche			1 DAY
		Professional	Pl	SS				1 DAY
			Voltaren	SS				1 DAY
			Dasen	SS				1 DAY
			Marzulene S	SS				1 DAY

				Solita-T3 Injection	SS		
1	DAY						
				Vitamedin	SS		
1	DAY						
				Primperan	SS		
1	DAY						

Date:02/12/02ISR Number: 3869275-1Report Type:Expedited (15-DaCompany Report #HQ8915128NOV2001
Age:4 MON Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Dystonia Medication Error	Health Professional	Reglan (Metoclopramide Hydrochloride, Syrup)	PS		ORAL
6 ML OVERDOSE						
AMOUNT, ORAL						

Date:02/13/02ISR Number: 3869578-0Report Type:Periodic Company Report #2012370
Age:41 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Intentional Misuse	Health Professional Other	Oxycodone Hydrochloride (Similar To Nda 20-553)	PS		
			Diazepam	SS		
			Acetaminophen	SS		

				Butalbital	SS		
				Caffeine	SS		
				Metoclopramide	SS		
				Zolpidem	SS		
				Diphenhydramine	SS		

Date:02/13/02ISR Number: 3876150-5Report Type:Periodic Company Report #2013599
Age:27 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Overdose	Consumer	Oxycontin Cr Tablets					
		Health	10 Mg (Oxycodone					
		Professional	Hydrochloride)	PS		ORAL	MG PO	
		Other	Hydrocodone					
			Bitartrate	SS				
			Carisoprodol	SS				
			Meprobamate	SS				
			Citalopram	SS				
			Metoclopramide	SS				
			Nicotine	SS				
			Caffeine	SS				

Date:02/13/02ISR Number: 3876685-5Report Type:Periodic Company Report #2014013
Age:45 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Health	Oxycontin Cr					
	Confusional State	Professional	Tablets, 80 Mg					
		Other	(Oxycodone					
			Hydrochloride)	PS		ORAL	80 MG PO	8 MON
			Hydrocodone					
			Bitartrate	SS				
			Dihydrocodeine					
			(Similar To Anda					
			88-584)	SS				
			Amitriptyline	SS				
			Acetaminophen	SS				
			Caffeine Anhydride	SS				
			Metoclopramide	SS				

			Amerge (Naratriptan Hcl)	C			
			Thyroid	C			

Date:02/13/02ISR Number: 3879488-0Report Type:Periodic Company Report #2012889
Age:56 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Health Professional Other	Oxycontin Cr Tablets, 40 Mg (Oxycodone Hydrochloride)	PS		ORAL	PO	
			Oxyir Capsules (Oxycodone Hydrochloride)	SS		ORAL	PO	
			Sertraline Hydrochloride	SS				
			Metoclopramide	SS				
			Ephedrine	SS				

			Acetaminophen	SS			
			Alcohol	SS			

Date:02/15/02ISR Number: 3871357-5Report Type:Expedited (15-DaCompany Report #306562
Age:13 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	Tamiflu (Oseltamivir) 75 Mg	PS		ORAL	2 DOSE FORM	DAILY
			Primperan (Metoclopramide Hydrochloride)	SS		ORAL	6 DOSE FORM	DAILY
			Cimetidine (Cimetidine)	C				

Date:02/19/02ISR Number: 3870401-9Report Type:Expedited (15-DaCompany Report #306562
Age:13 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Binocular Eye Movement Disorder		Tamiflu	PS	Roche		3	DAY
			Pramiel	SS			3	DAY
	Drug Interaction		Cimetidine	C				
	Dyskinesia		Lafutidine	C			3	DAY
	Speech Disorder		Unknown Drug	C				

Date:02/21/02ISR Number: 3872754-4Report Type:Direct Company Report #CTU 162025
Age:77 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Hospitalization - Initial or Prolonged	Tongue Oedema		Zyprexa 20mg Lilly	PS	Lilly	
			Metoclopramide 10mg Generic Par Pharma	SS	Par Pharma	
10MG BID						
			Insulin R	C		
			Insulin N	C		
			Atrovent	C		
			Vasotec	C		
			Cardura	C		

Date:02/21/02ISR Number: 3873298-6Report Type:Expedited (15-DaCompany Report #306562
Age:13 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Condition Aggravated	Foreign	Tamiflu			
	Dyskinesia	Health	(Oseltamivir) 75 Mg	PS		ORAL
150 MG DAILY						
	Feeling Abnormal	Professional				
ORAL						
	Influenza		Pramiel			
	Speech Disorder		(Metoclopramide Hydrochloride)	SS		ORAL
6 DOSE FORM						
DAILY ORAL						
			Cimetidine (Cimetidine)	C		
			Lafutidine (Lafutidine)	C		
			Unknown Drug (Generic Component			

(S) Unknown) C

Date:02/22/02ISR Number: 3875278-3Report Type:Expedited (15-DaCompany Report #3318
Age:38 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Toxicity Hepatitis		Cyclophosphamide Epirubicin	PS SS		INTRAVENOUS INTRAVENOUS	800 MG, IV 180 MG/90MG, IV	1 DAY 1 DAY
			Fluorouracil	SS		INTRAVENOUS	800 MG, IV	1 DAY
			Granisetron	SS		INTRAVENOUS	IV	1 DAY
			Ondansetron Hydrochloride	SS		ORAL	PO	3 DAY
			Metoclopramide	SS		INTRAVENOUS	IV	1 DAY

Date:02/22/02ISR Number: 3879454-5Report Type:Periodic Company Report #HQ0922216MAY2001
Age:40 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability Other	Dyskinesia Extrapyramidal Disorder	Health Professional	Reglan (Metoclopramide Hydrochloride)	PS		ORAL	ORAL	

Date:02/22/02ISR Number: 3879455-7Report Type:Periodic Company Report #HQ1097021MAY2001
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Tardive Dyskinesia	Health Professional	Reglan (Metoclopramide Hydrochloride)	PS				

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability Other	Tardive Dyskinesia	Health Professional	Reglan (Metoclopramide Hydrochloride)	PS		ORAL	10 MG QID, AC	AND HS ORAL
			Zestril (Lisinopril)	C				
			Dilacor Xr (Diltiazem Hydrochloride)	C				
			Methotrexate (Methotrexate)	C				
			Prednisone (Prednisone)	C				
			Prilosec (Omeprazole)	C				
			Wellbutrin (Amfebutamone Hydrochloride)	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/22/02ISR Number: 3879457-0Report Type:Periodic Company Report #HQ4572110AUG2001
Age:68 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Headache	Consumer	Reglan (Metoclopramide Hydrochloride)	PS		ORAL	20 MG, ORAL	
	Hypertension							
	Tremor							
	Weight Decreased		Flonase (Fluticasone Propionate)	C				
			Azmacort (Triamcinolone Acetonide)	C				
			Zantac (Ranitidine Hydrochloride0	C				
			Norvasc (Amloidpine)	C				
			Prilosec (Omeprazole)	C				

Date:02/22/02ISR Number: 3879458-2Report Type:Periodic Company Report #HQ5814511SEP2001
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hypertension	Health Professional	Reglan	PS		ORAL	10 MG EVERY 6 HOURS, ORAL	
	Pregnancy							

Date:02/22/02ISR Number: 3879459-4Report Type:Periodic Company Report #HQ8204609MAR2001
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Convulsion	Health Professional	Reglan (Metoclopramide Hydrochloride, Tablet)	PS				

Date:02/22/02ISR Number: 3879460-0Report Type:Periodic Company Report #HQ8453415MAR2001
Age:60 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Amnesia Anorexia Depression Disturbance In Attention Insomnia Movement Disorder Muscle Spasms Suicide Attempt Weight Decreased	Consumer	Reglan Synthroid (Levothyroxine Sodium)	PS C		ORAL	10 MG 3 X PER 1 DAY, ORAL	

Date:02/27/02ISR Number: 3877083-0Report Type:Expedited (15-DaCompany Report #HQ0839821FEB2002
Age:7 MON Gender:Female I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Chapped Lips Convulsion Dehydration Diarrhoea Eating Disorder Irritability

	Vomiting					
		Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
		Consumer	Reglan (Metoclopramide Hydrochloride, Syrup)	PS		ORAL
4.75 ML FOUR TIMES DAILY (OVERDOSE AMOUNT), ORAL						
			Zantac (Ranitidine Hydrochloride)	C		

Date:03/04/02ISR Number: 3877913-2Report Type:Direct Company Report #CTU 162626
Age:79 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
	Dystonia		Metoclopramide	PS		ORAL
5MG PO QID						
	Urosepsis		Coumadin	C		
			Nitro	C		
			Insulin 70/30	C		
			Digoxin	C		
			Cartia Xt	C		
			Lasix	C		
			Paxil	C		
			Vioxx	C		

Date:03/05/02ISR Number: 3880322-3Report Type:Direct Company Report #CTU 162799
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization -	White Blood Cell Count		Metoclopramide	PS		
INTRAVENOUS	10 MG IV					
Initial or Prolonged	Decreased		Morphine	C		
			Tylenol	C		

			Famotidine	C		

Date:03/06/02ISR Number: 3879601-5Report Type:Direct Company Report #CTU 162929
Age:26 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Dizziness		Reglan (5mg) (A.H. Robbins)	PS	A.H.Robins	
INTRAVENOUS 5MG IV Q8HR						
PRN						
			D5lr W/Mvc	C		

Date:03/08/02ISR Number: 3881742-3Report Type:Expedited (15-DaCompany Report #HQ0633311FEB2002
Age: Gender: I/FU:F

Outcome	PT
Life-Threatening	Coarctation Of The Aorta
Congenital Anomaly	Complications Of Maternal Exposure To Therapeutic Drugs
	Congenital Anomaly
	Maternal Drugs Affecting Foetus
	Pregnancy

Premature Baby

Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Health Professional	Effexor Xr (Venlafaxine Hydrochloride, Capsule, Extended Release	PS		ORAL	150 MG 1X PER	1 DAY, ORAL
	Insulin (Insulin, Injection)	SS				
	Neurontin (Gabapentin,)	SS		ORAL	300 MG 1X PER	1 DAY, ORAL
	Prilosec (Omeprazole,)	SS		ORAL	20 MG 1X PER	1 DAY, ORAL
	Reglan (Metoclopramide Hydrochloride, Tablet)	SS		ORAL	ORAL	

Date:03/08/02ISR Number: 3881769-1Report Type:Expedited (15-DaCompany Report #8-97148-001S
Age:6 MON Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability Other	Brain Damage Cognitive Disorder Complex Partial Seizures Developmental Delay	Consumer	Reglan (Metoclopramide Hydrochloride, Syrup)	PS		ORAL	SEE IMAGE	
	Grand Mal Convulsion Hypermobility Syndrome Hypotonia Ligament Laxity Masked Facies		Tylenol (Tylenol) Antibiotics (Antibiotics)	C C				

Memory Impairment
Motor Dysfunction
Neurotoxicity
Overdose
Somnolence
Tremor

Date:03/08/02ISR Number: 3881771-XReport Type:Expedited (15-DaCompany Report #HQ1211706MAR2002
Age:2 MON Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Abnormal Behaviour Accidental Overdose Aggression Anger	Consumer	Reglan (Metoclopramide Hydrochloride, Syrup)	PS		ORAL	SEE IMAGE	
	Attention Deficit/Hyperactivity Disorder Enuresis Mouth Haemorrhage Tremor		Tagamet (Cimetidine) Mylanta (Aluminium Hydroxide Gel, Dried/Dimeticone, Activated/Magnesium Hydroxide)	C C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/08/02ISR Number: 3881986-0Report Type:Expedited (15-DaCompany Report #HQ0633311FEB2002
Age: Gender:Unknown I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Coarctation Of The Aorta	Health Professional	Effexor Xr (Venlafaxine Hydrochloride, Capsule, Extended Release)	PS		ORAL	150 MG 1XPER	1 DAY, ORAL
Congenital Anomaly	Congenital Anomaly							
	Maternal Drugs Affecting Foetus							
	Pregnancy							
			Insulin (Insulin, Injection)	SS				
			Neurontin (Gabapentin,)	SS		ORAL	300 MG 1X PER	1 DAY, ORAL
			Prilosec (Omeprazole,)	SS		ORAL	20 MG 2X PER	1 DAY, ORAL
			Reglan (Metoclopramide Hydrochloride, Tablet)	SS		ORAL	ORAL	

Date:03/11/02ISR Number: 3880606-9Report Type:Expedited (15-DaCompany Report #306409
Age:29 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Flushing		Tamiflu	PS	Roche		1	DAY
	Pruritus		Voltaren	SS			1	DAY
	Urticaria		Primperan	SS			1	DAY
			Pl	C			1	DAY

				Dasen	C		

STRENGTH

REPORTED AS

5MG OR 10MG

TAB 1 DAY

				Marzulene S	C		

1 DAY

				Solita-T3 Injection	C		

1 DAY

				Vitamedin	C		

1 DAY

Date:03/12/02ISR Number: 3882600-0Report Type:Expedited (15-DaCompany Report #200211664GDDC
Age:56 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Hepatitis Jaundice	Foreign Other	Terbutaline Sulfate (Bricanyl)	PS		

RESPIRATORY

(INHALATION) INH 12 DAY

				Omeprazole (Mopral)	SS		ORAL

20 MG/DAY PO 5 DAY

				Augmentin	SS		ORAL

1 G TID PO 10 DAY

				Alprazolam	SS		

OPHTHALMIC PO 6 DAY

				Clonazepam (Rivotril)	SS		ORAL

PO 8 DAY

				Metoclopramide (Primperan)	SS		

4 DAY

				Morphine Sulfate (Skenan)	C		
				Morphine Sulfate (Sevredol)	C		
				Paracetamol (Doliprane)	C		
				Oxazepam (Seresta)	C		

				Cascara Dry Extract (Peristaltine)	C		
				Furosemide (Lasilix)	C		

Date:03/12/02ISR Number: 3882867-9Report Type:Expedited (15-DaCompany Report #306409
Age:29 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Arthritis	Foreign	Tamiflu					
	Chills	Health	(Oseltamivir)75 Mg	PS		ORAL	75 MG ORAL	
	Erythema	Professional	Voltaren (Diclofenac					
	Flushing		Sodium)25 Mg	SS		ORAL	25 MG ORAL	
	Headache		Primperan					
	Malaise		(Metoclopramide					
	Pharyngolaryngeal Pain		Hydrochloride)0.5%	SS		INTRAVENOUS	2 ML	
	Pruritus					INTRAVENOUS		
	Urticaria Papular		Pl					
	Vomiting		(Acetaminophen/Caffeine/Promethazine					
			Methylene Disalicylate/Salicyl	C				
			Dasen (Serrapeptase)	C				
			Marzulene S (Levoglutamide/Sodium Gualenate)	C				
			Solita.T3 Injection (Potassium Chloride/Sodium Chloride/Sodium Lactate)	C				
			Vitamedin (* Benfotiamine/*Cyanocobalamin/*Hydroxocobalamin/Pyridoxine Hydrochloride/*Thiam	C				

Date:03/13/02ISR Number: 3883217-4Report Type:Expedited (15-DaCompany Report #B0260186A
Age:34 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Erysipelas	Foreign	Zofran Solution (Ondansetron Hydrochloride)	PS		INTRAVENOUS	INTRAVENOUS	
			Navelbine (Formulation Unknown) (Vinorelbine Tartrate)	SS		INTRAVENOUS	INTRAVENOUS	
			Metoclopramide Hcl (Formulation Unknown) (Metoclopramide Hcl)	SS		INTRAVENOUS	INTRAVENOUS	
			Oxaliplatin Solution 100 Mg (Oxaliplatin)	SS		INTRAVENOUS	INFUS	
			Me-Prednisolone Na Succ. Solution (Me-Prednisolone Na Succ.)	SS		INTRAVENOUS	INTRAVENOUS	

				Tropisetron Hydrochloride Solution (Tropisetron Hydrochloride)	SS		
INTRAVENOUS	INTRAVENOUS						
				Celecoxib	C		

Date:03/13/02ISR Number: 3883261-7Report Type:Expedited (15-DaCompany Report #HQ1256211MAR2002
Age:70 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Drug Interaction Dyskinesia Injury	Health Professional Company Representative	Effexor Xr (Venlafaxine Hydrochloride, Capsule)	PS		ORAL
SEE IMAGE						
			Reglan (Metoclopramide Hydrochloride, Unspec)	SS		
SEE IMAGE						

Date:03/13/02ISR Number: 3886674-2Report Type:Periodic Company Report #HQ5441131AUG2001
Age:32 WK Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Medication Error Overdose	Health Professional	Reglan (Metoclopramide Hydrochloride, Injection)	PS		
INTRAVENOUS	1 MG/KG FOR 3					
DOSES,						
INTRAVENOUS						

Date:03/13/02ISR Number: 3886677-8Report Type:Periodic Company Report #HQ7522523OCT2001
Age:0 MON Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Bradycardia	Health Professional	Reglan (Metoclopramide Hydrochloride, Injection)	PS				
TRANSPLACENTAL WITH 20 MG PEPCID, TRANSPLACENTAL	10 MG REGLAN							
			Pepcid (Famotidine,)	SS				
TRANSPLACENTAL WITH 10 MG REGLAN, TRANSPLACENTAL	20 MG PEPCID							
			Ancef (Cefazolin Sodium)	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/15/02ISR Number: 3884683-0Report Type:Expedited (15-DaCompany Report #HQ0633311FEB2002
Age: Gender: I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Congenital Anomaly	Coarctation Of The Aorta Maternal Drugs Affecting Foetus Pregnancy Premature Baby	Health Professional	Effexor Xr (Venlafaxine Hydrochloride, Capsule, Extended Rellease)	PS		ORAL	150 MG 1X PER 1 DAY,	ORAL
			Insulin (Insulin , Injection)	SS				
			Neurontin (Gabapentin,)	SS		ORAL	300 MG 1X PER 1 DAY,	ORAL
			Prilosec (Omeprazole,)	SS		ORAL	20 MG 2X PER 1 DAY,	ORAL
			Reglan (Metoclopramide Hydrochloride, Tablet)	SS		ORAL		

Date:03/18/02ISR Number: 3885267-0Report Type:Expedited (15-DaCompany Report #HQ0633311FEB2002
Age: Gender: I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Congenital Anomaly	Coarctation Of The Aorta Congenital Anomaly Pregnancy Premature Baby	Health Professional	Effexor Xr (Venlafaxine Hydrochloride, Capsule, Extended Release)	PS		ORAL	150 MG 1X PER	

1 DAY, ORAL							
			Insulin (Insulin, Injection)	SS			
			Neurontin (Gabapentin,)	SS			ORAL
300 MG 1X PER 1 DAY, ORAL							
			Prilosec (Omeprazole,)	SS			ORAL
20 MG 2X PER 1 DAY, ORAL							
			Reglan (Metoclopramide Hydrochloride, Tablet)	SS			ORAL
ORAL							

Date:03/19/02ISR Number: 3885728-4Report Type:Expedited (15-DaCompany Report #002#4#2002-00037 (0)
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Coarctation Of The Aorta	Health	Reglan-Dose Unknown					
Congenital Anomaly	Congenital Anomaly	Professional	(Metoclopramide Hcl)	PS		ORAL	ORAL	
	Maternal Drugs Affecting	Other	Venlafaxine	SS		ORAL	150 MG, 1 IN	
	Foetus						1 D, ORAL	
	Pregnancy		Gabapentin	SS		ORAL	300 MG, 1 IN	
	Premature Baby						1 D, ORAL	
			Omeprazole	SS		ORAL	20 MG, 2 IN 1	
							D, ORAL	
			Insulin	SS				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/21/02ISR Number: 3887459-3Report Type:Expedited (15-DaCompany Report #HQ1278512MAR2002
Age:47 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Abdominal Pain Upper Blood Bicarbonate Increased Blood Chloride Decreased Blood Creatinine Increased Blood Urea Increased Impaired Gastric Emptying Nausea Oesophageal Ulcer Oesophagitis Vomiting White Blood Cell Count Increased	Literature	Reglan (Metoclopramide Hydrochloride, Unspec)	PS			2	YR

Date:03/22/02ISR Number: 3887144-8Report Type:Direct Company Report #CTU 163926
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Disability	Anxiety Confusional State Eating Disorder Symptom Nervousness Sleep Disorder Tremor		Reglan 10mg	PS		ORAL	10 MG X 3 ORAL	

Date:03/22/02ISR Number: 3887564-1Report Type:Expedited (15-DaCompany Report #002#8#2002-00044(0)
Age:47 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain Upper Blood Creatinine Abnormal Blood Urea Abnormal	Literature Other	Reglan-Dose -Unknown (Metoclopramide Hcl) Insulin	PS C				

	Haematocrit Abnormal		Calcium	C		
	Nausea		Fenofibrate	C		
	Oesophageal Ulcer					
	Oesophagitis					
	Vomiting					

Date:03/22/02ISR Number: 3887688-9Report Type:Expedited (15-DaCompany Report #HQ1328314MAR2002
Age:4 MON Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hyperacusis	Consumer	Reglan					
	Hyperhidrosis		(Metoclopramide					
	Medication Error		Hydrochloride,					
	Overdose		Syrup)	PS		ORAL		
OVERDOSE								
	Tardive Dyskinesia							
AMOUNT, 3 ML								
	Tremor							
ORAL								

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/27/02ISR Number: 3890899-XReport Type:Expedited (15-DaCompany Report #002#4#2002-00046(0)
Age:83 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anxiety	Consumer	Reglan-Dose-Unknown (Metoclopramide Hcl)	PS		ORAL		
	Confusional State	Other						
	Hypotension		Midodrine	SS		ORAL	2.5MG, 1 IN 1 D, ORAL	
	Parkinson'S Disease							
	Tremor		Acetylsalicylic Acid	C				
	Vision Blurred		Amiodarone	C				
	Weight Decreased		Carvedilol	C				
			Atorvastatin	C				
			Furosemide	C				
			Digoxin	C				
			Allopurinol	C				
			Potassium Chloride	C				
			Monopril	C				

Date:03/27/02ISR Number: 3891421-4Report Type:Expedited (15-DaCompany Report #HQ1414520MAR2002
Age:73 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Accidental Overdose	Foreign	Reglan (Metoclopramide Hydrochloride, Unspec)	PS				
	Depression	Literature						
	Hepatic Function Abnormal							
	Parkinsonism							
	Renal Impairment							

Date:03/28/02ISR Number: 3892976-6Report Type:Periodic Company Report #2001-046
Age:51 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Parkinson'S Disease	Consumer	Metoclopramide Tablets, Usp 10 Mg	PS		ORAL	10 MG PO QID	

Date:03/28/02ISR Number: 3892977-8Report Type:Periodic Company Report #2001-067
Age:30 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anaphylactic Reaction Dizziness Neuroleptic Malignant Syndrome Nystagmus	Consumer	Metoclopramide Tablets, 10mg Toradol Darvocet	PS C C			1 BEFORE MEALS PRN	

Date:04/03/02ISR Number: 3894914-9Report Type:Expedited (15-DaCompany Report #HQ1545829MAR2002
Age:4 MON Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Medication Error Overdose Restlessness Somnolence	Consumer	Reglan (Metoclopramide Hydrochloride, Syrup)	PS		ORAL	"1/2 TEASPOON" FOUR TIMES DAILY, STRENGTH	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/03/02ISR Number: 3895340-9Report Type:Expedited (15-DaCompany Report #2002AP00717
Age:63 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required	Renal Failure Acute	Foreign	Plendil	PS		ORAL	5 MG DAILY	PO
Intervention to		Health	Losec	SS			40 MG DAILY	
Prevent Permanent		Professional	Gentamicin Sulphate	SS				
INTRAVENOUS	180 MG DAILY							
Impairment/Damage		Other						
IV								
			Cefepime Hydrochloride	SS				
INTRAVENOUS	2 G DAILY IV							
			Lopresor	SS		ORAL	200 MG DAILY	
PO								
			Maxolon	SS		ORAL	40 MG DAILY	
PO								

Date:04/03/02ISR Number: 3895930-3Report Type:Expedited (15-DaCompany Report #001-0991-M0001948
Age:69 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Amnesia	Consumer	Rezulin					
	Atrioventricular Block	Health	(Troglitazone)	PS		ORAL	SEE IMAGE	
	First Degree	Professional	Reglan					
	Breast Tenderness		(Metoclopramide)	SS				
	Clumsiness		Asacol (Mesalazine)	C				
	Cognitive Disorder		Amaryl (Glimepiride)	C				
	Colitis		Furosemide	C				
	Dysphonia		Hydrochlorothiazide	C				
	Emotional Distress		Monopril (Fosinopril					
	Fall		Sodium)	C				
	Feeling Cold		Glucophage					
	Haemoglobin Decreased		(Metformin					
	Hepatic Cirrhosis		Hydrochloride)	C				
	Hepatic Failure		Clonidine	C				

	Hepato-Lenticular Degeneration		Digoxin	C
	Hyperreflexia		Slow-Fe (Ferrous Sulfate)	C
	Hypoaesthesia		Potassium	C
	Injury			
	Mental Disorder			
	Muscle Rigidity			
	Myelopathy			
	Neuropathy Peripheral			
	Nystagmus			
	Parkinsonian Gait			
	Platelet Count Decreased			
	Reading Disorder			
	Splenomegaly			
	Tremor			

Date:04/05/02ISR Number: 3897834-9Report Type:Expedited (15-DaCompany Report #HQ1600403APR2002
Age:32 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Convulsion	Literature	Effexor					
	Drug Interaction	Health	(Venlafaxine					
	Fall	Professional	Hydrochloride)	PS			225 MG 1X PER	
	Pneumothorax						1 DAY ORAL	3 YR
	Serotonin Syndrome		Reglan (Metoclopramide Hydrochloride,					

				Injection)	SS		
INTRAVENOUS	10 MG,						
INTRAVENOUS							
				Tylenol (Paracetamol)	C		
				Indomethacin (Indometacin)	C		
				Morphine (Morphine)	C		

Date:04/09/02ISR Number: 3897432-7Report Type:Expedited (15-DaCompany Report #3469
Age:32 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
	Agitation	Literature	Metoclopramide	PS		
INTRAVENOUS 10 MG IV						
	Coma	Health	Venlafaxine	SS		
225 MG 3 YR						
	Confusional State	Professional	Acetaminophen	C		
	Convulsion		Indomethacin	C		
	Drug Interaction		Morphine	C		
	Extrapyramidal Disorder					
	Fall					
	Serotonin Syndrome					

Date:04/09/02ISR Number: 3897756-3Report Type:Expedited (15-DaCompany Report #3468
Age:72 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
	Drug Interaction	Literature	Metoclopramids,			
	Extrapyramidal Disorder	Health	Sertraline	PS		
INTRAVENOUS 10 MG						
	Medication Error	Professional	Sertraline	SS		ORAL
10 MG ONCE 1 YR						
	Serotonin Syndrome		Celecoxib	C		
			Hydrocortisone	C		
			Acetaminophen	C		
			Morphine Sulfate	C		

Date:04/10/02ISR Number: 3898251-8Report Type:Expedited (15-DaCompany Report #HQ1414520MAR2002
Age:73 YR Gender:Female I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Accidental Overdose
Other	Anxiety
	Apathy
	Blood Lactate Dehydrogenase Increased
	Blood Potassium Decreased
	Blood Sodium Decreased
	Chills
	Depression
	Drug Toxicity
	Electrolyte Imbalance
	Extrapyramidal Disorder
	Fatigue
	Flat Affect
	Gamma-Glutamyltransferase Increased
	Hepatic Function Abnormal
	Hypokinesia
	Insomnia
	Nausea
	Parkinsonism
	Renal Impairment

		Sluggishness Speech Disorder Vomiting	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
			Literature	Reglan (Metoclopramide Hydrochloride), Unspec	PS		
10 MG 4X PER 1 DAY							
				Ethambutol	SS		
1600 MG 1X PER 1 DAY							
				Isoniazid	SS		
300 MG 1X PER 1 DAY							
				Paroxetine	SS		
20 MG 1X PER 1 DAY							
				Pyrazinamide	SS		
2 G 1X PER 1 DAY							
				Pyridoxine	SS		
20 MG 1X PER 1 DAY							
				Rifampicin	SS		
				Losartan	C		
				Tolbutamid (Tolbutamide)	C		
				Traimterene	C		
				Pantozol (Pantoprazole)	C		
				Magnesium Oxide	C		
				Carbasalate Calcium	C		
				Tramadol	C		

Date:04/10/02ISR Number: 3898556-0Report Type:Expedited (15-DaCompany Report #HQ1545829MAR2002
Age:4 MON Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Convulsion Medication Error Overdose Restlessness Sedation	Consumer	Reglan (Metoclopramide Hydrochloride, Syrup)	PS		ORAL	"1/2 TEASPOON" FOUR TIMES DAILY, ORAL	
			Zantac (Ranitidine Hydrochloride)	C				

Date:04/10/02ISR Number: 3898557-2Report Type:Expedited (15-DaCompany Report #HQ1554201APR2002
Age:7 WK Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Crying Insomnia Medication Error Overdose	Consumer	Reglan (Metoclopramide Hydrochloride, Syrup)	PS		ORAL	OVERDOSE AMOUNT, 5 CC INSTEAD OF 0.5 CC, ORAL	
			Zantac(Ranitidine Hydrochloride)	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/10/02ISR Number: 3898569-9Report Type:Expedited (15-DaCompany Report #002#8#2002-00065 (0)
Age:73 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Toxicity	Foreign	Metoclopramide-Hydro					
	Hepatic Function Abnormal	Literature	chloride					
	Parkinsonism	Other	(Metoclopramide Hcl)	PS		ORAL	10 MG, 4 IN 1	
	Renal Impairment						D, ORAL	
			Isoniazid	C				
			Pyrazinamide	C				
			Ethambutol	C				
			Losartan	C				
			Pyridoxine	C				
			Tolbutamide	C				
			Triamterene W/Epitizide	C				
			Pantoprazol	C				
			Magnesium Oxide	C				
			Carbasalate Calcium	C				
			Tramadol	C				

Date:04/10/02ISR Number: 3898599-7Report Type:Expedited (15-DaCompany Report #HQ1552601APR2002
Age:45 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Aspartate	Health	Reglan					
	Aminotransferase	Professional	(Metoclopramide					
	Increased		Hydrochloride,					
	Blood Creatine		Injection)	PS		INTRAVENOUS	10 MG 1X PER	
	Phosphokinase Increased						6 HR,	
	Cardiac Failure						INTRAVENOUS	
	Cardio-Respiratory Arrest		Neurontin					
	Heart Rate Increased		(Gabapentin)	C				
	Neuropathy Peripheral		Oxycodone					
	Pyrexia		(Oxycodone)	C				
	Renal Failure		Topamax (Topiramate)	C				
	Rhabdomyolysis		Flagyl					
	Sepsis		(Metronidazole)	C				

			Lovenox (Heparin-Fraction, Sodium Salt)	C		

Date:04/11/02ISR Number: 3899597-XReport Type:Expedited (15-DaCompany Report #HQ1571603APR2002
Age:72 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Brain Scan Abnormal Cerebral Atrophy Drug Interaction Serotonin Syndrome	Literature	Reglan (Metoclopramide Hydrochloride, Injection)	PS		
INTRAVENOUS 10 MG,	Tibia Fracture					
INTRAVENOUS						
			Sertraline (Sertraline,)	SS		
100 MG 1X PER						
1 DAY 18 MON						
			Celecoxib (Celecoxib)	C		
			Hydrocortisone (Hydrocortisone)	C		
			Tylenol (Paracetamol)	C		

			Morphine Sulfate (Morphine Sulfate)	C		

Date:04/13/02ISR Number: 3916440-0Report Type:Direct Company Report #CTU 167994
Age:74 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Hypertensive		Phenergan	PS		
	Encephalopathy		Reglan	SS		
	Mental Status Changes					

Date:04/16/02ISR Number: 3901196-8Report Type:Direct Company Report #CTU 165789
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Diarrhoea		Metoclopramide Hcl			
	Dysphoria		10mg/2ml Inj			
	Hyperhidrosis		(Baxter)	PS	Baxter	
INTRAVENOUS X 1 DOSE, IV						
	Respiratory Rate					
PUSH						
	Increased		Effexor	C		
	Restless Legs Syndrome		Cardura	C		
	Tremor		Norvasc	C		
			Proscar	C		
			Milk Thistle	C		
			Restoril	C		
			Vicodin 5/500	C		

Date:04/17/02ISR Number: 3902044-2Report Type:Expedited (15-DaCompany Report #2001080388JP
Age:71 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Life-Threatening	Acute Respiratory	Foreign	Idamycin(Idarubicin)			
	Distress Syndrome	Health	Powder,Sterile	PS		
INTRAVENOUS						
	Asthma	Professional				DRIP
15 MG ,						

	Chest Pain	Other			
DAILY, CYCLIC					
	Disseminated				
, IV DRIP					
	Intravascular Coagulation		Cylocide(Cytarabine)	SS	
INTRAVENOUS					
	Leukopenia				DRIP
120 MG,					
	Lung Disorder				
DAILY,					
	Lung Infiltration				
CYCLIC, IV					
	Necrosis				
DRIP					
	Pneumonia		Zofran (Ondansetron		
	Pulmonary Oedema		Hydrochloride)	SS	
INTRAVENOUS					
	Pyrexia				DRIP
4 MG, QD, IV					
	Respiratory Failure				
DRIP					
	Thrombocytopenia		Primperan		
			(Metoclopramide)	SS	
INTRAVENOUS					
					DRIP
20 MG, QD, IV					
DRIP					
			Marzulene S (Sodium		
			Galenate)	SS	ORAL
1.5 G, TID,					
ORAL					
			Neurer	SS	ORAL
600 MG , TID,					
ORAL					
			Amikamycin (Amikacin		
			Sulfate)	SS	
INTRAVENOUS					
					DRIP
200 MG , QD,					
IV DRIP					

			Pentcillin (Piperacillin Sodium)	SS		
INTRAVENOUS DRIP						
4 G, BID , IV						
DRIP						
			Carbazochrome Sodium Sulfonate (Carbazochrome Sodium Sufonate)	C		

Date:04/17/02ISR Number: 3902465-8Report Type:Expedited (15-DaCompany Report #3473
Age:92 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Life-Threatening	Convulsion	Literature	Metoclopramide	PS		ORAL	10 MG ONCE/10
Hospitalization -	Electrocardiogram Qrs	Health					MG TID
Initial or Prolonged	Complex Prolonged	Professional	Erythromycin	SS			500 MG TID
	Pneumonia Aspiration		Cisapride	SS			10 MG TID
	Syncope						
	Torsade De Pointes						
	Ventricular Extrasystoles						
	Ventricular Tachycardia						
	Vomiting						

Date:04/18/02ISR Number: 3903122-4Report Type:Expedited (15-DaCompany Report #002#8#2002-00065 (0)
Age:73 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Depression	Foreign	Metoclopramide-Hydro				
Initial or Prolonged	Nausea	Literature	chloride				
Other	Parkinsonism	Other	(Metoclopramide Hcl)	PS		ORAL	10 MG, 4 IN 1
	Therapeutic Agent						
D, ORAL							

	Toxicity		Isoniazid	SS		ORAL
300 MG, 1 IN						
1 D, ORAL						
			Pyrazinamide	SS		ORAL
2 G, 1 IN 1						
D, ORAL						
			Ethambutol	SS		ORAL
1600 MG, 1 IN						
1 D, ORAL						
			Pyridoxine	SS		ORAL
20 MG, 1 IN 1						
D, ORAL						
			Rifampicin	SS		
			Paroxetine	SS		ORAL
20 MG, 1 IN 1						
D, ORAL						
			Losartan	C		
			Tolbutamide	C		
			Triamterene W/Epitizide	C		
			Pantoprazol	C		
			Magnesium Oxide	C		
			Carbasalate Calcium	C		
			Tramadol	C		

Date:04/22/02ISR Number: 3903749-XReport Type:Expedited (15-DaCompany Report #304844
Age:38 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - 1 DAY	Hepatitis		Kytril	PS	Roche	
Initial or Prolonged			Endoxan	SS		
500 MG/M2.						

FIRST COURSE. 29 DAY

FIRST COURSE. 29 DAY

5 DAY

500 MG/M2.

FIRST COURSE. 29 DAY

1 DAY

Farmorubicine	SS
Zophren	SS
Fluorouracil	SS
Primperan	SS
Motilium	C

Date:04/23/02ISR Number: 3906081-3Report Type:Expedited (15-DaCompany Report #PHRM2002FR01125
Age:31 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Pancreatitis Acute	Foreign Health Professional	Syntocinon (Synthetic Oxytocin) Ampoule	PS		INTRAVENOUS	INTRAVENOUS	
		Other	Ephedrine	SS		INTRAVENOUS	INTRAVENOUS	
			Furadantine (Nitrofurantoin) Capsule	SS		ORAL	50 MG, TID,	ORAL
			Primperan (Metoclopramide) Sol	SS		INTRAVENOUS	INTRAVENOUS	
			Spasfon (Trimethylphlorogluc inol, Phloroglucinol)	C				

Date:04/23/02ISR Number: 3906154-5Report Type:Expedited (15-DaCompany Report #304844
Age:38 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Hospitalization - Hepatitis | Foreign | Kytril (Granisetron) | PS | INTRAVENOUS | INTRAVENOUS
Initial or Prolonged | Other | Endoxan (Cyclophosphamide) | SS | INTRAVENOUS | 800 MG 1 PER
ONE DOSE
INTRAVENOUS
Farmorubicine (Epirubicin Hydrochloride) | SS | INTRAVENOUS | 160 MG 1 PER
ONE DOSE
INTRAVENOUS
Zophren (Ondansetron Hydrochloride) | SS | ORAL | ORAL
Fluorouracil (Fluorouracil) | SS | INTRAVENOUS | 800 MG 1 PER
ONE DOSE
INTRAVENOUS
Primperan (Metoclopramide Hydrochloride) | SS | INTRAVENOUS | INTRAVENOUS
Motilium (Domperidone) | C

Date:04/25/02ISR Number: 3906997-8Report Type:Direct Company Report #CTU 166594
Age:30 YR Gender:Female I/FU:I

Outcome
Required
Intervention to

Prevent Permanent
Impairment/Damage

	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Muscle Twitching Vision Blurred		Reglan 5mg/M6 (A.H. Robins)	PS	A. H. Robins	INTRAVENOUS	30 MG OVER	24HR IV

Date:04/26/02ISR Number: 3908066-XReport Type:Expedited (15-DaCompany Report #8-96327-018S
Age:17 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Cyanosis Dystonia Overdose Sulphaemoglobinaemia	Literature	Reglan (Metoclopramide Hydrochloride, Unspec)	PS			2 MG/KG	6 DAY
	Vomiting		N-Acetylcysteine (Nac)	C				

Date:04/26/02ISR Number: 3908825-3Report Type:Expedited (15-DaCompany Report #FR8959816APR2002
Age:46 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Diabetes Insipidus	Health Professional Other	Lederfoline (Leucovorin Calcium, Injection, 0)	PS		INTRAVENOUS	50 MG WITHIN 6 HOURS/INTRAVENOUS	1 DAY
			Ledertrexate (Methotrexate, Injection, 0)	SS			SEE IMAGE	16 DAY
			...	SS				

				Primperan (Metoclopramide, 0)	SS
INTRAVENOUS	INTRAVENOUS	3	DAY		
				Zophren (Ondansetron Hydrochloride, 0)	SS
INTRAVENOUS		3	DAY		
				Lutenyl (Nomegestrol Acetate)	C
				Deroxat (Paroxetine Hydrochloride)	C
				Azantac (Ranitidine Hydrochloride)	C
				Dicynone (Etamsilate)	C
				Zyloric (Allopurinol)	C

Date:04/29/02ISR Number: 3909707-3Report Type:Expedited (15-DaCompany Report #HQ2009123APR2002
Age:29 YR Gender:Female I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Dermatitis Exfoliative
	Drug Ineffective
	Enanthema
	Inflammation
	Leukocytosis
	Polyarthritis
	Pruritus

	Pyrexia Rash Papular					
Dose	Duration	Report Source	Product	Role	Manufacturer	Route
"2/D" ORAL	1 DAY	Health Professional	Advil (Ibuprofen, Unspec)	PS		ORAL
INTRAVENOUS	INTRAVENOUS 1 DAY	Other	Celestene (Betamethasone)	SS		
"2/D"	1 DAY		Paracetamol (Paracetamol)	SS		
"2" DAILY			Primperan (Metoclopramide)	SS		ORAL
ORAL	1 DAY					

Date:04/30/02ISR Number: 3909420-2Report Type:Direct Company Report #CTU 166895
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Other	Pharmaceutical Product		Cartia Xt 300mg	PS		ORAL
300MG QD PO						
	Complaint		Metoclopramide 10mg	SS		ORAL
10MG QID PO						
	Vomiting		Diazepam	C		
			Naproxen	C		
			Nexium	C		
			Nifedipine	C		
			Ultram	C		

Date:04/30/02ISR Number: 3910800-XReport Type:Expedited (15-DaCompany Report #2002-04-2229
Age:29 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization - Initial or Prolonged	Arthritis Erythema Exanthem	Foreign Health Professional	Celestene (Betamethasone Sodium Phosphate)			

	Leukocytosis	Other	Injectable Solution	PS			
INTRAVENOUS 4 MG							
	Nasopharyngeal Disorder						
INTRAVENOUS							
	Pruritus		Primperan	SS			ORAL
20 MG ORAL							
	Pyrexia		Advil	SS			
400 MG							
	Rash Generalised		Dolko (Paracetamol)	SS			ORAL
2 TABS ORAL							
	Rash Papular						
	Systemic Inflammatory Response Syndrome						

Date:04/30/02ISR Number: 3911010-2Report Type:Expedited (15-DaCompany Report #HQ2016023APR2002
Age: Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hepatitis	Study Literature	Reglan (Metoclopramide Hydrochloride, Injection)	PS				
Other								
INTRAVENOUS							20-50 MG,	
INTRAVENOUS								

Date:04/30/02ISR Number: 3911109-0Report Type:Expedited (15-DaCompany Report #HQ1972319APR2002
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dystonia Sulphaemoglobinaemia	Study Literature	Reglan (Metoclopramide					

				Hydrochloride, Injection)	PS		
INTRAVENOUS	50 MG,						
INTRAVENOUS							

Date:04/30/02ISR Number: 3911112-0Report Type:Expedited (15-DaCompany Report #HQ2015823APR2002
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Hepatitis	Study Literature	Reglan (Metoclopramide Hydrochloride, Injection)	PS		
Other						
INTRAVENOUS	5-15 MG,					
INTRAVENOUS						

Date:05/01/02ISR Number: 3909252-5Report Type:Expedited (15-DaCompany Report #US-BRISTOL-MYERS SQUIBB COMPANY-11674629
Age:38 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Hepatitis		Endoxan Inj	PS	Bristol-Myers Squibb Company	
INTRAVENOUS						
			Farmorubicin	SS		
INTRAVENOUS						
			5-Fu	SS		
INTRAVENOUS						
			Kytril	SS		
INTRAVENOUS						
			Zophren	SS		ORAL
			Primperan	SS		
INTRAVENOUS						
			Motilium	C		

Date:05/07/02ISR Number: 3913924-6Report Type:Expedited (15-DaCompany Report #HQ2065225APR2002
Age:19 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Alanine Aminotransferase Increased	Literature	Advil (Ibuprofen, Unspec)	PS		ORAL	2	DAY
	Aspartate Aminotransferase Increased		Ceftriaxone (Ceftriaxone,)	SS		ORAL		
	Blood Alkaline Phosphatase Increased		Ciprofloxacin (Ciprofloxacin)	SS		INTRAVENOUS		
	Blood Bilirubin Increased		Ketorolac (Ketorolac,)	SS		ORAL		
	Blood Creatine Increased		Metoclopramide (Metoclopramide,)	SS		ORAL		
	Blood Pressure Diastolic Decreased							
	Cholecystitis							
	Cholestasis							
	Dilatation Intrahepatic Duct Acquired							
	Drug Ineffective							
	Heart Rate Increased							
	Lymphocyte Count Decreased							
	Neutrophil Count Increased							
	Scleral Discolouration							
	Sepsis							
	Stevens-Johnson Syndrome							
	Urinary Tract Infection							
	White Blood Cell Count Abnormal							

Date:05/13/02ISR Number: 3916416-3Report Type:Expedited (15-DaCompany Report #A02200200191
Age:69 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Intestinal Obstruction	Health Professional	Primperan (Metoclopramide)	PS		UNKNOWN	3 UNIT	
			Stilnox (Zolpidem)	SS		ORAL	5 MG OD	
			Di-Antalvic (Paracetamol/Dextropropoxyphene)	SS		ORAL	6 UNIT	
			Thalidomide	SS		ORAL	50 MG TID	
			Celectol (Celiprolol)	C				
			Vasten (Pravastatin Sodium)	C				
			Xanax (Alprazolam)	C				
			Mopral (Omeprazole)	C				
			Cordarone (Amiodarone Hydrochloride)	C				
			Aredia (Pamidronate Disodium)	C				

Date:05/14/02ISR Number: 3917091-4Report Type:Expedited (15-DaCompany Report #HQ2272010MAY2002
Age:76 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Hospitalization - Initial or Prolonged	Mucosal Inflammation Neutropenic Sepsis Vomiting	Study	Leucovorin (Leucovorin Calcium, Injection)	PS		INTRAVENOUS	20 MG	53 DAY
			Fluorouracil (Fluorouracil,)	SS		INTRAVENOUS	675 MG EVERY	OTHER DAY 53 DAY
			Metoclopramide (Metoclopramide Hydrochloride,					

Tablet) SS ORAL
10 MG DAILY 5 DAY

Date:05/15/02ISR Number: 3917447-XReport Type:Expedited (15-DaCompany Report #001-0991-M0001948
Age:67 YR Gender:Male I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Amnesia
Other	Anaemia
	Anorexia
	Aortic Atherosclerosis
	Atrioventricular Block First Degree
	Blood Creatinine Increased
	Blood Urea Increased
	Breast Tenderness
	Cardiomegaly
	Clumsiness
	Cognitive Disorder
	Colitis
	Conduction Disorder
	Diabetes Mellitus Inadequate Control
	Dysphonia

		Emotional Distress					
		Epistaxis					
		Extrapyramidal Disorder	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
		Fall	Consumer	Rezulin			
		Hepatic Cirrhosis	Health	(Troglitazone)	PS		ORAL
SEE IMAGE							
		Hepatic Failure	Professional	Reglan			
		Hepato-Lenticular		(Metoclopramide)	SS		
		Degeneration		Labetalol	SS		
		Hepatotoxicity		Asacol (Mesalazine)	C		
		Hyperreflexia		Amaryl (Glimepiride)	C		
		Hypoaesthesia		Furosemide	C		
		Injury		Hydrochlorothiazide	C		
		Metabolic Encephalopathy		Monopril (Fosinopril			
		Mitral Valve		Sodium)	C		
		Calcification		Glucophage			
		Muscle Rigidity		(Metformin			
		Myelopathy		Hydrochloride)	C		
		Neuropathy Peripheral		Clonidine	C		
		Nystagmus		Digoxin	C		
		Parkinsonian Gait		Slow-Fe (Ferrous			
		Peripheral Coldness		Sulfate)	C		
		Platelet Count Decreased		Potassium	C		
		Portal Hypertension					
		Respiratory Alkalosis					
		Splenomegaly					
		Tremor					
		Ventricular Hypertrophy					
		Vision Blurred					

Date:05/17/02ISR Number: 3919093-0Report Type:Expedited (15-DaCompany Report #HQ2220908MAY2002
Age:15 YR Gender:Female I/FU:I

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Hospitalization -		Anaemia	Literature	Reglan			
Initial or Prolonged		Cyanosis		(Metoclopramide			
Other		Methaemoglobinaemia		Hydrochloride,			
		Muscle Spasms		Injection)	PS		
INTRAVENOUS	1 MG/KG EVERY						
		Oxygen Saturation					
4 HOURS,							
		Decreased					
INTRAVENOUS	48 HR						

		Pco2 Decreased	Acetylcysteine				
		Po2 Increased	(Acetylcysteine,)	SS			ORAL
15.5 ML 1X							
		Reaction To Colouring					
PER 4 HR,							
		Sulphaemoglobinaemia					
ORAL	48	HR					
		Vomiting					

Date:05/20/02ISR Number: 3919559-3Report Type:Expedited (15-DaCompany Report #HQ1414520MAR2002
Age:73 YR Gender:Female I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Accidental Overdose
Other	Alanine Aminotransferase Increased
	Anxiety
	Apathy
	Aspartate Aminotransferase Increased
	Blood Lactate Dehydrogenase Increased

Blood Potassium Decreased Blood Sodium Decreased Chills	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Communication Disorder Creatinine Renal Clearance Decreased Depression	Literature	Reglan (Metoclopramide Hydrochloride, Unspec)	PS			10 MG 4X PER 1 DAY
Drug Toxicity Electrolyte Imbalance Fatigue		Ethambutol (Ethambutol)	SS			1600 MG 1X PER 1 DAY
Feeling Cold Flat Affect Gamma-Glutamyltransferase Increased		Isoniazid (Isoniazid)	SS			300 MG 1X PER 1 DAY
Hepatic Function Abnormal Muscle Rigidity Parkinsonism		Paroxetine (Paroxetine)	SS			20 MG 1X PER 1 DAY
Renal Impairment Sleep Disorder Sluggishness		Pyrazinamide (Pyrazinamide)	SS			2 G 1X PER 1 DAY
Vomiting		Pyridoxine (Pyridoxine)	SS			20 MG 1X PER 1 DAY
		Rifampicin (Rifampicin)	SS			
		Losartan (Losartan)	C			
		Tolbutamid (Tolbutamide)	C			
		Triamterene (Triamterene)	C			
		Pantozol (Pantoprazole)	C			
		Magnesioum Oxide (Magnesium Oxide)	C			

				Carbasalate Calcium (Carbasalate Calcium)	C		
				Tramadol (Tramadol)	C		

Date:05/22/02ISR Number: 3921251-6Report Type:Direct Company Report #CTU 168643
Age:24 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dystonia		Metoclopramide Inj 5mg/Ml Faulding	PS	Faulding	SUBCUTANEOUS	12.5MG/HR	CONTINUOUSLY
						SUBCUTANEOUS		

Date:05/30/02ISR Number: 3926417-7Report Type:Direct Company Report #CTU 169207
Age:26 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Methaemoglobinaemia		Metoclopramide 10mg	PS			10MG QID	
	Oxygen Saturation					OTHER		
	Decreased		Gabapentin	C				
			Diazepam	C				
			Carbamazepine	C				
			Levothyroxine	C				
			Guaifenesin	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Multiple Vitamin And Mineral	C
Lansoprazole	C
Ergocalciferol	C

Date:05/31/02ISR Number: 3968327-5Report Type:Periodic Company Report #001-0991-M0000388
Age:46 YR Gender:Female I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Abdominal Discomfort
Other	Abdominal Distension
	Acute Respiratory Distress Syndrome
	Agitation
	Anxiety
	Arrhythmia
	Ascites
	Asthenia
	Atelectasis
	Bacteraemia
	Blood Potassium Increased
	Candidiasis
	Cardiomegaly
	Cellulitis
	Chest Pain
	Chronic Obstructive Pulmonary Disease
	Condition Aggravated
	Confusional State
	Constipation
	Cough
	Depression
	Dermatitis Exfoliative
	Diabetes Mellitus Inadequate Control
	Diabetic Retinopathy
	Diarrhoea
	Dizziness
	Dyspnoea
	Encephalopathy
	Enteritis
	Generalised Oedema
	Haematochezia
	Haematuria
	Haemorrhage

Headache
Hepatocellular Damage
Hyperadrenalism
Hypokalaemia
Hypothermia
Ileus Paralytic
Intracranial Pressure
Increased
Iron Deficiency Anaemia
Ketonuria
Liddle'S Syndrome
Lipids Abnormal
Lung Infiltration
Nausea
Oedema

Oral Intake Reduced Osteoarthritis Pneumonia Proctalgia Proteinuria Pulmonary Oedema Rales Renal Tubular Necrosis Respiratory Distress Retinopathy Hypertensive Rhonchi Sepsis Sleep Apnoea Syndrome Ventricular Extrasystoles	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Consumer	Rezulin(Troglitazone)	PS			SEE IMAGE
		Prinivil (Lisinopril)	SS			20 MG
		Amphotercin B (Amphotericin B)	SS		INTRAVENOUS	50 MG/G,
		Reglan (Metoclopramide)	SS		INTRAVENOUS	
		E.E.S. (Erythromycin Ethylsuccinate)	C			400 MG/G (4X
		Prozac (Fluoxetine Hydrochloride)	C			DAILY)
		Verapamil (Verapamil)	C			
		Trental(Pentoxifylline)	C			
		Ferotrinsic (Ferrous Fumarate)	C			
		Norvasc (Amlodipine Besilate)	C			
		Clonidine(Clonidine)	C			
		Triamterene (Triamterene)	C			
		Potassium Chloride(Potassium Chloride)	C			
		Ferrous Sulfate (Ferrous Sulfate)	C			
		Magnesium Gluconate (Magnesium Gluconate)	C			
		Docusate Sodium(Docusate Sodium)	C			
		Zantac(Ranitidine				

Hydrochloride)	C
Nph (Insulin Injection, Isophane)	C
Atrovent (Ipratropium Bromide)	C
Demadex (Torasemide)	C
Glucophage (Metoformin Hydrochloride)	C
Ancef (Cefazolin Sodium)	C
Pepcid(Famotidine)	C
Colace (Docusate Sodium)	C
Vasotec (Enalapril Maleate)	C
Pentoxifylline (Pentoxifylline)	C
Fosphenytoin Sodium	C
Verapamil	

Hydrochloride (Verapamil Hydrochloride)	C
Urokinase (Urokinase)	C
Ativan (Lorazepam)	C
Ventolin(Salbutamol)	C
Nimbex (Cisatracurium Besilate)	C
Potassium Chloride (Potassium Chloride)	C
Propulsid(Cisapride)	C
Motrin (Ibuprofen)	C
Unasyn(Sultamicillin Tosilate)	C
Tobramycin Sulfate(Tobramycin Sulfate)	C
Piperacillin Sodium (Piperacillin Sodium)	C
Ritalin (Methylphenidate Hydrochloride)	C
Lidocaine(Lidocaine)	C
Heparin Sodium (Heparin)	C
Morphine (Morphine)	C
Decadron (Dexamethasone)	C
Dulcolax (Bisacodyl)	C
Diprivan(Propofol)	C
Nipride (Nitroprusside Sodium)	C
Nicardipine Hydrochloride (Nicardipine Hydrochloride)	C
Clonidine Hydrochloride (Clonidine Hydrochloride)	C
Hydralazine Hydrochloride (Hydralazine Hydrochloride)	C

Tylenol (Paracetamol)	C
Fleet Phospho Soda Liquid (Sodium Phosphate Diabasic, Sodium Phosphate Monobasic)	C
Reglan (Metoclopramide)	C
Ampicillin(Ampicillin)	C
Magnesium Sulfate(Magnesium Sulfate)	C

				Versed (Midazolam Hydrochloride)	C		
				Vitamin K (Phytomenadione)	C		
				Lasix (Furosemide)	C		

Date:06/03/02ISR Number: 3927336-2Report Type:Direct Company Report #CTU 169368
Age:12 MON Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Dystonia		Metoclopramide	PS			1.3 MG NG QID	
	Movement Disorder							
	Respiratory Distress							
	Urticaria							
	Visual Acuity Reduced							

Date:06/03/02ISR Number: 3928603-9Report Type:Expedited (15-DaCompany Report #HQ2425023MAY2002
Age:2 MON Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Irritability	Consumer	Reglan (Metoclopramide Hydrochloride, Syrup)	PS		ORAL	SEE IMAGE	
	Medication Error							
	Overdose							
	Sedation							
	Somnolence		Zantac (Ranitidine Hydrochloride)	C				
	Vomiting							

Date:06/03/02ISR Number: 3928606-4Report Type:Expedited (15-DaCompany Report #HQ2425223MAY2002
Age:2 MON Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Irritability	Consumer	Reglan (Metoclopramide Hydrochloride, Syrup)	PS		ORAL	SEE IMAGE	
	Medication Error							
	Overdose							
	Sedation							

		Somnolence		Zantac (Ranitidine			
		Vomiting		Hydrochloride)	C		

Date:06/03/02ISR Number: 3928678-7Report Type:Expedited (15-DaCompany Report #3656
Age:22 YR Gender:Male I/FU:I

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
		Intracranial Pressure	Literature	Metoclopramide	PS		
INTRAVENOUS	10 MG	2 DAY					
		Increased		Morphine	C		
		Mean Arterial Pressure		Medazolam	C		
		Decreased		Vecuronium	C		

Date:06/07/02ISR Number: 3929843-5Report Type:Direct Company Report #CTU 169723
Age:5 YR Gender:Male I/FU:I

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
		Convulsion		Metoclopramide (Reglan)	PS		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/10/02ISR Number: 3931695-4Report Type:Expedited (15-DaCompany Report #02895
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agitation Anxiety Asthenopia Decreased Activity Dehydration Depression Dizziness Dystonia Eye Injury Fatigue Gastrointestinal Disorder Hallucination Headache Impaired Gastric Emptying Mental Impairment Motion Sickness Nervous System Disorder Psychotic Disorder Suicidal Ideation	Other	Metoclopramide Tabs Usp, 10 Mg (Purepac)	PS		ORAL	1 TAB , BID, ORAL	

Date:06/12/02ISR Number: 3931643-7Report Type:Direct Company Report #CTU 169882
Age:5 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Convulsion Eye Movement Disorder		Metocopramide (Reglan)	PS				

Date:06/12/02ISR Number: 3932281-2Report Type:Direct Company Report #USP 54895
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Medication Error Pharmaceutical Product Complaint		Metoclopramide Hydrochloride	PS	Faulding			

Date:06/12/02ISR Number: 3933460-0Report Type:Expedited (15-DaCompany Report #PHRM2002FR01462
Age:66 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death Hospitalization - Initial or Prolonged	Aphthous Stomatitis Bone Marrow Toxicity Pancytopenia Renal Failure Acute	Foreign Health Professional Other	Sandostatine (For S.C. Inject.)(Octreotide Acetate) Ampoule	PS		SUBCUTANEOUS	300 UG, QD,	
	Septic Shock							
						SUBCUTANEOUS		
			Mopral(Omeprazole) Solution For Injection	SS		INTRAVENOUS	40 MG, QD,	
						INTRAVENOUS		
			Lovenox (Heparin-Fraction, Sodium Salt) Solution For Injection	SS		SUBCUTANEOUS	0.2 ML, QD,	
						SUBCUTANEOUS		
			Durogesic(Fentanyl)					

				Trans-The	SS		
TRANSDERMAL	TRANSDERMAL						
				Efferalgan (Paracetamol) Effervescent Tablet	SS		ORAL
ORAL							
				Topalgic "Houde" (Tramadol Hydrochloride) Capsule	SS		ORAL
ORAL							
				Primperan (Metoclpramide)	SS		
				Tranxene(Clorazepate Dipotassium)	SS		

Date:06/12/02ISR Number: 3936710-XReport Type:Expedited (15-DaCompany Report #B0267978A
Age:39 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Life-Threatening	Cardiac Arrest	Foreign	Paxil Tablet			
Other		Health	(Paroxetine			
		Professional	Hydrochloride)	PS		ORAL
ORAL						
			Midazolam (Formulation Unknown) (Midazolam)	SS		
			Propofol (Formulation Unknown) (Propofol)	SS		
INTRAVENOUS	INTRAVENOUS					
			Vecuronium Bromide (Formulation Unknown) (Vecuronium Bromide)	SS		
INTRAVENOUS	INTRAVENOUS					
			Droperidol (Formulation Unknown) (Droperidol)	SS		
			Metoclopramide (Formulation Unknown) (Metoclopramide)	SS		
INTRAVENOUS	INTRAVENOUS					

	Morphine (Formulation Unknown) (Morphine)	SS

Date:06/17/02ISR Number: 3935731-0Report Type:Expedited (15-DaCompany Report #002#2#2002-00091 (0)
Age:27 YR Gender:Male I/FU:I

Outcome	PT
Disability	Agitation
	Anxiety
	Asthenopia
	Balance Disorder
	Depression
	Disturbance In Attention
	Dizziness
	Dystonia
	Eye Injury
	Fatigue
	Hallucination
	Headache
	Injury
	Mental Impairment

	Motion Sickness Nervous System Disorder Psychotic Disorder	Report Source	Product	Role	Manufacturer	Route Dose Duration
	Suicidal Ideation Vertigo	Consumer	Reglan-10mg-Tablet (Metoclopramide Hcl)	PS		ORAL 10 MG, ORAL
	Vision Blurred		Regular-Insulin Nph-Insulin	C C		

Date:06/20/02ISR Number: 3936723-8Report Type:Direct Company Report #CTU 170591
Age:80 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	Dystonia		Metoclopramide Carbidopa/Levodopa Baclofen Docusate Na Furosemide Lansoprazole Lisinopril Hydrocodone/Acetaminophen	PS C C C C C C C		SEE IMAGE

Date:06/21/02ISR Number: 3936791-3Report Type:Direct Company Report #CTU 170644
Age:12 DY Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Hospitalization - Initial or Prolonged	Apnoea Methaemoglobinaemia		Metaclopramide Ranitidine(Zactac) Mylanta	PS C C		ORAL 1MG PO QID 4 DAY

Date:06/24/02ISR Number: 3941887-6Report Type:Expedited (15-DaCompany Report #EMADSS2002003162
Age:67 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration

Other	Anaemia	Foreign	Erypo (4000 U/Ml	
	Aplasia Pure Red Cell	Health	Injection)(Epoetin	
	Asthenia	Professional	Alfa)	PS

INTRAVENOUS 4000 IU, 3 IN

1 WEEK(S), IV

Azuprostat(Azuprostat)	C
Fusid (Furosemide)	C
Pantozol (Pantoprazole Sodium)	C
Cosmofer (Iron)	C
Aranesp (Darbepoetin Alfa)	C
Renacet (Calcium Carbonate)	C
Captohexal (Captopril)	C
Bifiteral (Lactulose)	C
Mcp (Metoclopramide)	I

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/26/02ISR Number: 3940416-0Report Type:Expedited (15-DaCompany Report #02P-056-0194731-00
Age:19 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Blood Culture Positive	Foreign	Tranxene					
Required	Bone Pain	Health	(Clorazepate					
Intervention to	Cerebrovascular Disorder	Professional	Dipotassium)					
Prevent Permanent	Coma	Other	(Clorazepate					
Impairment/Damage	Cyanosis		Dipotassium)	PS				
	Depressed Level Of		Ketoprofen	SS				
	Consciousness		Paracetomol/Dextropr					
	Headache		opoxyphene	SS				
	Meningitis Bacterial		Ondansetron					
	Myalgia		Hydrochloride	SS				
INTRAVENOUS							300 MG,	
	Respiratory Arrest							
INTRAVENOUS								
	Streptococcal Infection		Nalbuphine					
	Urinary Tract Infection		Hydrochloride	SS				
	Vomiting		Omeprazole	SS				
			Metoclopramide	SS				

Date:06/27/02ISR Number: 3941428-3Report Type:Expedited (15-DaCompany Report #PHRM2002FR01626
Age:79 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Agitation	Foreign	Ludiomil 75					
Initial or Prolonged	Balance Disorder	Health	(Maprotiline					
	Confusional State	Professional	Hydrochloride)					
	Disorientation	Other	Tablet	PS		ORAL		
75 MG QD ORAL								
	Fall		Primperan					
	Hyperreflexia		(Metoclopramide)					
			Solution	SS		ORAL		
5 ML TID ORAL								
			Deroxat (Paroxetine					
			Hydrochloride)					
			Tablet	SS		ORAL		
20 MG DAILY								
ORAL								
			Celebrex (Celecoxib)	C				
			Ogast (Lansoprazole)	C				

				Lexomil (Bromazepam) Tablet	C		
				Sulfarlem (Anethole Trithione) Tablet	C		

Date:07/02/02ISR Number: 3942972-5Report Type:Direct Company Report #CTU 171506
Age:68 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Cardiac Arrest		Metoclopramide 10mg/2ml Vial	PS		
INTRAVENOUS 10MG IV Q 6 HR X 1 DOSE GIVEN						
			Albuterol	C		
			Aspirin	C		
			Lovenox Regular Insulin Sliding Scale	C		
			Niferex	C		
			Diflucan	C		
			Mag Citrate	C		
			Tylenol	C		
			D 2.5 1/2ns With			

			Sodium Bicarb	C		
			Maxipime	C		
			Protonix	C		

Date:07/03/02ISR Number: 3944630-XReport Type:Expedited (15-DaCompany Report #B0271758A
Age:46 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization - Initial or Prolonged	Diabetes Insipidus Fluid Retention	Foreign	Zofran (Formulation Unknown) (Ondansetron Hydrochloride)	PS		
INTRAVENOUS	INTRAVENOUS					
			Calcium Folinate (Formulation Unknown) (Calcium Folinate)	SS		
INTRAVENOUS	50 MG					
INTRAVENOUS						
			Metoclopramide Hcl (Formulation Unknown) (Metoclopramide Hcl)	SS		
INTRAVENOUS	INTRAVENOUS					
			Methotrexate (Formulation Unknown) (Methotrexate)	SS		
INTRAVENOUS	INTRAVENOUS					
			Nomegestrol Acetate	C		
			Paroxetine Hydrochloride	C		
			Ranitidine Hydrochloride	C		
			Ethamsylate	C		
			Allopurinol	C		

Date:07/09/02ISR Number: 3946246-8Report Type:Expedited (15-DaCompany Report #HQ2425223MAY2002
Age:2 MON Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					

Other	Irritability Medication Error Prescribed Overdose Somnolence Vomiting	Consumer	Reglan (Metoclopramide Hydrochloride, Syrup)	PS	ORAL

OVERDOSE

AMOUNT, 3.5

CC THREE

TIMES DAILY,

ORAL

	Reglan (Metoclopramide Hydrochloride, Syrup)	SS	ORAL

"RECOMMENDED

DOSE", ORAL

	Zantac (Ranitidine Hydrochloride)	C

Date:07/09/02ISR Number: 3946248-1Report Type:Expedited (15-DaCompany Report #HQ2425023MAY2002
Age:2 MON Gender:Male I/FU:F

Outcome	PT
Other	Irritability Medication Error

	Prescribed Overdose Somnolence Vomiting	Report Source	Product	Role	Manufacturer	Route	Dose Duration
		Consumer	Reglan (Metoclopramide Hydrochloride, Syrup)	PS		ORAL	OVERDOSE AMOUNT, 3.5 CC THREE TIMES DAILY, ORAL
			Reglan (Metoclopramide Hydrochloride, Syrup)	SS		ORAL	"RECOMMENDED DOSE", ORAL
			Zantac (Ranitidine Hydrochloride)	C			

Date:07/11/02ISR Number: 3948760-8Report Type:Expedited (15-DaCompany Report #HQ2065225APR2002
Age:19 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Abdominal Pain Cholecystitis	Literature	Advil (Ibuprofen, Unspec)	PS		ORAL	ORAL 2 DAY
	Cholestasis Dilatation Intrahepatic		Ceftriaxone (Ceftriaxone)	SS		ORAL	ORAL
	Duct Acquired Drug Ineffective		Ciprofloxacin (Ciprofloxacin)	SS			INTRAVENOUS INTRAVENOUS
	Headache Pain		Ketorolac (Ketorolac)	SS		ORAL	ORAL
	Sepsis		Reglan				

	Stevens-Johnson Syndrome		(Metoclopramide			
	Urinary Tract Infection		Hydrochloride,			
	Vomiting		Unspec)	SS		ORAL
ORAL						
	White Blood Cell Count Decreased					

Date:07/12/02ISR Number: 3948060-6Report Type:Expedited (15-DaCompany Report #02920
Age:53 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Anaphylactic Shock	Consumer	Metoclopramide Tabs, 10 Mg (Purepac)	PS		
ONE TABLET						
DAILY						

Date:07/16/02ISR Number: 3949785-9Report Type:Expedited (15-DaCompany Report #HQ3147208JUL2002
Age:16 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Injection Site Erythema	Literature	Reglan			
	Injection Site Oedema		(Metoclopramide			
Other	Injection Site Pain		Hydrochloride,			
	Injection Site Reaction		Injection)	PS		
INTRAVENOUS 10 MG 1X PER						
	Joint Stiffness					
1 DAY						
	Medication Error					
INTRAVENOUS						
	Skin Discolouration					
ONE TIME DOSE						
			Midazolam			

				(Midazolam)	SS			
INTRAVENOUS	1.5 MG 1X PER							
1 DAY								
INTRAVENOUS								
ONE TIME DOSE								
				Pethidine (Pethidine)	SS			
INTRAVENOUS	50 MG 1X PER							
1 DAY								
INTRAVENOUS	1 DAY							
				Propofol (Propofol)	SS			
INTRAVENOUS	SEE IMAGE							
				Sevoflurane (Sevoflurane)	C			
				Nitrous Oxide (Nitrous Oxide)	C			

Date:07/16/02ISR Number: 3949931-7Report Type:Expedited (15-DaCompany Report #3902
Age:16 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Erythema	Literature	Midazolam	PS				
INTRAVENOUS	5 MG ONCE, IV							
Initial or Prolonged	Injection Site Pain	Health	Propofol	SS				
INTRAVENOUS	5 ML ONCE, IV							
	Medication Error	Professional	Pethidine	SS				
INTRAVENOUS	50 MG ONCE,							
	Oedema Peripheral							
IV								
	Skin Discolouration		Metoclopramide	SS				
INTRAVENOUS	10 MG ONCE,							
IV								
			Glucose Injection	C				
			Sevoflurane	C				

Date:07/23/02ISR Number: 3952922-3Report Type:Expedited (15-DaCompany Report #B0267978A
Age:39 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Other	Bradycardia Cardiac Arrest Syncope Vasovagal	Foreign Health Professional	Paxil Tablet (Paroxetine Hydrochloride)	PS		ORAL	ORAL	
			Midazolam (Formulation Unknown) (Midazolam)	SS				
			Propofol (Formulation Unknown) (Propofol)	SS				
INTRAVENOUS	INTRAVENOUS							
			Vecuronium Bromide (Formulation Unknown) (Vecuronium Bromide)	SS				
INTRAVENOUS	INTRAVENOUS							
			Droperidol (Formulation Unknown)	SS				
			Metoclopramide (Formulation Unknown) (Metoclopramide)	SS				
INTRAVENOUS	INTRAVENOUS							
			Morphine (Formulation Unknown) (Morphine)	SS				

Date:07/24/02ISR Number: 3953168-5Report Type:Expedited (15-DaCompany Report #002#2#2002-00109 (0)
Age:43 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Arthropathy	Consumer	Reglan-10mg-Tablet (Metoclopramide Hcl)	PS		ORAL	10MG, 4 IN 1	
Disability	Blepharospasm						D, ORAL	
	Blindness		Lisinopril	C				
	Chest Discomfort		Diazepam	C				
	Conversion Disorder		Mylanta	C				
	Disturbance In Attention							
	Dizziness							
	Drug Withdrawal Syndrome							
	Dyskinesia							
	Dysphagia							
	Dystonia							
	Eye Disorder							
	Feeling Abnormal							
	Haemangioma							
	Halo Vision							
	Headache							
	Movement Disorder							
	Muscle Spasms							
	Nausea							
	Nervousness							
	Pain							
	Paraesthesia							
	Photopsia							
	Photosensitivity Reaction							
	Restlessness							
	Shock							
	Speech Disorder							
	Strabismus							
	Tardive Dyskinesia							
	Tooth Disorder							
	Tremor							

Date:07/24/02ISR Number: 3953511-7Report Type:Expedited (15-DaCompany Report #2002AP02295
Age:16 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Hospitalization -	Erythema	Foreign	Propofol	PS			
INTRAVENOUS 5 ML IV							
Initial or Prolonged	Injection Site Pain	Literature	Midazolam	SS			
1.5 MG							
	Joint Stiffness	Health	Metoclopramide	SS			
10 MG							
	Medication Error	Professional	Pethidine	SS			
50 MG							
	Oedema Peripheral	Other					
	Pain In Extremity						
	Skin Discolouration						

Date:07/24/02ISR Number: 3953586-5Report Type:Expedited (15-DaCompany Report #2002AP02316
Age:63 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Dehydration	Foreign	Meropenem	PS		
	Diarrhoea	Health	Aldactone	SS		
50 MG DAILY						
	Hypocalcaemia	Professional	Irinotecan			
	Orthostatic Hypotension	Other	Hydrochloride	SS		
INTRAVENOUS 1 DF DAILY IV						
	Pneumonia		Cefepime			
	Renal Failure Acute		Hydrochloride	SS		
	Weight Decreased		Frusemide	SS		

			Metoclopramide Hydrochloride	SS			
			Nystatin	SS			
			Vancomycin Hydrochloride	SS			
			Loperamide Hydrochloride	SS			ORAL

24 MG DAILY

PO

Date:07/25/02ISR Number: 3954985-8Report Type:Expedited (15-DaCompany Report #B0274127A
Age:79 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Agitation Balance Disorder Confusional State	Foreign	Paxil Tablet (Paroxetine Hydrochloride)	PS		ORAL	20 MG/PER DAY/ORAL
	Disorientation Fall Hyperreflexia		Ludiomil Tablet (Ludiomil)	SS		ORAL	75 MG/PER DAY/ORAL
			Metoclopramide Hcl (Metoclopramide Hcl)	SS		ORAL	5 MG/PER DAY/ORAL
			Celecoxib	C			
			Bromazepam	C			
			Lansoprazole	C			
			Anethole Trithione	C			

Date:07/26/02ISR Number: 3953752-9Report Type:Expedited (15-DaCompany Report #A0139549A
Age:65 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Accidental Overdose		Lamictal	PS	Glaxo Wellcome	ORAL	

Initial or Prolonged			Balance Disorder	Prevacid	SS		ORAL 30MG Twice
Disability			Burning Sensation				
per day	3	DAY					
			Confusional State	Dilantin	SS		ORAL 300MG Three
			Convulsion				
times per day							
			Coordination Abnormal	Atenolol	SS		ORAL 25MG Per day
			Difficulty In Walking	Oxycontin	SS		ORAL 10MG Per day
			Dizziness	Pepcid	SS		ORAL
10MG Per day	2	DAY					
			Drug Interaction	Prilosec	SS		
			Dysstasia	Reglan	SS	Glaxo Wellcome	
			Fall				
			Gait Disturbance				
			Headache				
			Myasthenic Syndrome				
			Nausea				
			Pain				
			Speech Disorder				

Date:07/29/02ISR Number: 3956156-8Report Type:Expedited (15-DaCompany Report #HQ3327918JUL2002
Age: Gender:Male I/FU:I

Outcome	PT
Life-Threatening	Abnormal Behaviour
Hospitalization -	Agitation
Initial or Prolonged	Alcohol Withdrawal Syndrome

	Anxiety Aphasia Asthenia	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Atelectasis Cardio-Respiratory Arrest Cholelithiasis Confusional State	Consumer	Reglan (Metoclopramide Hydrochloride, Injection)	PS		INTRAVENOUS	10 MG 4X PER 1 DAY,
	Depressed Level Of Consciousness					INTRAVENOUS	
	Dysarthria Dyskinesia Electrolyte Imbalance Grimacing		Reglan (Metoclopramide Hydrochloride, Injection)	SS		ORAL	ORAL
	Hypotension Ileus Paralytic Ischaemia Moaning Oliguria Pulmonary Embolism Renal Impairment Restlessness Sepsis Wheezing		Darvocet-N (Dextropropoxyphene / Paracetamol) Reglan (Metoclopramide Hydrochloride, Unspec) Librium (Chlordiazepoxide Hydrochloride) .. Heparin (Heparin) Haldol (Haloperidol) Ativan (Lorazepam)	SS SS C C C C			

Date:07/31/02ISR Number: 3958078-5Report Type:Expedited (15-DaCompany Report #2002CG01152
Age:91 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Life-Threatening	Brain Scan Abnormal	Foreign	Nexium	PS		ORAL	40 MG QD PO
	Coma	Health	Mopral	SS		ORAL	10 MG DAILY
	Decubitus Ulcer	Professional				PO	

	Difficulty In Walking	Other	Mopral	SS	ORAL 20 MG DAILY
	Duodenal Ulcer				PO
	Duodenitis		Fungizone	SS	ORAL 15 ML DAILY
	Electroencephalogram				PO
	Abnormal		Primperan	SS	INTRAVENOUS 1 AMP TID IV
	Hiatus Hernia		Adancor	C	
	Necrosis		Lasilix	C	
	Oesophagitis				
	Osteitis				
	Skin Discolouration				
	Vomiting				

Date:08/01/02ISR Number: 3956822-4Report Type:Expedited (15-DaCompany Report #02934
Age: Gender:Male I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Alcohol Withdrawal Syndrome
	Anxiety
	Aphasia
	Asthenia
	Blood Pressure Decreased
	Cardio-Respiratory Arrest
	Cholelithiasis

		Confusional State					
		Dysarthria					
		Dyspnoea	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
		Grimacing	Other	Metoclopramide Tabs			
		Ileus Paralytic		Usp, (Purepac)	PS	Purepac	
		Moaning		Intravenous			
		Oliguria		Metoclopramide	C		
		Oxygen Saturation		Reglan	C		
		Decreased		Librium	C		
		Pulmonary Embolism		Heparin Infusion	C		
		Renal Impairment		Ativan	C		
		Wheezing		Darvocet	C		
				Haldol	C		

Date:08/05/02ISR Number: 3957888-8Report Type:Direct Company Report #CTU 173526
Age:69 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Required	Blood Pressure Increased		Reglan 10mg Robins	PS	Robins	ORAL
1	4 TIMES					
Intervention to	Headache					
ORAL						
Prevent Permanent	Pain In Jaw					
Impairment/Damage	Parkinsonism					

Date:08/05/02ISR Number: 3958518-1Report Type:Expedited (15-DaCompany Report #PHBS2002ZA08488
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Other	Extrapyramidal Disorder	Foreign	Aredia(Disodium			
		Health	Pamidronate)	PS		
		Professional	Maxolon			
		Other	(Metoclopramide			
			Hydrochloride)	SS		

Date:08/06/02ISR Number: 3960136-6Report Type:Expedited (15-DaCompany Report #002#8#2002-00110 (0)
Age:68 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Dyskinesia Sedation Tremor	Literature	Metoclopramide-Hydrochloride (Metoclopramide Hcl)	PS		ORAL	10 MG, 4 IN 1 D, ORAL	

Date:08/07/02ISR Number: 3960197-4Report Type:Expedited (15-DaCompany Report #002#2#2002-00116 (0)
Age: Gender:Male I/FU:I

Outcome	PT
Life-Threatening Hospitalization - Initial or Prolonged	Abnormal Behaviour Alcohol Withdrawal Syndrome Anxiety Cardio-Respiratory Arrest Cholelithiasis Confusional State Dysarthria Electrolyte Imbalance Ileus Paralytic Pulmonary Embolism

	Renal Impairment Sepsis Wheezing	Report Source	Product	Role	Manufacturer	Route	Dose Duration
		Consumer	Reglan-Dose-Unknown (Metoclopramide Hci)	PS		ORAL	ORAL
			Reglan-Injection	SS		INTRAVENOUS DRIP	10 MG, 4 IN 1 D, INTRAVENOUS DRIP
			Chlordiazepoxide	C			
			Heparin	C			
			Lorazepam	C			
			Darvocet-N	C			
			Haloperidol	C			

Date:08/09/02ISR Number: 3961763-2Report Type:Expedited (15-DaCompany Report #2002CG01160
Age:53 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Required Intervention to Prevent Permanent Impairment/Damage	Drug Abuser Headache	Foreign Literature Health Professional Other	Zomig Imigrane Migpriv Dafalgan	PS SS SS SS		ORAL ORAL	2.5 MG DAILY PO 6 MON 50 MG TID PO 6 MON DAILY INTAKE 6 MON DAILY INTAKE 6 MON

Date:08/09/02ISR Number: 3961963-1Report Type:Expedited (15-DaCompany Report #B0267978A
Age:39 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Cardiac Arrest	Foreign	Paroxetine					
Other	Procedural Complication	Health	Hydrchloride	PS		ORAL		
ORAL								
	Syncope Vasovagal	Professional	Midazolam (Midazolam)	SS				
			Propofol (Propofol)	SS				
INTRAVENOUS	INTRAVENOUS							
			Vecuronium Bromide (Vecuronium Bromide)	SS				
INTRAVENOUS	INTRAVENOUS							
			Droperidol (Droperidol)	SS				
			Metoclopramide (Metoclopramide)	SS				
INTRAVENOUS	INTRAVENOUS							
			Morphine (Morphine)	SS				

Date:08/12/02ISR Number: 3961459-7Report Type:Direct Company Report #CTU 173941
Age:32 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Anxiety		Reglan 10 Mg Iv	PS				
INTRAVENOUS	10 MG IVP							
	Dystonia							
OVER 4-5 MIN								
			Benadryl	C				

Date:08/14/02ISR Number: 3963317-0Report Type:Expedited (15-DaCompany Report #HQ3577002AUG2002
Age:21 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hepatitis	Literature	Metoclopramide	PS				
8-10 50 MG								
	Overdose							
TABLETS DAILY 2	MON							

			Full Potency Kava Kava (Kava, Kava Capsule)	SS			
			Anadin Paracetamol (Acetaminophen, Tablet)	SS			ORAL
ORAL							
			Metoclopramide (Metoclopramide Hydrochloride, Tablet)	SS			ORAL
ORAL							
			Pantozol (Pantoprazole, Unspec)	SS			ORAL
ORAL							
			Unknown	SS			ORAL
ORAL							
			Unspecified Narcotic	SS			ORAL
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		Haloperidol	PS		INTRAVENOUS	5MG QI-2HOURS	
	Neuroleptic Malignant Syndrome					BOLUS	IV BOLUS	
			Metoclopramide	SS		INTRAVENOUS	10MG Q6HOURS	
						BOLUS	PRN IV BOLUS	
			Metronidazole	C				
			Morphine	C				
			Kcl	C				
			Ranitidine	C				
			Acetaminophen	C				

Date:08/20/02ISR Number: 3965678-5Report Type:Expedited (15-DaCompany Report #2002CG01251
Age:60 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Renal Failure Acute	Foreign Health Professional Other	Mopral	PS		ORAL	20 MG DAILY PO	
			Mopral	SS		ORAL	20 MG DAILY PO	
			Renitec	SS		ORAL	5 MG DAILY PO	
			Renitec	SS		ORAL	5 MG DAILY PO	
			Augmentin	SS			INTRAVENOUS	3 G DAILY IV
			Gentalline	SS			INTRAVENOUS	180 MG DAILY IV
			Gentalline	SS			INTRAVENOUS	180 MG DAILY IV
			Cordarone	SS		ORAL	1 DF BID PO	
			Cordarone	SS		ORAL	1 DF BID PO	
			Primperan	SS			INTRAVENOUS	1 MG TID IV
			Primperan	SS			INTRAVENOUS	1 MG TID IV
			Zinnat	C				
			Clamoxyl	C				
			Durogesic	C				
			Pro-Dafalgan	C				
			Lasilix	C				
			Tahor	C				
			Stilnox	C				
			Heparine	C				

Previscan	C
Topalgic "Houde"	C
Mucomyst	C
Dafalgan Codeine	C
Cyclosporine	C
Prozac	C
Cortancyl	C
Lexomil	C
No Match	C
Glucose And Sodium Chloride Compound Injection	C

Date:08/21/02ISR Number: 3966263-1Report Type:Expedited (15-DaCompany Report #001-0945-M0200569
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Prolactin Increased Renal Failure Chronic	Health Professional	Neurontin (Gabapentin) Metoclopramide	PS SS				

Date:08/23/02ISR Number: 3966865-2Report Type:Expedited (15-DaCompany Report #001-0945-M0200569
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Prolactin Increased Renal Failure Chronic	Health Professional	Neurontin (Gabapentin) Metoclopramide	PS SS				

Date:08/23/02ISR Number: 3967123-2Report Type:Expedited (15-DaCompany Report #HQ3784015AUG2002
Age:30 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Abortion Spontaneous Complications Of Maternal Exposure To Therapeutic	Health Professional	Fentanyl Citrate (Fentanyl Citrate, Injection)	PS		INTRAVENOUS	20 MG IV, 25	

		Drugs		
MG IV",				
		Maternal Drugs Affecting		
INTRAVENOUS				
		Foetus	Reglan (Metoclopramide Hydrochloride, Injection)	SS
INTRAVENOUS	"10 MG IV			
DURING OR				
AFTER				
SURGERY",				
INTRAVENOUS				
			Versed (Midazolam Hydrochloride)	SS
INTRAVENOUS	"2 MG IV			
DURING OR				
AFTER				
SURGERY",				
INTRAVENOUS				
			Vicodin (Hydrocodone Bitartrate/Paracetamol)	SS
"GIVEN DURING				
OR AFTER				
SURGERY"				
			Zantac (Ranitidine	

				Hydrochloride)	SS		
INTRAVENOUS	"50 MG IV DURING OR AFTER SURGERY"						

Date:08/26/02ISR Number: 3967404-2Report Type:Expedited (15-DaCompany Report #02P-056-0198239-00
Age:63 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Bradyphrenia Cerebellar Syndrome Extrapyramidal Disorder Tremor	Foreign Health Professional	Depakine (Depakene) (Sodium Valproate/Valproic Acid) (Sodium Valproate/Valproic	PS		ORAL		
SEE IMAGE			Metoclopramide	SS				
			Lamotrigine	C				

Date:08/29/02ISR Number: 3968608-5Report Type:Direct Company Report #CTU 175336
Age:41 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Oculogyration		Reglan	PS		ORAL		
REGLAN 5MG PO TID								

Date:08/30/02ISR Number: 3969684-6Report Type:Expedited (15-DaCompany Report #4153
Age:71 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Feeling Abnormal		Fluourouracil	PS				
INTRAVENOUS	800 MG WEEKLY							
	Tongue Oedema		Metoclopramide	SS				
INTRAVENOUS	10 MG PRN IV						289	DAY

			Calcium Carbonate	C
			Perinopril Erbumine	C
			Indapamide	C
			Paracetamol	C
			Quinine Sulphate	C

Date:08/30/02ISR Number: 3969944-9Report Type:Expedited (15-DaCompany Report #2002-08-1000
Age:60 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Acute Endocarditis	Foreign	Gentalline					
Hospitalization -	Renal Failure Acute	Health	(Gentamycin Sulfate)					
Initial or Prolonged	Renal Impairment	Professional	Injectable Solution					
		Other	(Like Garamycin)	PS				
							INTRAVENOUS	180 MG/D
							INTRAVENOUS	
			Renitec Tablets	SS		ORAL		
							5 MG QD ORAL	
			Augmentin Injectable Solution	SS				
							INTRAVENOUS	3 GM QD
							INTRAVENOUS	
			Cordarone Tablets	SS		ORAL		
							400 MG QD	
							ORAL	
			Primperan Injectable Solution	SS				
							INTRAVENOUS	3 MG QD
							INTRAVENOUS	
			Mopral (Omeprazole)	SS		ORAL		
							20 MG QD ORAL	
			Zinnat	C				
			Clamoxyl	C				
			Durogesic (Fentanyl)	C				

Pro-Dafalgan	C
Lasilix	C
Stilnox	C
Heparine	C
Previscan	C
Topalgic (Tramadol Hcl)	C
Mucomyst	C
Dafalgan	C
Ciclosporin	C
Prozac	C
Cortancyl	C
Lexomil (Bromazepam)	C
Atorvastatin Calcium	C

Date:08/30/02ISR Number: 3970240-4Report Type:Expedited (15-DaCompany Report #DSA_21887_2002
Age:60 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Acute Endocarditis	Foreign	Vasotec	PS		ORAL	5 MG QD PO	
Hospitalization -	Arrhythmia	Other	Vasotec	SS		ORAL	5 MG DAILY PO	
Initial or Prolonged	Nausea		Amoxicilin Trihydrate/Clavulanate Potassium	SS		INTRAVENOUS	3 G INFUSION	
	Oesophagitis							
	Pyoderma							
	Pyoderma Gangrenosum						IV	
	Renal Failure Acute		Gentamicin	SS		INTRAVENOUS	180 MG QD IV	
	Vomiting		Gentamicin	SS		INTRAVENOUS	180 MG QD IV	
			Amiodarone Hydrochloride	SS		ORAL	200 MG BID PO	
			Amiodarone Hydrochloride	SS		ORAL	200 MG BID PO	
			Metoclopramide	SS		INTRAVENOUS	1 MG TID IV;	

SEE IMAGE

			Omeprazole	SS		ORAL
20 MG QD PO;						
SEE IMAGE						
			Cefuroxime Axetil	C		
			Amoxicillin Trihydrate	C		
			Fentanyl	C		
			Propacetamol	C		
			Furosemide	C		
			Atorvastatin	C		
			Zolpidem Tartrate	C		
			Heparin Sodium	C		
			Tramadol	C		
			Cyclosporin	C		
			Fluoxetine	C		
			Prednisone	C		
			Bromazepam	C		

Date:08/30/02ISR Number: 3970341-0Report Type:Expedited (15-DaCompany Report #HQ3953526AUG2002
Age:60 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Pyoderma Gangrenosum Renal Failure Acute	Health Professional Other	Cordarone (Amiodarone, Tablet) Augmentin (Amoxicillin Sodium	PS		ORAL	200 MG 2X PER 1 DAY	ORAL 71 DAY

			/Clavulanate Potassium, Injection)	SS		
INTRAVENOUS	3 G 1X PER 1 DAY					
INTRAVENOUS	6	DAY				
			Gentalline (Gentamicin Sulfate)	SS		
INTRAVENOUS	180 MG 1X PER 1 DAY					
INTRAVENOUS	5	DAY				
			Mopral (Omeprazole)	SS		ORAL
20 MG 1X PER 1 DAY ORAL	81	DAY				
			Primperan (Metoclopramide)	SS		
INTRAVENOUS	10 MG 3X PER 1 DAY					
INTRAVENOUS	8	DAY				
			Renitec (Enalapril Maleate)	SS		ORAL
5 MG 1X PER 1 DAY ORAL	58	DAY				
			Zinnat (Cefuroxime Axetil)	C		
			Clamoxyl (Amoxicillin Trihydrate)	C		
			Durogesic (Fentanyl)	C		
			Pro-Dafalgan (Propacetamol Hydrochloride)	C		
			Lasilix (Furosemide)	C		
			Tahor (Atorvastatin)	C		
			Stilnox (Zolpidem)	C		
			Heparine (Heparin)	C		
			Previscan (Fluindione)	C		
			Topalgic Houde (Tramadol			

Hydrochloride)	C
Mucomyst (Acetylcysteine)	C
Dafalgan (Paracetamol)	C
Cyclosporne (Cyclosporine)	C
Prozac (Fluoxetine Hydrochloride)	C
Cortancyl (Prednisone)	C
Lexomil (Bromazepam)	C

Date:08/30/02ISR Number: 3970446-4Report Type:Expedited (15-DaCompany Report #2002CG01152
Age:91 YR Gender:Female I/FU:F

Outcome	PT
Life-Threatening	Abdominal Pain
	Brain Scan Abnormal
	Coma
	Decubitus Ulcer
	Difficulty In Walking
	Duodenal Ulcer
	Duodenitis
	Dyspepsia
	Hiatus Hernia

		Necrotising Oesophagitis Nervous System Disorder Osteitis	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
		Skin Discolouration	Foreign	Nexium	PS		ORAL
40 MG QD PO							
		Somnolence	Health	Mopral	SS		ORAL
10 MG DAILY							
		Vomiting	Professional				
PO							
			Other	Mopral	SS		
INTRAVENOUS	20 MG DAILY						
IV							
				Fungizone	SS		ORAL
15 ML DAILY							
PO							
				Primperan	SS		
INTRAVENOUS	1 AMP TID IV						
				Adancor	C		
				Lasilix	C		

Date:08/30/02ISR Number: 3970473-7Report Type:Expedited (15-DaCompany Report #HQ3919622AUG2002
Age:92 YR Gender:Male I/FU:I

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Hospitalization - Initial or Prolonged Other		Clonic Convulsion Dyspnoea Muscle Contractions Involuntary	Consumer	Reglan (Metoclopramide Hydrochloride, Syrup)	PS		
2 TEASPOONS							
TWICE DAILY,							
INTRAGASTRIC							

Date:08/30/02ISR Number: 3970744-4Report Type:Expedited (15-DaCompany Report #2015259
Age:50 YR Gender:Female I/FU:F

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						

Death Other	Accidental Overdose Anaemia Anxiety Coma Fall Fear Haemorrhage Head Injury Pain Subarachnoid Haemorrhage Toxicologic Test Abnormal	Health Professional Other	Oxycontin Tablets(Oxycodone Hydrochloride) Cr Tablet Promethazine Hcl(Promethazine Hydrochloride) Metoclopramide(Metoc lopramide) Sertraline Hydrochloride(Sertra line Hydrochloride) Meperidine Hcl (Pethidine Hydrochloride) Morphine (Morphine)	PS SS SS SS C		ORAL ORAL 5 DAY 5 DAY 5 DAY 5 DAY

Date:09/03/02ISR Number: 3969651-2Report Type:Expedited (15-DaCompany Report #4167
Age:41 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Cardiac Arrest	Literature	Metoclopramide	PS		INTRAVENOUS	10 MG TID IV	2 DAY
			Midazolam	C				
			Propofol	C				
			Fentanyl	C				
			Dopamine	C				
			Cefotaxime	C				
			Paracetamol	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/04/02ISR Number: 3971210-2Report Type:Expedited (15-DaCompany Report #HQ3937923AUG2002
Age:41 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Other	Cardiac Arrest	Literature	Reglan (Metoclopramide Hydrochloride, Injection)	PS		INTRACARDIAC	10 MG THREE TIMES DAILY (DURATION: DAY 12, OVER 48 HR PERIOD	
			Dopamine (Dopamine,)	SS		INTRAVENOUS	4-10 MCG/KG/MIN (DURATION: 12 DAYS AND TAPERED)	
			Midazolam	C				
			Propofol	C				
			Fentanyl	C				
			Cefotaxime	C				
			Paracetamol	C				
			Nimodipine	C				
			Norepinephrine	C				

Date:09/09/02ISR Number: 3973066-0Report Type:Expedited (15-DaCompany Report #4153
Age:71 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Feeling Abnormal		Fluorouracil	PS		INTRAVENOUS	800 MG WEEKLY	

Tongue Oedema
IV 289 DAY

INTRAVENOUS 10 MG PRN IV

Metoclopramide	SS
Calcium Carbonate	C
Perindopril Erbumine	C
Indapamide	C
Paracetamol	C
Quinine Bisulfate	C

Date:09/09/02ISR Number: 3974090-4Report Type:Expedited (15-DaCompany Report #002#2#2002-00109(0)
Age:43 YR Gender:Female I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Akathisia
Disability	Apraxia
	Arthralgia
	Asthenia
	Blepharospasm
	Bruxism
	Conversion Disorder
	Depression
	Diarrhoea
	Disturbance In Attention
	Dizziness
	Dry Mouth
	Dyskinesia
	Dyspepsia
	Dysphagia
	Dysphemia
	Dyspnoea

		Dystonia					
		Endoscopy Abnormal					
		Eye Movement Disorder	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
		Eye Pain	Consumer	Reglan-10mg-Tablet			
		Feeling Abnormal		(Metoclopramide Hcl)	PS		ORAL
10MG, 4 IN 1							
		Haemangioma					
D, ORAL							
		Hypoaesthesia		Lisinopril	C		
		Malaise		Diazepam	C		
		Migraine		Mylanta	C		
		Muscle Spasms					
		Nausea					
		Nervousness					
		Nocturnal Dyspnoea					
		Obsessive-Compulsive					
		Disorder					
		Orthopnoea					
		Pain In Extremity					
		Palpitations					
		Paraesthesia					
		Photosensitivity Reaction					
		Restlessness					
		Sleep Apnoea Syndrome					
		Speech Disorder					
		Strabismus					
		Tardive Dyskinesia					
		Vomiting					

Date:09/10/02ISR Number: 3972762-9Report Type:Expedited (15-DaCompany Report #US-BRISTOL-MYERS SQUIBB COMPANY-12027744
Age:49 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Other	Leukopenia		Platinol	PS	Bristol-Myers Squibb	
	Myelodysplastic Syndrome				Company	
	Polyarteritis Nodosa		Mutamycin	SS	Bristol-Myers Squibb	
	Psychiatric Symptom				Company	
			Cytoxan	SS	Bristol-Myers Squibb	
					Company	
			Prednisone	SS		
			Imuran	SS		
			Folic Acid	SS		

Norco	SS

1 - 2 as

needed

Reglan	SS
Vitamin B12	SS
Mso4	SS
Actigall	SS
Azathioprine	SS

Date:09/11/02ISR Number: 3974637-8Report Type:Expedited (15-DaCompany Report #HQ3692612AUG2002
Age: Gender:Female I/FU:I

Outcome	PT
Disability	Apathy
	Arthritis
	Cardiomegaly
	Chest Pain
	Choking
	Coordination Abnormal
	Cough

		Decreased Appetite					
		Depression					
		Dizziness	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
		Dyskinesia	Consumer	Reglan			
		Dyspnoea		(Metoclopramide			
		Electrocardiogram		Hydrochloride,			
		Abnormal		Unspec)	PS		
10 MG 2X PER							
		Fall					
1 DAY							
		Fatigue		Atenolol			
		Glossodynia		Hydrochloride			
		Heart Rate Abnormal		(Atenolol			
		Hyperhidrosis		Hydrochloride)	C		
		Impaired Driving Ability					
		Insomnia					
		Laceration					
		Mouth Ulceration					
		Nervousness					
		Pain In Jaw					
		Speech Disorder					
		Tardive Dyskinesia					
		Tongue Biting					
		Tongue Disorder					
		Tremor					
		Weight Decreased					

Date:09/12/02ISR Number: 3975294-7Report Type:Expedited (15-DaCompany Report #B0278535A
Age:60 YR Gender:Male I/FU:I

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Death		Acute Endocarditis	Foreign	Amox.			
		Condition Aggravated		Trihyd+Pot.Clavulan.			
		Pyoderma Gangrenosum		Dry Substance With			
		Renal Failure Acute		Solvent (Non-Us			
				Product)	PS		
INTRAVENOUS	3 GRAM (S)/						
PER DAY/							
INTRAVENOUS							
				Renitec Tablet			

		(Renitec)	SS	ORAL
5 MG/ PER DAY/ORAL				
		Gentamicin Sulphate (Gentamicin Sulfate)	SS	
INTRAMUSCULAR	180 MG / PER DAY/ INTRAVENOUS			
		Amiodarone Hydrochloride Tablet (Amiodarone Hydrochloride)	SS	ORAL
200 MG/ TWICE PER DAY/ORAL				
		Metoclopramide Hcl (Metoclopramide Hcl)	SS	
1 MG / THREE TIMES PER DAY/INTRA				
		Omeprazole Capsule (Omeprazole)	SS	ORAL
20 MG / PER DAY/ ORAL				
		Cefuroxmie Axetil	C	
		Amoxicillin Trihydrate	C	
		Fentanyl	C	
		Propacetamol Hcl	C	

Frusemide	C
Atorvastatin Calcium	C
Zolpidem	C
Heparin	C
Fluindione	C
Tramadol Hydrochloride	C
Acetylcysteine	C
Defalgan Codeine	C
Cyclosporin	C
Fluoxetine Hydrochloride	C
Prednisone	C
Bromazepam	C
Dextrose+ Sodium Chloride	C

Date:09/17/02ISR Number: 3976789-2Report Type:Direct Company Report #CTU 176718
Age:88 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Asthenia		Reglan 10 Mg (Metoclopram) Sl 430					
Disability	Blood Potassium Decreased							
Required	Difficulty In Walking		On Tablet	PS			1 TAB BEFORE MEALS AND AT BEDTIME	
Intervention to	Dysphagia							
Prevent Permanent Impairment/Damage	Joint Stiffness							
	Parkinson'S Disease		K-Dur	C				
			Ranitidine	C				

Date:09/18/02ISR Number: 3977518-9Report Type:Direct Company Report #CTU 176800
Age:81 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dizziness		Metoclopramide	PS				
	Somnolence							

Date:09/18/02ISR Number: 3977664-XReport Type:Direct Company Report #CTU 176785
Age:69 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Inappropriate Antidiuretic Hormone Secretion		Metoclopramide	PS			10MG QID	
			Folic Acid	C				
			Thiamine	C				
			Prednisone	C				

Date:09/24/02ISR Number: 3981466-8Report Type:Expedited (15-DaCompany Report #002#2#2002-00109 (0)
Age:43 YR Gender:Female I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Akathisia
Disability	Anxiety
	Apraxia
	Arthralgia
	Asthenia
	Blepharospasm
	Blindness
	Chest Discomfort

		Conversion Disorder					
		Depression					
		Diarrhoea	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
		Disturbance In Attention	Consumer	Reglan-10mg-Tablet			
		Dizziness		(Metoclopramide Hcl)	PS		ORAL
10MG, 4 IN 1							
		Dry Mouth					
D, ORAL							
		Dysphagia		Lisinopril	C		
		Dysphemia		Diazepam	C		
		Dystonia		Mylanta	C		
		Eye Disorder		Metoprolol	C		
		Eye Movement Disorder		Heparin	C		
		Eye Pain		Clopidogrel	C		
		Eyelid Function Disorder					
		Facial Pain					
		Feeling Abnormal					
		Grimacing					
		Haemangioma					
		Hyperhidrosis					
		Hypoaesthesia					
		Malaise					
		Migraine					
		Movement Disorder					
		Muscle Spasms					
		Nausea					
		Obsessive-Compulsive					
		Disorder					
		Pain					
		Pain In Extremity					
		Palpitations					
		Paraesthesia					
		Photopsia					
		Photosensitivity Reaction					
		Restlessness					
		Sleep Apnoea Syndrome					
		Speech Disorder					
		Tardive Dyskinesia					
		Tic					
		Trismus					
		Visual Disturbance					
		Vomiting					

Date:09/25/02ISR Number: 3981066-XReport Type:Direct Company Report #CTU 177119
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Dysarthria		Metoclopramide	PS			10 MG AC AND	
	Dysphagia						HS	
	Tongue Oedema							

Date:09/26/02ISR Number: 3981934-9Report Type:Direct Company Report #CTU 177310
Age:77 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Face Oedema		Metoclopramide 10					
	Wheezing		Mg	PS		ORAL	10 MG ONCE	
							ORAL	
			Calcitrol	C				
			Calcium Carbonate	C				
			Clopidogrel					

Bisulfate	C
Epoetin Alfa	C
Felodipine	C
Fosinopril	C
Furosemide	C
Haloperidol	C
Insulin	C
Insulin Nph Human	C
Labetalol	C
Latanoprost	C
Multivitamin	C
Piroxicam	C
Ranitidine	C
Nacl	C
Terazosin	C
Tolterodine Tartrate	C

Date:10/01/02ISR Number: 3982821-2Report Type:Expedited (15-DaCompany Report #HQ4381626SEP2002
Age:78 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Difficulty In Walking Muscular Weakness	Health Professional	Cordarone (Amiodarone, Tablet)	PS		ORAL	200 MG 1X PER	1 DAY, ORAL
			Lovastatin (Lovastatin,)	SS				
			Reglan (Metoclopramide Hydrochloride, Unspec)	SS				
			Prednisone (Prednisone)	C				
			Digoxin (Digoxin)	C				
			Glyburide (Glibenclamide)	C				
			Hydralazine (Hydralazine)	C				
			Isorbid (Isosorbide Dinitrate)	C				
			Prevacid (Lansoprazole)	C				
			Lisinopril (Lisinopril)	C				

Date:10/08/02ISR Number: 3985538-3Report Type:Expedited (15-DaCompany Report #A0379632A
Age:73 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Agitation	Health	Zofran	PS	Glaxo Wellcome	INTRAVENOUS	4MG See	
Initial or Prolonged	Delusion	Professional						
dosage text							90	MIN
Other	Dyskinesia		Droperidol	SS		UNKNOWN		
	Moaning		Reglan	SS	Glaxo Wellcome	INTRAVENOUS		1 DAY
			Celebrex	C		ORAL		
			Pepcid	C		ORAL		
20MG As								
required								
			Demerol	C				
INTRAMUSCULAR	50MG Per day							
			Dilaudid	C				
INTRATHECAL								
			Bupivacaine	C				
INTRATHECAL								
			Clonidine	C				
INTRATHECAL								

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/11/02ISR Number: 3988251-1Report Type:Expedited (15-DaCompany Report #306562
Age:13 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Interaction Dyskinesia	Health Professional	Tamiflu Pramiel Cimetidine Lafutidine Unknown Drug	PS SS C C C	Roche		3 DAY 4 DAY 3 DAY	

Date:10/14/02ISR Number: 3989478-5Report Type:Expedited (15-DaCompany Report #306562
Age:13 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dyskinesia		Tamiflu Pramiel Cimetidine Lafutidine Unknown Drug	PS SS C C C	Roche		3 DAY 4 DAY 3 DAY	

Date:10/15/02ISR Number: 3992491-5Report Type:Expedited (15-DaCompany Report #02068
Age:52 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain Akathisia Angiopathy Anxiety Aortic Valve Stenosis Aphasia Chest Pain Coronary Artery Disease Depression	Consumer Other	Metoclopramide Tabs, 10 Mg (Purepac)	PS	Purepac		10 MG QID	

Dry Mouth
Dyskinesia
Dyspepsia
Dysphagia
Dyspnoea
Dystonia
Enzyme Abnormality
Extrapyramidal Disorder
Eye Disorder
Hypotension
Laboratory Test Abnormal
Laryngospasm
Movement Disorder
Muscle Twitching
Myasthenic Syndrome
Mydriasis
Myocardial Infarction
Myocardial Ischaemia
Nausea
Pain
Paraesthesia
Photophobia
Photosensitivity Reaction
Urinary Retention
Vomiting

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/16/02ISR Number: 3990235-4Report Type:Expedited (15-DaCompany Report #WAES 0210USA01193
Age:34 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Stevens-Johnson Syndrome		Pepcid	PS	Merck & Co., Inc	ORAL	2	DAY
			Mucosta	SS		ORAL	2	DAY
Other			Primperan	SS		ORAL	2	DAY

Date:10/16/02ISR Number: 3993533-3Report Type:Expedited (15-DaCompany Report #PHBS2002BR11854
Age:9 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Agitation Dehydration	Foreign Health	Cataflam (Diclofenac Potassium) Drops	PS		ORAL	ORAL	
	Diarrhoea Drug Toxicity Heart Rate Increased Hypotonia Mydriasis Overdose Vomiting	Professional Other	Plasil(Metoclopramide Hydrochloride)	SS				

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 Blepharospasm	Consumer	Reglan (Metoclopramide Hcl) 10 MG, 4 IN 1	PS		ORAL		
Disability	Blood Pressure Increased						D, ORAL	
	Bruxism Conversion Disorder Dizziness Dystonia Eye Disorder		Prochlorperazine - Edisylate Haloperidol Gabapentin Olanzapine	SS SS SS SS				

	Feeling Abnormal	Lisinopril	C
	Grimacing	Diazepam	C
	Haemangioma	Mylanta	C
	Halo Vision	Metoprolol	C
	Movement Disorder	Heparin	C
	Muscle Spasms	Clopidogrel	C
	Nausea		
	Nervousness		
	Nightmare		
	Pain		
	Paraesthesia		
	Photopsia		
	Photosensitivity Reaction		
	Restlessness		
	Strabismus		
	Tardive Dyskinesia		

Date:10/18/02ISR Number: 3996412-0Report Type:Expedited (15-DaCompany Report #PHBS2002BR11854
Age:9 YR Gender:Male I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Agitation
	Blood Pressure Diastolic Increased
	Dehydration

		Diarrhoea Heart Rate Increased Hypertonia	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
		Mydriasis Overdose	Foreign Health	Cataflam (Diclofenac Potassium)	PS		ORAL
ORAL							
		Vomiting	Professional Other	Plasma (Metoclopramide Hydrochloride)	SS		

Date:10/18/02ISR Number: 3997786-7Report Type:Expedited (15-DaCompany Report #2015259
Age:50 YR Gender:Female I/FU:F

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Death Other		Accidental Overdose Anaemia Anxiety	Health Professional Other	Oxycontin (Oxycodone Hydrochloride)Cr	PS		ORAL
ORAL							
		Aortic Atherosclerosis Blood Pressure Systolic Increased		Promethazine Hcl (Promethazine Hydrochloride)	SS		
5	DAY						
		Body Temperature Increased		Metoclopramide (Metoclopramide)	SS		
5	DAY						
		Cardiac Disorder Cardio-Respiratory Arrest Coronary Artery Atherosclerosis Fall Fear Fibrosis		Sertraline Hydrochloride (Sertraline Hydrochloride) Meperidine Hcl (Pethidine Hydrochloride)	SS SS		
5	DAY						
		Haemosiderosis Head Injury Laceration Liver Disorder Nephritis Interstitial Pain Pleural Adhesion Renal Disorder Renal Failure Acute Respiratory Rate		Morphine (Morphine) Rocephin (Ceftriaxone Sodium)	C C		

	Increased					
	Spleen Disorder					
	Subarachnoid Haemorrhage					
	Toxicologic Test Abnormal					

Date:10/22/02ISR Number: 3994308-1Report Type:Expedited (15-DaCompany Report #US-BRISTOL-MYERS SQUIBB COMPANY-12027744
Age:49 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Leukopenia		Platinol	PS	Bristol-Myers Squibb Company			
	Myelodysplastic Syndrome							
	Polyarteritis Nodosa		Mutamycin	SS	Bristol-Myers Squibb Company			
	Psychiatric Symptom							
	Pyrexia		Cytoxan	SS	Bristol-Myers Squibb Company			
			Prednisone	SS				
			Imuran	SS				
			Folic Acid	SS				
			Norco	SS			1 - 2 as needed	
			Reglan	SS				

Vitamin B12	SS
Mso4	SS
Actigall	SS
Azathioprine	SS

Date:10/22/02ISR Number: 3995948-6Report Type:Direct Company Report #CTU 179215
Age:47 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		Metoclopramide	15mg	PS		ORAL	15MG Q6H	

Date:10/22/02ISR Number: 3997882-4Report Type:Expedited (15-DaCompany Report #4396
Age:42 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Diarrhoea		Amphotericin	PS				
	Renal Failure Acute		Paracetamol	SS			INTRAVENOUS	97 MG 1 DAY
			Metoclopramide Hydrochloride	SS				4 DAY
			Fentanyl	SS				11 DAY
			Lenograstim	C				6 DAY
			Pantoprazole	C				
			Teicoplantin	C				
			Valaciclovir Hydrochloride	C				
			Meropenem	C				
			Salbutamol	C				

Date:10/23/02ISR Number: 3999602-6Report Type:Expedited (15-DaCompany Report #A0383143A
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Death	Literature Health Professional	Wellbutrin Unspecified Tablet (Bupropion Hydrochloride)	PS		ORAL		
			Tramadol Hydrochloride (Formulation Unknown) (Tramadol Hydrochloride)	SS				
			Metoclopramide (Formulation Unknown) (Metoclopramide)	SS				

Date:10/30/02ISR Number: 4002582-0Report Type:Expedited (15-DaCompany Report #4396
Age:42 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Diarrhoea	Health	Amphotericin B,	PS		INTRAVENOUS	97 MG	1 DAY
	Renal Failure Acute	Professional	Paracetamol	SS				4 DAY
			Metoclopramide Hydrochloride	SS				11 DAY

			Fentanyl	SS			
6 DAY							
			Lenograstim	C			
			Pantoprazole	C			
			Teicoplanin	C			
			Valaciclovir Hydrochloride	C			
			Meropenem	C			
			Salbutamol	C			

Date:10/31/02ISR Number: 4003383-XReport Type:Expedited (15-DaCompany Report #HQ4381626SEP2002
Age:78 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Urea Abnormal Difficulty In Walking Muscular Weakness Myopathy Pneumonia Red Blood Cell Sedimentation Rate Increased White Blood Cell Count Abnormal	Health Professional	Cordarone (Amiodarone, Tablet)	PS		ORAL	400 MG 1X PER 1 DAY, ORAL ; 200 MG 1X PER 1 DAY, ORAL	
			Lovastatin (Lovastatin,)	SS				
			Reglan (Metoclopramide Hydrochloride, Unspec)	SS		ORAL	10 MG 3X PER 1 DAY, ORAL	
			Prednisone (Prednisone)	C				
			Digoxin (Digoxin)	C				
			Hydralazine (Hydralazine)	C				
			Lisinopril (Lisinopril)	C				
			Lipitor (Atorvastatin)	C				
			Glipizide					

				(Glipizide)	C		
				Imdur (Isosorbide Mononitrate)	C		
				Flagyl (Metronidazole)	C		
				Aspirin (Acetylsalicylic Acid)	C		
				Asacol (Mesalazine)	C		
				Lasix (Furosemide)	C		

Date:11/05/02ISR Number: 4006923-XReport Type:Expedited (15-DaCompany Report #HQ4926530OCT2002
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Cardio-Respiratory Arrest Overdose	Literature	Metoclopramide (Metoclopramide Hydrochloride,	PS		ORAL
OVEDOSE						
AMOUNT						
UNKNOWN, ORAL						
			Bupropion (Amfebutamone,)	SS		ORAL
OVERDOSE						
AMOUNT						

UNKNOWN, ORAL

			Tramadol (Tramadol,)	SS		ORAL

OVERDOSE

AMOUNT

UNKNOWN, ORAL

Date:11/07/02ISR Number: 4009376-0Report Type:Expedited (15-DaCompany Report #HQ2632828JUN2001
Age:72 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Anorexia	Other	Maintate					
Hospitalization -	Aplastic Anaemia		(Bisoprolol, Tablet)	PS		ORAL	5 MG 1X PER	1
Initial or Prolonged	Chills							
DAY								40 DAY
Other	Faeces Discoloured		Cilostazol					
	Mouth Haemorrhage		(Cilostazol,)	SS		ORAL	50 MG 1X PER	
	Rash							
1 DAY								19 DAY
			Gaster (Famotidine, Gas)	SS		ORAL	20 MG 1X PER	
1 DAY								13 DAY
			Ethyl Icosapentate (Ethyl Icosapentate,)	SS		ORAL	900 MG 1X PER	
1 DAY								78 DAY
			Losartan Potassium (Losartan Potassium,)	SS		ORAL	50 MG 1X PER	
1 DAY								60 DAY
			Primperan (Metoclopramide,)	SS				
INTRAVENOUS			10 MG 1X PER					

1 DAY	13 DAY						
				Solcoseryl (Blood, Calf, Deprot, Lmw Portion,)	SS		
INTRAVENOUS							
				Norvasc (Amlodipine Besilate,)	SS		ORAL
5 MG 1X PER 1							
DAY	25 DAY						
				Elcitonin (Elcatonin)	C		
				Strong Neo-Minophagen C (Aminoacetic Acid/Cysteine/Glycyrrhizic Acid)	C		
				Glutathione (Glutathione)	C		

Date:11/08/02ISR Number: 4010631-9Report Type:Expedited (15-DaCompany Report #HQ4381626SEP2002
Age:78 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Urea Increased Difficulty In Walking Muscular Weakness Myopathy Pneumonia Red Blood Cell Sedimentation Rate Increased White Blood Cell Count Abnormal	Health Professional	Cordarone (Amiodarone, Tablet)	PS		ORAL	400; 200 MG 1X PER 1 DAY, ORAL	
			Lipitor (Atorvastatin)	SS		ORAL	20 MG 1X PER 1 DAY, ORAL	
			Reglan (Metoclopramide Hydrochloride)	SS		ORAL	10 MG 3X PER	

1 DAY, ORAL

Prednisone (Prednisone)	C
Digoxin (Digoxin)	C
Hydralazine (Hydralazine)	C
Lisinopril (Lisinopril)	C
Glipizide (Glipizide)	C
Imdur (Isosorbide Mononitrate)	C
Flagyl (Metronidazole)	C
Aspirin (Acetylsalicylic Acid)	C
Asacol (Mesalazine)	C
Lasix (Furosemide)	C

Date:11/09/02ISR Number: 4006792-8Report Type:Expedited (15-DaCompany Report #WAES 0210USA01193
Age:34 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Condition Aggravated		Pepcid	PS	Merck & Co., Inc	ORAL	2	DAY
Initial or Prolonged	Stevens-Johnson Syndrome		Mucosta	SS		ORAL	2	DAY
	Stomatitis		Primperan	SS		ORAL	2	DAY

Date:11/12/02ISR Number: 4008828-7Report Type:Expedited (15-DaCompany Report #02-00019
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Overdose	Health	Metoclopramide					
Initial or Prolonged	Tremor	Professional	Tablets, 10 Mg (Purepac)	PS				

ONE TAB Q 30

MINTUES

Date:11/13/02ISR Number: 4010905-1Report Type:Expedited (15-DaCompany Report #002#2#2002-00259(0)
Age:78 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Depression Dizziness Migraine	Consumer	Reglan-Dose-Unknown (Metoclopramide Hcl)	PS		ORAL	40MG, 4 IN 1 D, ORAL	
	Parkinson'S Disease		Allopurinol	C				
	Transient Ischaemic Attack		Iron	C				
			Erythropoietin	C				
			Tamsulosin	C				

Date:11/15/02ISR Number: 4014244-4Report Type:Expedited (15-DaCompany Report #002#8#2002-00264 (0)
Age:65 YR Gender:Male I/FU:I

Outcome	PT
Other	Agitation
	Akathisia
	Anxiety
	Dizziness
	Hallucination, Auditory

	Ideas Of Reference Nausea Persecutory Delusion	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
	Tremor	Foreign Literature	Reglan-5mg Tablet (Metclopramide Hcl)	PS		ORAL
5 MG, 4 IN 1						
D, ORAL						
			Amlodipine	C		
			Metoprolol	C		
			Acetylsalicylic-Acid	C		
			Nicergoline	C		
			Zolpidem	C		

Date:11/15/02ISR Number: 4014248-1Report Type:Expedited (15-DaCompany Report #002#8#2002-00263 (0)
Age:74 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Other	Anxiety Hallucination	Foreign Literature	Reglan-5mg Tablet (Metoclopramide Hci)	PS		ORAL
5MG, 4 IN 1						
	Persecutory Delusion					
D, ORAL						
	Restlessness		Acetylsalicylic-Acid	C		
	Sleep Disorder		Nicergoline	C		
	Tremor		Metformin	C		
			Glyburide	C		

Date:11/18/02ISR Number: 4013389-2Report Type:Expedited (15-DaCompany Report #324953
Age:16 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization - Initial or Prolonged	Erythema Joint Stiffness Medication Error Oedema	Foreign Other	Midazola Hydrochloride (Midazolam Hydrochloride)	PS		
1.5 MG DAILY						
	Oedema Peripheral		Propofol (Propofol)	SS		
INTRAVENOUS	INTRAVENOUS					
	Pain In Extremity		Metoclopramide			

	Skin Discolouration		(Metoclopramide Hydrochloride)	SS			
10 MG DAILY							
			Pethidine (Meperidine Hydrochloride)	SS			

Date:11/19/02ISR Number: 4012757-2Report Type:Direct Company Report #CTU 181294
Age:29 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required	Dysphagia		Metoclopramide	PS				
INTRAVENOUS	10 MG IV Q 8							
Intervention to	Fatigue							
HOURS, 1 DOSE								
Prevent Permanent	Throat Tightness		Dhe	SS				
INTRAVENOUS	1 MG IV Q 8							
Impairment/Damage								
HOURS, 1 DOSE								

Date:11/21/02ISR Number: 4016953-XReport Type:Expedited (15-DaCompany Report #02-00019(1)
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Overdose	Health	Metoclopramide					
Initial or Prolonged	Tremor	Professional	Tablets, 10mg (Purepac)	PS				
ONE TAB Q 30								
MINUTES								

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/25/02ISR Number: 4016211-3Report Type:Expedited (15-DaCompany Report #HQ3692612AUG2002
Age:67 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Akathisia	Consumer	Reglan (Metoclopramide Hydrochloride, Unspec)	PS			10 MG 2X PER	1 DAY
	Arthritis							
	Arthropathy							
	Asthenia							
	Cardiomegaly							
	Chest Pain		Atenolol Hydrochloride (Atenolol Hydrochloride)	C				
	Choking							
	Choking Sensation							
	Coordination Abnormal							
	Cough		Zantac (Ranitidine Hydrochloride)	C				
	Decreased Activity							
	Decreased Appetite		Aciphex (Aciphex)	C				
	Depression		Claritin (Loratadine)	C				
	Dizziness							
	Drug Ineffective		Nasacort (Triamcinolone Acetonide)	C				
	Duodenitis							
	Dysarthria							
	Dyskinesia		Ultram (Tramadol Hydrochloride)	C				
	Dyspnoea							
	Electrocardiogram Abnormal		Mobic (Meloxicam)	C				
	Electrocardiogram T Wave Abnormal							
	Extrapyramidal Disorder							
	Fatigue							
	Gastritis							
	Glossodynia							
	Heart Rate Abnormal							
	Hiatus Hernia							
	Hyperhidrosis							
	Hypertension							
	Impaired Healing							
	Insomnia							
	Laceration							
	Mouth Ulceration							
	Nervousness							
	Osteoarthritis							
	Pain In Jaw							
	Speech Disorder							
	Tardive Dyskinesia							

Tongue Biting
Tongue Disorder
Tongue Ulceration
Tremor
Weight Decreased
Weight Increased

Date:11/27/02ISR Number: 4019231-8Report Type:Expedited (15-DaCompany Report #325796
Age:39 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Bradycardia	Foreign	Ducene (Diazepam)	PS		ORAL	15 MG DAILY	
	Cardiac Arrest	Other				ORAL		
			Midazolam (Midazolam Hydrochloride)	SS		INTRAMUSCULAR	5 MG 1 PER	ONE DOSE
						INTRAMUSCULAR		

			Propofol (Propofol)	SS	
INTRAVENOUS	1 DOSE FORM 1				
PER ONE DOSE					
INTRAVENOUS					
			Vecuronium Bromide (Vecuronium Bromide)	SS	
INTRAVENOUS	1 DOSE FORM 1				
PER ONE DOSE					
INTRAVENOUS					
			Droperidol (Droperidol)	SS	
INTRAMUSCULAR	1 DOSE FORM 1				
PER ONE DOSE					
INTRAMUSCULAR					
			Maxolon (Metoclopramide Hydrochloride)	SS	
INTRAVENOUS	1 DOSE FORM 1				
PER ONE DOSE					
INTRAVENOUS					
			Morphine Sulphate(Morphine Sulfate)	SS	
INTRAVENOUS	INTRAVENOUS				

Date:12/03/02ISR Number: 4017997-4Report Type:Expedited (15-DaCompany Report #US-BRISTOL-MYERS SQUIBB COMPANY-12119350
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Congenital Anomaly	Cerebral Ventricle Dilatation	Health Professional	Glucophage	PS	Bristol-Myers Squibb Company			
	Hemivertebra		Levothyrox	SS				
	Maternal Drugs Affecting Foetus		Amarel	SS				
			Migpriv	SS				
	Multiple Congenital Abnormalities		Mopral	SS				
			Contraceptive	C		ORAL		

Pregnancy
Renal Agenesis
Spinal Osteoarthritis

Date:12/03/02ISR Number: 4021869-9Report Type:Expedited (15-DaCompany Report #324953
Age:16 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Injection Site Pain Medication Error Oedema Peripheral Post Procedural	Foreign Other	Midazolam Hydrochloride (Midazolam Hydrochloride)	PS		INTRAVENOUS	1.5 MG	DAILY
	Complication					INTRAVENOUS		
	Rash Erythematous		Propofol (Propofol)	SS		INTRAVENOUS	5 ML	DAILY
	Skin Discolouration					INTRAVENOUS		
			Metoclopramide (Metoclopramide Hydrochloride)	SS		INTRAVENOUS	10 MG	DAILY
						INTRAVENOUS		
			Pethidine (Meperidine Hydrochloride)	SS		INTRAVENOUS	50 MG	DAILY
						INTRAVENOUS		
			Glucose	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/04/02ISR Number: 4018753-3Report Type:Expedited (15-DaCompany Report #B0282226A
Age:38 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Apnoea	Health	Melphalan	PS	Glaxo Wellcome	INTRAVENOUS	60MGM2 per day	3 DAY
	Blood Pressure Fluctuation	Professional	Zovirax	SS	Glaxo Wellcome	ORAL	1G per day	42 DAY
	Loss Of Consciousness		Metoclopramide	SS	Glaxo Wellcome	INTRAVENOUS	10MG per day	1 DAY
			Furosemide	SS	Glaxo Wellcome	INTRAVENOUS	20MG per day	3 DAY
			Granisetron	SS	Glaxo Wellcome	INTRAVENOUS	6MG per day	3 DAY
			Famotidine	SS		ORAL	40MG per day	
			Fluconazole	SS		ORAL	200MG per day	59 DAY
			Levofloxacin	SS		ORAL	300MG per day	29 DAY
			Sulfamethoxazole + Trimethoprim	SS	Glaxo Wellcome		3TAB per day	50 DAY
			Sodium Bicarbonate	SS		INTRAVENOUS	100ML per day	7 DAY
			Polypharmacy	C				
			Allopurinol	C	Glaxo Wellcome			

Date:12/05/02ISR Number: 4021717-7Report Type:Expedited (15-DaCompany Report #2015259
Age:50 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death Other	Accident Accidental Overdose Anxiety Aortic Atherosclerosis Cardiac Disorder Cardio-Respiratory Arrest Coma	Health Professional Other	Oxycontin Tablets(Oxycodone Hydrochloride) Cr Tablet Promethazine Hcl (Promethazine Hydrochloride)	PS SS		ORAL	MG, ORAL MG,	 5 DAY

			Condition Aggravated	Metoclopramide	
			Coronary Artery	(Metoclopramide)	SS
MG,	5	DAY			
			Atherosclerosis	Sertraline	
			Dehydration	Hydrochloride	
			Drug Toxicity	(Sertraline	
			Fall	Hydrochloride)	SS
MG,	5	DAY			
			Fear	Meperidine Hcl	
			Fibrosis	(Pethidine	
			Haemoglobin Decreased	Hydrochloride)	SS
MG,	5	DAY			
			Haemorrhage	Morphine (Morphine)	C
			Haemosiderosis	Rocephin	
			Head Injury	(Ceftriaxone Sodium)	C
			Hypertension		
			Injury		
			Kidney Enlargement		
			Mydriasis		
			Nephritis Interstitial		
			Nephropathy		
			Pain		
			Pain In Extremity		
			Pleural Adhesion		
			Renal Cyst		
			Renal Failure Acute		
			Respiratory Rate		
			Increased		
			Splenomegaly		
			Subarachnoid Haemorrhage		
			Toxicologic Test Abnormal		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/06/02ISR Number: 4020365-2Report Type:Direct Company Report #CTU 182185
Age:47 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agitation Convulsion		Metoclopramide 10 Mg - Sidmak Lab	PS	Sidmak Lab	ORAL	10 MG PO QID	
	Fall		Digoxin	C				
	Gait Disturbance		Asa-Ec	C				
	Injury							
	Posturing							
	Restlessness							
	Self Mutilation							

Date:12/16/02ISR Number: 4026596-XReport Type:Expedited (15-DaCompany Report #2002GB02751
Age:16 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Erythema	Foreign	Propofol	PS		INTRAVENOUS	5 ML ONCE IV	
	Injection Site Pain	Health	Midazolam	SS			1.5 MG ONCE IV	
	Joint Stiffness	Professional						
	Medication Error	Other	Pethidine	SS		INTRAVENOUS	50 MG ONCE IV	
	Oedema Peripheral		Metoclopramide	SS		INTRAVENOUS	10 MG ONCE IV	
	Pitting Oedema		Glucose	C				
	Skin Discolouration							

Date:12/16/02ISR Number: 4026893-8Report Type:Expedited (15-DaCompany Report #2015259
Age:50 YR Gender:Female I/FU:F

Outcome	PT
Death	Accidental Overdose
Other	Anaemia
	Anxiety
	Aortic Atherosclerosis
	Cardio-Respiratory Arrest
	Coma

Coronary Artery
Atherosclerosis
Dehydration
Diarrhoea
Diuretic Abuse
Drug Ineffective
Drug Screen Positive
Drug Toxicity
Fall
Fear
Fibrosis
Haemosiderosis
Head Injury
Nephritis Interstitial
Pain
Pain In Extremity
Pleural Adhesion
Renal Cyst
Renal Failure Acute
Respiratory Rate
Increased
Sickle Cell Anaemia
Sickle Cell Anaemia With
Crisis
Spleen Disorder

Splenomegaly
Subarachnoid Haemorrhage
Vomiting

Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Health Professional Other	Oxycontin Tablets 10 Mg (Oxycontin Hydrochloride) Tablet	PS		ORAL		
	Phenergan (Promethazine Hydrochloride)	SS		INTRAVENOUS	12.5 MG,	
				INTRAVENOUS		
	Reglan (Metoclopramide)	SS		INTRAVENOUS	10 MG, Q6H,	
				INTRAVENOUS		
	Zoloft (Sertraline Hydrochloride)	SS		50 MG	5 DAY	
	Demerol (Pethidine Hydrochloride)	SS		25 MG		
	Morphine (Morphine)	C				
	Rocephin (Ceftriaxone Sodium)	C				
	Folic Acid (Folic Acid)	C				
	Premarin (Estrogens Conjugated)	C				
	Provera (Medroxyprogesterone Acetate)	C				
	Procardia Xl	C				
	Imodium A-D (Loperamide Hydrochloride)	C				
	Paxil (Paroxetine Hydrochloride)	C				
	Tylenol Extra-Strength	C				
	Benadryl (Diphenhydramine Hydrochloride)	C				

Tums (Calcium Carbonate)	C
Lasix (Furosemide)	C
Maalox (Aluminium Hydroxide Gel, Magnesium Hydroxide)	C
Monopril (Fosinopril Sodium)	C
Kayexalate (Sodium Polystyrene Sulfonate)	C

Date:12/20/02ISR Number: 4029152-2Report Type:Direct Company Report #CTU 183154
Age:55 YR Gender:Male I/FU:I

Outcome	PT
Other	Abnormal Behaviour
	Blood Pressure Inadequately Controlled
	Clonic Convulsion
	Serotonin Syndrome

	Tachycardia Tremor						
		Report Source	Product	Role	Manufacturer	Route	Dose Duration
			Ultram 50mg	PS		ORAL	50MG QID
			Reglan 10mg	SS		ORAL	10MG BID
			Prozac	C			
			K-Dur	C			
			Lasix	C			
			Actos	C			
			Altace	C			
			Allopurinol	C			
			Lipitor	C			
			Prevacid	C			
			Aspirin	C			
			Digoxin	C			
			Insulin	C			
			Zosyn	C			
			Pericolace	C			
			Neurontin	C			
			Iron	C			
			Multivitamin	C			
			Celebrex	C			
			Dulcoax	C			
			Oxandrin	C			

Date:12/23/02ISR Number: 4028060-0Report Type:Expedited (15-DaCompany Report #WAES 0210USA01193
Age:34 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Stevens-Johnson Syndrome		Pepcid	PS	Merck & Co., Inc	ORAL	2 DAY
Initial or Prolonged	Stomatitis		Mucosta	SS		ORAL	2 DAY
			Primperan	SS		ORAL	2 DAY

Date:12/23/02ISR Number: 4029169-8Report Type:Direct Company Report #CTU 183284
Age:63 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Dystonia		Metoclopramide 10mg Tid Po	PS		ORAL		

Date:12/24/02ISR Number: 4033663-3Report Type:Expedited (15-DaCompany Report #HQ3692612AUG2002
Age:67 YR Gender:Female I/FU:F

Outcome	PT
Disability	Akathisia
	Arthritis
	Arthropathy
	Asthenia
	Automatism
	Cardiomegaly
	Chest Pain
	Choking Sensation
	Condition Aggravated
	Coordination Abnormal
	Cough
	Decreased Appetite

	Depression						
	Dizziness						
	Duodenitis	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Dysarthria	Consumer	Reglan				
	Dyskinesia		(Metoclopramide				
	Dysphagia		Hydrochloride,				
	Dyspnoea		Unspec)	PS			10 MG 2X PER
	Dystonia						1 DAY
	Eating Disorder		Atenolol				
	Electrocardiogram		Hydrochloride				
	Abnormal		(Atenolol				
	Extrapyramidal Disorder		Hydrochloride)	C			
	Fall		Zantac (Ranitidine				
	Fatigue		Hydrochloride)	C			
	Gastritis		Aciphex (Aciphex)	C			
	Gastrooesophageal Reflux		Claritin				
	Disease		(Loratadine)	C			
	Glossodynia		Nasacort				
	Haematemesis		(Triamcinolone				
	Heart Rate Abnormal		Acetonide)	C			
	Hiatus Hernia		Ultram (Tramadol				
	Hyperhidrosis		Hydrochloride)	C			
	Hypertension		Mobic (Meloxicam)	C			
	Insomnia		Maxzide				
	Mouth Ulceration		(Triamterene/Hydroch				
	Nervousness		lorothiazide)	C			
	Pain In Jaw		Tylenol				
	Restless Legs Syndrome		(Paracetamol)	C			
	Speech Disorder		Caffeine (Caffeine)	C			
	Tardive Dyskinesia		Dihydrocodeine				
	Tongue Biting		(Dihydrocodeine)	C			
	Tongue Disorder						
	Tremor						
	Weight Decreased						

Date:12/30/02ISR Number: 4036410-4Report Type:Expedited (15-DaCompany Report #2002071787
Age:74 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Blood Pressure	Health	Norvasc (Amlodipine)	PS		ORAL	10 MG

Initial or Prolonged (DAILY), ORAL	Fluctuation	Professional			
Other	Dementia Alzheimer'S Type Fall		Accupril(Quinapril Hydrochloride)	SS	ORAL 10 MG (DAILY), ORAL
	Haemorrhagic Stroke Pruritus Rash Traumatic Haematoma Urticaria		Metoprolol Tartrate(Metoprolol Tartrate)	SS	ORAL 100 MG (Q12H), ORAL
			Metoclopramide (Metoclopramide)	SS	ORAL 40 MG (Q12H), ORAL
			Paracetamol	C	
			Peri-Colace	C	
			Famotidine	C	
			Phenytoin	C	
			General Nutrients	C	
			...	C	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/03/03ISR Number: 4034665-3Report Type:Expedited (15-DaCompany Report #A0390326A
Age:55 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Convulsion		Navelbine	PS	Glaxo Wellcome	INTRAVENOUS	30MG per day	
Initial or Prolonged	Discomfort		Metoclopramide	SS	Glaxo Wellcome	UNKNOWN		
Other	Hyperventilation		Cisplatin	C		UNKNOWN		
			Halcion	C			10	DAY
			Cefdinir	C			8	DAY
			Povidone Iodine	C				
			Kytril	C	Glaxo Wellcome		1	DAY
			Lasix	C	Glaxo Wellcome		1	DAY
			Intravenous Fluids	C		INTRAVENOUS		
			Antiemetics	C				

Date:01/03/03ISR Number: 4035388-7Report Type:Direct Company Report #CTU 183814
Age:82 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Tremor		Metoclopramide	PS				
			Triamcinolone	C				
			Lorazepam	C				
			Ipratropium Inh	C				
			Albuterol	C				
			Acetaminophen	C				
			Terazosin	C				
			Ranitidine	C				
			Lisinopril	C				
			Furosemide	C				
			Ferrous Sulfate	C				
			Diltiazem	C				
			Metoclopramide	C				
			Hydrocortisone	C				
			Influenza Vaccine	C				
			Ipratropium Inh	C				

Date:01/09/03ISR Number: 4039805-8Report Type:Direct Company Report #CTU 184168
Age:61 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Anxiety		Metoclopramide 10mg					
	Confusional State		(Tb*312*430*5589*93)	PS			1 TAB	4 X A DAY, 30 MIN PRIOR TO MEALS/EVERY NITE
	Psychomotor Hyperactivity							
	Restlessness							
	Somnolence							

Date:01/10/03ISR Number: 4041296-8Report Type:Expedited (15-DaCompany Report #EMADSS2003000095
Age:67 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Condition Aggravated	Foreign	Topalgic					
Hospitalization - Initial or Prolonged	Extrapyramidal Disorder	Health	(Unspecified)					
	Gait Disturbance	Professional	(Tramadol					
	Gastric Ulcer		Hydrochloride)	PS		ORAL	300 MG,	DAILY, ORAL
	Gastrointestinal							
	Haemorrhage		Motilium					
	Muscle Rigidity		(Unspecified)					
	Tremor		(Domperidone)	SS		ORAL	60 MG,	DAILY,

ORAL						
			Primperan (Metoclopramide)	SS		ORAL
ORAL						
			Gemzar (Gemcitabine Hydrochloride)	SS		
INTRAVENOUS	IV					

Date:01/13/03ISR Number: 4041202-6Report Type:Direct Company Report #CTU 184277
Age:65 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Atrioventricular Block		Fluconazole 2mg/Ml					
Required			Roche	PS	Roche			
INTRAVENOUS	200MG QD IV							
Intervention to			Metoclopramide 10mg					
Prevent Permanent			Roche	SS	Roche			
INTRAVENOUS	2.5MG Q12 IV							
Impairment/Damage			Enoxaparin	C				
			Omeprazole	C				
			Aspirin	C				
			Imipenem	C				
			Dopamine	C				
			Dobutamine	C				
			Epinephrine	C				
			Insulin	C				
			Heparin	C				

Date:01/13/03ISR Number: 4041857-6Report Type:Expedited (15-DaCompany Report #A02200201160
Age:55 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Confusional State	Health	Eloxatin-					
Initial or Prolonged	Disorientation	Professional	(Oxaliplatin)-					
	Hypotonia		Solution	PS				
INTRAVENOUS								
	Memory Impairment					DRIP		
140 MG DISC								
	Meningism							
INTRAVENOUS								

Mydriasis

DRIP; A FEW

Tremor

HOURS

Primperan - (Metoclopramide) - Solution - Unit Dose : Unknown SS

INTRAVENOUS

DRIP

4 UNIT

INTRAVENOUS

DRIP 2 DAY

Fluorouracil C
Folinic Acid C
Anzemet (Dolasetron Mesilate) C
Solumedrol (Methylprednisolone Sodium Succinate) C

Date:01/14/03ISR Number: 4041257-9Report Type:Expedited (15-DaCompany Report #US-BRISTOL-MYERS SQUIBB COMPANY-12036836
Age:47 YR Gender:Male I/FU:F

Outcome
Hospitalization - Initial or Prolonged

PT
Blood Creatine Phosphokinase Increased
Cardiogenic Shock
Dialysis
Myocardial Infarction

Renal Failure

Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Pravasin	PS	Bristol-Myers Squibb Company	ORAL		
	Acetylcysteine	SS	Apothecon			
	Acetylsalicylic Acid	SS				
	Metoclopramide	SS				
	Clopidogrel Bisulfate	SS	Regulatory Health Authority South Africa			
	Allopurinol	SS				
	Pantoprazole	SS				
	Meropenem	SS				
	Ciprofloxacin	SS				
	Fentanyl	SS				
	Midazolam	SS				
	Norepinephrine	SS				
	Amiodarone	SS				
	Erythromycin	SS				

Date:01/17/03ISR Number: 4043760-4Report Type:Direct Company Report #CTU 184778
Age:12 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Aspiration Coma		Metoclopramide 10mg/2ml Abbott	PS	Abbott	INTRAVENOUS	10MG IV	
Required INTERVENTION to Prevent Permanent Impairment/Damage	Dystonia Hypotension Hypoxia Nausea Rash Erythematous Tachycardia Tachypnoea Vomiting		Metoclopramide 10mg/Ml Abbott	SS				

Date:01/17/03ISR Number: 4045350-6Report Type:Expedited (15-DaCompany Report #102172ISR
Age:29 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Glomerulonephritis		Amoxicillin	PS		ORAL	1000 MILLIGRAM,BY MOUTH	
	Nephropathy							
	Renal Failure Acute							
	Renal Tubular Disorder		Acetylsalicylate Lysine	SS		ORAL	1000 MILLIGRAM,BY MOUTH	
			Metoclopramide	SS		ORAL	BY MOUTH	
			Prednisolone Sodium Sulfobenzoate	SS		ORAL	BY MOUTH	
			Oropivalone	SS				
			Metopimazine	SS				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/21/03ISR Number: 4044775-2Report Type:Expedited (15-DaCompany Report #HQ3692612AUG2002
Age:67 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Akathisia	Consumer	Reglan					
	Anxiety		(Metoclopramide					
	Arthropathy		Hydrochloride,					
	Asthenia		Unspec)	PS			10 MG 2X PER	
	Automatism						1 DAY	
	Cardiomegaly		Atenolol					
	Chest Pain		Hydrochloride					
	Choking Sensation		(Atenolol					
	Condition Aggravated		Hydrochloride)	C				
	Coordination Abnormal		Zantac (Ranitidine					
	Cough		Hydrochloride)	C				
	Decreased Appetite		Aciphex (Aciphex)	C				
	Depression		Claritin					
	Disease Recurrence		(Loratadine)	C				
	Dizziness		Nasacort					
	Drug Ineffective		(Triamcinolone					
	Duodenitis		Acetonide)	C				
	Dysarthria		Ultram (Tramadol					
	Dyskinesia		Hydrochloride)	C				
	Dysphagia		Mobic (Meloxicam)	C				
	Dysphonia		Maxzide					
	Dyspnoea		(Triamterene/Hydroch					
	Eating Disorder		lorothiazide)	C				
	Electrocardiogram		Tylenol					
	Abnormal		(Paracetamol)	C				
	Electrocardiogram T Wave		Caffeine (Caffeine)	C				
	Abnormal		Dihydrocodeine					
	Extrapyramidal Disorder		(Dihydrocodeine)	C				
	Fall							
	Fatigue							
	Gastritis							
	Gastrooesophageal Reflux							
	Disease							
	Glossodynia							
	Haematemesis							
	Heart Rate Abnormal							
	Hyperhidrosis							
	Impaired Driving Ability							
	Insomnia							
	Loss Of Consciousness							

Mouth Ulceration
Nervousness
Oesophageal Haemorrhage
Pain In Jaw
Restless Legs Syndrome
Speech Disorder
Tardive Dyskinesia
Tongue Biting
Tongue Disorder
Weight Decreased
Weight Increased

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/21/03ISR Number: 4045328-2Report Type:Expedited (15-DaCompany Report #2003000887
Age:54 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Flushing Oedema Peripheral Pyrexia Rash Erythematous Rash Macular	Foreign Health Professional	Diflucan Tablets (Fluconazole)	PS		ORAL	50 MG (DAILY); ORAL	
			Allopurinol	SS		ORAL	300 MG (DAILY); ORAL	
			Lansoprazole	SS		ORAL	30 MG (DAILY); ORAL	
			Bactrim	SS		ORAL	1920 MG (BID); ORAL	
			Metoclopramide	SS		ORAL	10 MG (DAILY); ORAL	
			Dexamethasone	C				

Date:01/21/03ISR Number: 4045548-7Report Type:Expedited (15-DaCompany Report #2003141774FR
Age:52 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Bacteraemia Cholestasis Hepatitis C Antibody Positive Hypersensitivity Peritoneal Carcinoma Streptococcal Infection	Foreign Other	Solu-Medrol(Methylprednisolone) Powder, Sterile	PS		INTRAVENOUS	120 MG, QD, IV	
			Primperan(Metoclopramide)	SS		ORAL	10 MG, TID, ORAL	

		Morphine(Morphine)	SS	
INTRAVENOUS	SEE IMAGE			
		Clamoxyl(Amoxicillin Trihydrate)	SS	
INTRAVENOUS	1 G, TID, IV			
		Caelyx(Doxorubicin Hydrochloride)	SS	
INTRAVENOUS	84 MG, QD, IV			
		Mopral(Omeprazole)	SS	ORAL
SEE IMAGE				

Date:01/23/03ISR Number: 4046991-2Report Type:Expedited (15-DaCompany Report #2015259
Age:50 YR Gender:Female I/FU:F

Outcome	PT
Death	Accident
Other	Accidental Overdose
	Anxiety
	Cardio-Respiratory Arrest
	Coma
	Coronary Artery Atherosclerosis
	Diarrhoea
	Drug Ineffective
	Drug Toxicity
	Fall
	Fear
	Fibrosis
	Haemorrhage
	Haemosiderosis
	Head Injury
	Hypertension
	Liver Disorder
	Mydriasis
	Nephritis Interstitial
	Pain

Pain In Extremity Peripheral Coldness Renal Cyst Renal Failure Acute Respiratory Rate Increased Sickle Cell Anaemia With Crisis Splenomegaly Subarachnoid Haemorrhage	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Health Professional Other	Oxycontin Tablets 10 Mg(Oxycodone Hydrochloride) Cr Tablet	PS		ORAL	
		Phenergan (Promethazine Hydrochloride)	SS		INTRAVENOUS	12.5 MG,
		Reglan (Metoclopramide)	SS		INTRAVENOUS	10 MG, Q6H,
		Zoloft (Sertraline Hydrochloride)	SS		INTRAVENOUS	50 MG 5 DAY
		Demerol (Pethidinei Hydrochloride)	SS			25 MG
		Morphine (Morphine)	C			
		Rocephin (Ceftriaxone Sodium)	C			
		Folic Acid (Folic Acid)	C			
		Premarin (Estrogens Conjugated)	C			
		Provera (Medroxyprogesterone Acetate)	C			
		Procardia Xl	C			
		Imodium A-D (Loperamide Hydrochloride)	C			
		Paxil (Paroxetine Hydrochloride)	C			
		Tylenol Extra-Strength	C			
		Benadryl (Diphenhydramine Hydrochloride)	C			

Tums (Calcium Carbonate)	C
Lasix (Furosemide)	C
Maalox (Aluminium Hydroxide Gel, Magnesium Hydroxide)	C
Monopril (Fosinopril Sodium)	C
Kayexalate (Sodium Polystyrene Sulfonate)	C

Date:01/23/03ISR Number: 4047106-7Report Type:Expedited (15-DaCompany Report #2002071787
Age:74 YR Gender:Female I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Dementia Alzheimer'S Type
Other	Fall
	Haemorrhagic Stroke
	Hyperventilation
	Pruritus

	Rash Urticaria					
		Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
		Consumer	Norvasc (Amlodipine)	PS		ORAL
10 MG						
		Health				
(DAILY), ORAL						
		Professional	Accupril (Quinapril Hydrochloride)	SS		ORAL
10 MG						
(DAILY), ORAL						
			Metoprolol Tartrate (Metoprolol Tartrate)	SS		ORAL
100 MG						
(Q12H), ORAL						
			Metoclopramide (Metoclopramide)	SS		ORAL
40 MG (Q12H),						
ORAL						
			Paracetamol	C		
			Peri-Colace	C		
			Famotidine	C		
			Phenytoin	C		
			General Nutrients	C		

Date:01/29/03ISR Number: 4048838-7Report Type:Direct Company Report #CTU 185517
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Other	Muscle Spasms		Perinorm	PS		ORAL
5 3 ORAL						
	Oculogyration		Promethazine	C		

Date:01/30/03ISR Number: 4053086-0Report Type:Direct Company Report #CTU 186276
Age:38 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Blood Ph Decreased		Labetalol	PS				
INTRAVENOUS							10MG	ONCE
	Bradycardia		Metoclopramide	SS				
INTRAVENOUS							10MG	ONCE
	Cardio-Respiratory Arrest		Lisinopril	C				
	Circulatory Collapse		Mepivacaine	C				
	Coma		Bupivacine	C				
	Dilatation Atrial		Midazolam	C				
	Dilatation Ventricular							
	Hypotension							
	Nausea							
	Pco2 Decreased							
	Po2 Increased							
	Pulse Absent							
	Sinus Tachycardia							
	Vomiting							

Date:02/03/03ISR Number: 4051427-1Report Type:Expedited (15-DaCompany Report #HQ6332223JAN2003
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Rhabdomyolysis	Health Professional	Reglan (Metoclopramide Hydrochloride)	PS				
			Unknown (Unknown)	C				

Date:02/03/03ISR Number: 4051596-3Report Type:Expedited (15-DaCompany Report #PHBS2003JP01012
Age:67 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Dialysis	Foreign	Diovan (Valsartan)	PS		ORAL	SEE IMAGE	
	Myoglobin Blood Increased	Health Professional Other	Primperan(Metoclopramide)	SS				
	Renal Failure Acute		Adona (Ac-17) (Carbazochrome Sodium Sulfonate)	C				
			Transamin (Tranexamic Acid)	C				

Date:02/03/03ISR Number: 4051932-8Report Type:Expedited (15-DaCompany Report #200214592FR
Age:34 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Congenital Anomaly	Cerebral Ventricle Dilatation	Foreign Health Professional Other	Glimepiride (Amarel) Tablets	PS		ORAL	1 U/DAY	PO
	Complications Of Maternal Exposure To Therapeutic Drugs		Levothyroxine Sodium (Levothyrox) Tablets	SS		ORAL	PO	
	Deformity Thorax		Metformin Hydrochloride (Glucophage) Tablests	SS		ORAL	1700 MG/DAY	PO
	Hemivertebra							
	Maternal Drugs Affecting Foetus							
	Multiple Congenital Abnormalities		Migpriv Powder For Oral Solution	SS		ORAL	PRN	PO
	Pregnancy On Oral Contraceptive		Hydroxyzine Hydrochloride (Atarax)	SS				
	Scoliosis							
	Single Functional Kidney							

Date:02/03/03ISR Number: 4052145-6Report Type:Expedited (15-DaCompany Report #NSADSS2003003694
Age:52 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Ascites General Physical Health Deterioration Hepatitis C Hydronephrosis Jaundice Cholestatic Metastatic Neoplasm Streptococcal Sepsis	Foreign Health Professional Distributor	Caelyx (2 Mg/Ml Liposome Injection) (Doxorubicin Hydrochloride)	PS			INTRAVENOUS	84 MG, IV
			Chemotherapy Nos	SS				
			Primperan (Metoclopramide)	SS		ORAL	10 MG, 3 IN 1	DAY(S), ORAL
			Morphine Hydrochloride (Morphine Hydrochloride)	SS			INTRAVENOUS	10 MG, 1 IN 1 DAY(S), IV
			Clamoxyl (Amoxicillin Trihydrate)	SS			INTRAVENOUS	1 G, 3 IN 1 DAY(S), IV
			Mopral (Omeprazole)	SS		ORAL	20 MG, 1 IN 1	DAILY, ORAL
			Solu-Medrol (Methylprednisolone Sodium Succinate)	SS			INTRAVENOUS	120 MG, 3 IN 1 DAY(S), IV

			Morphine Sulfate	C			
			Oflocet (Ofloxacin)	C			
			Rocephine	C			
			Lovenox (Heparin-Fraction, Sodium Salt)	C			
			Gaviscon (Gaviscon/ Old Form/)	C			
			Rivotril (Clonazepam)	C			

Date:02/04/03ISR Number: 4051692-0Report Type:Expedited (15-DaCompany Report #FLUV00302003132
Age:25 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Breast Abscess	Foreign	Luvox 25 (Fluvoxamine Maleate)	PS		ORAL	100 MG DAILY	
Other	Galactorrhoea	Health Professional					PO	
	Mastitis							
	Wound Dehiscence	Other						
	Wound Secretion		Primperan (Metoclopramide)	SS		ORAL	2 DF DAILY PO	
			Ludiomil (Maprotiline Hydrochloride)	C				
			Doral (Quazepam)	C				
			Lexotan (Bromazepam)	C				

Date:02/07/03ISR Number: 4054359-8Report Type:Expedited (15-DaCompany Report #03-00155
Age:19 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Overdose	Literature	Metoclopramide	PS				
		Health Professional	Tramadol	SS				
		Other	Bupropion	C				

Date:02/12/03ISR Number: 4054826-7Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0291617A
Age:52 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Cholestasis		Clamoxyl	PS	Glaxosmithkline		INTRAVENOUS	1G Three
Initial or Prolonged	Hepatitis C Antibody						times per day	7 DAY
	Positive		Primperan	SS	Glaxosmithkline	ORAL	10MG Three	
							times per day	17 DAY
			Morphine	SS			INTRAVENOUS	10MG Per day
			Caelyx	SS			INTRAVENOUS	84MG Per day 1 DAY
			Mopral	SS		ORAL	20MG Per day	18 DAY
			Solumedrol	SS			INTRAVENOUS	120MG Three
							times per day	
			Oflocet	C				
			Gaviscon	C	Glaxosmithkline		UNKNOWN	
			Rivotril	C			UNKNOWN	1.5MG Per day
			Actiskenan	C	Glaxosmithkline		UNKNOWN	10MG Per day

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/13/03ISR Number: 4058124-7Report Type:Expedited (15-DaCompany Report #2003PL000006
Age:38 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Blood Ph Decreased	Literature	Trandate	PS		INTRAVENOUS	10 MG;	ONCE A
	Bradycardia	Health						DAY;
	Coma	Professional				INTRAVENOUS		
	Dilatation Atrial		Metoclopramide	SS		INTRAVENOUS	10 MG;	ONCE A
	Dilatation Ventricular							DAY;
	Hypotension					INTRAVENOUS		
	Nausea		Midazolam	C				
	Pco2 Decreased		Propofol	C				
	Po2 Increased		Metoclopramide	C				
	Pulse Absent		Atropine	C				
	Shock		Epinephrine	C				
	Vomiting		Dobutamine	C				
			Mepivacaine	C				
			Bupivacaine	C				
			Dopamine	C				
			Norepinephrine	C				
			Lisinopril	C				

Date:02/14/03ISR Number: 4057010-6Report Type:Direct Company Report #CTU 186736
Age:10 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Oculogyration		Reglan 10 Mgm Iv	PS		INTRAVENOUS	10 MGM IV	

Date:02/18/03ISR Number: 4056351-6Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0291617A
Age:52 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Hospitalization -	Cholestasis	Clamoxyl	PS	Glaxosmithkline	
INTRAVENOUS 1G Three					
Initial or Prolonged	Dysaesthesia				
times per day 7 DAY					
	Hepatitis C Antibody	Primperan	SS	Glaxosmithkline	ORAL
10MG Three					
	Positive				
times per day 17 DAY					
	Streptococcal Bacteraemia	Morphine	SS		
INTRAVENOUS 10MG Per day					
		Caelyx	SS		
INTRAVENOUS 84MG Per day 1 DAY					
		Mopral	SS		ORAL
20MG Per day 18 DAY					
		Solumedrol	SS		
INTRAVENOUS 120MG Three					
times per day					
		Oflocet	C		
		Gaviscon	C	Glaxosmithkline	
UNKNOWN					
		Rivotril	C		
UNKNOWN 1.5MG Per day					
		Actiskenan	C	Glaxosmithkline	
UNKNOWN 10MG Per day					

Date:02/18/03ISR Number: 4056372-3Report Type:Expedited (15-DaCompany Report #10948867
Age:80 YR Gender:Female I/FU:F

Outcome	PT
Death	Anaemia
Hospitalization -	Hepatic Failure
Initial or Prolonged	Hepatic Steatosis
Other	Hepatitis
	Hepatocellular Damage
	Lactic Acidosis
	Metabolic Acidosis
	Pancreatitis
	Renal Failure Acute

	Shock Thrombocytopenia					
		Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
			Cefacidal Inj 1 G	PS	Apothecon	
INTRAVENOUS						
			Primperan	SS		
			Temgesic	SS		
			Profenid	SS		
PARENTERAL						
			Marcaine	SS		
			Novatrex	SS		
15 mg/w						
			Chibro-Atropine	SS		
INTRAVENOUS						
			Efferalgan Codeine	C	Comptoir Medical Du Cambodge	
			Pro-Dafalgan	C	Comptoir Medical Du Cambodge	
INTRAVENOUS						
			Doliprane	C		ORAL
			Spasfon	C		

Date:02/19/03ISR Number: 4057515-8Report Type:Direct Company Report #CTU 186865
Age:61 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Disability	Parkinson'S Disease		Metoclopramide 5mg	PS		ORAL
5MG QID ORAL						
	Tardive Dyskinesia					

Date:02/19/03ISR Number: 4060360-0Report Type:Expedited (15-DaCompany Report #A-US2003-01843
Age:63 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
	Alanine Aminotransferase Increased	Health Professional	Tracleer (Bosentan) Tablet	PS		
SEE IMAGE						
	Aspartate Aminotransferase Increased	Distributor	Simvastatin (Simvastatin) Metoclopramide	SS		

Blood Alkaline Phosphatase Increased	(Metoclopramide)	SS
Blood Bilirubin Increased	Acetaminophen (Paracetamol)	SS
Fatigue	Warfarin (Warfarin)	C
	Potassium (Potassium)	C
	Furosemide (Furosemide)	C
	Lansoprazole (Lansoprazole)	C
	Sudafed (Pseudoephedrine Hydrochloride)	C
	Atrovent (Ipratropium Bromide)	C
	Hydroxyzine (Hydroxyzine)	C
	Hydroxychloroquine (Hydroxychloroquine)	C
	Capsaicin (Capsaicin)	C
	Estradiol (Estradiol)	C
	Calcium (Calcium)	C
	Bethanechol	

(Bethanechol) C

Date:02/20/03ISR Number: 4058533-6Report Type:Direct Company Report #CTU 186950
Age:85 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Neuroleptic Malignant		Metoclopramide 10mg	PS		ORAL	10MG	QID
Hospitalization -	Syndrome							
ORAL								
Initial or Prolonged	Urinary Tract Infection							

Date:02/20/03ISR Number: 4059523-XReport Type:Expedited (15-DaCompany Report #A-US2003-01843
Age:63 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Alanine Aminotransferase	Health	Tracleer(Bosentan)					
	Increased	Professional	Tablet	PS			62.5 MG,	BID;
	Aspartate	Distributor					125 MG,	
	Aminotransferase							
	Increased							
	Blood Alkaline		Simvastatin(Simvastatin)	SS				
	Phosphatase Increased		Metoclopramide(Metoclopramide)	SS				
	Blood Bilirubin Increased		Acetaminophen(Paracetamol)	SS				
	Fatigue		Warfarin (Warfarin)	C				
	Gamma-Glutamyltransferase		Potassium (Potassium)	C				
	Increased		Furosemide (Furosemide)	C				
	Pruritus		Lansoprazole (Lansoprazole)	C				
			Sudafed (Pseudoephdrine Hydrochloride)	C				
			Atrovent (Ipratropium Bromide)	C				

Hydroxyzine (Hydroxyzine)	C
Hydroxychloroquine (Hydroxychloroquine)	C
Capsaicin (Capsaicin)	C
Estradiol (Estradiol)	C
Calcium (Calcium)	C
Bethanechol (Bethanechol)	C

Date:02/20/03ISR Number: 4060875-5Report Type:Expedited (15-DaCompany Report #A-US2003-01843
Age:63 YR Gender:Female I/FU:I

Outcome	PT
	Alanine Aminotransferase Increased
	Aspartate Aminotransferase Increased
	Bilirubin Conjugated

	Increased Blood Alkaline Phosphatase Increased Blood Bilirubin Increased	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Fatigue	Health	Tracleer (Bosentan)				
	Gamma-Glutamyltransferase Increased	Professional	Tablet	PS			SEE IMAGE
	Pruritus	Distributor	Simvastatin (Simvastatin)	SS			
			Metoclopramide (Metoclopramide)	SS			
			Acetaminophen (Paracetamol)	SS			
			Warfarin (Warfarin)	C			
			Potassium (Potassium)	C			
			Furosemide (Furosemide)	C			
			Lansoprazole (Lansoprazole)	C			
			Sudafed (Pseudoephedrine Hydrochloride)	C			
			Atrovent (Ipratropium Bromide)	C			
			Hydroxyzine (Hydroxyzine)	C			
			Hydroxychloroquine (Hydroxychloroquine)	C			
			Capsaicin (Capsaicin)	C			
			Estradiol (Estradiol)	C			
			Calcium (Calcium)	C			
			Bethanechol (Bethanechol)	C			

Date:02/25/03ISR Number: 4065597-2Report Type:Expedited (15-DaCompany Report #NSADSS2003003694
Age:52 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Ascites General Physical Health	Foreign Health	Caelyx (2 Mg/Ml Liposome Injection)				

Other		Deterioration Hepatitis C	Professional Distributor	(Doxorubicin Hydrochloride)	PS		
INTRAVENOUS	84 MG, IV	Hydronephrosis Peritoneal Carcinoma Streptococcal Sepsis		Primperan (Metoclopramide)	SS		ORAL
10 MG, 3 IN 1 DAY(S), ORAL							
				Morphine Hydrochloride (Morphine Hydrochloride)	SS		
INTRAVENOUS	10 MG, 1 IN 1 DAY(S), IV						
				Clamoxyl (Amoxicillin Trihydrate)	SS		
INTRAVENOUS	1 G, 3 IN 1 DAY(S), IV						
				Mopral (Omeprazole)	SS		ORAL
20 MG, 1 IN 1 DAILY, ORAL							
				Solu-Medrol (Methylprednisolone			

				Sodium Succinate)	SS		
INTRAVENOUS	120 MG, 3 IN 1 DAY(S), IV						
				Morphine Sulfate (Morphine Sulfate)	C		
				Oflocet (Ofloxacin)	C		
				Rocephine	C		
				Lovenox (Heparin-Fraction, Osdium Salt)	C		
				Gaviscon (Gaviscon / Old Form /)	C		
				Rivotril (Clonazepam)	C		

Date:03/03/03ISR Number: 4066125-8Report Type:Direct Company Report #CTU 187798
Age:49 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Laryngospasm		Metoclopramide 10mg					
	Pharmaceutical Product		Teva/Usa	PS	Teva/Usa	ORAL	10 MG QHS	
	Complaint						ORAL	
			Nexium	C				

Date:03/03/03ISR Number: 4084978-4Report Type:Periodic Company Report #002#2#2002-00010 (0)
Age:69 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Tardive Dyskinesia	Consumer Health Professional	Reglan-Dose-Unknown (Metoclopramide Hcl)	PS		ORAL	20MG,ASNEC,OR AL	
			Simvastatin	C				
			Lansoprazole	C				
			Acetylsalicylic Acid	C				
			Megestrol-Acetate	C				
			Prednisone	C				
			Procarbazine	C				

Date:03/03/03ISR Number: 4084984-XReport Type:Periodic Company Report #002#2#2002-00047(0)
Age:58 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Back Pain Dizziness Headache Tardive Dyskinesia Tremor	Consumer	Reglan-10mg-Tablet (Metoclopramide Hcl) Omeprazole Pantoprazole Conjugated-Estrogens	PS C C C		ORAL	10MG, 2 IN 1 D, ORAL	

Date:03/03/03ISR Number: 4084987-5Report Type:Periodic Company Report #002#2#2002-00074 (0)
Age:78 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Disability	Extrapyramidal Disorder	Health Professional	Reglan-Dose-Unknown (Metoclopramide Hcl)	PS		ORAL	ORAL	

Date:03/04/03ISR Number: 4069897-1Report Type:Expedited (15-DaCompany Report #PHBS2003JP01012
Age:67 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Blood Creatine Phosphokinase Increased	Foreign Health	Diovan (Valsartan)	PS		ORAL	20 MG/DAY,	ORAL
	Colonic Polyp Dialysis Hiccups	Professional Other	Adona (Ac-17) (Carbazochrome Sodium Sulfonate)	SS		INTRAVENOUS	25 MG, BID,	INTRAVENOUS
	Myoglobin Blood Increased Oedema Renal Failure Acute		Transamin (Tranexamic Acid)	SS		INTRAVENOUS	1 G, BID,	INTRAVENOUS
	Weight Increased		Primperan (Metoclopramide)	SS		ORAL	5 MG, TID,	ORAL

Date:03/05/03ISR Number: 4066303-8Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0291617A
Age:52 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Cholestasis Hepatitis C Antibody Positive	Consumer	Clamoxyl	PS	Glaxosmithkline	INTRAVENOUS	1G Three times per day	6 DAY
			Primperan	SS	Glaxosmithkline	ORAL	10MG Three times per day	17 DAY
			Morphine	SS		INTRAVENOUS	10MG Per day	
			Caelyx	SS		INTRAVENOUS	84MG Per day	1 DAY
			Mopral	SS		ORAL	20MG Per day	11 DAY

			Solumedrol	SS		
INTRAVENOUS	120MG Three times per day					
			Oflocet	C		
			Gaviscon	C	Glaxosmithkline	
UNKNOWN						
			Rivotril	C		
UNKNOWN	1.5MG Per day					
			Actiskenan	C	Glaxosmithkline	
UNKNOWN	10MG Per day					

Date:03/05/03ISR Number: 4067307-1Report Type:Direct Company Report #CTU 187988
Age:4 MON Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Erythema Multiforme		Ranitidine	PS				
			Metoclopramide	SS				

Date:03/06/03ISR Number: 4071749-8Report Type:Expedited (15-DaCompany Report #03H-163-0211531-00
Age:38 YR Gender:Female I/FU:I

Outcome	PT
Death	Blood Ph Decreased
	Blood Pressure Diastolic Increased
	Bradycardia
	Cardio-Respiratory Arrest
	Coma
	Dilatation Atrial
	Dilatation Ventricular
	Hypotension
	Pco2 Decreased
	Po2 Increased
	Post Procedural Complication

		Post Procedural Nausea Post Procedural Vomiting Sinus Tachycardia	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
			Literature Health Professional	Metoclopramide Hydrochloride Injection (Metoclopramide Hydrochloride)	PS		
INTRAVENOUS	10 MG, ONCE,						
INTRAVENOUS				Labetalol Hcl Inj., 5mg/Ml Vial (Labetalol Hcl Inj., Usp, 5mg/Ml) (Labetalol	SS		
INTRAVENOUS	10 MG, ONCE,						
INTRAVENOUS				Lisinopril	C		
				Mepivacaine	C		
				Bupivacaine	C		
				Midazolam	C		
				Propofol	C		
				Oxygen	C		

Date:03/07/03ISR Number: 4069639-XReport Type:Direct Company Report #CTU 188146
Age:28 YR Gender:Female I/FU:I

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Required Intervention to Prevent Permanent Impairment/Damage		Anger Anxiety Nervousness Psychomotor Hyperactivity		Reglan (Metocloperamide) 10mg/2m	PS		
INTRAVENOUS	20 MH IVP 30" BEFORE MEALS & WHS						
				Tpn/Lipids	C		
				Zofran	C		

Date:03/10/03ISR Number: 4073250-4Report Type:Expedited (15-DaCompany Report #HQWYE655825FEB03
Age:38 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Blood Pressure Increased	Literature	Reglan					
	Bradycardia		(Metoclopramide					
	Coma		Hydrochloride,					
	Dilatation Atrial		Injection					
	Dilatation Ventricular		Lisininopril	PS				
INTRAVENOUS							10 MG 1X PER	
	Hypotension							
1 DAY,								
	Nausea							
INTRAVENOUS								
	Nodal Arrhythmia		Lisinopril					
	Post Procedural		(Lisinopril,)	SS				
UNKNOWN							UNKNOWN	
	Complication		Trandate (Labetalol					
	Shock		Hydrochloride)	SS				
INTRAVENOUS							10 MG 1X PER	
	Sinus Tachycardia							
1 DAY;								
	Vomiting							
INTRAVENOUS								
			Midazolam	C				
			Propofol	C				
			Mepivacaine	C				
			Bupivacaine	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/11/03ISR Number: 4074069-0Report Type:Expedited (15-DaCompany Report #NSADSS2003003694
Age:52 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Cholestasis Hepatitis C Virus Hypersensitivity Metastatic Neoplasm	Foreign Health Professional Distributor	Caelyx(2 Mg/Ml Liposome Injection)(Doxorubicin Hydrochloride)	PS			INTRAVENOUS	84 MG, IV
	Streptococcal Sepsis		Primperan(Metoclopramide)	SS		ORAL	10MG, 3 IN 1	DAY(S), ORAL
			Morphine Hydrochloride(Morphine Hydrochloride)	SS			INTRAVENOUS	10 MG, 1 IN 1 DAY(S), IV
			Clamoxyl(Amoxicillin Trihydrate)	SS			INTRAVENOUS	1 G, 3 IN 1 DAY(S), IV
			Mopral(Omeprazole)	SS		ORAL	20 MG, 1 IN 1 DAY(S), ORAL	
			Solu-Medrol(Methylprednisolone Sodium Succinate)	SS			INTRAVENOUS	120 MG, 3 IN 1 DAY(S), IV
			Morphine Sulfate(Morphine Sulfate)	C				
			Oflocet(Ofloxacin)	C				
			Rocephine	C				
			Rocephine	C				
			Lovenox(Heparin-Fraction, Sodium Salt)	C				
			Gaviscon(Gaviscon /Old Form/)	C				
			Rivotril(Clonazepam)	C				

Date:03/12/03ISR Number: 4072955-9Report Type:Direct Company Report #CTU 188590
Age:45 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Anxiety		Metoclopramide	PS			INTRAVENOUS	10 MG IV
	Cardiomyopathy							
	Convulsion							
	Dystonia							
	Hypertension							
	Migraine							
	Respiratory Arrest							

Date:03/14/03ISR Number: 4076559-3Report Type:Expedited (15-DaCompany Report #2015259
Age:50 YR Gender:Female I/FU:F

Outcome	PT
Death	Accident
Hospitalization - Initial or Prolonged	Accidental Overdose
	Anaemia
Other	Anxiety
	Aortic Atherosclerosis
	Atherosclerosis
	Blood Disorder
	Cardio-Respiratory Arrest

Coma Condition Aggravated Coronary Artery Atherosclerosis Dehydration Diarrhoea Drug Abuser Drug Ineffective Drug Toxicity Fall Fear Fibrosis Gastroenteritis Haemorrhage Haemosiderosis Head Injury Hypertension Liver Disorder Mydriasis Nephritis Interstitial Nephrolithiasis Pain In Extremity Pleural Adhesion Renal Cyst Renal Failure Acute Respiratory Rate Increased Sickle Cell Anaemia With Crisis Spleen Disorder Splenomegaly Subarachnoid Haemorrhage	Report Source Health Professional Other	Product	Role	Manufacturer	Route	Dose Duration
		Oxycontin Tablets 10 Mg (Oxycodone Hydrochloride) Cr Tablet	PS		ORAL	10 MG, BID, ORAL; SEE IMAGE
		Phenergan (Promethazine Hydrochloride)	SS		INTRAVENOUS	12.5 MG, INTRAVENOUS
		Reglan (Metoclopramide)	SS		ORAL	10 MG, BID, ORAL
		Zoloft (Sertraline Hydrochloride)	SS			50 MG
		Demerol (Pethidine Hydrochloride)	SS			25 MG
		Morphine (Morphine)	C			
		Rocephin (Ceftriaxone Sodium)	C			

Date:03/17/03ISR Number: 4077763-0Report Type:Expedited (15-DaCompany Report #2003PK00417
Age:30 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Aggression	Foreign	Seroquel	PS		ORAL	50 MG DAILY;	
Life-Threatening	Brain Damage	Other					PO	
Hospitalization - Initial or Prolonged	Cardiac Arrest		Seroquel	SS		ORAL	100 MG DAILY; PO	
	Delusion							
	Drug Screen Positive		Seroquel	SS		ORAL	150 MG, DAILY; PO	
	Drug Toxicity							
	Refusal Of Treatment By Patient		Seroquel	SS		ORAL	200 MG DAILY; PO	
	Suicidal Ideation		Seroquel	SS		ORAL	250 MG DAILY; PO	
	Tachycardia							
			Seroquel	SS		ORAL	300 MG DAILY; PO	
			Seroquel	SS		ORAL	400 MG DAILY; PO	
			Seroquel	SS		ORAL	450 MG DAILY; PO	
			Seroquel	SS		ORAL	500 MG DAILY; PO	
			Seroquel	SS		ORAL	550 MG DAILY; PO	
			Seroquel	SS		ORAL	800 MG DAILY; PO	
			Glianimon	SS		ORAL	20 MG DAILY;	

PO	Glianimon	SS	ORAL
32 MG DAILY;			
PO	Glianimon	SS	ORAL
38 MG DAILY;			
PO	Glianimon	SS	ORAL
40 MG DAILY;			
PO	Glianimon	SS	ORAL
30 MG DAILY;			
PO	Valiquid	SS	ORAL
20 MG DAILY;			
PO	Valiquid	SS	ORAL
40 MG DAILY;			
PO	Valiquid	SS	ORAL
30 MG DAILY;			
PO	Neurocil	SS	ORAL
100 MG DAILY;			
PO	Neurocil	SS	ORAL
200 MG DAILY;			
PO	Neurocil	SS	ORAL
250 MG DAILY;			
PO	Neurocil	SS	ORAL
300 MG DAILY;			
PO	Neurocil	SS	ORAL
275 MG DAILY;			

PO			Neurocil	SS		ORAL
250 MG DAILY;						
PO			Neurocil	SS		ORAL
225 MG DAILY;						
PO			Neurocil	SS		ORAL
200 MG DAILY;						
PO			Akineton Retard	SS		ORAL
4 MG DAILY;						
PO			Bifiteral	SS		ORAL
30 ML DAILY;						
PO			Lefax	SS		ORAL
252 MG DAILY;						
PO			Beloc Zok	SS		ORAL
47.5 MG						
DAILY; PO			Paspertin	SS		ORAL
15 GTT DAILY;						
PO			Paracetamol	SS		ORAL
1000 MG						
DAILY; PO			Zuclopenthixol	SS		
NOT STATED						

Date:03/18/03ISR Number: 4074802-8Report Type:Direct Company Report #CTU 188918
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Nausea		Reglan	PS		
	Pain					
	Pharmaceutical Product Complaint					
	Vomiting					

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/18/03ISR Number: 4076421-6Report Type:Direct Company Report #CTU 189034
Age:69 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Abdominal Pain		Metoclopramide 10mg					
	Nausea		Mfr-					
	Pharmaceutical Product		Sidmak-Labrotory	PS	Sidmak Labrotory		10MG ONE QID	
	Complaint							
	Vomiting							

Date:03/21/03ISR Number: 4082054-8Report Type:Expedited (15-DaCompany Report #EMADSS2003001924
Age:73 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardio-Respiratory Arrest	Foreign	Contramal					
	Circulatory Collapse	Health	(Tramadol					
	Conduction Disorder	Professional	Hydrochloride)	PS			INTRAMUSCULAR	100 MG, IM
	Nausea		Metoclopramide					
	Syncope		(Metoclopramide)	SS			INTRAMUSCULAR	10 MG
							IM	

Date:03/21/03ISR Number: 4082101-3Report Type:Expedited (15-DaCompany Report #4372
Age:62 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Dyspnoea	Foreign	Erythromycin	PS		ORAL	500 MG ONCE;	
	Hypertension	Health					PO	
	Pyrexia	Professional	Metoclopramide					
	Tachycardia	Other	Hydrochloride	SS		ORAL	10 MG ONCE;	
	Tremor						PO	
			Gentamicin Sulfate	C				
			Ceftriaxone	C				

			Roxithromycin	C		
			Codeine	C		
			Epirubicin Hydrochloride	C		
			Cyclophosphamide	C		
			Vincristine Sulfate	C		
			Prednisone	C		
			Ondansetron	C		

Date:03/24/03ISR Number: 4079732-3Report Type:Direct Company Report #CTU 189320
Age:85 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
	Tardive Dyskinesia		Metoclopramide 10 Mg Inj	PS		
INTRAVENOUS	10 MG IV Q6 H					
			Metoclopramide Tab 10 Mg	SS		ORAL
10 MG PO TID						
AC						
			Tpn	C		
			Duragesic	C		
			Mylicon	C		
			Miralox	C		
			Paxil	C		
			Prevacid	C		
			Ferrosquels	C		
			Duonebson	C		
			Flomax	C		

			Senokot	C			

Date:03/26/03ISR Number: 4083463-3Report Type:Expedited (15-DaCompany Report #002#4#2003-00160(0)
Age:78 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Feeling Abnormal	Consumer	Reglan-5mg-Tablet					
	Musculoskeletal Stiffness	Distributor	(Metoclopramide Hc1)	PS		ORAL	5 MG, 1 IN 1	D, ORAL
	Oedema Peripheral							
	Speech Disorder							
	Tardive Dyskinesia							

Date:03/28/03ISR Number: 4083702-9Report Type:Direct Company Report #CTU 189726
Age:17 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Galactorrhoea		Metoclopropamide 5mg	PS		ORAL	5MG AC	ORAL
			Seroquel	SS		ORAL	25MG HS	ORAL

Date:03/28/03ISR Number: 4084264-2Report Type:Direct Company Report #CTU 189755
Age:54 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Asthenia		Furosemide	PS		ORAL	20 MG PO QD	
Hospitalization -	Blood Creatine		Metoclopramide	SS		ORAL	10 MG PO BID	
Initial or Prolonged	Phosphokinase Increased		Amitriptyline	C				
Required	Diarrhoea		Aspirin	C				
Intervention to	Difficulty In Walking		Atenolol	C				
Prevent Permanent	Hypokalaemia		Clonidine	C				
Impairment/Damage	Myalgia		Prozac	C				

Potassium	C
Percocet	C
70/30 Insulin	C
Cyclobenzaprine	C
Ultracet	C

Date:04/02/03ISR Number: 4088344-7Report Type:Expedited (15-DaCompany Report #USA-2002-0001677
Age:41 YR Gender:Female I/FU:I

Outcome	PT
Death	Alopecia
Hospitalization - Initial or Prolonged	Anxiety
	Arterial Occlusive Disease
	Arthralgia
	Asthma
	Back Pain
	Carpal Tunnel Syndrome
	Coma
	Depression
	Disturbance In Attention
	Drug Ineffective
	Emphysema
	Fatigue
	Feeling Abnormal
	Flushing

	Hilar Lymphadenopathy Influenza Insomnia Irritability Libido Decreased Memory Impairment Nausea	Report Source Consumer Health Professional Other	Product Oxycontin Tablets 10 Mg(Oxycodone Hydrochloride)Cr Tablet	Role PS	Manufacturer	Route
10 MG	Nervousness Night Sweats Overdose Pain		Oxycontin Tablets 20 Mg(Oxycodone Hydrochloride)Cr Tablet	SS		
20 MG	1008 DAY Pain In Extremity Pneumonia Pulmonary Oedema Rash Generalised Rash Pruritic		Hydrocodone Bitartrate(Similar To Ind 59,175)(Hydrocodone Bitartrate)Unknown	SS		
1008 DAY	Rash Scaly Skin Nodule		Alprazolam (Alprazolam)	SS		
1008 DAY	Somnolence		Ephedrine(Epedrine)	SS		
1008 DAY	Upper Respiratory Tract Infection		Pseudoephedrine (Pseudoephedrine)	SS		
1008 DAY	Urinary Incontinence Weight Increased		Effexor(Venlafaxine Hydrochloride)	SS		
75 MG, DAILY	1008 DAY		Codeine(Codeine)	SS		
1008 DAY			Neutrontin(Gabapenti n)	SS		
100 MG, TID	1008 DAY		Metoclopramide (Metoclopramide)	SS		
1008 DAY			Quetiapine(Quetiapin e)	SS		
1008 DAY			Claritin (Loratadine)	C		
			Vitamin C (Ascorbic Acid)	C		
			Celebrex(Celecoxib)	C		

Prilosec(Omeprazole)	C
Daypro(0xaproxin)	C
Trandate(Labetalol Hydrochloride)	C
Axid(Nizatidine)	C
Paxil(Paroxetine Hydrochloride)	C
Medrol (Methylprednisoone)	C
Macro Antioxidant(Ascorbic Acid, Cystine, Tocopherol, Calcium Ascorbate,	C
Zocor (Smvasatin)	C
Risperdal (Risperidone)	C
Fioricet(Butalbital)	C
Flonase (Fluticasone Propionate)	C
Phenobarbital (Phenobarbital)	C
Donnatal (Atropine Sulfate,Hyoscine Hydrobromide, Hyoscyamine Sulfate,	

Phenobarbital)	C
Bellergal-S (Belladonna Alkaloids, Erogotamine Tartrate, Weight Loss Supplment	C
Ibuprofen	C
Ambien (Zolpidem Tartrate)	C
Baclofen (Baclfoen)	C
(Labetalol Hydrochloride)	C
Celexa (Cialopram Hydrobromide)	C
Cortisone (Cortisone)	C
Atarax (Hydroxyzine Hydrochloride)	C
Proventil Tablet (Salbutamol Sulfate)	C
Amitrptyline (Amitriptyline)	C
Cyclobenzaprine (Cyclobenzaprine)	C

Date:04/08/03ISR Number: 4092120-9Report Type:Expedited (15-DaCompany Report #HQ3692612AUG2002
Age:67 YR Gender:Female I/FU:F

Outcome	PT
Disability	Akathisia
	Arthritis
	Arthropathy
	Asthenia
	Automatism
	Cardiomegaly
	Chest Pain
	Choking
	Choking Sensation
	Cognitive Disorder
	Condition Aggravated
	Coordination Abnormal
	Cough
	Decreased Appetite
	Depression

Difficulty In Walking
Dizziness
Drug Tolerance Decreased
Duodenitis
Dyskinesia
Dyspepsia
Dysphagia
Dyspnoea
Dystonia
Electrocardiogram T Wave
Abnormal
Extrapyramidal Disorder
Fall
Fatigue
Gastritis

	Gastrooesophageal Reflux Disease						
	Glossodynia	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Haematemesis	Consumer	Reglan				
	Heart Rate Abnormal		(Metoclopramide				
	Hyperhidrosis		Hydrochloride,				
	Hypertension		Unspec)	PS			10 MG 2X PER
	Impaired Driving Ability						1 DAY
	Impaired Work Ability		Atenolol				
	Insomnia		Hydrochloride				
	Laceration		(Atenolol				
	Lethargy		Hydrochloride)	C			
	Loss Of Consciousness		Zantac (Ranitidine				
	Mouth Ulceration		Hydrochloride)	C			
	Nervousness		Aciphex (Aciphex)	C			
	Oesophageal Haemorrhage		Claritin				
	Pain In Jaw		(Loratadine)	C			
	Restless Legs Syndrome		Nasacort				
	Speech Disorder		(Triamcinolone				
	Tardive Dyskinesia		Acetonide)	C			
	Tongue Biting		Ultram (Tramadol				
	Tongue Disorder		Hydrochloride)	C			
	Tremor		Mobic (Meloxicam)	C			
	Weight Fluctuation		Maxzide				
			(Triamterene/Hydroch				
			lorothiazide)	C			
			Tylenol				
			(Paracetamol)	C			
			Caffeine (Caffeine)	C			
			Dihydrocodeine				
			(Dihydrocodeine)	C			

Date:04/08/03ISR Number: 4092174-XReport Type:Expedited (15-DaCompany Report #USA-2002-0001677
Age:41 YR Gender:Female I/FU:F

Outcome	PT
Death	Alopecia
Hospitalization -	Amnesia
Initial or Prolonged	Angiopathy
	Anxiety
	Arterial Bruit
	Arterial Occlusive

Disease
Arthritis
Back Pain
Carpal Tunnel Syndrome
Chest Pain
Coma
Depression
Disturbance In Attention
Drug Ineffective
Emphysema
Fatigue
Flushing
Influenza
Insomnia
Irritability
Libido Decreased
Lymphadenopathy
Nausea

		Nervousness Night Sweats Overdose	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
		Pneumonia Pulmonary Oedema Pulse Absent Rash Generalised	Consumer Health Professional Other	Oxycontin Tablets 10 Mg(Oxycodone Hydrochloride) Cr Tablet	PS		
10 MG							
		Rash Pruritic Rash Scaly Somnolence Upper Respiratory Tract		Oxycontin Tablets 20mg(Oxycodone Hydrochloride) Cr Tablet	SS		
20 MG	1008 DAY						
		Infection Urinary Incontinence Weight Increased		Hydrocodone Bitartrate (Similar To Ind 59, 175)(Hydrocodone Bitartrate) Unknown	SS		
1008 DAY							
				Alprazolam(Alprazolam)	SS		
1008 DAY							
				Ephedrine(Ephedrine)	SS		
1008 DAY							
				Pseudoephedrine(Pseudoephedrine)	SS		
1008 DAY							
				Effexor(Venlafaxine Hydrochloride)	SS		
75 MG, DAILY	1008 DAY						
				Codeine(Codeine)	SS		
1008 DAY							
				Neurontin(Gabapentin)	SS		
100 MG, TID	1008 DAY						
				Metoclopramide(Metoclopramide)	SS		
1008 DAY							
				Quetiapine(Quetiapine)	SS		
1008 DAY							
				Claritin (Loratadine)	C		
				Vitamin C(Ascorbic Acid)	C		
				Celebrex(Celecoxib)	C		

Prilosec(Omeprazole)	C
Daypro(Oxaprozin)	C
Trandate(Labetalol Hydrochloride)	C
Axid (Nizatidine)	C
Paxil (Paroxetine Hydrochloride)	C
Medrol (Methylprednisolone)	C
Macro Antioxidant (Ascorbic Acid, Cystine, Tocopherol, Calcium Ascorbate, Beta Carotene,	C
Zocor (Simvastatin)	C
Risperdal (Risperidone)	C
Fioricet (Butalbital)	C
Phenobarbital (Phenobarbital)	C
Donnatal (Atropine Sulfate, Hyoscine Hydrobromide, Hyoscyamine Sulfate, Phenobarbital)	C

Bellergal-S (Belldadonna Alkaloids, Erogotamine Tartrate, Weight Loss Supplement (Does Not Code)	C
Ibuprofen	C
Ambien (Zolpidem Tartrate)	C
Baclofen(Baclofen)	C
Trandate (Labetalol Hydrochloride)	C
Celexa (Citalopram Hydrobromide)	C
Cortisone (Cortisone)	C
Atarax (Hydroxyzine Hydrochloride)	C
Proventil Tablet (Salbutamol Sulfate)	C
Amitriptyline (Amitriptyline)	C
Cyclobenzaprine (Cyclobenzaprine)	C
Augmentin (Amoxicillin Trihydrate, Clavulanate Potassium)	C
Ergobel (Nicergoline)	C

Date:04/08/03ISR Number: 4092311-7Report Type:Expedited (15-DaCompany Report #002#2#2002-00259(0)
Age:78 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Depression Dizziness Drug Withdrawal Syndrome	Consumer	Reglan-Dose-Unknown (Metoclopramide Hcl)	PS		ORAL	40 MG, 4 IN 1 D, ORAL	
	Migraine		Allopurinol	C				

Parkinsonian Gait	Iron	C
Transient Ischaemic Attack	Erythropoietin	C
Tremor	Tamsulosin	C

Date:04/08/03ISR Number: 4092320-8Report Type:Expedited (15-DaCompany Report #002#1#2003-00176(0)
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Anxiety Stress	Health Professional	Reglan-10mg-Tablet (Metoclopramide Hcl)	PS		ORAL	10 MG, 6 IN 1 D, ORAL	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/09/03ISR Number: 4090363-1Report Type:Direct Company Report #CTU 190517
Age:79 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blood Pressure Increased		Metoclopramide 10					
	Bradycardia		Mg/2ml; 1/2 Vial	PS				
INTRAVENOUS							5 MG IV Q 6	
	Heart Rate Decreased							
HR								
	Respiratory Rate		Human Insulin (Reg)	C				
	Increased		Lasix	C				
			Cordarone	C				
			Famotidine	C				
			Levofloxacin	C				
			Clopidogrel	C				
			Ipratroplum Inhaler	C				
			Albuterol	C				
			Digoxin Injection	C				
			Nystatin Oral Suspension	C				
			Kcl Elixir	C				
			Norvasource	C				
			Kcl Ivp	C				
			Promethazine	C				
			Temazepam	C				
			Lorazepam	C				
			Midazolam	C				
			Acetaminophen	C				
			Atropine	C				
			Dopamine	C				
			Heparin	C				

Date:04/15/03ISR Number: 4095253-6Report Type:Expedited (15-DaCompany Report #03-04-0431
Age:38 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Blood Ph Decreased	Literature	Labetalol Injectable					
	Bradycardia	Health	Solution	PS				
INTRAVENOUS							10 MG	
	Cardio-Respiratory Arrest	Professional						
INTRAVENOUS								
	Coma		Metoclopramide					

		Hypotension		Injectable Solution	SS		
INTRAVENOUS	10MG						
		Nausea					
INTRAVENOUS							
		Shock		Bupivacaine	C		
		Vomiting		Mepivacaine	C		
				Midazolam	C		
				Propofol	C		
				Oxygen Nasal	C		

Date:04/16/03ISR Number: 4097453-8Report Type:Expedited (15-DaCompany Report #S03-USA-01477-01
Age:85 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Completed Suicide	Health	Lexapro			
	Drug Interaction	Professional	(Escitalopram)	PS		ORAL
10 MG QD PO						
		Company	Reglan			
		Representative	(Metoclopramide)	SS		
			Norvasc (Amlodipine			
			Besilate)	C		
			Flomax			
			(Morniflumate)	C		
			Glucosamine	C		
			Zyrtec (Cetirizine			

Hydrochloride)	C
Relafen (Nabumetone)	C

Date:04/16/03ISR Number: 4097987-6Report Type:Expedited (15-DaCompany Report #USA-2002-0001677
Age:41 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Alopecia	Consumer	0xycontin Tablet 10					
Hospitalization -	Angiopathy	Health	Mg(Oxycodoen					
Initial or Prolonged	Anxiety	Professional	Hydrochloride) Cr					
	Apnoea	Other	Tablet	PS			10 MG ,	
	Arterial Occlusive		0xycontin Tablet 20					
	Disease		Mg(Oxycodoen					
	Arthropathy		Hydrochloride) Cr					
	Asthma		Tablet	SS			20 MG	1008 DAY
	Atherosclerosis		Hydrocodone					
	Back Pain		Bitartrate Similar					
	Cardiac Arrest		To Ind					
	Carpal Tunnel Syndrome		59,175)(Hydrocodone					
	Chest Pain		Betartrate)Unknown	SS			1008 DAY	
	Coma		Alprazolam					
	Depression		(Alprazolam)	SS			1008 DAY	
	Disturbance In Attention		Ephedrine (Epedrine)	SS			1008 DAY	
	Drug Ineffective		Pseudoephedrine					
	Fatigue		(Pseudoephedrine)	SS			1008 DAY	
	Finger Deformity		Effexor (Venlafaxine					
	Flushing		Hydrochloride)	SS			75 MG, DAILY	1008 DAY
	Hilar Lymphadenopathy		Codeine (Codeine)	SS			1008 DAY	
	Hypoaesthesia		Neurontin					
	Influenza Like Illness		(Gabapetin)	SS			100 MG, TID	1008 DAY
	Insomnia		Metoclopramide					
	Libido Decreased		(Metoclopramide)	SS			1008 DAY	
	Liver Disorder		Quetiapine					
	Memory Impairment		(Quetiapine)	SS			1008 DAY	

Myofascial Pain Syndrome	Claritin	
Nausea	(Loratadine)	C
Nervousness	Vitamin C (Ascorbic	
Night Sweats	Acid)	C
Osteoarthritis	Celebrex (Celecoxib)	C
Overdose	Prilosec	
Paraesthesia	(Omeprazole)	C
Peripheral Vascular	Daypro (Oxaprozin)	C
Disorder	Trandate (Labetalol	
Pneumonia	Hydrochloride)	C
Pulmonary Interstitial	Axid (Nizatidine)	C
Emphysema Syndrome	Paxil (Paroxetine	
Pulmonary Oedema	Hydrochloriede)	C
Pulse Abnormal	Medrol	
Rash Pruritic	(Methylprednisolone)	C
Rash Scaly	Marco Antioxidant	
Shock	(Ascorgic Acid,	
Somnolence	Cystine, Tocopherol,	
Upper Respiratory Tract	Calcium Ascorgate,	
Infection	Betacarotene,Mangane	C
Urinary Incontinence	Zocor (Simvastatin)	C
Weight Increased	Risperdal	
	(Risperidone)	C
	Fioricet	
	(Butalbital)	C
	Flonase (Fluticasone	
	Propionate)	C

Phenobarbital (Phenobarbital)	C
Donnatal (Atropine Sulfate, Hyoscine Hydrobromide, Hyoscyamine Sulfate, Phenobarbital)	C
Bellergal-S (Belladonna Alkaloids, Ergotamine Tartrate, Phenobarbital)	C
Weight Loss Supplement (Does Not Code)	C
Ibuprofen	C
Ambien(Zolpidem Tartrate)	C
Balcofen (Balcofen)	C
Trandate (Labetalol Hydrochloride)	C
Celexa (Citalopram Hydrobromide)	C
Cortisone (Cortisone)	C
Atarax (Hydroxyzine Hydrochloriede)	C
Proventil Tablet (Salbutamol Sulfate)	C
Amitriptyline (Amitriptyline)	C
Cyclobenzaprine (Cyclobenzaprine)	C
Aaugmentin (Amoxicillin Trihydrate, Clavulanate Potassium)	C
Ergobel (Nicergoline)	C

Date:04/17/03ISR Number: 4092459-7Report Type:Expedited (15-DaCompany Report #US-BRISTOL-MYERS SQUIBB COMPANY-12232922
Age:57 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain		Atenolol	PS	Apothecon	INTRAVENOUS	Administered	
Other	Constipation		Ixabepilone	SS			over 3 hr on day 1 every 21 days-Therapy	
	Dyspnoea							
	Dysuria							
	Haematuria							
	Oedema							
			Effexor	SS				
			Humulin Insulin	SS				
			Reglan	SS				
			Lactulose	SS				
			Hctz	SS				
			Accupril	SS				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/18/03ISR Number: 4098714-9Report Type:Expedited (15-DaCompany Report #HQ3692612AUG2002
Age:67 YR Gender:Female I/FU:F

Outcome	PT
Disability	Akathisia
	Anxiety
	Arthritis
	Arthropathy
	Asthenia
	Automatism
	Bronchospasm
	Cardiomegaly
	Chest Pain
	Choking
	Choking Sensation
	Cognitive Disorder
	Condition Aggravated
	Coordination Abnormal
	Cough
	Decreased Appetite
	Depression
	Dizziness
	Drug Ineffective
	Drug Intolerance
	Duodenitis
	Dysarthria
	Dysgraphia
	Dyskinesia
	Dysphagia
	Dyspnoea Exertional
	Dystonia
	Eating Disorder
	Electrocardiogram T Wave Abnormal
	Extrapyramidal Disorder
	Fall
	Fatigue
	Gastritis
	Gastrooesophageal Reflux Disease
	Glossodynia
	Haematemesis
	Heart Rate Abnormal
	Hyperhidrosis
	Insomnia
	Laceration
	Lethargy

Loss Of Consciousness
Mouth Breathing
Mouth Ulceration
Nervousness
Oesophageal Haemorrhage
Oesophageal Stenosis
Osteoarthritis
Pain In Jaw
Restless Legs Syndrome
Sleep Disorder
Speech Disorder
Tardive Dyskinesia
Tongue Biting
Tongue Disorder
Tremor

Weight Fluctuation
Wheezing

Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Consumer	Reglan (Metoclopramide Hydrochloride,)	PS			10 MG 2X PER 1 DAY	
	Atenolol Hydrochloride (Atenolol Hydrochloride)	C				
	Zantac (Ranitidine Hydrochloride)	C				
	Aciphex (Aciphex)	C				
	Claritin (Loratadine)	C				
	Nasacort (Triamcinolone Acetonide)	C				
	Ultram (Tramadol Hydrochloride)	C				
	Mobic (Meloxicam)	C				
	Maxzide (Triamterene/Hydrochlorothiazide)	C				
	Tylenol (Paracetamol)	C				
	Caffeine (Caffeine)	C				
	Dihydrocodeine (Dihydrocodeine)	C				

Date:04/21/03ISR Number: 4099259-2Report Type:Expedited (15-DaCompany Report #HQ3692612AUG2002
Age:67 YR Gender:Female I/FU:F

Outcome	PT
Disability	Akathisia
	Anxiety
	Apathy
	Arthritis
	Arthropathy
	Asthenia
	Automatism

Blood Pressure Increased
Bronchospasm
Cardiomegaly
Chest Pain
Choking
Choking Sensation
Cognitive Disorder
Condition Aggravated
Coordination Abnormal
Cough
Decreased Appetite
Depression
Disturbance In Attention
Dizziness
Duodenitis
Dysarthria
Dysgraphia
Dyskinesia

Dyspepsia Dysphagia Dyspnoea	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Dystonia Electrocardiogram T Wave Abnormal Endoscopy Abnormal	Consumer	Reglan (Metoclopramide Hydrochloride, Unspec)	PS			10 MG 2X PER 1 DAY
Extrapyramidal Disorder Fall Fatigue Gastritis Gastrooesophageal Reflux Disease Glossodynia Haematemesis Heart Rate Abnormal Hiatus Hernia Hyperhidrosis Impaired Healing Insomnia Laceration Memory Impairment Mouth Ulceration Nervousness Oedema Mucosal Oesophageal Haemorrhage Oesophageal Stenosis Pain In Jaw Restless Legs Syndrome Speech Disorder Tardive Dyskinesia Tongue Biting Tongue Disorder Tremor Weight Decreased Weight Increased Wheezing		Atenolol, Hydrochloride (Atenolol Hydrochloride) Zantac (Ranitidine Hydrochloride) Aciphex (Aciphex) Claritin (Loratadine) Nasacort (Triamcinolone Acetonide) Ultram (Tramadol Hydrochloride) Mobic (Meloxicam) Maxzide (Triamterene/Hydrochlorothiazide) Tylenol (Paracetamol) Caffeine (Caffeine) Dihydrocodeine (Dihydrocodeine)	C C C C C C C C C			

Date:04/22/03ISR Number: 4099966-1Report Type:Direct Company Report #CTU 191442
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 Intervention to Prevent Permanent Impairment/Damage	Neuroleptic Malignant Syndrome		Metoclopramide	PS			10MG PO Q 6 HR PRN; FOLLOWED BY 10MG IV Q 6 HR	1 WK
			Vancomycin	C				
			Gentamicin	C				
			Docusate	C				
			Senna	C				
			Lansoprazole	C				
			Fluoxetine	C				
			Cyclobenzaprine	C				
			Phenobarbital	C				
			Nafcillin	C				
			Hydralazine	C				
			Ondansetron	C				
			Acetaminophen	C				
			Codeine	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/23/03ISR Number: 4103251-9Report Type:Expedited (15-DaCompany Report #2015259
Age:50 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Abdominal Pain	Health	Oxycontin Tablets 10					
Hospitalization -	Accident	Professional	Mg(Oxycodone					
Initial or Prolonged	Accidental Overdose	Other	Hydrochloride) Cr					
Other	Anaemia		Tablet	PS		ORAL	SEE IMAGE	
	Anxiety		Phenergan(Promethazi					
	Atherosclerosis		ne Hydrochloride)	SS		INTRAVENOUS	12.5 MG,	
	Blood Pressure Systolic					INTRAVENOUS		
	Increased		Reglan					
	Cardio-Respiratory Arrest		(Metoclopramide)	SS		INTRAVENOUS	10 MG, Q6H,	
	Cold Sweat					INTRAVENOUS		
	Coma		Zoloft (Sertraline					
	Coronary Artery		Hydrochloride)	SS		50 MG		
	Atherosclerosis		Demerol (Pethidine					
	Diarrhoea		Hydrochloride)	SS		25 MG		
	Drug Ineffective		Morphine (Morphine)	C				
	Drug Toxicity		Rocephin					
	Fall		(Ceftriaxone Sodium)	C				
	Fear		Folic Acid (Folic					
	Fibrosis		Acid)	C				
	Gastroenteritis		Premarin (Estrogens					
	Haemorrhage		Conjugated)	C				
	Haemosiderosis		Provera					
	Head Injury		(Medroxyprogesterone					
	Nausea		Acetate)	C				
	Nephritis Interstitial		Procardia Xl	C				
	Nephrolithiasis		Imodium A-D					
	Nephropathy		(Loperamide					
	Pain		Hydrochloride)	C				
	Renal Cyst		Paxil (Paroxetine					
	Renal Failure Acute		Hydrochloride)	C				
	Respiratory Rate		Tylenol					
	Increased		Extra-Strength	C				
	Sickle Cell Anaemia With		Benadryl					
	Crisis		(Diphenhydramine					
	Splenomegaly		Hydrochloride)	C				

Subarachnoid Haemorrhage	
Toxicologic Test Abnormal	
Ultrasound Scan Abnormal	
Vomiting	

Tums (Calcium Carbonate)	C
Lasix (Furosemide)	C
Maalox (Aluminium Hydroxide Gel, Magnesium Hydroxide)	C
Monopril (Fosinopril Sodium)	C
Kayexalate (Sodium Polystyrene Sulfonate)	C
Folate Sodium (Folate Sodium)	C
Prempro (Estrogens Conjugated, Medroxyprogesterone Acetate)	C
Percocet	C
Procrit (Erythopoietin)	C
Vitamin E (Tocopherol)	C
Neupogen	

(Filgrastim)	C
Acetam1nophen W/Hydrocodone Bitartrate	C
Prilosec (Omeprazole)	C
Flagyl "Aventis" (Metronidazole)	C
Triple Sulfa (Sulfadiazine, Sulfadimidine, Sulfamerazine)	C

Date:04/24/03ISR Number: 4099681-4Report Type:Expedited (15-DaCompany Report #03-00520
Age:24 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Confusional State	Consumer	Metoclopramide	PS			1/2 TABLET	
Hospitalization - Initial or Prolonged	Delusion						WITH EACH MEAL	
	Depression							
	Fatigue							
	Hallucination							
	Self Injurious Behaviour							

Date:04/25/03ISR Number: 4097421-6Report Type:Expedited (15-DaCompany Report #US-BRISTOL-MYERS SQUIBB COMPANY-12232922
Age:57 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain		Atenolol	PS	Apothecon			
	Constipation		Ixabepilone	SS			INTRAVENOUS	Administered over 3 hr on day 1 every 21 days-Therapy
Other	Dizziness							
	Dyspnoea							
	Dysuria							
	Enterococcal Infection							

Haematuria		Lactulose	SS	
Infection		Accupril	SS	
Oedema		Effexor	SS	
		Hctz	SS	
		Humulin Insulin	SS	
		Reglan	SS	

Date:04/25/03ISR Number: 4097888-3Report Type:Direct Company Report #USP 51391
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
	Medication Error		Zantac	PS	Glaxo Wellcome	
			Reglan	SS	Robins	

Date:04/25/03ISR Number: 4098025-1Report Type:Direct Company Report #USP 51595
Age:57 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Medication Error		Reglan *Metoclorpramide)	PS	Robbins	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/25/03ISR Number: 4117226-7Report Type:Periodic Company Report #NSADSS2002032542
Age:19 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardiac Arrest	Literature	Ultram (50 Mg Tablet) (Tramadol Hydrochloride)	PS		ORAL	ORAL	
	Respiratory Depression	Health Professional						
	Therapeutic Response							
	Increased		Metoclopramide(Metoclopramide)	SS		ORAL	ORAL	
			Bupropion (Amfebutamone)	SS		ORAL	ORAL	

Date:04/29/03ISR Number: 4099738-8Report Type:Expedited (15-DaCompany Report #WAES 0210USA00929
Age:57 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Blood Cholesterol	Health Professional	Vioxx	PS	Merck & Co., Inc	ORAL	696	DAY
Initial or Prolonged	Increased		Reglan	SS				
Other	Carotid Artery Stenosis		Catapres	C				
	Carpal Tunnel Syndrome		Prilosec	C				
	Cerebellar Infarction		Flonase	C				
	Cerebrovascular Accident		Robaxin	C				
	Cerebrovascular Disorder		Celebrex	C				
	Chest Discomfort		Lopid	C				
	Deafness Neurosensory							
	Diabetes Mellitus							
	Fall							
	Fatigue							
	Gallbladder Disorder							
	Glossitis							
	Haematochezia							
	Low Density Lipoprotein Increased							
	Major Depression							
	Neuropathy Peripheral							
	Radiculopathy							
	Subclavian Steal Syndrome							
	Syncope							
	Treatment Noncompliance							

Tremor

Date:05/05/03ISR Number: 4102987-3Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0298055A
Age:11 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Abdominal Pain	Consumer	Clamoxyl	PS	Glaxosmithkline	ORAL	5	DAY
Hospitalization -	Acute Pulmonary Oedema		Doliprane	SS	Glaxosmithkline	ORAL	5	DAY
Initial or Prolonged	Coagulation Factor V		Primperan	SS	Glaxosmithkline	RECTAL	1	DAY
	Level Decreased		Aspegic	SS		ORAL	1G Twice per day	5 DAY
	Coma							
	Hepatocellular Damage							
	Hyperammonaemia							
	Loss Of Consciousness							
	Respiratory Alkalosis							
	Reye'S Syndrome							
	Torsade De Pointes							
	Ventricular Fibrillation							
	Vomiting							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/05/03ISR Number: 4105737-XReport Type:Direct Company Report #CTU 192218
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Medication Error		Metoclopramide 5mg/Ml-2ml Abbott	PS	Abbott	INTRAVENOUS		
							BOLUS	
							10MG Q6H	
							INTRAVENOUS	
							BOLUS	
			Zemplar 5 Mcg/Ml-1ml Abott	SS				
INTRAVENOUS							5 MCG TIW	
							INTRAVENOUS	

Date:05/05/03ISR Number: 4107963-2Report Type:Expedited (15-DaCompany Report #HQWYE886323APR03
Age:5 MON Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Nystagmus	Health Professional	Reglan (Metoclopramide Hydrochloride, Syrup)	PS		ORAL		
	Weight Increased							
SEE IMAGE								

Date:05/06/03ISR Number: 4108957-3Report Type:Expedited (15-DaCompany Report #WAES 0210USA00929
Age:57 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Cholesterol	Consumer	Tab Vioxx 25 Mg	PS		ORAL	25 MG/DAILY/PO	
Other	Carpal Tunnel Syndrome	Health Professional	Reglan 10 Mg	SS			10 MG/QID	
	Cerebellar Infarction		Catapres	C				

Cerebrovascular Disorder	Celebrex	C
Chest Discomfort	Flonase	C
Cognitive Disorder	Lopid	C
Condition Aggravated	Prilosec	C
Deafness Neurosensory	Robaxin	C
Dementia		
Depression		
Diabetes Mellitus		
Drug Ineffective		
Faecal Occult Blood Positive		
Fall		
High Density Lipoprotein Decreased		
Hypertension		
Hypotension		
Low Density Lipoprotein Increased		
Neuropathy Peripheral		
Sinusitis		
Sleep Apnoea Syndrome		
Subclavian Steal Syndrome		
Tongue Discolouration		
Tongue Disorder		
Tongue Oedema		
Tremor		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/08/03ISR Number: 4109867-8Report Type:Direct Company Report #USP 081071
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Medication Error		Reglan	PS	Robins			
			Reglan (Metoclopramide Hydrochloride)	SS	Robins			

Date:05/08/03ISR Number: 4110136-0Report Type:Direct Company Report #USP 51888
Age:83 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Medication Error		Reglan 10mg	PS	Robins		10 MG	
			Reglan Metoclopramide Hcl	SS	Robins			

Date:05/12/03ISR Number: 4111010-6Report Type:Direct Company Report #USP 51768
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Medication Error		Toradol	PS	Roche Laboratories			
			Metoclopramide Hydrochloride	SS	Gensia Labs			

Date:05/13/03ISR Number: 4112664-0Report Type:Direct Company Report #CTU 192842
Age:29 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required	Akathisia		Morphine Sulfate	PS		INTRAVENOUS	5 MG IV	
Intervention to	Dyskinesia		Phenergan	SS		INTRAVENOUS	25 MG IV	
Prevent Permanent	Psychomotor Hyperactivity		Demerol	SS		INTRAVENOUS	25 MG IV	

Impairment/Damage			Reglan	SS			
INTRAVENOUS	10 MG IV						

Date:05/15/03ISR Number: 4109988-XReport Type:Expedited (15-DaCompany Report #US-BRISTOL-MYERS SQUIBB COMPANY-12232922
Age:57 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain		Atenolol	PS	Apothecon		Dosing and therapy dates	
Other	Anorexia						not provided	
	Constipation						Dosing and therapy dates	
	Dizziness		Lactulose	SS			not provided	
	Dyspnoea						Dosing and therapy dates	
	Dysuria						not provided	
	Enterococcal Infection		Accupril	SS			Dosing and therapy dates	
	Haematuria						not provided	
	Infection						Dosing and therapy dates	
	Intestinal Obstruction		Hctz	SS			not provided	
	Obstruction						Dosing and therapy dates	
	Oedema						not provided	
	Treatment Noncompliance		Reglan	SS			Dosing and therapy dates	
	Ureteral Disorder						not provided	
	Vomiting						Dose and therapy dates	
			Ambien	SS			not provided	
			Detrol	SS			Dose and therapy dates	

not provided					
Dose and therapy dates not provided			Phenergan	SS	
Dose and therapy dates not provided			Lortab	SS	
Dose and therapy dates not provided			Coumadin	SS	Bristol-Myers Squibb Company
Dose and therapy dates not provided			Accuretic	SS	
Dosing and therapy dates not provided			Humulin Insulin	SS	
Dosing and therapy dates not provided			Effexor	SS	
Dosing and therapy dates not provided			Ixabepilone	C	
INTRAVENOUS	over 3 hr on day 1 every 21d-started 31 Jan				

Date:05/20/03ISR Number: 4114804-6Report Type:Direct Company Report #CTU 193490
Age:31 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Anxiety Restlessness		Metoclopramide 10mg/2ml Vial Metoclopramide	PS SS	Faulding/Mayne		10 MG IV X 1	

Date:05/20/03ISR Number: 4114820-4Report Type:Direct Company Report #CTU 193495
Age:76 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Anxiety Crying		Metoclopramide 10mg /2ml Vial Faulding/Mayne Metoclopramide	PS SS	Faulding/Mayne	INTRAVENOUS	10 MG IV X 1	

Date:05/20/03ISR Number: 4114821-6Report Type:Direct Company Report #CTU 193496
Age:16 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Crying Refusal Of Treatment By Patient		Metoclopramide 10mg/2ml Vial Faulding/Mayne Metoclopramide	PS SS	Faulding/Mayne	INTRAVENOUS	10MG IV X 1	

Date:05/20/03ISR Number: 4114824-1Report Type:Direct Company Report #CTU 193498
Age:24 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Anxiety Condition Aggravated		Metoclopramide 10mg/2ml Vial					

			Faulding/Mayne	PS	Faulding/Mayne		
INTRAVENOUS	10MG IV X 1						
			Metoclopramide	SS			

Date:05/20/03ISR Number: 4115421-4Report Type:Expedited (15-DaCompany Report #HQ3692612AUG2002
Age:67 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Acquired Oesophageal Web	Consumer	Reglan					
	Akathisia		(Metoclopramide					
	Anxiety		Hydrochloride,					
	Arthropathy		Unspec)	PS				
10 MG 2X PER								
	Automatism							
1 DAY								
	Bronchospasm		Atenolol					
	Cardiomegaly		Hydrochloride	C				
	Chest Pain		Zantac	C				
	Choking		Aciphex	C				
	Choking Sensation		Claritin	C				
	Cognitive Disorder		Nasacort	C				
	Condition Aggravated		Ultram	C				
	Coordination Abnormal		Mobic	C				
	Cough		Maxzide	C				
	Decreased Appetite		Tylenol	C				
	Depression		Caffeine	C				
	Disease Recurrence		Dihydrocodeine	C				
	Dizziness							
	Drug Ineffective							
	Drug Intolerance							
	Duodenitis							
	Dysarthria							
	Dyspepsia							
	Dysphagia							
	Dyspnoea							
	Electrocardiogram Abnormal							
	Extrapyramidal Disorder							
	Fall							
	Gastritis							
	Gastrointestinal Disorder							
	Gastrooesophageal Reflux Disease							
	Heart Rate Abnormal							
	Hyperhidrosis							

Laceration
Loss Of Consciousness
Nervousness
Oedema Mucosal
Oesophageal Haemorrhage
Oesophageal Stenosis
Restless Legs Syndrome
Tardive Dyskinesia
Tongue Biting
Tongue Disorder
Tremor
Weight Decreased
Weight Increased

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/21/03ISR Number: 4118089-6Report Type:Direct Company Report #CTU 193537
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Feeling Jittery		Metoclopramide	PS		INTRAVENOUS		
Initial or Prolonged	Pharmaceutical Product					BOLUS	10MG ONE TIME	
	Complaint					IV BOLUS		
	Tremor		Metoclopramide	SS				

Date:05/22/03ISR Number: 4116640-3Report Type:Expedited (15-DaCompany Report #200214592FR
Age:34 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Congenital Anomaly	Abortion Induced	Foreign	Glimepiride (Amarel)					
Other	Drug Exposure During	Health	Tablets	PS		ORAL	1 U/DAY PO	
	Pregnancy	Professional	Levothyroxine Sodium					
	Maternal Drugs Affecting	Other	(Levothyrox) Tablets	SS		ORAL	PO	
	Foetus		Metformin					
	Multiple Congenital		Hydrochloride					
	Abnormalities		Tablets	SS		ORAL	1700 MG/DAY	
	Pregnancy On Oral						PO	
	Contraceptive		Migpriv Powder For					
			Oral Solution	SS		ORAL	PRN PO	
			Hydroxyzine					
			Hydrochloride					
			(Atarax)	SS				
			Omeprazole (Mopral)	C				

Date:05/27/03ISR Number: 4117771-4Report Type:Expedited (15-DaCompany Report #2003-051
Age:45 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Other	Depression	Consumer	Metoclopramide		
	Dry Mouth	Health	Tablets, Usp 5 Mg	PS	ORAL 5 MG QID,
	Nausea	Professional			ORAL
	Phobia Of Driving		Prevacid	C	
	Suicidal Ideation		Vitamins/Herbal Supplements	C	
			Siberian Ginseng	C	
			Black Cohosh	C	
			Ginko Biloba	C	
			Flax Seed Oil	C	
			B-Complex	C	
			Vitex	C	
			Pycnogenol	C	
			Soy Supplement	C	
			St. John'S Wort	C	

Date:05/27/03ISR Number: 4117844-6Report Type:Expedited (15-DaCompany Report #USA-2002-0001677
Age:41 YR Gender:Female I/FU:F

Outcome	PT
Death	Alopecia
Hospitalization - Initial or Prolonged	Amnesia
	Angiopathy
	Anxiety
	Arterial Occlusive Disease
	Arthralgia

	Asthma					
	Atherosclerosis					
	Back Pain	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
	Carpal Tunnel Syndrome	Consumer	Oxycontin Tablets 10			
	Chest Pain	Health	Mg(Oxycodone			
	Coma	Professional	Hydrochloride) Cr			
	Condition Aggravated	Other	Tablet	PS		
10 MG,						
	Depression		Oxycontin Tablets 20			
	Disturbance In Attention		Mg(Oxycodone			
	Drug Ineffective		Hydrochloride) Cr			
	Emphysema		Tablet	SS		
20 MG,	1008 DAY					
	Fatigue		Hydrocodone			
	Femoral Bruit		Bitartrate (Similar			
	Finger Deformity		To Ind 59,175)			
	Flushing		(Hydrocodone			
	Hilar Lymphadenopathy		Bitartrate) Unknown	SS		
1008 DAY						
	Hypoaesthesia		Alprazolam			
	Influenza		(Alprazolam)	SS		
1008 DAY						
	Influenza Like Illness		Ephedrine			
	Insomnia		(Ephedrine)	SS		
1008 DAY						
	Irritability		Pseudoephedrine			
	Libido Decreased		(Pseudoephedrine)	SS		
1008 DAY						
	Memory Impairment		Effexor(Venlafaxine			
	Myalgia		Hydrochloride)	SS		
75 MG, DAILY	1008 DAY					
	Nausea		Codeine (Codeine)	SS		
1008 DAY						
	Nervousness		Neurontin(Gabapentin			
	Night Sweats		)	SS		
100 MG, TID,	1008 DAY					
	Overdose		Metoclopramide(Metoc			
	Pain		lopramide)	SS		
1008 DAY						
	Pain In Extremity		Quetiapine(Quetiapin			
	Paraesthesia		e)	SS		
1008 DAY						
	Peripheral Occlusive		Claritin			
	Disease		(Loratadine)	C		
	Pneumonia		Vitamin C (Ascorbic			
	Pulmonary Oedema		Acid)	C		

Pulse Absent	Celebrex (Celecoxib)	C
Rash Pruritic	Prilosec (Omeprazole)	C
Shock	Daypro (Oxaprozin)	C
Somnolence	Trandate (Labetaolol Hydrochloride)	C
Toxicologic Test Abnormal	Axid (Nizatidine)	C
Upper Respiratory Tract Infection	Paxil (Paroxetine Hydrochloride)	C
Urinary Incontinence	Medrol (Methylprednisolone)	C
Weight Increased	Macro Antioxidant (Ascorbic Acid, Cystine, Tocopherol, Calcium Ascorbate, Betacarotene,	C
	Zocor (Simvastatin)	C
	Risperdal (Risperidone)	C
	Fioricet (Butalbital)	C
	Flonase (Fluticasone Propionate)	C
	Phenobarbital (Phenobarbital)	C
	Donnatal (Atropine	

Sulfate, Hyoscine Hydrobromide, Hyoscyamine Sulfate, Phenobarbital)	C
Bellergal-S (Belladonna Alkaloids, Ergotamine Tartrate, Phenobarbital)	C
Weight Loss Supplement (Does Not Code)	C
Ibuprofen	C
Ambien (Zolpidem Tartrate)	C
Baclofen (Baclofen)	C
Trandate (Labetatol Hydrochloride)	C
Celexa (Citalopram Hydrbromide)	C
Cortisone (Cortisone)	C
Atarax (Hydroxyzine Hydrochloride)	C
Proventil Tablet (Salbutamol Sulfate)	C
Amitriptyline (Amitriptyline)	C
Cyclobenzaprine (Cyclobenzaprine)	C
Augmentin (Amoxicillin Trihydrate, Clavulanate Potassium)	C
Ergobel (Nicergoline)	C

Date:05/27/03ISR Number: 4117934-8Report Type:Expedited (15-DaCompany Report #2003160893FR
Age:50 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardiac Arrest	Foreign	Xanax (Alprazolam)					
	Coma	Health	Tablet	PS		ORAL	0.5 MG, TID,	

	Loss Of Consciousness	Professional			
ORAL					
	Mydriasis	Other	Seropram (Citalopram Hydrobromide)	SS	ORAL
	Respiratory Arrest				
40 MG/DAY,					
	Shock				
ORAL					
			Colchimax (Dicycloverine Hydrochloride, Colchicine)	SS	ORAL
0.5 MG/DAY,					
ORAL					
			Primperan (Metoclopramide)	SS	ORAL
ORAL					
			Forlax (Macrogol)	SS	ORAL
ORAL					
			Depakote (Valproate Semisodium)	SS	ORAL
500 MG/DAY,					
ORAL					
			Equanil (Meprobamate)	C	

Date:05/28/03ISR Number: 4118282-2Report Type:Expedited (15-DaCompany Report #03-00520 (1)
Age:24 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Hospitalization - Initial or Prolonged	Confusional State Depression Fatigue Hallucination Intentional Self-Injury Treatment Noncompliance	Consumer	Metoclopramide Tablets, 10 Mg, Purepac	PS			1/2 TABLET WITH EACH MEAL	

Date:05/30/03ISR Number: 4119561-5Report Type:Expedited (15-DaCompany Report #US-BRISTOL-MYERS SQUIBB COMPANY-12232922
Age:57 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Abdominal Pain Anorexia Constipation Dizziness Dyspnoea Dysuria Haematuria Infection Micturition Urgency Oedema Pollakiuria Vomiting		Atenolol Ixabepilone Lactulose Accupril	PS SS SS SS	Apothecon		Dosing and therapy dates not provided INTRAVENOUS Dosing and therapy dates not provided	over 3 hr on day 1 every 21d-started 31 Jan 03,C3-20 Mar Dosing and therapy dates not provided

therapy dates not provided			
Dosing and therapy dates not provided	Effexor	SS	
Dosing and therapy dates not provided	Hctz	SS	
Dosing and therapy dates not provided	Humulin Insulin	SS	
Dosing and therapy dates not provided	Reglan	SS	
Dosing and therapy dates not provided	Accuretic	SS	
Dosing and therapy dates not provided	Ambien	SS	
Dose and therapy dates not provided	Coumadin	SS	Bristol-Myers Squibb Company
Dose and therapy dates not provided	Detrol	SS	
Dose and therapy dates not provided			

	Lortab	SS
Dose and therapy dates not provided		
	Phenergan	SS
Dose and therapy dates not provided		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/30/03ISR Number: 4120107-6Report Type:Expedited (15-DaCompany Report #B0299892A
Age:34 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Literature	Paxil (Formulation					
		Health	Unknown) (Paroxetine					
		Professional	Hydrochloride)	PS		ORAL		
ORAL								
			Metoclopramide					
			(Formulation					
			Unknown)					
			(Metoclorpramide)	SS		ORAL		
ORAL								
			Amitriptyline					
			(Formulation					
			Unknown)					
			(Amitriptyline)	SS		ORAL		
ORAL								

Date:05/30/03ISR Number: 4120632-8Report Type:Expedited (15-DaCompany Report #USA-2002-0001677
Age:41 YR Gender:Female I/FU:F

Outcome	PT
Death	Alopecia
Hospitalization -	Amnesia
Initial or Prolonged	Anxiety
	Apnoea
	Arthralgia
	Arthritis
	Atherosclerosis
	Back Pain
	Cardiac Arrest
	Cardiac Disorder
	Chest Pain
	Coma
	Condition Aggravated
	Depression
	Disturbance In Attention
	Drug Ineffective
	Emphysema
	Fatigue
	Finger Deformity
	Flushing
	Hilar Lymphadenopathy

Hyperventilation
Hypoaesthesia
Increased Tendency To
Bruise
Influenza
Initial Insomnia
Insomnia
Irritability
Libido Decreased
Memory Impairment
Muscular Weakness
Nausea
Nervousness
Night Sweats
Overdose
Pain
Pain In Extremity
Paraesthesia
Peripheral Occlusive
Disease

		Pneumonia Portal Triaditis Pruritus	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
		Pulmonary Oedema Rash Pruritic Rash Scaly Shock	Consumer Health Professional Other	Oxycontin Tablets 10 Mg (Oxycodone Hydrochloride) Cr Tablet	PS		
10 MG							
		Somnolence Upper Respiratory Tract Infection Urinary Incontinence		Oxycontin Tablets 20 Mg (Oxycodone Hydrochloride) Cr Tablet	SS		
20 MG	1008 DAY						
		Weight Increased		Hydrocodone Bitartrate (Similar To Ind 59,175) (Hydrocodone Bitartrate)	SS		
1008 DAY							
				Alprazolam (Alprazolam)	SS		
1008 DAY							
				Ephedrine (Ephedrine)	SS		
1008 DAY							
				Pseudoephedrine (Pseudoephedrine)	SS		
1008 DAY							
				Effexor (Venlafaxine Hydrochloride)	SS		
75 MG, DAILY	1008 DAY						
				Codeine (Codeine)	SS		
1008 DAY							
				Neurontin (Gabapentin)	SS		
100 MG, TID	1008 DAY						
				Metoclopramide (Metoclopramide)	SS		
1008 DAY							
				Quetiapine (Quetiapine)	SS		
1008 DAY							
				Claritin (Loratadine)	C		
				Vitamin C (Ascorbic Acid)	C		

Celebrex (Celecoxib)	C
Prilosec (Omeprazole)	C
Daypro (Oxaprozin)	C
Trandate (Labetalol Hydrochloride)	C
Axid (Nizatidine)	C
Paxil (Paroxetine Hydrochloride)	C
Medrol (Methylprednisolone)	C
Macro Antioxidant (Ascorbic Acid, Cystine, Tocopherol, Calcium Ascorbate, Betacarotene,	C
Zocor (Simvastatin)	C
Risperdal (Risperidone)	C
Fioricet (Butalbital)	C
Flonase (Fluticasone Propionate)	C
Phenobarbital (Phenobarbital)	C
Donnatal (Atropine	

Sulfate, Hyoscine Hydrobromide, Hyoscyamine Sulfate, Phenobarbital)	C
Bellergal-S (Belladonna Alkaloids, Ergotamine Tartrate, Phenobarbital)	C
Weight Loss Supplement (Does Not Code)	C
Ibuprofen	C
Ambien (Zolpidem Tartrate)	C
Baclofen (Baclofen)	C
Trandate (Labetalol Hydrochloride)	C
Celexa (Citalopram Hydrobromide)	C
Cortisone (Cortisone)	C
Atarax (Hydroxyzine Hydrochloride)	C
Proventil Tablet (Salbutamol Sulfate)	C
Amitriptyline (Amitriptyline)	C
Cyclobenzaprine (Cyclobenzaprine)	C
Augmentin (Amoxicillin Trihydrate, Clavulanate Potassium)	C
Ergobel (Nicergoline)	C

Date:05/30/03ISR Number: 4121296-XReport Type:Expedited (15-DaCompany Report #DSA_60319_2003
Age:45 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Cerebrovascular Accident	Health Professional Company	Dhe-45	PS				
			Reglan	SS				
			Compazine	SS				

Date:05/30/03ISR Number: 4121373-3Report Type:Expedited (15-DaCompany Report #S03-FRA-02278-01
Age:50 YR Gender:Female I/FU:I

Outcome	PT
Death	Amyloidosis
	Arrhythmia
	Blood Pressure Abnormal
	Cardiac Disorder
	Cardio-Respiratory Arrest
	Coma
	Condition Aggravated
	Gastrointestinal Disorder
	Pupil Fixed

	Pupils Unequal Shock					
Dose	Duration	Report Source	Product	Role	Manufacturer	Route
		Foreign Health	Seropram (Citalopram Hydrobromide)	PS		
INTRAVENOUS	20 MG QD IV					
		Professional Other	Seropram (Citalopram Hydrobromide)	SS		
INTRAVENOUS	40 MG QD IV					
			Seropram (Citalopram Hydrobromide)	SS		ORAL
40 MG QD PO						
			Colchicine "Houde" (Colchicine)	SS		ORAL
0.5 UNK BID						
PO						
			Primperan (Metoclopramide)	SS		
			Xanax (Alprazolam)	SS		ORAL
0.5 MG TID PO						
			Forlax (Macrogol)	SS		
			Depakote (Valproate Semisodium)	SS		ORAL
500 MG QD PO						
			Equanil (Meprobamate)	SS		
			Di-Antalvic	C		
			Hepta-A-Myl (Heptaminol Hydrochloride)	C		
			Dogmatil (Sulpiride)	C		

Date:05/30/03ISR Number: 4121641-5Report Type:Expedited (15-DaCompany Report #S03-USA-01477-01
Age:85 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Death	Completed Suicide	Health Professional	Lexapro (Escitalopram)	PS		
	Drug Interaction					
10 MG QD PO						
	Injury Asphyxiation	Company Representative	Reglan (Metoclopramide)	SS		
			Norvasc (Amlodipine			

Besilate)	C
Flomax (Morniflumate)	C
Glucosamine	C
Zyrtec (Cetirizine Hydrchloride)	C
Relafen (Nabumetone)	C
Halcion (Triazolam)	C

Date:06/02/03ISR Number: 4121967-5Report Type:Expedited (15-DaCompany Report #PHBS2003ES05317
Age:27 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Hepatic Failure Liver Transplant		Voltaren (Diclofenac Sodium) Solution For Injection	PS		INTRAMUSCULAR	150 MG/DAY,	
			Sevorane (Sevoflurane)	SS		RESPIRATORY (INHALATION)	INHALATION	
			Toriol (Ranitidine Hydrochloride)	SS		INTRAVENOUS	200 MG/DAY,	
			Clexane			INTRAVENOUS		

				(Heparin-Fraction, Sodium Salt)	SS		
SUBCUTANEOUS	20 MG/DAY,						
SUBCUTANEOUS							
				Primperan (Metoclopramide)	SS		ORAL
ORAL							
				Propofol (Propofol)	SS		
INTRAVENOUS	INTRAVENOUS						
				Contraceptives Uns (Contraceptives Uns)	C		
				Atracuri	C		
				Atropine (Atropine)	C		
				Prostigmin (Neostigmine Bromide)	C		
				Nitrose Oxid	C		
				Fentanyl (Fentanyl)	C		

Date:06/03/03ISR Number: 4121766-4Report Type:Direct Company Report #CTU 194590
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Other	Chills		Metoclopramide	PS		
INTRAVENOUS	10MG IVP Q3 H					
	Confusional State					
PRN 1 DOSE						
	Hyperhidrosis					
	Hypersensitivity					
	Tachypnoea					

Date:06/03/03ISR Number: 4122240-1Report Type:Direct Company Report #CTU 195732
Age:33 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Other	Dysarthria		Metoclopramide	PS		
INTRAVENOUS	10MG DAILY IV					
	Muscle Spasms		Ketamine	C		
	Pain In Extremity		Versed	C		
	Torticollis		Fentanyl	C		
	Vision Blurred		Celebrex	C		

			Perocet	C		
			Flexeril	C		
			Benadryl	C		
			Cogentin	C		

Date:06/04/03ISR Number: 4122944-0Report Type:Direct Company Report #USP 51284
Age: Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Medication Error Overdose		Metoclopramide Hydrochloride	PS		
SYRUP						

Date:06/04/03ISR Number: 4124190-3Report Type:Expedited (15-DaCompany Report #03H-144-0219588-00
Age:27 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Life-Threatening Hospitalization - Initial or Prolonged	Hepatic Failure Hepatitis Fulminant	Foreign Health Professional	Sevorane Liquid For Inhalation (Sevoflurane) (Sevoflurane)	PS		
RESPIRATORY						
(INHALATION) AS NEEDED,						
INHALATION						
			Combaren	SS		
INTRAMUSCULAR 75 MG,						

INTRAMUSCULAR			
		Ranitidine Hydrochloride	SS
INTRAVENOUS	50 MG,		
INTRAVENOUS			
		Heparin-Fraction, Sodium Salt	SS
SUBCUTANEOUS	20 MG , 1 IN		
1 D,			
SUBCUTANEOUS			
		Metoclopramide	SS
10 MG			
		Propofol	SS
INTRAVENOUS	AS NEEDED,		
INTRAVENOUS			
		Propofol	C
		Fentanex	C
		Atracurium	C
		Atropine Sulfate	C
		Neostigmine Bromide	C
		Nitrous Oxide	C
		Fentanyl	C
		Oral Contraceptive Nos	C

Date:06/10/03ISR Number: 4126272-9Report Type:Direct Company Report #CTU 195444
Age:33 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dysarthria		Metoclopramide	PS				
INTRAVENOUS	10 MG DAILY							
	Muscle Spasms							
IV								
	Torticollis		Ketamine	C				
	Vision Blurred		Versed	C				
			Fentanyl	C				

Date:06/11/03ISR Number: 4127193-8Report Type:Direct Company Report #CTU 195563
Age:67 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Electrocardiogram Qt		Fluconazole Pfizer	PS	Pfizer	INTRAVENOUS	200 MG	QD IV
Hospitalization - Initial or Prolonged	Prolonged		Metoclopramide Synthelabo France	SS	Synthelabo France	INTRAVENOUS	5 MG	Q 8 HRS
Required IV Intervention to Prevent Permanent Impairment/Damage			Ciprofloxacin	C				
			Hydrocortisone	C				
			Thyroxine	C				
			Haloperidol	C				
			Septra	C				
			Insulin	C				

Date:06/11/03ISR Number: 4128094-1Report Type:Expedited (15-DaCompany Report #03P-056-0217775-00
Age:52 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Arrhythmia	Foreign	Depakote (Divalproex Sodium) (Divalproex Sodium)	PS		ORAL	500 MG, 1 IN	1 D, ORAL
Required Intervention to Prevent Permanent Impairment/Damage	Blood Pressure Abnormal	Health Professional Company Representative						
	Cardio-Respiratory Arrest							
	Cardiomyopathy							
	Coma		Metoclopramide	SS		ORAL	SEE IMAGE	
	Loss Of Consciousness		Colchicine	SS		ORAL	0.5 MG, 2 IN	1 D, ORAL
	Shock		Alprazolam	SS		ORAL	0.5 MG,3 IN	1D,ORAL

				Macrogol	SS		ORAL
10GM, 2 IN 1							
D, ORAL							
				Citalopram Hydrobromide	SS		
INTRAVENOUS	20-40						
MILLIGRAMS,							
INTRAVENOUS							
				Sulpiride	C		
				Heptaminol Hydrochloride	C		
				Aporex	C		

Date:06/12/03ISR Number: 4129011-0Report Type:Expedited (15-DaCompany Report #200311720EU
Age:27 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Life-Threatening	Hepatic Failure	Foreign	Heparin-Fraction, Sodium Salt			
	Liver Transplant	Other	(Clexane)	PS		
SUBCUTANEOUS	20 MG/DAY SC 5 DAY					
			Sevoflurane (Sevorane)	SS		
RESPIRATORY						
(INHALATION)	INH 1 DAY					
			Diclofenac Sodium (Voltaren)	SS		
INTRAMUSCULAR	75 MG BID IM 3 DAY					
			Ranitidine Hydrochloride (Toriol)	SS		
INTRAVENOUS	50 MG QID IV 3 DAY					
			Metoclopramide (Primperan) Tablets	SS		ORAL
PO	3 DAY					
			Propofol	SS		
INTRAVENOUS	IV 1 DAY					
			Oral Contraceptive Nos	C		
			Atracurium	C		

Atropine	C
Neostigmine (Prostigmine)	C
Nitrous Oxide	C
Fentanyl	C

Date:06/12/03ISR Number: 4129325-4Report Type:Expedited (15-DaCompany Report #2015259
Age:50 YR Gender:Female I/FU:F

Outcome	PT
Death	Abdominal Pain
Hospitalization - Initial or Prolonged	Accidental Overdose
	Anaemia
Other	Anxiety
	Atherosclerosis
	Blood Creatinine Increased
	Blood Pressure Increased
	Blood Urea Increased
	Cardio-Respiratory Arrest
	Coma
	Dehydration
	Diarrhoea
	Drug Ineffective
	Drug Toxicity
	Fall
	Fear

		Fibrosis Gastroenteritis Haemorrhage	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
		Haemosiderosis Head Injury Injury Mydriasis	Health Professional Other	Oxycontin Tablets 10 Mg (Oxycodone Hydrochloride) Cr Tablet	PS		ORAL	SEE IMAGE	
		Nausea Nephritis Interstitial		Phenergan(Promethazine Hydrochloride)	SS		INTRAVENOUS	12.5 MG,	
		Nephrolithiasis					INTRAVENOUS		
		Pain Pain In Extremity		Reglan(Metoclopramide)	SS		INTRAVENOUS	10 MG, Q6H,	
		Pericarditis Adhesive					INTRAVENOUS		
		Pleural Adhesion Poisoning		Zoloft(Sertraline Hydrochloride)	SS			50 MG,	
		Renal Cyst Renal Failure		Demerol(Pethidine Hydrochloride)	SS			25 MG	
		Renal Failure Acute Respiratory Rate Increased Sickle Cell Anaemia With Crisis Splenomegaly Subarachnoid Haemorrhage Vomiting		Morphine	C				
				Rocephin (Ceftriaxone Sodium)	C				
				Folic Acid	C				
				Premarin (Estrogens Conjugated)	C				
				Provera (Medroxyprogesterone Acetate)	C				
				Procardia Xl	C				
				Imodium A-D (Loperamide Hydrochloride)	C				
				Paxil (Paroxetine Hydrochloride)	C				
				Tylenol Extra-Strength	C				
				Benadryl (Diphenhydramine Hydrochloride)	C				
				Tums (Calcium Carbonate)	C				

Lasix (Furosemide)	C
Maalox (Aluminium Hydroxide Gel, Magnesium Hydroxide)	C
Monopril (Fosinopril Sodium)	C
Kayexalate (Sodium Polystyrene Sulfonate)	C
Folate Sodium	C
Prempro (Estrogens Conjugated, Medroxyprogesterone Acetate)	C
Percocet	C
Procrit (Erythropoietin)	C
Vitamin E (Tocopherol)	C
Neupogen (Filgrastim)	C
Acetaminophen	

				W/Hydrocodone Bitartrate	C		
				Prilosec (Omeprazole)	C		
				Flagyl "Aventis" (Metronidazole)	C		
				Triple Sulfa (Sulfadiazine, Sulfadimidine, Sulfamerazine)	C		

Date:06/16/03ISR Number: 4129436-3Report Type:Direct Company Report #CTU 195842
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Pharmaceutical Product Complaint		Metoclopramide Inj 10mg/2ml Vial (Abbott)	PS	Abbott			

Date:06/16/03ISR Number: 4129548-4Report Type:Direct Company Report #CTU 195876
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Medication Error Pharmaceutical Product Complaint		Metoclopramide 10mg/2ml	PS				

Date:06/16/03ISR Number: 4129580-0Report Type:Direct Company Report #CTU 195890
Age:43 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Torsade De Pointes		Azithromycin	PS				
			Metoclopramide	SS				

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
Hospitalization - Initial or Prolonged	Akathisia
Disability	Arthropathy
	Blepharospasm
	Blood Pressure Increased
	Chest Discomfort
	Condition Aggravated
	Conversion Disorder
	Depression
	Diarrhoea
	Disturbance In Attention
	Drug Withdrawal Syndrome
	Dry Mouth
	Dysphagia
	Dysphemia
	Dyspnoea
	Dystonia
	Eye Pain
	Feeling Abnormal
	Halo Vision
	Headache

		Hyperhidrosis					
		Impaired Driving Ability					
		Malaise	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
		Migraine	Consumer	Reglan-10mg-Tablet			
		Muscle Spasms		(Metoclopramide Hcl)	PS		ORAL
10MG, 4 IN 1							
		Nausea					
D, ORAL							
		Nervousness		Prochlorperazine-Edi			
		Nightmare		sylate	SS		
		Obsessive-Compulsive		Haloperidol	SS		
		Disorder		Gabapentin	SS		
		Palpitations		Olanzapine	SS		
		Paraesthesia		Lisinopril	C		
		Photosensitivity Reaction		Diazepam	C		
		Posture Abnormal		Mylanta	C		
		Restlessness		Metoprolol	C		
		Sleep Apnoea Syndrome		Heparin	C		
		Speech Disorder		Clopidogrel	C		
		Strabismus					
		Syncope					
		Tardive Dyskinesia					
		Tic					
		Tremor					
		Visual Acuity Reduced					

Date:06/17/03ISR Number: 4131682-XReport Type:Expedited (15-DaCompany Report #03P-056-0217775-00
Age:52 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Death	Abdominal Pain	Foreign	Depakote (Divalproex			
Required	Arrhythmia	Health	Sodium) (Divalproex			
Intervention to	Cardio-Respiratory Arrest	Professional	Sodium)	PS		ORAL
500 MG, 1 IN						
Prevent Permanent	Cardiomyopathy	Company				
1 D, ORAL						
Impairment/Damage	Coma	Representative	Metoclopramide	SS		ORAL
AS REQUIRED,						
	Ejection Fraction					
OAL						
	Decreased		Colchicine	SS		ORAL
0.5 MG, 2 IN						

	Electroencephalogram				
1 D, ORAL					
	Abnormal	Alprazolam	SS		ORAL
0.5 MG, 3 IN					
	Familial Mediterranean				
1 D, ORAL					
	Fever	Macrogol	SS		ORAL
10 GM, 2 IN 1					
	Gastrointestinal Disorder				
D, ORAL					
	Shock	Citalopram			
	Vomiting	Hydrobromide	SS		
INTRAVENOUS	20-40				
MILLIGRAMS,					
INTRAVENOUS					
		Sulpiride	C		
		Heptaminol Hydrochloride	C		
		Aporex	C		

Date:06/18/03ISR Number: 4132193-8Report Type:Expedited (15-DaCompany Report #HQWYE531109JUN03
Age:84 YR Gender:Male I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Activities Of Daily Living Impaired
Other	Confusional State
	Depressive Symptom
	Dysphagia
	Failure To Thrive

		Incontinence Parkinsonism Weight Decreased	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
			Study Literature Health Professional	Reglan (Metoclopramide Hydrochloride)	PS		
10 MG 3X PER 1 DAY							

Date:06/18/03ISR Number: 4132335-4Report Type:Expedited (15-DaCompany Report #HQWYE550210JUN03
Age:87 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 Anorexia Condition Aggravated Failure To Thrive Incontinence Muscle Contracture Parkinsonism	Study Literature	Reglan (Metoclopramide Hydrochloride)	PS		
5 MG 4X PER 1 DAY						

Date:06/18/03ISR Number: 4132597-3Report Type:Expedited (15-DaCompany Report #HQWYE550410JUN03
Age:71 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Akinesia Condition Aggravated Drug Ineffective Dysphagia Dysphonia Failure To Thrive Parkinson'S Disease	Study Literature	Reglan (Metoclopramide Hydrochloride, Unspec)	PS		
10 MG 4X PER 1 DAY						

Date:06/18/03ISR Number: 4132599-7Report Type:Expedited (15-DaCompany Report #HQWYE550310JUN03
Age:69 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Abasia	Study	Reglan					
	Activities Of Daily Living Impaired	Literature	(Metoclopramide Hydrochloride, Unspec)	PS			10 MG 4X PER	1 DAY
	Decubitus Ulcer							
	Failure To Thrive							
	Muscle Rigidity							

Date:06/19/03ISR Number: 4131471-6Report Type:Expedited (15-DaCompany Report #WAES 0305USA01777
Age:77 YR Gender:Male I/FU:F

Outcome	PT
Life-Threatening	Blood Creatinine Increased
	Blood Pressure Diastolic Decreased
	Blood Urea Increased
	Body Temperature Increased
	Cardiac Failure Congestive

		Glucose Urine Present Haematocrit Decreased Haemoglobin Decreased	Report Source	Product	Role	Manufacturer	Route	Dose Duration
		Interstitial Lung Disease	Health	Primaxin	PS	Merck & Co., Inc	INTRAVENOUS	7 DAY
		Platelet Count Decreased	Professional	Teicoplanin	SS		INTRAVENOUS	7 DAY
		Protein Urine Present		Metoclopramide	SS		INTRAVENOUS	5 DAY
		Red Blood Cell Count Decreased		Dinoprost	SS		INTRAVENOUS	2 DAY

Date:06/20/03ISR Number: 4132973-9Report Type:Direct Company Report #CTU 196234
Age:56 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Life-Threatening	Dystonia		Risperidone 1mg	PS		ORAL	1MG BID
Required Intervention to Prevent Permanent Impairment/Damage	Extrapyramidal Disorder					ORAL	
	Respiratory Failure		Metoclopramide 10mg	SS		ORAL	10MG QID
			Ondansetron Prn	C			
			Chlordiazepoxide Prn	C			
			Zolpidem	C			

Date:06/24/03ISR Number: 4135536-4Report Type:Expedited (15-DaCompany Report #2003AP02288
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Death	Bradycardia	Literature	Bupivacaine	PS			100 MG ONCE
	Cardiac Arrest	Health	Mepivacaine	SS			300 MG ONCE
	Cardiotoxicity	Professional				BPB	

	Circulatory Collapse		Metoclopramide	SS		
	Drug Interaction		Labetalol	SS		
	Drug Toxicity					
	Hypertension					
	Metabolic Acidosis					
	Nausea					

Date:06/24/03ISR Number: 4135769-7Report Type:Expedited (15-DaCompany Report #2003AP02288
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Bradycardia	Literature	Bupivacaine	PS		
100 MG ONCE						
	Cardiac Arrest	Health	Mepivacaine	SS		
300 MG ONCE						
	Circulatory Collapse	Professional				
BPB						
	Drug Interaction		Metoclopramide	SS		
	Drug Toxicity		Labetalol	SS		
	Hypertension					
	Hypotension					
	Metabolic Acidosis					
	Nausea					

Date:06/25/03ISR Number: 4135618-7Report Type:Direct Company Report #CTU 196637
Age:37 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Headache		Paxil Cr 12.5 Mg Tab			
	Medication Tampering		Gsk	PS	Gsk	
1 TABLET						
EVERY DAY						

			Metoclopromide 10 Mg Tab	SS		1 TABLET EVERY 6 HOURS

Date:06/26/03ISR Number: 4137077-7Report Type:Expedited (15-DaCompany Report #HQ5724311MAY2000
Age:11 WK Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Agitation Asthma Blood Phosphorus Increased Constipation Convulsion Cough Dyspnoea Haemoglobin Decreased Hyperacusis Hypercalcaemia Hyperhidrosis Hyperkalaemia Irritability Laryngeal Disorder Lung Disorder Medication Error Nausea Overdose Renal Tubular Acidosis Respiratory Distress Tardive Dyskinesia Tracheal Disorder Tremor Urine Calcium/Creatinine Ratio Increased Vomiting Wheezing	Health Professional	Reglan (Metoclopramide Hydrochloride, Syrup) Zantac (Ranitidine Hydrochloride) Augmentin Oral (Amoxicillin Trihydrate/Clavulanate Potassium) Prednisolone (Prednisolone)	PS C C C		ORAL	3 ML EVERY 6 HOURS (OVERDOSE AMOUNT), ORAL	

Date:06/26/03ISR Number: 4137080-7Report Type:Expedited (15-DaCompany Report #HQ1328314MAR2002
Age:4 MON Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hyperacusis Hyperhidrosis Medication Error Overdose Tardive Dyskinesia Tremor	Consumer	Reglan (Metoclopramide Hydrochloride, Syrup)	PS		ORAL	OVERDOSE AMOUNT, 3 ML, ORAL	

Date:07/02/03ISR Number: 4141237-9Report Type:Expedited (15-DaCompany Report #2003AP02288
Age: Gender:Female I/FU:I

Outcome	PT
Death	Bradycardia Cardiac Arrest Circulatory Collapse Drug Toxicity Hypertension Hypotension

	Metabolic Acidosis Nausea						
Dose	Duration		Report Source	Product	Role	Manufacturer	Route
			Literature	Bupivacaine	PS		
100 MG ONCE							
			Health				
BPB							
			Professional	Mepivacaine	SS		
300 MG ONCE							
BPB							
				Metoclopramide	SS		
				Labetalol	SS		

Date:07/02/03ISR Number: 4141563-3Report Type:Expedited (15-DaCompany Report #HQWYE797930JUN03
Age:1 DY Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Other	Congenital Hand Malformation Maternal Drugs Affecting	Foreign Health Professional	Efexor (Venlafaxine Hydrochloride, Tablet)	PS		ORAL
75 MG 1 X PER						
	Foetus	Other				
1 DAY						
			Alprazolam (Alprazolam)	SS		ORAL
40 MG 1 X PER						
1 TOT						
			Nefadar (Nefazodone Hydrochloride)	SS		ORAL
"200-100"						
DAILY						
			Ponstan (Mefenamic Acid,)	SS		ORAL
"OCCASIONALLY						
(4-5						
TIME/MONTH)"						
			Prazine (Promazine Hydrochloride,			

				Tablet)	SS		ORAL
50 MG 1 X PER							
1 TOT	1	DAY					
				Primperan (Metoclopramide,)	SS		ORAL
10 MG 1 X PER							
1 DAY	23	DAY					
				Seresta (Oxazepam, Tablet)	SS		ORAL
30 MG 1 X PER							
1 DAY	55	DAY					
				Topamax (Topiramate)	SS		ORAL
"200-100 MG"							
DAILY	55	DAY					
				Trittico (Trazodone Hydrochloride)	SS		ORAL
"50-100 MG"							
DAILY							
				Zyprexa (Olanzapine,)	SS		ORAL
2.5 MG 1 X							
PER 1 DAY							

Date:07/07/03ISR Number: 4144379-7Report Type:Expedited (15-DaCompany Report #02P-056-0198239-00
Age:63 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	Balance Disorder Bradyphrenia Cerebellar Syndrome Cognitive Disorder Extrapyramidal Disorder Tremor	Foreign Health Professional	Depakine (Depakene) (Sodium Valproate/Valproic Acid) Metoclopramide Lamotrigine	PS SS C		ORAL		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/09/03ISR Number: 4145966-2Report Type:Expedited (15-DaCompany Report #USA-2002-0001677
Age:41 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Alopecia	Consumer	Oxycontin Tablets 10					
Hospitalization -	Anxiety	Health	Mg(Oxycodone					
Initial or Prolonged	Arterial Occlusive	Professional	Hydrochloride) Cr					
	Disease	Other	Tablet	PS			10 MG	
	Asthenia		Oxycontin Tablets					
	Back Pain		20mg(Oxycodone					
	Cardiac Arrest		Hydrochloride) Cr					
	Cardiac Enzymes Increased		Tablet	SS			20 MG	1008 DAY
	Cardiac Murmur		Hydrocodone					
	Chest Pain		Bitartrate (Similat					
	Coma		To Ind 59,159)					
	Contusion		(Hydrocodone					
	Depression		Bitartrate) Unknown	SS			1008 DAY	
	Diabetes Mellitus		Alprazolam(Alprazola					
	Disturbance In Attention		m)	SS			1008 DAY	
	Drug Ineffective		Ephedrine(Ephedrine)	SS			1008 DAY	
	Dyspnoea		Metoclopramide(Metoc					
	Flushing		lopramide)	SS			1008 DAY	
	Hyperhidrosis		Quetiapine(Quetiapin					
	Hyperventilation		e)	SS			1008 DAY	
	Hypoxia		Pseudoephedrine(Pseu					
	Influenza		doephedrine)	SS			1008 DAY	
	Insomnia		Effexor (Venlafaxine					
	Irritability		Hydrochloride)	SS			75 MG, DAILY,	1008 DAY
	Libido Decreased		Codeine(Codeine)	SS			1008 DAY	
	Memory Impairment		Neurontin(Gabapentin					
	Muscular Weakness		)	C			100 MG, TID	1008 DAY
	Nausea		Claritin					
	Nervousness		(Loratadine)	C				
	Night Sweats		Vitamin C (Ascorbic					
	Overdose		Acid)	C				

Pain	Celebrex (Celecoxib)	C
Peripheral Occlusive Disease	Prilosec (Omeprazole)	C
Pneumonia	Daypro (Oxaprozin)	C
Pruritus	Trandate (Labetalol Hydrochloride)	C
Pulse Absent	Axid (Nizatidine)	C
Rash Pruritic	Paxil (Paroxetine Hydrochloride)	C
Somnolence	Medrol (Methylprednisolone)	C
Suicide Attempt	Macro Antioxidant (Ascorbic Acid, Cystine, Tocopherol, Calcium Ascorbate, Betacarotene,	C
Upper Respiratory Tract Infection	Zocor (Simvastatin)	C
Urinary Incontinence	Risperdal (Risperidone)	C
Weight Increased	Fioricet (Butalbital)	C
	Flonase (Fluticasone Propionate)	C
	Phenobarbital (Phenobarbital)	C
	Donnatal (Atropine Sulfate, Hyoscine	

Hydrobromide, Hyoscyamine Sulfate, Phenobarbital)	C
Bellergal-S (Belladonna Alkaloids, Ergotamine Tartrate, Phenobarbital)	C
Weight Loss Supplement (Does Not Code)	C
Ibuprofen	C
Ambien (Zolpidem Tartrate)	C
Baclofen (Baclofen)	C
Trandate (Labetalol Hydrochloride)	C
Celexa (Citalopram Hydrobromide)	C
Cortisone (Cortisone)	C
Atarax (Hydroxyzine Hydrochloride)	C
Proventil Tablet(Salbutamol Sulfate)	C
Amitriptyline (Amitriptyline)	C
Cyclobenzaprine (Cyclobenzaprine)	C
Augmentin (Amoxicillin Trihydrate, Clavulanate Potassium)	C
Ergobel (Nicergoline)	C
Glucotrol Xl (Glipizide)	C
Humuline Nph (Insulin Human Injection, Isophane)	C
Capoten	C
Albuterol (Salbutamol)	C
Azmacort (Triamcinolone Acetonide)	C

Aciphex (Rabeprazole Sodium)	C
Seroquel (Quetiapine)	C

Date:07/09/03ISR Number: 4147064-0Report Type:Expedited (15-DaCompany Report #03H-144-0219588-00
Age:27 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
	Coagulopathy Encephalopathy Hepatic Failure Hepatitis Fulminant	Foreign Health Professional	Sevorane Liquid For Inhalation (Sevoflurane) (Sevoflurane) (Sevoflurane)	PS				
RESPIRATORY								
(INHALATION)							AS NEEDED,	
INHALATION								
			Combaren	SS				
INTRAMUSCULAR							75 MG,	
INTRAMUSCULAR								
			Ranitidine Hydrochloride	SS				
INTRAVENOUS							50 MG,	
INTRAVENOUS								
			Heparin-Fraction, Sodium Salt	SS				
SUBCUTANEOUS							20 MG, 1 IN 1	
D,								
SUBCUTANEOUS								
			Metoclopramide	SS				
10 MG								
			Propofol	SS				
INTRAVENOUS							INTRAVENOUS	
			Propofol	C				
			Fentanex	C				
			Atracurium	C				
			Atropine Sulfate	C				
			Neostigmine Bromide	C				
			Nitrous Oxide	C				
			Fentanyl	C				
			Oral Contraceptive Nos	C				

Date:07/10/03ISR Number: 4146788-9Report Type:Expedited (15-DaCompany Report #HQWYE805801JUL03
Age:15 MON Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blepharospasm Eye Rolling Grimacing Tic	Consumer	Reglan (Metoclopramide Hydrochloride, Syrup)	PS		ORAL	SEE IMAGE	
			Prilosec (Omeprazole)	C				

Date:07/10/03ISR Number: 4147373-5Report Type:Expedited (15-DaCompany Report #HQWYE797930JUN03
Age:1 DY Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Congenital Hand Malformation Maternal Drugs Affecting Foetus	Health Professional Other	Effexor (Venlafaxine Hydrochloride, Tablet)	PS		ORAL	75 MG 1X PER	1 DAY, ORAL 14 DAY
			Alprazolam (Alprazolam,)	SS		ORAL	"PROBALBY" 2 MG DAILY, ORAL	
			Entumin (Clotiapine,)	SS		ORAL	40 MG 1X PER	1 TOT, ORAL 1 DAY
			Nefadar (Nefazodone Hydrochloride,)	SS		ORAL	"200-100 MG"	

DAILY, ORAL						
				Ponstan (Mefenamic Acid,)	SS	ORAL
"OCCASIONALLY (4-5 TIME/MONTH)", ORAL, YEARS						
				Prazine (Promazine Hydrochloride, Tablet)	SS	ORAL
50 MG 1X PER 1 TOT, ORAL	1	DAY				
				Primperan (Metoclopramide,)	SS	ORAL
10 MG, 1X PER 1 DAY, ORAL	23	DAY				
				Seresta (O0xazepam, Tablet)	SS	ORAL
30 MG 1X PER 1 DAY, ORAL	55	DAY				
				Topamax (Topiramate,)	SS	ORAL
"200-100 MG" DAILY, ORAL	55	DAY				
				Trittico (Trazodone Hydrochloride,)	SS	ORAL
"50-100 MG" DAILY, ORAL						
				Zyprexa(Olanzapine,)	SS	ORAL
2.5 MG 1X PER 1 DAY, ORAL						

Date:07/14/03ISR Number: 4148853-9Report Type:Expedited (15-DaCompany Report #03H-122-0223607-00
Age:41 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Bradyarrhythmia	Foreign	Dopamine					
Required	Cardiac Arrest	Literature	Hydrochloride					
Intervention to	Drug Interaction	Health	Injection (Dopamine					
Prevent Permanent	Impaired Gastric Emptying	Professional	Hydrochloride)					
Impairment/Damage			(Dopamine	PS		INTRAVENOUS	4 TO 10	
MCG/KG/MIN,								
						INTRAVENOUS	12	DAY
			Metoclopramide	SS				
						INTRAVENOUS	10 MG, 3	
TIMES A DAY,								
						INTRAVENOUS	48	HR
			Propofol	SS				
						INTRAVENOUS	INTRAVENOUS	
			Midazolam	C				
			Fentanyl	C				
			Norepinephrine	C				
			Nimodipine	C				
			Cefotaxime	C				
			Paracetamol	C				

Date:07/24/03ISR Number: 4153743-1Report Type:Direct Company Report #CTU 198627
Age:37 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Headache		Paxil Cr 12.5 Mg Tab					
	Hypoaesthesia		Gsk	PS	Gsk			
ONE EVERYDAY								
	Pharmaceutical Product		Metoclopramide 10 Mg					
	Complaint		Tabs	SS				
ONE EVERY SIX								
HOURS								

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/24/03ISR Number: 4156496-6Report Type:Expedited (15-DaCompany Report #CH-JNJFOC-20030702042
Age: Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability Congenital Anomaly	Drug Interaction	Foreign Health	Topamax (Topiramate) Tablets	PS			200MG-100MG	
		Professional	Seresta (Oxazepam) Tablets	SS		INTRA-UTERINE	30 MG, 1 IN 1	DAY,
			Zyprexa (Olanzapine) Tablets	SS		INTRA-UTERINE	2.5 MG, 1 IN	1 DAY,
			Nefadar (Nefazodone Hydrochloride) Tablets	SS		INTRA-UTERINE	100-100MG/DAI	LY
			Efexor (Venlafaxine Hydrochloride) Capsule	SS		INTRA-UTERINE	75 MG, 1 IN 1	DAY,
			Mefenamic Acid (Mefenamic Acid) Tablets	SS		INTRA-UTERINE	500 MG, 4 IN	1 MONTH,
			Trittico (Trazodone Hydrochloride)			INTRA-UTERINE		

				Tablets	SS		
150-100MG/DAI LY							
				Entumine (All Other Therapeutic Products) Tablets	SS		
INTRA-UTERINE	40 MG, 1 IN 1 DAY,						
INTRA-UTERINE				Primperan (Metoclopramide) Tablets	SS		
INTRA-UTERINE	10 MG, 1 IN 1 , INTRA-URINE						
				Prazine (Promazine Hydrochloride) Tablets	SS		
INTRA-UTERINE	50 MG, 1 IN 1 DAY,						
INTRA-UTERINE							

Date:07/25/03ISR Number: 4153901-6Report Type:Direct Company Report #CTU 198662
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dystonia Hypertension		Metoclopramide 10mg Sidmak	PS	Sidmak	ORAL	5MG TID ORAL	
	Muscle Spasms Tremor		Prevacid Buspar Celexa Magaldrate/Simethicone Mom Senokot Docusate	C C C C C C C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/25/03ISR Number: 4157540-2Report Type:Expedited (15-DaCompany Report #HQWYE830822APR03
Age:53 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Activities Of Daily Living Impaired Affective Disorder Anxiety Blepharospasm Claustrophobia Depression Disturbance In Attention Diverticulum Intestinal Dysgraphia Dysphonia Dyspnoea Dystonia Lethargy Muscle Spasms Nervousness Oral Pain Panic Disorder With Agoraphobia Parkinsonism Rash Somnolence Tardive Dyskinesia Trismus	Consumer	Metoclopramide (Metoclopramide Hydrochloride, Tablet) Reglan (Metoclopramide Hydrochloride, Tablet) Avandia (Rosiglitazone Maleate) Hydrochlorothiazide (Hydrochlorothtiazide) Prevacid (Lansoprazole) Glucotrol (Glipizide) Zestril (Lisinopril) Flovent (Fluticasone Propionate) Allegra-D (Fexofenadine Hydrochloride/Pseudoephedrine Hydrochloride) Serevent (Salmeterol Xinafoate) Cephalexin (Cefalexin) Erythromycin (Erythromycin) Premarin (Conjugated Estrogens) Prometrium (Progesterone)	PS SS C C C C C C C C C C		ORAL ORAL	20 MG BEFORE MEALS AND AT BEDTIME, ORAL SEE IMAGE	

Date:07/28/03ISR Number: 4158275-2Report Type:Expedited (15-DaCompany Report #200214592FR
Age:34 YR Gender:Female I/FU:F

Outcome	PT
Congenital Anomaly	Abortion Induced
Other	Complications Of Maternal
	Exposure To Therapeutic
	Drugs
	Congenital Arterial
	Malformation
	Congenital Central
	Nervous System Anomaly
	Congenital
	Musculoskeletal Anomaly
	Congenital Scoliosis
	Deformity Thorax
	Facial Dysmorphism
	Foetal Disorder

		Hemivertebra Maternal Drugs Affecting Foetus	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
		Micrognathia Multiple Congenital	Foreign Health	Glimepiride (Amarel) Tablets	PS		ORAL
1 U/DAY PO							
		Abnormalities Pregnancy On Oral	Professional Other	Levothyroxine Sodium (Levothyrox) Tablets	SS		ORAL
PO							
		Contraceptive Renal Agenesis Retrognathia		Metformin Hydrochloride Tablets	SS		ORAL
1700 MG/DAY							
		Skull Malformation					
PO							
				Migpriv Powder For Oral Solution	SS		ORAL
PRN PO							
				Hydroxyzine Hydrochloride (Atarax)	SS		
				Omeprazole (Mopral)	C		

Date:07/29/03ISR Number: 4164611-3Report Type:Expedited (15-DaCompany Report #2003-05-0743
Age: Gender: I/FU:F

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Other		Tardive Dyskinesia	Health Professional	Intron A (Interferon Alfa-2b Recombinant) Injectable	PS		
				Reglan	SS		

Date:07/31/03ISR Number: 4158692-0Report Type:Direct Company Report #CTU 198973
Age:33 YR Gender:Female I/FU:I

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Life-Threatening		Aphasia		Reglan	PS		
10 MG 4 X							
Other		Bite					
DAILEY							

Required Intervention to Prevent Permanent Impairment/Damage	Bruxism Dyskinesia Hypoaesthesia Muscle Disorder Muscle Twitching Tremor Trismus

Date:08/04/03ISR Number: 4161301-8Report Type:Direct Company Report #USP 50402
Age:82 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Medication Error		Tofranil	PS	Biocraft			
SEE IMAGE								
			Reglan	SS	Biocraft			
SEE IMAGE								

Date:08/04/03ISR Number: 4161452-8Report Type:Direct Company Report #USP 50438
Age:71 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Medication Error		Reglan Iv	PS	Robins			
INTRAVENOUS	IV							

Date:08/05/03ISR Number: 4165850-8Report Type:Expedited (15-DaCompany Report #FRWYE236830JUL03
Age:70 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Agranulocytosis Bone Marrow Toxicity Infection Pyrexia	Health Professional Other	Tazocilline (Piperacillin/Tazobactam)	PS		INTRAVENOUS	4 G 3X PER 1 DAY	24 DAY
			Ciflox (Ciprofloxacin)	SS		INTRAVENOUS	200 MG 2X PER 1 DAY	24 DAY
			Mopral (Omeprazole)	SS		OTHER	20 MG 1X PER 1 DAY	22 DAY
			Primperan (Metoclopramide)	SS		INTRAVENOUS		24 DAY
			Actrapid Penfill (Insulin Human)	C				
			Acupan (Nefopam Hydrochloride)	C				
			Paracetamol (Paracetamol)	C				
			Morphine (Morphine)	C				
			Spasfon (Phloroglucinol/Trimethylphloroglucinol)	C				
			Imodium (Loperamide Hydrochloride)	C				
			Heparine (Heparin)	C				

Date:08/07/03ISR Number: 4166746-8Report Type:Expedited (15-DaCompany Report #HQWYE904005AUG03
Age:54 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Confusional State Drug Toxicity Hepatic Failure	Health Professional Other	Ketoprofen (Ketoprofen, Capsule, Sustained					

	Jaundice Lethargy Myalgia Renal Failure Acute	Release)	PS	ORAL
		Dothiepin Hydrochloride (Dothiepin Hydrochloride,)	SS	ORAL
150 MG				
		Metoclopramide (Metoclopramide,)	SS	ORAL
30 MG				
		Monofeme-28 (Levonorgestrel/Ethinyl Estradiol/Inert, Tablet)	SS	
1 DOSE				
		Normison (Temazepam, Capsule)	SS	
UNKNOWN				
		Panadeine Forte (Codeine Phosphate/Paracetamol,)	SS	
"PROBABLY AT LEAST 4 GRAMS A DAY"				
		Ranitidine (Ranitidine,)	SS	
UNKNOWN				
		Serepax (Oxazepam, Capsule)	SS	ORAL
AS NEEDED				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/14/03ISR Number: 4170806-5Report Type:Expedited (15-DaCompany Report #2003AP02448
Age:70 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anorexia	Foreign	Iressa	PS		ORAL	250 MG DAILY	
	Base Excess	Health					PO	
	Blood Ph Decreased	Professional	Iressa	SS		ORAL	250 MG DAILY	
	C-Reactive Protein	Other					PO	
	Increased		Dogmatyl	SS		ORAL	150 MG DAILY	
	Disease Recurrence						PO	
	Dyskinesia		Loxonin	SS		ORAL	3 DF DAILY PO	
	Dyspnoea		Loxonin	SS		ORAL	3 DF DAILY PO	
	Haemodialysis		Loxonin	SS		ORAL	3 DF DAILY PO	
	Laboratory Test Abnormal		Voltaren					
	Liver Function Test		"Ciba-Geigy"	SS			SUBCUTANEOUS	50 MG DAILY
	Abnormal						SC	
	Lung Neoplasm Malignant		Mobic	SS		ORAL	1 DF DAILY PO	
	Malaise		Hypen	SS		ORAL	400 MG DAILY	
	Pco2						PO	
	Po2		Primperan	SS		ORAL	2 DF DAILY PO	
	Pyuria		Norvasc	C				
	Rash		Gaster	C				
	Renal Failure Acute		Lendormin	C				
	Renal Hypertrophy		Alfarol	C				
	Renal Tubular Necrosis		Cravit	C				
	Spinal Compression Fracture							
	Tremor							
	Urinary Tract Infection							

Date:08/19/03ISR Number: 4174025-8Report Type:Expedited (15-DaCompany Report #HQWYE904005AUG03
Age:54 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Drug Toxicity	Health	Ketoprofen	PS		ORAL		
	Hepatic Failure	Professional						
(THERAPY								
	Renal Failure Acute	Other						
DURATION:								
LONG TERM)								
			Dothiepin Hydrochloride	SS		ORAL	150 MG	
			Metoclopramide	SS		ORAL	30 MG	
			Monofeme-28	SS			1 DOSE	
			Normison	SS				
			Panadeine Forte	SS			"PROBABLY AT	
LEAST 4 GRAMS								
A DAY"								
			Ranitidine	SS				
			Serepax (Oxazepam)	SS		ORAL	AS NEEDED	

Date:08/22/03ISR Number: 4177279-7Report Type:Expedited (15-DaCompany Report #200317421US
Age:39 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Glucose Increased	Consumer	Insulin Glargine (Lantus) Solution For Injection	PS				
	Drug Ineffective							
	Hypoaesthesia						32 U QAM	1 YR
	Hypoglycaemia		Metoclopramide (Reglan) Tablets	SS		ORAL	20 MG QID PO	
			Metoclopramide (Reglan) Tablets	SS			10 MG QID	

Tegaserod	C
Losartan Potassium (Cozaar)	C
Insulin Aspart (Novolog)	C
Lexapro	C
Esomeprazole (Nexium)	C
Multivitamin	C

Date:08/25/03ISR Number: 4173799-XReport Type:Direct Company Report #CTU 200581
Age:34 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Agitation		-Reglan-					
Hospitalization -	Asthenia		Metoclopramide	10mg				
Initial or Prolonged	Balance Disorder		Purepac	PS		ORAL	10 MG	3 X
Disability	Burning Sensation							DAY
ORAL								
Required	Condition Aggravated							
Intervention to	Convulsion							
Prevent Permanent	Coordination Abnormal							
Impairment/Damage	Discomfort							
	Disturbance In Attention							
	Dizziness							
	Drug Ineffective							
	Dyskinesia							
	Dysphemia							
	Dyspnoea							
	Dystonia							
	Economic Problem							
	Fatigue							
	Feeling Abnormal							
	Head Injury							
	Headache							
	Heart Rate Increased							
	Hypervigilance							
	Memory Impairment							
	Mental Impairment							
	Movement Disorder							
	Muscle Spasms							
	Muscle Tightness							
	Musculoskeletal Stiffness							

Myocardial Infarction
Nausea
Neck Pain
Nervous System Disorder
Pain
Palpitations
Paraesthesia
Parkinson'S Disease
Post-Traumatic Stress
Disorder
Psychomotor Hyperactivity
Pulse Pressure Increased
Restlessness
Sensation Of Pressure
Tremor
Vertigo

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/25/03ISR Number: 4173802-7Report Type:Direct Company Report #CTU 200579
Age:33 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Supraventricular Tachycardia		Metoclopramide 10mg/2ml Abbott	PS	Abbott	INTRAVENOUS	10MG Q6H	Required
Intervention to Prevent Permanent Impairment/Damage			Protonix 40mg Wyeth	SS	Wyeth	DRIP	80 MG Q24HRS	
			Zofran	C				

Date:08/25/03ISR Number: 4178190-8Report Type:Expedited (15-DaCompany Report #C-03-0047
Age:10 MON Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Haematochezia	Other	Metoclopramide Oral Solution, Usp 5 Mg/Ml	PS				
			Zantac	C				

Date:08/28/03ISR Number: 4182247-5Report Type:Expedited (15-DaCompany Report #2003173329AU
Age:71 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Haematemesis	Foreign Health Professional	Celebrex (Celecoxib) Capsule	PS		ORAL	200 MG, QD,	
		Other	Metoclopramide Hydrochloride					

	(Metoclopramide Hydrochloride)	SS
30 MG, QD,		
	Oxycontin (Oxycodone Hydrochloride)	SS
30 MG, QD,		
	Prednisone (Prednisone)	SS
	Cyprone	C
	Sertraline (Sertraline)	C

Date:09/02/03ISR Number: 4178572-4Report Type:Direct Company Report #CTU 201146
Age:8 YR Gender:Female I/FU:I

Outcome	PT
Required	Abnormal Behaviour
Intervention to	Anxiety
Prevent Permanent	Confusional State
Impairment/Damage	Dyspnoea
	Fear
	Generalised Anxiety
	Disorder
	Insomnia
	Obsessive-Compulsive
	Disorder
	Pharmaceutical Product
	Complaint
	Psychotic Disorder

	Screaming Suicidal Ideation Thinking Abnormal	Report Source	Product	Role	Manufacturer	Route	Dose Duration
			Metoclopramide Pliva (Formerly Sidma)	PS	Pliva (Formerly Sidma)		5 MG TAB. 1/2 DAILY

Date:09/02/03ISR Number: 4183662-6Report Type:Expedited (15-DaCompany Report #USA-2002-0001677
Age:41 YR Gender:Female I/FU:F

Outcome	PT
Death	Alopecia
Hospitalization - Initial or Prolonged	Angiopathy
	Anxiety
	Asthenia
	Back Pain
	Cardiac Enzymes Increased
	Chest Pain
	Coma
	Depressed Mood
	Diabetes Mellitus
	Disturbance In Attention
	Drug Ineffective
	Dyspnoea
	Emphysema
	Fatigue
	Finger Deformity
	Flushing
	Hilar Lymphadenopathy
	Hyperglycaemia
	Hyperhidrosis
	Hyperventilation
	Hypoxia
	Influenza
	Insomnia
	Irritability
	Libido Decreased
	Lobar Pneumonia
	Lung Disorder
	Nausea
	Nervousness

Night Sweats
Overdose
Pain
Peripheral Occlusive Disease
Pleurisy
Portal Triaditis
Pruritus
Pulmonary Congestion
Pulmonary Oedema
Pulse Absent
Rash Pruritic
Rash Scaly
Somnolence
Troponin Increased
Upper Respiratory Tract Infection
Urinary Incontinence

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Weight Increased

Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Consumer Health Professional Other	Oxycontin Tablets 10 Mg(Oxycodone Hydrochloride) Cr Tablet	PS			10 MG	
	Oxycontin Tablets 20 Mg (Oxycodone Hydrochloride) Cr Tablet	SS			20 MG	1008 DAY
	Hydrocodone Bitartrate(Similar To Ind 59,175)(Hydrocodone Bitartrate)	SS			1008 DAY	
	Alprazolam(Alprazolam)	SS			1008 DAY	
	Ephedrine(Ephedrine)	SS			1008 DAY	
	Pseudoephedrine(Pseudoephedrine)	SS			1008 DAY	
	Effexor (Venlafaxine Hydrochloride)	SS			75 MG, DAILY	1008 DAY
	Codeine (Codeine)	SS			1008 DAY	
	Neurontin (Gabapentin)	SS			100 MG, TID	1008 DAY
	Metoclopramide (Metoclopramide)	SS			1008 DAY	
	Quetiapine (Quetiapine)	SS			1008 DAY	
	Claritin (Loratadine)	C				
	Vitamin C (Ascorbic Acid)	C				
	Celebrex (Celecoxib)	C				

Prilosec (Omeprazole)	C
Daypro (Oxaprozin)	C
Trandate (Labetalol Hydrochloride)	C
Axid (Nizatidine)	C
Paxil (Paroxetine Hydrochloride)	C
Medrol (Methylprednisolone)	C
Macro Antioxidant (Ascorbic Acid, Cystine, Tocopherol, Calcium Ascorbate, Betacarotene,	C
Zocor (Simvastatin)	C
Risperidal (Risperidone)	C
Fioricet (Butalbital)	C
Flonase (Fluticasone Propionate)	C
Phenobarbital (Phenobarbital)	C
Donnatal (Atropine Sulfate, Hyoscine	

Hydrobromide, Hyoscyamine Sulfate, Phenobarbital)	C
Bellergal-S (Belladonna Alkaloids, Ergotamine Tartrate, Phenobarbital)	C
Weight Loss Supplement (Does Not Code)	C
Ibuprofen	C
Ambien (Zolpidem Tartrate)	C
Baclofen (Baclofen)	C
Trandate (Labetalol Hydrochloride)	C
Celexa (Citalopram Hydrobromide)	C
Cortisone (Cortisone)	C
Atarax (Hydroxyzine Hydrochloride)	C
Proventil Tablet (Salbutamol Sulfate)	C
Amitriptyline (Amitriptyline)	C
Cyclobenzaprine (Cyclobenzaprine)	C
Augmentin (Amoxicillin Trihydrate, Clavulanate Potassium)	C
Ergobel (Nicergoline)	C
Glucotrol Xl (Glipizide) Tablet	C
Humuline Nph (Insulin Human Injection, Isophane) Injectable	C
Capoten Tablet	C
Albuterol (Salbutamol) Inhaler	C
Azmacort (Triamcinolone Acetonide) Inhaler	C

Aciphex (Rabeprazole Sodium) Tablet	C
Seroquel (Quetiapine) Tablet	C

Date:09/02/03ISR Number: 4183739-5Report Type:Expedited (15-DaCompany Report #DSA_23166_2003
Age:38 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Fatigue	Foreign	Tavor	PS		ORAL	10 MG ONCE PO	
	Intentional Misuse	Health	Hyoscine	SS		ORAL	90 MG ONCE PO	
	Vomiting	Professional	Metoclopramide	SS		ORAL	120 MG ONCE PO	
		Other						

			Oxazepam	SS		ORAL
2500 MG ONCE PO						

Date:09/03/03ISR Number: 4184726-3Report Type:Expedited (15-DaCompany Report #C-03-0047
Age:10 MON Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Diarrhoea Haemorrhagic Pruritus Ani Underweight	Health Professional Other	Metoclopramide Oral Solution, Usp 5 Mg/5ml (Mgp Product Code: 7622)	PS		ORAL
0.5 CC THREE TIMES A DAY, VIA NASOGASTRIC TUBE						
			Digoxin	C		
			Furosemide	C		
			Ranitidine	C		
			Omeprazole	C		

Date:09/03/03ISR Number: 4184925-0Report Type:Expedited (15-DaCompany Report #USA-2003-0009283
Age:34 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other Required Intervention to Prevent Permanent Impairment/Damage	Convulsion Heart Rate Decreased Hypotension Hypoventilation Miosis	Consumer Other	Oxycontin Tablets (Oxycodone Hydrochloride) Cr Tablet	PS		ORAL
60 MG, SEE TEXT, ORAL						
	Pain Post Procedural		Reglan (Metoclopramide)	SS		
INTRAVENOUS 10 MG, SEE						

Complication
TEXT,
Respiratory Arrest
INTRAVENOUS
Demerol (Pethidine Hydrochloride) SS
INTRAMUSCULAR 75 MG, SEE
TEXT,
INTRAMUSCULAR
Phenergan () SS
INTRAMUSCULAR 25 MG, SEE
TEXT,
INTRAMUSCULAR

Date:09/04/03ISR Number: 4179878-5Report Type:Direct Company Report #CTU 201302
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dehydration		Iressa	PS		ORAL	250 MG QD PO	
	Diarrhoea		Cisplatin	SS		INTRAVENOUS	44 MG QD IV	
	Renal Failure Acute		5-Fluorouracil	SS		INTRAVENOUS	2200 MG QD IV	
	Retching		Atenolol	SS		ORAL	100 MG QD PO	
			Nexium	SS		ORAL	40 MG BID PO	
			Reglan	SS		ORAL	10 MG QID PO	
			Megace	SS		ORAL	80 MG BID PO	
			Diovan Hctz	SS			QD PO	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/04/03ISR Number: 4179943-2Report Type:Direct Company Report #USP 042203
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Medication Error		Reglan	PS	Robins/Elkins-Sinn		AMP	
			Lanoxin	SS	Burroghus Wellcome		AMP	

Date:09/08/03ISR Number: 4180895-XReport Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0307854A
Age:53 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Death		Deroxat	PS	Glaxosmithkline	ORAL	23	DAY
Life-Threatening	Thrombocytopenia		Tavanic	SS		ORAL	1UNIT Per day	8 DAY
Hospitalization -			Primperan	SS	Glaxosmithkline	ORAL	23	DAY
Initial or Prolonged			Rivotril	SS		ORAL	20DROP Per	
							day	21 DAY
			Solumedrol	SS			INTRAVENOUS	120MG Per day
			Morphine	SS			SUBCUTANEOUS	10MG Twice
							per day	

Date:09/08/03ISR Number: 4180925-5Report Type:Expedited (15-DaCompany Report #DE-GLAXOSMITHKLINE-D0041826A
Age:44 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Burning Sensation		Zinacef	PS	Glaxosmithkline		INTRAVENOUS	1.5G Twice
Initial or Prolonged	Chills						per day	2 DAY
	Conjunctivitis		Fragmin P	SS			SUBCUTANEOUS	1AMP Per day 13 DAY

		Mucosa Vesicle	Paspertin	SS	Glaxosmithkline		
INTRAVENOUS	1AMP Twice						
		Mucosal Erosion					
per day	1 DAY						
		Ocular Hyperaemia	Acc	SS	Glaxosmithkline		
INTRAVENOUS	1AMP Twice						
		Pneumonia					
per day	3 DAY						
		Pyrexia	Euthyrox	SS	Glaxosmithkline	ORAL	
50UG Per day							
		Stevens-Johnson Syndrome	Ben-U-Ron	SS	Glaxosmithkline		
UNKNOWN	1SUP Per day						
		Swelling Face	Paspertin	SS	Glaxosmithkline	ORAL	
20DROP Three							
		Varicella					
times per day	1 DAY						
			Acc	SS	Glaxosmithkline	ORAL	
1BAG Three							
times per day	1 DAY						
			Orelox	SS		ORAL	
200MG Twice							
per day	7 DAY						
			Adumbran	SS		ORAL	
1TAB At night							
			Mucosolvan	SS	Glaxosmithkline	ORAL	
10ML Three							
times per day	2 DAY						
			Mucosolvan	SS	Glaxosmithkline		
RESPIRATORY							
(INHALATION)	1U Twice per						
day	7 DAY						
			Hydrocodein	SS		ORAL	
20DROP per							
day	4 DAY						
			Dynexan	C			
TRANSDERMAL							

Date:09/08/03ISR Number: 4181076-6Report Type:Expedited (15-DaCompany Report #FR-ROCHE-345795
Age:6 DY Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Agitation Neonatal		Rocephine	PS	Roche			
INTRAVENOUS							4	DAY

Initial or Prolonged	Feeding Problem In	Amiklin	SS	
INTRAVENOUS	2 DAY			
	Newborn	Primperan	SS	ORAL
4 DAY				
	Methaemoglobinaemia	Vitamin K1	C	
UNKNOWN				
	Neonatal Disorder	Claforan	C	
UNKNOWN	2 DAY			
		Gaviscon	C	ORAL
REPORTED AS 1				

ML 6 TIME. 6 DAY

			Zymaduo	C		ORAL
			Clamoxyl	C		
UNKNOWN						
			Un-Alfa	C		
UNKNOWN						

Date:09/08/03ISR Number: 4185835-5Report Type:Expedited (15-DaCompany Report #2003174659FR
Age:53 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Thrombocytopenia	Foreign	Solu-Medrol			
Life-Threatening		Health	(Methylprednisolone)			
		Professional	Powder, Sterile	PS		
INTRAVENOUS 120 MG, IV						
		Other	Tavanic			
			(Levofloxacin)	SS		ORAL
1 DF, ORAL						
			Primperan			
			(Metoclopramide)	SS		ORAL
100 MG, ORAL						
			Derotax	SS		ORAL
20 MG , UNK,						
ORAL						
			Morphine (Morphyine)	SS		ORAL
20 MG, UNK						
ORAL						
			Rivotril			
			(Clonazepam)	SS		ORAL
50 MG, ORAL						
			Mannitol	C		

Date:09/08/03ISR Number: 4186045-8Report Type:Expedited (15-DaCompany Report #002#4#2003-00432(0)
Age:37 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Asthenia	Consumer	Reglan - 10mg -			
Initial or Prolonged	Hypoaesthesia	Other	Tablet			

	Hypoglycaemia		(Metoclopramide Hcl)	PS		ORAL
20 MG, 4 IN 1						
D ORAL						
			Insulin	SS		
SUBCUTANEOUS	32IU/ML, 1 IN					
1 D,						
SUBCUTANEOUS						
			Insulin Aspart	C		
			Escitalopram	C		
			Esomeprazole	C		
			Tegaserod	C		

Date:09/10/03ISR Number: 4186698-4Report Type:Direct Company Report #CTU 201596
Age:71 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Drug Ineffective		Metoclopramide 5 Mg			
	Unevaluable Event		Sidmak	PS	Sidmak	
1 TAB 4X A						
DAY						

Date:09/10/03ISR Number: 4188843-3Report Type:Expedited (15-DaCompany Report #2003175304DE
Age:73 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Multi-Organ Failure	Foreign	Fragmin P			
Life-Threatening	Pulmonary Function Test	Health	(Delteparin Sodium)			
	Decreased	Professional	Solution, Sterile			
	Toxic Epidermal		2500iu	PS		
SUBCUTANEOUS	2500 IU, QD,					
	Necrolysis					
SUBCUTANEOUS						
			Ciprobay			

		(Ciprofloxaxin)	SS	ORAL
ORAL				
		Lasix (Furosemide)	SS	
INTRAVENOUS	IV			
		Norvasc (Amlodipine Besilate)	SS	ORAL
ORAL				
		Novodigal (Digoxin)	SS	ORAL
ORAL				
		Corvation Slow Release (Hoechst) (Molsidomine)	SS	ORAL
ORAL				
		Insulin (Insulin)	SS	
SUBCUTANEOUS	SUBCUTANEOUS			
		Amaryl (Glimepiride)	SS	ORAL
ORAL				
		Sortis "Parke-Davis" (Atorvastatin Calcium)	SS	ORAL
ORAL				
		Diazepam (Diazepam)	SS	ORAL
ORAL				
		Mediabet (Metformin Hydrochloride)	SS	ORAL
ORAL				
		Concor (Bisoprolol Fumarate)	SS	ORAL
ORAL				
		Capothexal (Captopril)	SS	ORAL
QD ORAL				
		Delix (Ramipril)	SS	ORAL
ORAL				
		Acetylsalicylic Acid (Acetylsalicylic Acid)	SS	ORAL
QD ORAL				
		Pantozol (Pantoprazole Sodium)	SS	ORAL
ORAL				
		Irenat (Sodium Perchlorate)	SS	ORAL
ORAL				
		Carbimazole (Carbimazole)	SS	ORAL
ORAL				

		Rocephin (Ceftriazone Sodium)	SS	
INTRAVENOUS	2 G QD IV			
		Decortin (Prednisone)	SS	
INTRAVENOUS	50 MG QD IV			
		Mono Mack (Isosorbide Mononitrate)	SS	ORAL
ORAL				
		Ampho -Moronal (Amphotericin B)	SS	
		Mcp "Hexal" (Metoclopramide Hydrochloride)	SS	ORAL
ORAL				
		Plavix (Clopidogrel Sulfate)	SS	ORAL
ORAL				
		Eunerpan (Melperone Hydrochloride)	SS	ORAL
ORAL				
		Tranxilium (Clorazepate Dipotassium)	SS	ORAL
ORAL				
		Ben-U-Ron (Paracetamol)	SS	ORAL
ORAL				
		Perenterol (Yeast Dried)	SS	ORAL
ORAL				
		Zaroxolyn (Metolazone)	SS	ORAL
ORAL				
		Kalium-Duriles	C	
		Lexotanil	C	
		Haldol	C	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/11/03ISR Number: 4186079-3Report Type:Direct Company Report #USP 042183
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Medication Error		Phenylephrine Hcl	PS	Gensia		INJECTABLE	
			Metoclopramide Hcl	SS	Gensia		INJECTABLE	

Date:09/11/03ISR Number: 4189449-2Report Type:Expedited (15-DaCompany Report #2003175309DE
Age:44 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Burning Sensation	Foreign	Fragmin P(Dalteparin Soidum) Solution, Sterile	PS		ORAL	1 AMP, DAILY,	
	Conjunctivitis	Health					ORAL	
	Erythema Multiforme	Professional						
	Ocular Hyperaemia	Other						
	Oedema Mouth		Adumbran(Oxazepam)	SS		ORAL	ORAL	
	Swelling Face		Orelox (Cefpodoxime Proxetil)	SS		ORAL	ORAL	
			Acc For Injection (Acetylcysteine Sodium)	SS			INTRAVENOUS	2 AMP, DAILY,
							IV	
			Zinacef(Cefuroxime)	SS			3G. DAILY	
			Ben-U-Ron(Paracetamol) Suppository	SS			RECTAL	RECTAL
			Paspertin(Metoclopramide Hydrochloride)	SS			INTRAVENOUS	IV
			Euthyrox(Levothyroxine Sodium) Tablet	SS		ORAL	1 DF, DAILY,	
							ORAL	

			Acc(Acetylcysteine)	SS		ORAL	ORAL
			Mucosolvan(Ambroxol Hydrochloride)	SS		ORAL	ORAL
			Codeine Phosphate (Codeine Phosphate)	SS		ORAL	ORAL

Date:09/12/03ISR Number: 4190287-5Report Type:Expedited (15-DaCompany Report #2003175307DE
Age:71 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Epidermolysis Erythema Multiforme Pulmonary Embolism Stevens-Johnson Syndrome Toxic Epidermal Necrolysis	Foreign Health Professional Other	Sobelin Solubile 300/600/900(Clindamycin) Solution, Sterile	PS		INTRAVENOUS	600 MG, QD, IV	
			Bifiteral(Lactulose)	SS		ORAL	ORAL	
			Beloc Zok(Metoprolol Succinate)	SS		ORAL	ORAL	
			Lasix(Furosemide)	SS		ORAL	ORAL	
			Kalinor(Potassium Chloride)	SS		ORAL	ORAL	
			Rocephin(Ceftriaxone Sodium)	SS		INTRAVENOUS	IV	
			Refobacin(Gentamicin Sulfate)	SS		INTRAVENOUS	IV	
			Liquemin(Heparin)	SS		SUBCUTANEOUS	5000 U, BID, SUBCUTANEOUS	
			Omeprazole(Omeprazole)	SS		ORAL	ORAL	
			Adumbran(Oxazepam)	SS		ORAL	1 DF, QD,	

ORAL			
		Tramal(Tramadol Hydrochloride)	SS	ORAL
ORAL				
		Novalgin(Metamizole Sodium)	SS	ORAL
ORAL				
		Ben-U-Ron(Paracetamol)	SS	
RECTAL	RECTAL			
		Vancomycin(Vancomycin)	SS	
INTRAVENOUS	1 G, QD, IV			
		Vomex A "Endopharm" (Dimenhydrinate)	SS	
RECTAL	1 DF, QD,			
RECTAL				
		Paspertin(Metoclopramide Hydrochloride)	SS	ORAL
ORAL				
		Saroten(Amitriptyline Hydrochloride)	SS	ORAL
ORAL				
		Irenat(Sodium Perchlorate)	SS	ORAL
ORAL				
		Staphylex (Flucloxacillin Sodium)	C	
		Mono-Embolex (Heparin-Fraction, Sodium Salt)	C	
		Magnesium	C	
		Pantozol (Pantoprazole Sodium)	C	
		Psyquil (Triflupromazine)	C	
		Fenistil (Dimetindene Maleate)	C	
		Morphine	C	

Date:09/16/03ISR Number: 4191010-0Report Type:Direct Company Report #USP 080575
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Blood Pressure Increased		Metoclopramide	PS			TAB	
	Medication Error		Atenolol	SS			TAB	

Date:09/16/03ISR Number: 4191066-5Report Type:Direct Company Report #USP 081163
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Medication Error		Metoclopramide 10 Mg Tablets	PS	Apothecon		TABLET	
			Furosemide 20 Mg Tablets	SS	Geneva		TABLET	

Date:09/17/03ISR Number: 4188713-0Report Type:Expedited (15-DaCompany Report #FR-BRISTOL-MYERS SQUIBB COMPANY-12374690
Age:5 DY Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Methaemoglobinaemia Neonatal Disorder		Amiklin Inj 50mg/Ml	PS	Geneva Pharmaceuticals Technology, Corp.		INTRAVENOUS	2 DAY
			Primperan	SS		ORAL	4 DAY	

				Rocephine	SS		
INTRAVENOUS	4 DAY						
				Clamoxyl	C		
				Zymaduo	C		
				Gaviscon	C		
				Un-Alfa	C		
				Vitamin K	C		

Date:09/17/03ISR Number: 4191436-5Report Type:Expedited (15-DaCompany Report #A04200300550
Age:73 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Diarrhoea	Health	Plavix -					
Hospitalization -	Erythema	Professional	(Clopidogrel					
Initial or Prolonged	Hypertension		Sulfate) - Tablet -					
	Multi-Organ Failure		75 Mg	PS		ORAL	(SEE IMAGE)	
	Pain		Tranxillium -					
	Pyrexia		(Clorazepate					
	Respiratory Disorder		Dipotassium) -					
	Toxic Epidermal		Tablet - 10 Mg	SS		ORAL	SEE IMAGE	
	Necrolysis		(Diazepam) - Tablet					
			- 5 Mg	SS		ORAL	SEE IMAGE	
			(Acetylsalicylic					
			Acid) - Tablet - 100					
			Mg	SS		ORAL	SEE IMAGE	
			Ciprobay -					
			(Ciprofloxacin					
			Hydrochloride) -					
			Tablet - 500 Mg /					
			Tablet - 250 Mg	SS		ORAL	SEE IMAGE	
			Rocephin -					
			(Ceftriaxone Sodium)					
			- Solution - 1g	SS				
INTRAVENOUS	SEE IMAGE							
			Solu-Decortin-H -					
			(Prednisolone Sodium					
			Succinate) -					
			Solution - 50 Mg	SS				
INTRAVENOUS	SEE IMAGE							

		Fragmin - (Heparin-Fraction, Sodium Salt) - Solution - 2500 Iu			
SUBCUTANEOUS	SEE IMAGE	Axa	SS		
		Lasix - (Furosemide) - Solution - 40 Mg	SS		
INTRAVENOUS	SEE IMAGE				
		Norvasc - (Amlodipine Besilate) - Tablet - 5 Mg	SS		ORAL
SEE IMAGE					
		Novodigal - (Digoxin) - Tablet - 0.2 Mg	SS		ORAL
SEE IMAGE					
		Corvaton - Slow Release "Aventis Pharma" - (Molsidomine) - Tablet Pr - 8 Mg	SS	Aventis Pharma	ORAL
SEE IMAGE					
		Mono Mack - (Isosorbide Mononitrate) - Tablet - Unit Dose: Unknown	SS		ORAL
SEE IMAGE					

	Ampho Moronal "Bristol-Myers Squibb" - (Amphotericin B) - Suspension - 100	SS	Bristol-Myers Squibb	ORAL	
SEE IMAGE					
	(Metoclopramide) - Drops - 5.2 Mg/Ml	SS		ORAL	
SEE IMAGE					
	Eunerpan - (Melperone Hydrochloride) - Suspension - 5 Mg/Ml	SS		ORAL	
SEE IMAGE					
	Ben-U-Ron - (Paracetamol) - Tablet - 500 Mg	SS		ORAL	
SEE IMAGE					
	Perenterol - (Yeast Dried) - Capsule - 50 Mg	SS		ORAL	
SEE IMAGE					
	Zaroxolyn - (Metolazone) - Tablet - 2.5 Mg	SS		ORAL	
SEE IMAGE					
	Lantus (Insulin Glargine)	C			
	Amaryl (Glimepiride)	C			
	Sortis (Atorvastatin Calcium)	C			
	Mediabet (Metformin Hydrochloride)	C			
	Concor (Bisoprolol Fumarate)	C			
	Captohexal (Captopril)	C			
	Delix 5 (Ramipril)	C			
	Pantozol (Pantoprazole Sodium)	C			
	Irenat (Sodium Perchlorate)	C			
	Carbimazol (Carbimazol)	C			
	Kalium Duriles (Potassium Chloride)	C			

Lexotanil (Bromazepam)	C
Haldol (Haloperidol)	C

Date:09/17/03ISR Number: 4192248-9Report Type:Expedited (15-DaCompany Report #HQWYE605910SEP03
Age: Gender:Female I/FU:I

Outcome	PT
Other	Abdominal Pain
	Asthenia
	Choking
	Condition Aggravated
	Dysarthria
	Dysphagia
	Dyspnoea
	Fatigue
	Gastrooesophageal Reflux
	Disease
	Insomnia

	Tardive Dyskinesia Throat Tightness Tongue Disorder	Report Source	Product	Role	Manufacturer	Route	Dose Duration
		Consumer	Metoclopramide	PS		ORAL	
			Metoclopramide (Metoclopramide,)	SS		ORAL	

Date:09/19/03ISR Number: 4189307-3Report Type:Expedited (15-DaCompany Report #PHBS2003CH08887
Age:59 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Coma Status Epilepticus		Zelmac	PS	Novartis Sector: Pharma		6 mg/day
			Paspertin	SS			Other 6.7 mg, TID
			Voltaren	SS			UNK, UNK
			Pantozol	C			40 mg/day
			Clopamide	C			

Date:09/22/03ISR Number: 4190450-3Report Type:Expedited (15-DaCompany Report #DE-BRISTOL-MYERS SQUIBB COMPANY-12380408
Age:73 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Death	Diarrhoea		Ampho-Moronal Os	PS	Apothecon	ORAL	
Hospitalization - Initial or Prolonged	Multi-Organ Failure Nausea Restlessness Toxic Epidermal Necrolysis		Plavix Tabs	SS	Regulatory Health Authority South Africa	ORAL	500 mg twice daily from 20-Jun-2001
			Diazepam	SS		ORAL	
			Ben-U-Ron	SS		ORAL	
			Tranxilium	SS		ORAL	
			Acetylsalicilic Acid	SS		ORAL	
			Ciprobay	SS		ORAL	

to			
28-Jun-2001,			
INTRAVENOUS		Rocephin	SS
INTRAVENOUS		Solu-Decortin-H	SS
SUBCUTANEOUS		Fragmin	SS
INTRAVENOUS	dose ranged	Lasix	SS
from 80-120			
mg daily		Norvasc	SS ORAL
		Novodigal	SS ORAL
		Corvaton	SS ORAL
dose reduced			
from 16 to 8			
mg daily		Mono Mack	SS ORAL
		Metoclopramide	SS ORAL
		Eunerpan	SS ORAL
dose ranged			
from 80-105			
mg daily		Perenterol	SS ORAL
100 mg to 300			
mg		Zaroxolyn	SS ORAL
		Lantus	C
SUBCUTANEOUS		Amaryl	C ORAL
		Sortis	C ORAL
		Mediabet	C ORAL
		Concor	C ORAL

			Captohexal	C		ORAL
			Delix	C		ORAL
			Pantozol	C		ORAL
dose decreased from 80 to 40 mg dialy						
			Irenat	C		ORAL
total daily dose ranged from 1376.8 mg to 2065.2 mg						
			Carbimazole	C		ORAL
dose ranged from 20-30 mg daily						
			Kalium	C		ORAL
			Lexotanil	C		ORAL
			Haldol	C		ORAL

Date:09/22/03ISR Number: 4195142-2Report Type:Expedited (15-DaCompany Report #6004949
Age:44 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Erythema Multiforme Pneumonia Mycoplasmal	Study Health Professional	Euthyrox 50 (Tablets) (Levothyroxine Sodium)	PS		ORAL	50,000 MCG (50 MCG, 1 IN 1 D)	
			Fragmin P					

SUBCUTANEOUS	(1 IN 1 D)	11	DAY				
SEE IMAGE							
SEE IMAGE	2	DAY					
INTRAVENOUS	3,00 GM (1,5 GM, 2 IN 1 D)	1	DAY				
RECTAL	3000,0 MG (1000 MG, 3 IN 1 D)						
	400,0000 MG (200 MG, 2 IN 1 D)	5	DAY				
	(1 IN 1 D)						
SEE IMAGE		5	DAY				
20 DOSAGE FORMS		2	DAY				

(Injection) (Heparin-Fraction, Sodium Salt)	SS	
Paspertin (Solution) (Metoclopramide Hydrochloride)	SS	ORAL
Acc (Powder) (Acetylcysteine)	SS	ORAL
Zinacef (Injection) (Cefuroxime)	SS	
Ben-U-Ron (Suppository) (Paracetamol)	SS	
Orelox (Tablets) (Cefpodoxime Proxetil)	SS	ORAL
Adumbran Tablets (Oxazepam)	SS	ORAL
Mucosolvan (Syrup) (Ambroxol Hydrochloride)	SS	ORAL
Hydrocodein (Drops) (Codeine Phosphace)	SS	ORAL

Date:09/22/03ISR Number: 4195422-0Report Type:Expedited (15-DaCompany Report #200318736GDDC
Age:13 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Electrocardiogram Qt Prolonged	Foreign Literature	Fexofenadine Hydrochloride	PS		ORAL	600 MG ONCE	
	Intentional Misuse	Health Professional					PO	
	Suicide Attempt		Metoclopramide	SS		ORAL	25 MG PO	
		Other	Paracetamol	SS		ORAL	2500 MG PO	
			Tramadol	SS		ORAL	PO	

Date:09/22/03ISR Number: 4195885-0Report Type:Expedited (15-DaCompany Report #2003160893FR
Age:50 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Arrhythmia	Foreign	Xanax (Alprazolam)					
	Blood Pressure Abnormal	Health Professional	Tablet	PS		ORAL	0.5 MG, TID,	
	Cardiac Amyloidosis						ORAL	
	Cardiac Arrest Cardiac Disorder		Seropram(Citalopram Hydrobromide)	SS		ORAL	40 MG/DAY,	
	Cardiomegaly						ORAL	
	Coma Ejection Fraction Decreased Mydriasis		Colchimax (Dicycllverine Hydrochloride, Colchicine)	SS		ORAL	0.5 MG/DAY,	
	Pupils Unequal						ORAL	
	Pyrexia Respiratory Arrest		Primperan(Metoclopramide)	SS		ORAL	ORAL	
	Shock		Forlax (Macrogol)	SS		ORAL	ORAL	
			Depakote (Valproate					

			Semisodium)	SS		ORAL
500 MG/DAY,						
ORAL						
			Equanil (Meprobamate)	C		

Date:09/22/03ISR Number: 4196012-6Report Type:Expedited (15-DaCompany Report #030911-PM0111-00
Age:73 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardiac Failure	Foreign	Tranxene					
Life-Threatening	Cholecystitis	Health	(Clorazepate					
	Cholelithiasis	Professional	Dipotassium)	PS		ORAL	10 MG, QD, PO	
	Coronary Artery Disease	Other	Plavix (Clopidogrel					
	Diarrhoea		Sulfate)	SS		ORAL	75 MG, QD, PO	
	Electrolyte Imbalance		Diazepam	SS		ORAL	5 MG, TID, PO	
	Erythema		Acetylsalicylic Acid	SS		ORAL	100 MG, QD,	
	Hypertension						PO	
	Hypothyroidism		Ciprofloxacin					
	Lung Disorder		Hydrochloride	SS		ORAL	500 MG, BID,	
	Multi-Organ Failure						PO	
	Myocardial Infarction		Ciprofloxacin					
	Nausea		Hydrochloride	SS		ORAL	250 MG, BID,	
	Pain						PO	
	Pyrexia		Ceftriaxone Sodium	SS				
INTRAVENOUS	2 G, QD,							
	Restlessness							
INTRAVENOUS								
	Toxic Epidermal		Prednisolone Sodium					
	Necrolysis		Succinate	SS				
INTRAVENOUS	50 MG, ONCE,							
INTRAVENOUS								
			Dalteparin Sodium (Heparin-Fraction					

		Sodium Salt)	SS		
SUBCUTANEOUS	2500 IU, QD, SC				
		Furosemide	SS		
INTRAVENOUS	80 - 120MG INTRAVENOUS				
		Norvasc (Amlodipine Besilate)	SS		ORAL
5 MG, BID, PO					
		Digoxin	SS		ORAL
0.2 MG, QD, PO					
		Molsidomine (Aventis Pharma)	SS	Aventis Pharma	ORAL
16 MG - 8MG P					
		Isosorbide Mononitrate	SS		ORAL
PO					
		Amphotericin B (Bristol Myers Squibb)	SS	Bristol Myers Squibb	ORAL
200 MG QID PO					
		Metoclopramide	SS		ORAL
7.22 MG, TID, PO					
		Melperone Hydrochloride	SS		ORAL
80 - 105 MG PO					
		Paracetamol	SS		ORAL
500 MG ONCE PO					
		Yeast Dried	SS		ORAL
100 MG - 300 MG PO					
		Metolazone	SS		ORAL
2.5 MG QD PO					
		Insulin Glargine	C		
		Glimepiride	C		
		Atorvastatin Calcium	C		
		Metformin			

Hydrochloride	C
Bisoprolol Fumarate	C
Captopril	C
Ramipril	C
Pantoprazole Sodium	C
Sodium Perchlorate	C
Carbimazole	C
Potassium Chloride	C
Bromazepam	C
Haloperidol	C

Date:09/23/03ISR Number: 4195230-0Report Type:Direct Company Report #USP 080297
Age: Gender:Not SpecifiI/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Medication Error Overdose		Ritalin 10 Mg Methylphenidate	PS	Ciba		10 MG TAB	
			Reglan 10 Mg Metoclorpamide	SS			10 MG TAB	

Date:09/26/03ISR Number: 4197063-8Report Type:Direct Company Report #CTU 202653
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Pharmaceutical Product Complaint		Metoclopramide Injection 5 Mg/Ml - 2ml Vial Abbott Labs	PS	Abbott Labs			

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/29/03ISR Number: 4202113-6Report Type:Expedited (15-DaCompany Report #002#4#2003-00445
Age:69 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Arthralgia	Consumer	Reglan-10mg-Tablet (Metoclopramide Hcl)	PS		ORAL	10MG, 3 IN 1	
Disability	Parkinson'S Disease						D, ORAL	
	Somnolence							
	Tremor							

Date:09/30/03ISR Number: 4203588-9Report Type:Expedited (15-DaCompany Report #S03-FRA-02278-01
Age:50 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Abdominal Pain	Foreign	Seropram (Citalopram Hydrobromide)	PS		INTRAVENOUS	20 MG QD IV	
	Amyloidosis	Health						
	Cardiac Arrest	Professional	Seropram (Citalopram Hydrobromide)	SS		INTRAVENOUS	40 MG QD IV	
	Cardiac Failure	Other						
	Coma		Seropram (Citalopram Hydrobromide)	SS		ORAL	40 MG QD PO	
	Ejection Fraction							
	Decreased		Colchicine "Houde" (Colchicine)	SS		ORAL	0.5 BID PO	
	Gastrointestinal Disorder							
	Hypertrophic Cardiomyopathy		Primperan (Metoclopramide)	SS				
	Loss Of Consciousness		Xanax (Alprazolam)	SS		ORAL	0.5 MG TID PO	
	Mydriasis		Forlax (Macrogol)	SS				
	Respiratory Arrest		Depakote (Valproate Semisodium)	SS		ORAL	500 MG QD PO	
	Shock							
	Vomiting		Equanil (Meprobamate)	SS				

Date:10/01/03ISR Number: 4204319-9Report Type:Expedited (15-DaCompany Report #03P-056-0217775-00
Age:50 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Arrhythmia	Foreign	Depakote (Divalproex Sodium) (Divalproex Sodium)	PS		ORAL	500 MG, 1 IN	
Required Intervention to Prevent Permanent Impairment/Damage	Blood Pressure Abnormal	Health Professional						
	Cardiac Amyloidosis							
	Cardio-Respiratory Arrest	Company Representative						
	Cardiomyopathy		Metoclopramide	SS		ORAL	SEE IMAGE	
	Coma		Colchicine	SS		ORAL	0.5 MG, 2 IN	1 D, ORAL
	Depression							
	Hypertrophy		Alprazolam	SS		ORAL	0.5 MG, 3 IN	1 D, ORAL
	Loss Of Consciousness							
	Shock		Macrogol	SS		ORAL	10 GM, 2 IN 1	D, ORAL
	Vomiting							
			Citalopram Hydrobromide	SS			SEE IMAGE	
			Sulpiride	C				
			Heptaminol Hydrochloride	C				
			Aporex	C				

Date:10/02/03ISR Number: 4205216-5Report Type:Expedited (15-DaCompany Report #2003-BP-07174RO
Age:73 YR Gender:Female I/FU:I

Outcome	PT
Death	Diarrhoea
Life-Threatening	Dyspnoea

	Electrolyte Imbalance Hypertension Hyperthyroidism	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
	Lung Disorder	Foreign	Diazepam (Diazepam)	PS		ORAL
5 MG TID (5						
	Multi-Organ Failure	Health				
MG, 3 IN 1						
	Nausea	Professional				
D), PO						
	Pain	Other	Furosemide			
	Pyrexia		(Furosemide)	SS		
INTRAVENOUS 80 - 120 MG,						
	Respiratory Disorder					
IV						
	Restlessness		Digoxin (Digoxin)	SS		ORAL
0.2 MG QD						
	Toxic Epidermal					
(0.2 MG, 2 IN						
	Necrolysis					
1 D),PO						
			Metoclopramide			
			(Metoclopramide			
			Hydrochloride)	SS		ORAL
7.22 MG TID						
(7.22 MG, 3						
IN 1 D), PO						
			Tranxene			
			(Clorazepate			
			Dipotassium)	SS		ORAL
10 MG QD (10						
MG, 1 IN 1						
D), PO						
			Plavix (Clopidogrel			
			Sulfate)	SS		ORAL
75 MG QD (1						
IN 1 D), PO						
			Acetylsalicylic Acid			
			(Acetylsalicylic			
			Acid)	SS		ORAL
100 MG QD (11						

IN 1 D), PO				
		Ciprofloxacin Hydrochloride (Ciprofloxacin Hydrochloride)	SS	ORAL
SEE IMAGE				
INTRAVENOUS	2 G (1 IN 1 D), IV	Ceftriaxone Sodium (Ceftriaxone Sodium)	SS	
		Prednisolone Sodium Succinate (Prednisolone Sodium Succinate)	SS	
INTRAVENOUS	50 MG (50 MG, ONCE), IV			
		Dalteparin Sodium (Heparin-Fraction, Sodium Salt)	SS	
SUBCUTANEOUS	2500 U (1 IN 1 D), SC			
		Norvasc (Amlodipine Besilate)	SS	ORAL
10 MG (5 MG, 2 IN 1 D), PO				
		Molsidomine (Molsidomine)	SS	ORAL
16 MG - 8 MG, PO				
		Isosorbide Mononitrate (Isosorbide Mononitrate)	SS	ORAL
PO				
		Amphotericin B (Amphotericin B)	SS	ORAL
800 MG (200 MG, 4 IN 1 D), PO				
		Melperone Hydrochloride		

	(Melperone Hydrochloride)	SS	ORAL
80 - 105 MG, PO			
	Paracetamol (Paracetamol)	SS	ORAL
500 MG (500 MG, ONCE), PO			
	Yeast Dried (Yeast Dried)	SS	ORAL
100 MG - 300 MG, PO			
	Metolazone (Metolazone)	SS	ORAL
2.5 MG (2.5 MG, 1 IN 1 D), PO			
	Insulin Glargine (Insulin)	C	
	Glimepiride	C	
	Atorvastatin Calcium	C	
	Metformin Hyfrochloride (Metformin Hydrochloride)	C	
	Bisoprolol Fumarate (Bisoprolol Fumarate)	C	
	Captopril (Captopril)	C	
	Ramipril (Ramipril)	C	
	Pantoprazole Sodium	C	
	Sodium Perchlorate Sodium (Sodium Perchlorate)	C	
	Carbimazole (Carbimazole)	C	
	Potassium Chloride (Potassium Chloride)	C	
	Bromazepam (Bromazepam)	C	
	Haloperidol (Haloperidol)	C	

Date:10/08/03ISR Number: 4206260-4Report Type:Direct Company Report #USP 080110
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Cardiac Disorder		Reglan	PS	Robins		TAB	
	Medication Error		Enduron	SS	Abbott		TAB	

Date:10/08/03ISR Number: 4207059-5Report Type:Direct Company Report #USP 080148
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Medication Error		Reglan	PS	Pbi		SYRUP	
			Hycodan	SS	Dupont		SYRUP	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/13/03ISR Number: 4207261-2Report Type:Expedited (15-DaCompany Report #DE-GLAXOSMITHKLINE-D0042106A
Age:74 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Diarrhoea		Digoxin	PS	Glaxosmithkline	ORAL	12	DAY
Life-Threatening	Dyspnoea		Tranxene	SS		ORAL	5	DAY
	Erythema		Plavix	SS		ORAL	11	DAY
	Hypertension		Diazepam	SS		ORAL		
	Lung Disorder		Acetylsalicylic Acid	SS	Glaxosmithkline	ORAL		
	Multi-Organ Failure		Ciprofloxacin Hydrochloride	SS	Glaxosmithkline	ORAL	500MG Twice per day	9 DAY
	Nausea							
	Pain							
	Restlessness		Ciprofloxacin Hydrochloride	SS	Glaxosmithkline	ORAL	250MG Twice per day	5 DAY
	Toxic Epidermal Necrolysis							
			Ceftriaxone Sodium	SS			INTRAVENOUS	5 DAY
			Prednisolone	SS			INTRAVENOUS	50MG Single dose 1 DAY
			Dalteparin Sodium	SS			SUBCUTANEOUS	12 DAY
			Furosemide	SS	Glaxosmithkline		INTRAVENOUS	12 DAY
			Norvasc	SS		ORAL	5MG Twice per day	12 DAY
			Molsidomine	SS		ORAL	12	DAY
			Isosorbide Mononitrate	SS		ORAL	12	DAY
			Amphotericin B	SS		ORAL	12	DAY
			Metoclopramide	SS	Glaxosmithkline	ORAL	9	DAY
			Melperone					

				Hydrochloride	SS		ORAL
7 DAY							
				Paracetamol	SS	Glaxosmithkline	ORAL
500MG Single							
dose	1 DAY						
				Yeast	SS		ORAL
4 DAY							
				Metolazone	SS		ORAL
2 DAY							
				Insulin	C		
SUBCUTANEOUS							
				Glimepiride	C		ORAL
				Atorvastatin	C		ORAL
				Metformin Hydrochloride	C		ORAL
				Bisoprolol Fumarate	C		

Date:10/13/03ISR Number: 4207469-6Report Type:Expedited (15-DaCompany Report #DE-ROCHE-348350
Age:74 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Diarrhoea		Diazepam	PS	Roche	ORAL
	Dyspnoea		Acetylsalicylic Acid	SS	Roche	ORAL
	Electrolyte Imbalance		Ceftriaxone Sodium	SS	Roche	
INTRAVENOUS	5 DAY					
	Hypertension		Digoxin	SS	Roche	ORAL
12 DAY						
	Hypothyroidism		Isosorbide Mononitrate	SS	Roche	ORAL
	Multi-Organ Failure					
12 DAY						
	Nausea		Tranxene	SS		ORAL
5 DAY						
	Pain		Plavix	SS		ORAL
11 DAY						
	Pyrexia		Ciprofloxacin Hydrochloride	SS		ORAL
	Respiratory Disorder					
9 DAY						
	Restlessness		Ciprofloxacin Hydrochloride	SS		ORAL
	Toxic Epidermal					
2 DAY						
	Necrolysis		Prednisolone Sodium 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
12	DAY						
				Metoclopramide	SS		ORAL
9	DAY						
				Melperone Hydrochloride	SS		ORAL
7	DAY						
				Paracetamol	SS	Roche	ORAL
1	DAY						
				Yeast Dried	SS		ORAL
4	DAY						
				Metolazone	SS		ORAL
2	DAY						
				Insulin Glargine	C		
SUBCUTANEOUS							
				Glimepiride	C		ORAL
				Atorvastatin Calcium	C		ORAL
				Metformin Hydrochloride	C		ORAL
				Bisoprolol Fumarate	C		ORAL
				Captopril	C		ORAL
				Ramipril	C		ORAL
				Sodium Perchlorate	C		ORAL
27	DAY						
				Carbimazole	C		ORAL
24	DAY						
				Potassium Chloride	C		ORAL
12	DAY						
				Bromazepam	C		ORAL
2	DAY						
				Haloperidol	C		ORAL
2	DAY						
				Pantoprazole Sodium	C		ORAL

Date:10/15/03ISR Number: 4210458-9Report Type:Expedited (15-DaCompany Report #2003041703
Age:73 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardiac Failure	Foreign	Norvasc (Amlodipine)	PS		ORAL	5 MG (BID),	
Life-Threatening	Cholecystitis	Health						
ORAL								

Hospitalization - Initial or Prolonged	Cholelithiasis Contrast Media Reaction Diarrhoea Dyspnoea Electrolyte Imbalance Hypertension Hyperthyroidism Multi-Organ Failure Myocardial Infarction Nausea Pain Pulmonary Function Test Abnormal Pyrexia Restlessness Toxic Epidermal Necrolysis	Professional	Paracetamol (Paracetamol)	SS	ORAL	500 MG (ONCE), ORAL
			Acetylsalicylic Acid (Acetylsalicylic Acid)	SS	ORAL	100 MG (DAILY), ORAL
			Isosorbide Mononitrate (Isosorbide Mononitrate)	SS	ORAL	ORAL
			Metoclopramide Hydrochloride (Metoclopramide Hydrochloride)	SS	ORAL	7.22 MG (TID), ORAL
			Prednisolone (Prednisolone)	SS	INTRAVENOUS	50 MG (ONCE), INTRAVENOUS
			Digoxin (Digoxin)	C		
			Ciprofloxacin (Ciprofloxacin)	C		
			Ceftriaxone (Ceftriaxone)	C		
			Furosemide (Furosemide)	C		
			Clorazepate Dipotassium (Clorazepate Dipotassium)	C		

Diazepam (Diazepam)	C
Contrast Media	C
Heparin-Fraction, Sodium Salt (Heparin-Fraction, Sodium Salt)	C
Molsidomine (Molsidomine)	C
Amphotericin B (Amphotericin B)	C
Clopidogrel Sulfate (Clopidogrel Sulfate)	C
Melperone (Melperone)	C
Yeast Dried (Yeast Dried)	C
Metolazone (Metolazone)	C
Insulin Glargine (Insulin Glargine)	C
Glimepiride (Glimepiride)	C
Atorvastatin (Atorvastatin)	C
Metformin Hydrochloride (Metformin Hydrochloride)	C
Bisoprolol (Bisoprolol)	C
Captopril (Captopril)	C
Ramipril (Ramipril)	C
Pantoprazole Sodium (Pantoprazole Sodium)	C
Sodium Perchlorate (Sodium Perchlorate)	C
Carbimazole (Carbimazole)	C
Potassium Chloride (Potassium Chloride)	C
Bromazepam (Bromazepam)	C

	Haloperidol (Haloperidol)	C

Date:10/15/03ISR Number: 4210589-3Report Type:Expedited (15-DaCompany Report #200313103GDS
Age:73 YR Gender:Female I/FU:I

Outcome	PT
Death	Blister
Life-Threatening	Cardiac Failure
	Cholecystitis
	Cholelithiasis
	Contrast Media Reaction
	Diarrhoea

Dose	Duration	Dyspnoea Electrolyte Imbalance Hypertension	Report Source	Product	Role	Manufacturer	Route
100 MG, TOTAL		Hyperthyroidism	Foreign	Acetylsalicylic Acid	PS		ORAL
DAILY; ORAL		Multi-Organ Failure	Health				
250 MG, BID;		Myocardial Infarction Nausea	Professional Other	Ciprofloxacin Hydrochloride	SS		ORAL
ORAL, 500 MG,		Pain					
BID; ORAL		Pulmonary Function Test					
500 MG, TOTAL		Decreased		Paracetamol	SS		ORAL
DAILY; ORAL		Pyrexia					
		Respiratory Disorder Restlessness		Tranxene (Clorazepate			
10 MG, TOTAL		Toxic Epidermal		Dipotassium)	SS		ORAL
DAILY, ORAL		Necrolysis					
				Plavix (Clopidogrel			
75 MG TOTAL				Sulfate)	SS		ORAL
DAILY; ORAL							
5 MG, TID;				Diazepam	SS		ORAL
ORAL							
INTRAVENOUS	2 G, TOTAL			Ceftriaxone Sodium	SS		
DAILY;							
INTRAVENOUS							
				Prednisolone Sodium			
INTRAVENOUS	50 MG, TOTAL			Succinate	SS		
DAILY;							
INTRAVENOUS							

SUBCUTANEOUS	2500 IU, TOTAL DAILY; SUBCUTANEOUS	Dalteparin Sodium	SS	
INTRAVENOUS	NI, UNK; INTRAVENOUS	Furosemide	SS	
5 MG, BID; ORAL		Norvasc (Amlodipine Besilate)	SS	ORAL
0.2 MG, TOTAL DAILY; ORAL		Digoxin	SS	ORAL
NI, UNK; ORAL		Molsidomine	SS	ORAL
NI, UNK; ORAL		Isosorbide Mononitrate	SS	ORAL
200 MG, QID; ORAL		Amphotericin B (Bristol-Myers Squibb) (Amphotericin B)	SS	ORAL
7.22 MG, TID; ORAL		Metoclopramide	SS	ORAL
NI, UNK; ORAL		Melperone Hydrochloride	SS	ORAL
NI, U NK; ORAL		Yeast Dried	SS	ORAL
2.5 MG, TOTAL DAILY; ORAL		Metolazone	SS	ORAL
		Insulin Glargine	C	
		Glimepiride	C	
		Atorvastatin Calcium	C	
		Metformin Hydrochloride	C	
		Bisoprolol Fumarate	C	
		Captopril	C	

	Ramipril	C

Pantoprazole Sodium	C
Sodium Perchlorate	C
Carbimazole	C
Potassium Chloride	C
Bromazepam	C
Haloperidol	C

Date:10/15/03ISR Number: 4211021-6Report Type:Expedited (15-DaCompany Report #001#4#2003-00198
Age:73 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Blister	Other	Isosorbide Mononitrate	PS		ORAL	12	DAY
Life-Threatening	Diarrhoea							
	Dyspnoea		Ciprofloxacin Hydrochloride (Ciprofloxacin Hydrochloride0	SS		ORAL	SEE IMAGE	2 DAY
	Electrolyte Imbalance							
	Erythema							
	Hypertension							
	Multi-Organ Failure		Clorazepate Dipotassium (Clorazepate Dipotassium)	SS		ORAL	10 MG	5 DAY
	Nausea							
	Pain							
	Pyrexia							
	Respiratory Disorder		Ceftriaxone Sodium (Ceftriaxone Sodium)	SS			INTRAVENOUS	2G
	Restlessness							
	Toxic Epidermal Necrolysis		Prednisolone Sodium Succinate (Prednisoloone Sodium Succinate)	SS			INTRAVENOUS	50 MG ONCE 1 DAY
			Diazepam (Diazepam)	SS		ORAL	5 MG	
			Clopidogrel Sulfate	SS		ORAL	75 MG	11 DAY
			Acetylsalicylic Acid (Acetylsalicylic Acid)	SS		ORAL	100 MG	
			Molsidomide (Molsidomide)	SS		ORAL	16 MG-8 MG	12 DAY

5 MG - 10 MG				Ramipril (Ramipril)	SS	ORAL
				Amlodipine Besilate (Amlodipine Besilate)	SS	ORAL
10 MG	12	DAY				
				Dalteparin Sodium (Heparin-Fraction, Sodium Salt)	SS	
SUBCUTANEOUS	2500 IU	12	DAY			
				Digoxin (Digoxin)	SS	ORAL
0.3 MG/DAY	12	DAY				
				Furosemide (Furosemide)	SS	
INTRAVENOUS	80 MG - 120					
MG	12	DAY				
				Amphotericin B (Amphotericin B)	SS	ORAL
200 MG	12	DAY				
				Melperone Hydrochloride (Melperone Hydrochloride)	SS	ORAL
80 MG - 105						
MG	7	DAY				
				Paracetamol (Paracetamol)	SS	ORAL
500 MG	7	DAY				
				Yeast Dried (Yeast Dried)	SS	ORAL
100 MG - 300						
MG	4	DAY				
				Metolazone (Metolazone)	SS	ORAL
2.5 MG	2	DAY				
				Metoclopramide		

				(Metoclopramide)	SS			ORAL
7.23 MG	9	DAY						
				Carbimazole (Carbimazole)	C			
				Potassium Chloride (Potassium Chloride)	C			
				Bromazepam (Bromazepam)	C			
				Haloperidol (Haloperidol)	C			
				Captopril (Captopril)	C			
				Pantoprazole Sodium	C			
				Sodium Perchlorate (Sodium Perchlorate)	C			
				Insulin Glargine	C			
				Glimepiride	C			
				Atorvastatin Calcium	C			
				Metformin Hydrochloride (Metformin Hydrochloride)	C			
				Bisoprolol Fumarate (Bisoprolol Fumarate)	C			
				Ramipril (Ramipril)	C			

Date:10/16/03ISR Number: 4210854-XReport Type:Direct Company Report #CTU 203986
Age:35 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dizziness		Metoclopramide 10 Mg	PS			10 MG ONE PO	
	Dysarthria						30 MIN QAM	
	Dyskinesia						AND Q HS	5 YR
	Somnolence		Zantac	C				
			Singulair	C				
			Albuterol Mdi	C				

Date:10/16/03ISR Number: 4213309-1Report Type:Expedited (15-DaCompany Report #2003175304DE
Age:73 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Diarrhoea	Foreign	Fragmin P					
Life-Threatening	Dyspnoea	Health	(Dalteparin Sodium)					
	Hypertension	Professional	Solution, Sterile,					
	Hyperthyroidism	Other	2500iu	PS			SUBCUTANEOUS	2500 IU, QD,
	Multi-Organ Failure						SUBCUTANEOUS	
	Nausea		Ciprobay					
	Pulmonary Function Test Decreased		(Ciprofloxacin Hydrochloride)	SS		ORAL	SEE IMAGE	
	Pyrexia		Lasix (Furosemide)	SS			INTRAVENOUS	80 MG 20 MG,
	Restlessness						IV	
	Toxic Epidermal Necrolysis		Norvasc (Amlodipine Besilate)	SS		ORAL	5 MG, BID,	
							ORAL	
			Novodigal (Digoxin)	SS		ORAL	0.2 MG, QD,	
							ORAL	
			Corvaton - Slow Release "Hoechst" (Molsidomine)	SS		ORAL	16 MG - 8 MG,	
							ORAL	

		Insulin (Insulin)	SS	
SUBCUTANEOUS	16 IU, QD,			
SUBCUTANEOUS		Amaryl (Glimepiride)	SS	ORAL
3 MG, QD,				
ORAL				
		Sortis "Parke-Davis" (Atorvastatin Calcium)	SS	ORAL
20 MG, QD,				
ORAL				
		Diazepam (Diazepam)	SS	ORAL
5 MG, TID,				
ORAL				
		Mediabet (Metformin Hydrochloride)	SS	ORAL
250 MG, TID,				
ORAL				
		Concor (Bisoprolol Fumarate)	SS	ORAL
5 MG - 7.5				
MG, ORAL				
		Captohexal (Captopril)	SS	ORAL
QD, ORAL				
		Delix (Ramipril)	SS	ORAL
5 MG - 10 MG,				
ORAL				
		Acetylsalicylic Acid (Acetylsalicylic Acid)	SS	ORAL
100 MG, QD,				
ORAL				
		Pantozol (Pantoprazole Sodium)	SS	ORAL
80 MG - 40				
MG, ORAL				

		Irenat (Sodium Perchlorate)	SS	ORAL
1376.8 MG - 2065.2 MG, ORAL				
		Carbimazole (Carbimazole)	SS	ORAL
20 MG - 30 MG, ORAL				
		Rocephin (Ceftriaxone Sodium)	SS	
INTRAVENOUS	2 G, QD, IV			
		Decortin (Prednisone)	SS	
INTRAVENOUS	50 MG, QD, IV			
		Mono Mack (Isosorbide Mononitrate)	SS	ORAL
ORAL				
		Ampho-Moronal (Amphotericin B)	SS	OTHER
200 MG, QD, OTHER				
		Mcp "Hexal" (Metoclopramide Hydrochloride)	SS	ORAL
7.22 MG, TID, ORAL				
		Plavix (Clopidogrel Sulfate)	SS	ORAL
75 MG, QD, ORAL				
		Eunerpan (Melperone Hydrochloride)	SS	ORAL
80MG - 105 MG, ORAL				
		Tranxilium (Clorazepate Dipotassium)	SS	ORAL
10 MG, QD, ORAL				
		Ben-U-Ron (Paracetamol)	SS	ORAL
500, ORAL				

			Perenterol (Yeast Dried)	SS		ORAL 100 MG - 300 MG, ORAL
			Zaroxolyn (Metolazone)	SS		ORAL 2.5 MG, QD, ORAL
			Kalium-Duriles	C		
			Lexotanil	C		
			Haldol	C		

Date:10/22/03ISR Number: 4213820-3Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0311745A
Age:19 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain Upper		Augmentin Iv	PS	Glaxosmithkline	INTRAVENOUS	3G Single dose	1 DAY
	Blood Alkaline Phosphatase Increased		Primperan	SS	Glaxosmithkline			
	C-Reactive Protein Increased		Profenid	SS		INTRAVENOUS	2G Single dose	1 DAY
	Food Intolerance		Perfalgan	SS	Glaxosmithkline			
	Gamma-Glutamyltransferase Increased		Diprivan	C		INTRAVENOUS	1 DAY	
	Hepatitis		Sufentanyl	C				
	Vomiting		Tracrium	C	Glaxosmithkline	INTRAVENOUS	1 DAY	

Date:10/24/03ISR Number: 4220244-1Report Type:Expedited (15-DaCompany Report #S03-USA-04353-01
Age:50 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Tardive Dyskinesia	Health	Lexapro					

		Professional	(Escitalopram)	PS	ORAL
30 MG QD PO					
		Company Representative	Reglan (Metoclopramide)	SS	
			Prilosec (Omeprazole)	C	

Date:10/27/03ISR Number: 4219531-2Report Type:Direct Company Report #CTU 204615
Age:76 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Anxiety		Metoclopramide	PS		ORAL
ORAL 1 DAY						
Initial or Prolonged	Restlessness		Compazine	SS		
			Synthroid	C		
			Duragesic	C		
			Coumadin	C		
			Lorazepam	C		
			Compazine (Prochlorperazine)	C		

Date:10/27/03ISR Number: 4221080-2Report Type:Expedited (15-DaCompany Report #USA-2003-0007803
Age:75 YR Gender:Male I/FU:F

Outcome	PT
Death	Benign Prostatic Hyperplasia
	Cardiomegaly
	Completed Suicide

		Coronary Artery Atherosclerosis					
		Drug Screen Positive	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
		Gun Shot Wound	Health	Oxycodone			
		Hepatic Steatosis	Professional	Hydrochloride			
		Kyphoscoliosis	Other	(Similar To Nda			
		Lung Neoplasm Malignant		20-553)(Oxycodone			
		Metastases To Spine		Hydrochloride)	PS		
		Nephrosclerosis		Amitriptyline(Amitri			
		Spinal Osteoarthritis		ptyline)	SS		
		Urine Ketone Body Present		Salicylic			
				Acid(Salicylic Acid)	SS		
				Diphenhydramine(Diph			
				enhydramine)	SS		
				Metoclopramide(Metoc			
				lopramide)	SS		
				Nortriptyline(Nortri			
				ptyline)	SS		
				Acetone(Acetone)	SS		

Date:10/28/03ISR Number: 4219707-4Report Type:Expedited (15-DaCompany Report #DE-ROCHE-349844
Age:71 YR Gender:Female I/FU:I

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Death		Pulmonary Embolism		Rocephin	PS	Roche	
INTRAVENOUS		14 DAY					
Life-Threatening		Stevens-Johnson Syndrome		Liquemin	SS	Roche	
SUBCUTANEOUS							
		Toxic Epidermal		Lasix	SS		ORAL
		Necrolysis		Refobacin	SS		
INTRAVENOUS							
				Omeprazol	SS		ORAL
				Adumbran	SS		ORAL
1	DAY						
				Adumbran	SS		ORAL
2	DAY						
				Adumbran	SS		ORAL
3	DAY						
				Adumbran	SS		ORAL
1	DAY						
				Tramal	SS		ORAL
3	DAY						

3	DAY				
				Tramal	SS	ORAL
				Tramal	SS	ORAL
				Novalgin	SS	ORAL
2	DAY				
				Novalgin	SS	ORAL
3	DAY				
				Novalgin	SS	ORAL
				Novalgin	SS	ORAL
				Ben-U-Ron	SS	
UNKNOWN		13	DAY		
				Vancomycin	SS	
INTRAVENOUS					
				Vomex A	SS	
UNKNOWN		1	DAY		
				Paspertin	SS	ORAL
1	DAY				
				Saroten 25	SS	ORAL
				Irenat	SS	ORAL
				Sobelin	SS	
INTRAVENOUS					
				Novalgin	SS	
UNKNOWN		1	DAY		
				Staphylex	C	ORAL
				Mono-Embolex	C	
SUBCUTANEOUS					
				Magnesium Verla	C	ORAL
				Pantozol	C	ORAL
				Bifiteral	C	ORAL
				Beloc-Zok	C	ORAL
				Kalinor Brause	C	ORAL
				Fraxiparin	C	
SUBCUTANEOUS		6	DAY		
				Psyquil	C	
1	DAY				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/31/03ISR Number: 4223685-1Report Type:Expedited (15-DaCompany Report #DE-ROCHE-349950
Age:62 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Stevens-Johnson Syndrome		Dormicum	PS	Roche	ORAL	6	DAY
Initial or Prolonged	Toxic Epidermal Necrolysis		Aurorix	SS	Roche	ORAL	12	DAY
			Zentropil	SS		ORAL	1	DAY
			Novalgin	SS		ORAL	1	DAY
			Adumbran	SS		ORAL	21	DAY
			Phenhydan	SS		ORAL	SUBCUTANEOUS	
			Innohep	SS			PRN	2 DAY
			Acerbon	SS		ORAL	PRN	3 DAY
			Pantozol	SS		ORAL	PRN	2 DAY
			Ass	SS		ORAL	PRN	3 DAY
			Ass	SS		ORAL	MAX DOSE	
			Fortecortin	SS		ORAL	4/DAY	2 DAY
			Fortecortin	SS		ORAL	5	DAY
			Paracetamol	SS	Roche	ORAL	1	DAY
			Imeson	SS		ORAL	5	DAY
			Paspertin	SS		ORAL	SUBCUTANEOUS	
			Cotrim Forte	SS		ORAL	DOSE PRN	
			Liquemin N	C			INTRAVENOUS	1 DAY
			Pepdul	C		ORAL		
			Fortecortin	C		ORAL		
			Rohypnol	C		ORAL		
			Novalgin	C				

				Pancuronium	C		
INTRAVENOUS	1 DAY						
				Fentanyl	C		
INTRAVENOUS	1 DAY						
				Thiopental	C		
INTRAVENOUS	1 DAY						
				Atosil	C		ORAL
2 DAY							
				Doxepin	C		ORAL
2 DAY							
				Bifiteral	C		ORAL
DOSE=1							
MEASURING CUP	1 DAY						
				Valdispert	C		ORAL
DOSE ON 7, 9,							
18-22 AND 25							
MAR 2001	19 DAY						
				Systral	C		
TOPICAL	PRN						

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							

12 DAY	Norvasc	SS ORAL
12 DAY	Molsidomine	SS ORAL
DOSE FORM	Amphotericin B	SS ORAL
STATED AS		

PIPETTES. 12 DAY

9 DAY

FORM REPORTED

AS LIQUID 7 DAY

1 DAY

DOSE STATED

AS 2. NO

UNITS

PROVIDED.

REPORTED AS 1

DOSE FORM 2 DAY

2 DAY

INTRAVENOUS 1 DAY

DOSE REPORTED

AS 1 DOSE

FORM

SUBCUTANEOUS

DOSE REPORTED

AS 1 DF DAILY

27 DAY

Metoclopramide	SS		ORAL
Melperone Hydrochloride	SS		ORAL
Paracetamol	SS	Roche	ORAL
Perenterol	SS		ORAL
Metolazone	SS		ORAL
Haldol	SS		ORAL
Decortin	SS		
Novodigal	SS		ORAL
Atorvastatin Calcium	C		ORAL
Insulin Glargine	C		
Glimepiride	C		ORAL
Metformin Hydrochloride	C		ORAL
Bisoprolol Fumarate	C		ORAL
Captopril	C		ORAL
Ramipril	C		ORAL
Sodium Perchlorate	C		ORAL

			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: 4225245-5Report Type:Expedited (15-DaCompany Report #KII-2003-0003497
Age:89 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Heart Rate Decreased	Health Professional	Oxycontin Tablets(Oxycodone Hydrochloride) Cr			
Other	Medication Error					
	Sedation					
	Somnolence		Tablets	PS		ORAL
20 MG,						
SINGLE,ORAL						
			Ambien (Zolpidem Tartrate)	SS		ORAL
10 MG,						
SINGLE, ORAL						
			Xanax (Alprazolam)	SS		ORAL
0.25 MG,						
SINGLE, ORAL						
			Prevacid (Lansoprazole)	SS		ORAL
15 MG,						
SINGLE, ORAL						
			Azulfidine (Sulfasalazine)	SS		ORAL
500 MG,						
SINGLE, ORAL						

	Reglan (Metoclopramide)	SS	ORAL

10 MG,

SINGLE, ORAL

			Risperdal (Risperidone)	SS		ORAL
0.5 MG, SINGLE, ORAL						

Date:10/31/03ISR Number: 4226082-8Report Type:Expedited (15-DaCompany Report #HQWYE447823OCT03
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Disability Impaired Work Ability Injury Nervous System Disorder Shock	Consumer	Reglan (Metoclopramide Hydrochloride,)	PS		

Date:11/03/03ISR Number: 4226594-7Report Type:Expedited (15-DaCompany Report #200312575DE
Age:73 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Diarrhoea	Foreign	Corvaton Retard	PS		ORAL
PO 12 DAY						
Life-Threatening	Multi-Organ Failure	Study	Lasix	SS		
INTRAVENOUS IV 12 DAY						
	Pain	Other	Tranxilium	SS		ORAL
10 MG/DAY PO 5 DAY						
	Respiratory Disorder		Plavix	SS		ORAL
75 MG/DAY PO 11 DAY						
	Restlessness		Diazepam	SS		ORAL
5 MG TID PO						
	Toxic Epidermal		Ass	SS		ORAL
100 MG/DAY PO						
	Necrolysis		Ciprobay	SS		ORAL
500 MG BID PO 9 DAY						
			Ciprobay	SS		ORAL
250 MG BID PO 2 DAY						
			Rocephin	SS		
INTRAVENOUS 2 G/DAY IV 5 DAY						
			Decortin	SS		
INTRAVENOUS 50 MG/DAY IV 1 DAY						

SUBCUTANEOUS	2500 IU/DAY	
SC	12	DAY
5 MG BID PO	12	DAY
QAM PO	12	DAY
QD PO	12	DAY
PO	1	WK
500 MG/DAY PO	1	DAY
PO	4	DAY
2.5 MG/DAY PO	2	DAY
QID	12	DAY
25-25-25 DROP		
TID PO	11	DAY

Fragmin	SS	
Norvasc	SS	ORAL
Novodigal	SS	ORAL
Mono Mack	SS	ORAL
Eunerpan Liqu.	SS	ORAL
Benuron	SS	ORAL
Perenterol	SS	ORAL
Zaroxolyn Mite	SS	ORAL
Ampho Moronal	SS	
Mcp	SS	ORAL

Lantus	C
Amaryl	C
Atorvastatin Calcium	C
Metformin Hydrochloride	C
Bisoprolol Fumarate	C
Captopril	C
Delix	C
Pantoprazole Sodium	C
Sodium Perchlorate	C
Carbimazole	C
Potassium Chloride	C
Bromazepam	C
Haloperidol	C

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/04/03ISR Number: 4225209-1Report Type:Expedited (15-DaCompany Report #DE-BRISTOL-MYERS SQUIBB COMPANY-12380408
Age:73 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cholecystitis		Ampho-Moronal Os	PS	Apothecon	ORAL		
Hospitalization - Initial or Prolonged	Cholelithiasis		Plavix Tabs	SS	Regulatory Health Authority South Africa	ORAL		
	Diarrhoea							
	Electrolyte Imbalance							
	Hyperthyroidism		Captohexal	SS		ORAL		
	Multi-Organ Failure		Diazepam	SS		ORAL		
	Nausea		Ben-U-Ron	SS		ORAL		
	Restlessness		Tranxilium	SS		ORAL		
	Toxic Epidermal		Acetylsalicilic Acid	SS		ORAL		
	Necrolysis		Ciprobay	SS		ORAL	500 mg twice daily from 20-Jun-2001 to 28-Jun-2001,	
			Rocephin	SS			INTRAVENOUS	
			Solu-Decortin-H	SS			INTRAVENOUS	
			Fragmin	SS			SUBCUTANEOUS	
			Lasix	SS			INTRAVENOUS	dose ranged from 80-120 mg daily
			Norvasc	SS		ORAL		
			Novodigal	SS		ORAL		
			Corvaton	SS		ORAL	dose reduced from 16 to 8 mg daily	
			Mono Mack	SS		ORAL		
			Metoclopramide	SS		ORAL		
			Kalium	SS		ORAL		

	Carbimazole	SS	ORAL
dose ranged from 20-30 mg daily			
	Pantozol	SS	ORAL
dose decreased from 80 to 40 mg dialy			
	Delix	SS	ORAL
	Concor	SS	ORAL
	Mediabet	SS	ORAL
	Sortis	SS	ORAL
	Amaryl	SS	ORAL
	Lantus	SS	
SUBCUTANEOUS			
	Zaroxolyn	SS	ORAL
	Perenterol	SS	ORAL
100 mg to 300 mg			
	Eunerpan	C	ORAL
dose ranged from 80-105 mg daily			
	Irenat	C	ORAL
total daily dose ranged from 1376.8 mg to 2065.2 mg			
	Lexotanil	C	ORAL
	Haldol	C	ORAL

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/04/03ISR Number: 4226724-7Report Type:Direct Company Report #CTU 205199
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dyspnoea		Metaclorpromide 20	PS				
	Muscle Spasms		Rantidine	C				

Date:11/04/03ISR Number: 4227012-5Report Type:Expedited (15-DaCompany Report #2003113834
Age:2.5 MON Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Drug Level	Consumer	Diphenhydramine					
	Murder		(Diphenhydramine)	PS		ORAL		
			Dextromethorphan					
			(Dextromethorphan)	SS				
			Clomipramine					
			(Clomipramine)	SS				
			Metoclopramide					
			(Metoclopramide)	SS				
			Guaifenesin					
			(Guaifenesin)	SS				

Date:11/04/03ISR Number: 4227310-5Report Type:Expedited (15-DaCompany Report #200312661DE
Age:71 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Pulmonary Embolism	Foreign	Novalgin Drops	PS		ORAL	PO	2 DAY
Life-Threatening	Stevens-Johnson Syndrome	Study	Novalgin Drops	SS		ORAL	PO	3 DAY
	Toxic Epidermal	Health	Novalgin Drops	SS		ORAL	PO	4 DAY
	Necrolysis	Professional	Novalgin					
		Other	Suppositories	SS			1 G ONCE R	1 DAY
			Lasix Tablets	SS		ORAL	40 MG QAM PO	29 DAY
			Adumbran Tablets	SS		ORAL	PO	1 DAY

PO	2	DAY			Adumbran Tablets	SS	ORAL
PO	3	DAY			Adumbran Tablets	SS	ORAL
PO	1	DAY			Adumbran Tablets	SS	ORAL
PO	3	DAY			Tramal Drops	SS	ORAL
PO	3	DAY			Tramal Drops	SS	ORAL
PO	10	DAY			Tramal Drops	SS	ORAL
R	1	DAY			Ben-U-Ron Suppositories	SS	
R	6	DAY			Ben-U-Ron Suppositories	SS	
25 MG HS PO	6	DAY			Saroten	SS	ORAL
INTRAVENOUS	2 G QAM IV	2	WK		Rocephin	SS	
INTRAVENOUS	QAM IV	4	WK		Refobacin	SS	
SUBCUTANEOUS	5000 IU BID				Liquemin	SS	
SC	23	DAY			Omeprazol	SS	ORAL
40 MG AM&PM							
PO	23	DAY			Vancomycin	SS	
INTRAVENOUS	1 G/DAY IV	16	DAY		Vomex A Suppositories	SS	
ONCE R	1	DAY			Paspertin Drops	SS	ORAL
20 DROP/DAY							
PO	1	DAY			Paspertin Drops	SS	ORAL
20 DROPS/DAY							
PO	2	DAY			Irenat Tropfen Drops	SS	ORAL
20 DROPS/DAY							
PO	1	DAY			Sobelin	SS	
INTRAVENOUS	600 MG/DAY IV						

Staphylex	C
Mono-Embolex	C
Magnesium Verla	C
Pantozol	C
Bifiteral	C
Beloc-Zok	C
Kalinor-Brause	C
Fraxiparin	C
Psyquil "Sanofi"	C
Fenistil Retard	C
Morphin	C

Date:11/04/03ISR Number: 4227395-6Report Type:Expedited (15-DaCompany Report #2003175309DE
Age:44 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Erythema Multiforme Stevens-Johnson Syndrome	Foreign Health Professional	Fragmin P (Dalteparin Sodium) Solution, Sterile	PS				
Other		Other						
SUBCUTANEOUS							1 AMP,	DAILY
SUBCUTANEOUS								
			Adumbran(Oxazepam)	SS		ORAL		
1 DF	DAILY							
			Vantin (Cefpodoxime Proxetil, Cefpodoxime Proxetil) Tablet	SS		ORAL		
200 MG,	BID,							
ORAL								
			Acc For Injection (Acetylcysteine Sodium)	SS				
INTRAVENOUS							2 AMP	DAILY,
IV								
			Zinacef (Cefuroxime)	SS				
INTRAVENOUS							3 G,	DAILY,
IV								
			Ben-U-Ron(Paraceamol) Suppository	SS				
RECTAL							RECTAL	

			Paspertin (Metoclopramide Hydrochloride)	SS		
INTRAVENOUS						
			Euthyrox(Levothyroxine Sodium) Tablet	SS		ORAL
1 DF, DAILY,						
ORAL						
			Acc (Acetylcysteine)	SS		ORAL
30 ML BID						
ORAL						
			Mucosolvan (Ambroxol Hydrochloride)	SS		
SEE IMAGE						
			Codeine Phosphate (Codeine Phosphate)	SS		ORAL
20 DROPS						
DAILY, ORAL						

Date:11/05/03ISR Number: 4228943-2Report Type:Expedited (15-DaCompany Report #6005756
Age:44 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Erythema Multiforme Stevens-Johnson Syndrome	Study Health Professional Other	Euthyrox 50 (Tablets) (Levothyroxine Sodium)	PS		ORAL	1 IN 1 D	
			Fragmin P(Amp Sc.)(Heparin-Fraction, Sodium Salt)	SS				
SUBCUTANEOUS							1,00 DOSAGE	11 DAY

				Paspertin (Amp Iv)(Metoclopramide Hydrochloride)	SS	
INTRAVENOUS	2,00 DOSAGE FORMS (1 DOSAGE FORMS 2 IN 1 D)	1	DAY			
				Acc(Amp Iv)(Acetylcysteine)	SS	
INTRAVENOUS	2,00 DOSAGE FORMS (1 DOSAGE FORMS,2 IN 1 D)	2	DAY			
				Acc(Cachet)(Acetylcysteine)	SS	ORAL
3,00 DOSAGE FORM (1 DOSAGE FORMS,3 IN 1 D		1	DAY			
				Zinacef (Injection)(Cefuroxime)	SS	
INTRAVENOUS	3,00 GM (1,5 GM, 2 IN 1 D)	1	DAY			
				Ben-U-Ron(1000 Mg, Suppository)(Paracetamol)	SS	
1000, 0 MG (1000 MG, 1 IN 1 ONCE),						

3000,0 MG (1000 MG,3 IN 60,000 DOSAGE FORMS (20 DOSAGE FORMS, 3 IN 1 D)	1	DAY		Paspertin (Drops) (Metoclopramide Hydrochloride)	SS	ORAL
400,0000 MG,2IN 1DAY	5	DAY		Orelox(200 Mg, Tablets)(Cefpodoxime Proxetil)	SS	ORAL
1,00 DOSAGE FORMS (1 DOSAGE FORMS, 1IN 1 D)	4	DAY		Adumbran(Tablets)(Oxazepam)	SS	ORAL
30,000 ML (10 ML, 3 IN 1 D)	1	DAY		Mucosolvan(Ameroxol Hydrochlride)	SS	ORAL
RESPIRATORY (INHALATION)	(2 IN 1 D)	5 DAY		Mucosolvan (Inhalant)(Ambroxol Hydrochloride)	SS	
20 DOSAGE FORMS	2	DAY		Hydrocodeine(Drops) (Dihydrocodeine)	SS	ORAL

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/06/03ISR Number: 4228313-7Report Type:Expedited (15-DaCompany Report #C-03-0047
Age:10 MON Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Diarrhoea Haemorrhagic Pruritus Ani	Health Professional	Metoclopramide Oral Solution, Usp 5 Mg/5ml (Mgp Code: 7622)	PS		NASAL	0.5 CC THREE TIMES A DA VIA NASOGASTRIC TUBE	
			Digoxin	C				
			Furosemide	C				
			Ranitidine	C				
			Omeprazole	C				

Date:11/06/03ISR Number: 4228317-4Report Type:Expedited (15-DaCompany Report #C-03-0047
Age:10 MON Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Haematochezia	Other	Metoclopramide Oral Solution, Usp 5 Mg/5 Ml (Mgp Code: 7622)	PS		ORAL		
			Zantac	C				

Date:11/07/03ISR Number: 4231410-3Report Type:Expedited (15-DaCompany Report #2002CG00011
Age:60 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Culture Positive Coma	Foreign Health	Mopral	PS		ORAL	20 MG DAILY PO	

	Encephalopathy	Professional	Tercian	SS	ORAL
12 MG DAILY					
	Hyperammonaemia	Other			
PO					
	Nervous System Disorder		Largactil	SS	ORAL
10 MG DAILY					
	Psychomotor Retardation				
PO					
	Somnolence		Kidrolase	SS	
INTRAVENOUS	7000 IU ONCE				
	Staphylococcal Infection				
IV					
			Kidrolase	SS	
INTRAVENOUS	7000 IU DAILY				
IV					
			Methotrexate	SS	
INTRAVENOUS	140 MG ONCE				
IV					
			Methotrexate	SS	
INTRAVENOUS	210 MG ONCE				
IV					
			Etopophos	SS	
INTRAVENOUS	260 MG ONCE				
IV					
			Etopophos	SS	
INTRAVENOUS	260 MG ONCE				
IV					
			Primperan	SS	
			Uricozyme	SS	

Date:11/10/03ISR Number: 4233843-8Report Type:Expedited (15-DaCompany Report #2003-03567
Age:44 YR Gender:Female I/FU:I

Outcome
Other
Required
Intervention to
Prevent Permanent

Impairment/Damage

	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Coma Joint Dislocation Opisthotonus	Foreign Literature Health Professional Other	Metoclopramide (Watson Laboratories)(Metoclopramide) Tablet, 10 Mg	PS	Watson Laboratories		INTRAMUSCULAR	10 MG, SINGLE

,

INTRAMUSCULAR

Date:11/12/03ISR Number: 4234015-3Report Type:Direct Company Report #CTU 205839
Age:21 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dyspnoea		Zantac 50 Ivp	PS			INTRAVENOUS	50 MG IVP
	Feeling Hot		Reglan 10 Mg Ivp	SS			INTRAVENOUS	10 MG IVP

Date:11/12/03ISR Number: 4234850-1Report Type:Expedited (15-DaCompany Report #2003038410
Age:62 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dyskinesia Extrapyramidal Disorder	Health Professional	Norvasc (Amlodipine)	PS		ORAL	5 MG (DAILY)	
	Tongue Disorder		Metoclopramide (Metoclopramide)	SS			ORAL	
			Quetiapine Fumarate (Quetiapine Fumarate)	C				
			All Other Therapeutic Products	C				

Date:11/13/03ISR Number: 4234223-1Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0410083A
Age:4 WK Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Diarrhoea		Zantac	PS	Glaxosmithkline	ORAL	.6ML	Three
	Irritability							
	Tremor		Metoclopramide	SS	Glaxosmithkline		UNKNOWN	.4ML Per day
			Mylicon	SS	Glaxosmithkline		UNKNOWN	
			Neocate (Baby Formula)	SS		ORAL		

Date:11/14/03ISR Number: 4235346-3Report Type:Expedited (15-DaCompany Report #11003597
Age:60 YR Gender:Male I/FU:F

Outcome	PT
Death	Acute Lymphocytic
Hospitalization - Initial or Prolonged	Leukaemia
	Aplasia
	Coma
	Encephalopathy
	Hepatitis Cholestatic
	Hyperammonaemia
	Hyperbilirubinaemia
	Psychomotor Retardation
	Sepsis

		Somnolence Staphylococcal Bacteraemia	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
		Staphylococcal Infection		Etopophos For Inj	PS	Bristol-Myers Squibb Company	
INTRAVENOUS							
				Kidrolase	SS		
				Chlorpromazine	SS		
				Cyamemazine	SS		
				Omeprazole	SS		
				Methotrexate	SS	Bristol-Myers Squibb Company	
21-Mar:							
dose=210mg							
				Primperan	SS		
				Uricozyme	SS		

Date:11/14/03ISR Number: 4236467-1Report Type:Expedited (15-DaCompany Report #200306879
Age:10 MON Gender:Male I/FU:I

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Death		Multiple Drug Overdose	Consumer	Tylenol Analgesic			
			Other	Unknown Unknown	PS		ORAL
PO							
				Dextromethorphan	SS		
				Chlorpheniramine	SS		
				Diphenhydramine	SS		
				Metoclopramide	SS		

Date:11/20/03ISR Number: 4238044-5Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0383143A
Age:19 YR Gender:Female I/FU:F

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Death		Cardio-Respiratory Arrest		Bupropion	PS	Glaxosmithkline	ORAL
				Tramadol	SS		
UNKNOWN							
				Metoclopramide	SS	Glaxosmithkline	
UNKNOWN							

Date:11/21/03ISR Number: 4239126-4Report Type:Expedited (15-DaCompany Report #AU-ROCHE-352138
Age:56 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Akathisia		Hypnovel	PS	Roche	SUBCUTANEOUS		
	Hepatitis		Maxolon	SS		SUBCUTANEOUS		
	Hepatorenal Failure		Morphine	SS	Roche	UNKNOWN		
	Respiratory Depression		Fentanyl	C				
	Vomiting		Prednisone	C				
			Ranitidine	C				
			Amiloride	C				
			Domperidone	C				
			Temazepam	C				
			Docusate	C				
			Senna Extract	C				

Date:11/21/03ISR Number: 4240352-9Report Type:Expedited (15-DaCompany Report #200317421US
Age:39 YR Gender:Female I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Blood Glucose Increased
	Drug Ineffective
	Hypoaesthesia

Hypoglycaemia

Dose	Duration	Report Source	Product	Role	Manufacturer	Route
		Consumer Health Professional	Insulin Glargine (Lantus) Solution For Injection	PS		
32 U QAM	1 YR					
			Metoclopramide (Reglan) Tablets	SS		ORAL
20 MG QID PO						
			Metoclopramide (Reglan) Tablets	C		
10 MG BID	5 MON					
			Losartan Potassium (Cozaar)	C		
			Insulin Aspart (Novolog)	C		
			Lexapro	C		
			Esomeprazole (Nexium)	C		
			Multivitamin	C		
			Tegaserod	C		

Date:11/21/03ISR Number: 4240550-4Report Type:Expedited (15-DaCompany Report #031111-PM0198-00
Age:64 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Death	Atherosclerosis	Foreign Literature	Nembutal (Pentobarbital Sodium)	PS		ORAL
	Brain Oedema					
	Circulatory Collapse					
UNK, UNK; PO						
	Completed Suicide		Ethanol	SS		
UNKNOWN	UNK, UNK; UNK					
	Drug Screen Positive		Phenobarbital	SS		
UNKNOWN	UNK, UNK; UNK					
	Pulmonary Oedema		Venlafaxine	SS		
UNKNOWN	UNK, UNK; UNK					
	Stasis Syndrome		Lorazepam	SS		
UNKNOWN	UNK, UNK; UNK					
			Metoclopramide	SS		
UNKNOWN	UNK, UNK, UNK					

Date:11/26/03ISR Number: 4244028-3Report Type:Expedited (15-DaCompany Report #03-00895
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability Other	Decreased Activity Depression Dyskinesia Impaired Work Ability Movement Disorder Parkinson'S Disease	Other	Metoclopropamide Tablets (Strength Unknown) (Purepac)	PS	Purepac			

Date:11/26/03ISR Number: 4244307-XReport Type:Expedited (15-DaCompany Report #2003186502FR
Age:39 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Ascites Galactorrhoea	Foreign Health	Aldactone(Spironolctone) Tablet	PS		ORAL		ORAL
	Hepatic Encephalopathy	Professional	Lasilix (Furosemide)	SS		ORAL		ORAL
	Hyperprolactinaemia Oedema	Other	Primperan (Metoclopramide)	SS		ORAL		ORAL
			Subtex (Buprenorphine Hydrochloride)	SS		ORAL	2 MG/DAY,	ORAL

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/03/03ISR Number: 4245129-6Report Type:Expedited (15-DaCompany Report #PHFR2003GB04543
Age:59 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Interaction		Cyclosporine	PS	Novartis Sector: Pharma	ORAL	75mg/day	
	Hypertension							
	Hypotension		Metoclopramide	SS			UNKNOWN	
	Nausea		Epirubicin	C			INTRAVENOUS	102mg/day 31680MIN
			Fluorouracil	C			INTRAVENOUS	1025mg/day 31680MIN
			Metoprolol	C		ORAL	100mg/day	
			Doxazosin	C		ORAL	4mg/day	
			Simvastatin	C		ORAL	20mg/day	

Date:12/03/03ISR Number: 4246611-8Report Type:Expedited (15-DaCompany Report #200314366FR
Age:39 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Ascites	Foreign	Furosemide (Lasilix) Tablets	PS		ORAL	3 U/DAY PO	
	Galactorrhoea	Other						
	Hepatic Encephalopathy		Spironolactone (Aldactone) Coated Tablets	SS		ORAL	2 U/DAY PO	
	Hyperprolactinaemia							
	Oedema		Metoclopramide (Primperan)	SS		ORAL	3 U/DAY PO	3 WK
			Buprenorphine Hydrochloride (Subutex) Sublingual Tablets	SS			2 MG/DAY SL	

Date:12/05/03ISR Number: 4248381-6Report Type:Expedited (15-DaCompany Report #2003CG01687
Age:68 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Leukopenia Neutropenia	Foreign Health Professional Other	Mopral	PS		ORAL	20 MG DAILY PO	
			Bi-Profenid	SS		ORAL	150 MG BID PO	
			Dafalgan	SS			INTRAVENOUS	300 MG ONCE IV
			Remicade	SS			INTRAVENOUS	300 MG ONCE IV
			Remicade	SS			INTRAVENOUS	300 MG ONCE IV
			Remicade	SS			INTRAVENOUS	300 MG ONCE IV
			Rifadine	SS		ORAL	300 MG BID PO	
			Rimifon	SS		ORAL	300 MG DAILY PO	
			Anausin	SS		ORAL	3 DF DAILY PO	
			Rivotril	SS		ORAL	10 GTT DAILY PO	
			Fenofibrate	SS		ORAL	300 MG DAILY PO	
			Altizide	SS		ORAL	1 DF DAILY PO	
			Actonel	SS		ORAL	1 DF WEEK PO	
			Topalgic "Hoechst"	SS		ORAL	100 MG QID PO	
			Levothyrox	SS		ORAL	100 UG DAILY PO	
			Prozac	SS		ORAL	1 DF DAILY PO	

	Stilnox	SS	ORAL
1 DF DAILY PO			
	Forlax	SS	ORAL
3 DF DAILY PO			
	Orocal Vitamin D	SS	ORAL
2 DF DAILY PO			

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/05/03ISR Number: 4248408-1Report Type:Expedited (15-DaCompany Report #HQWYE318601DEC03
Age:67 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Atrial Fibrillation Blood Pressure Decreased Drug Interaction	Foreign Health Professional	Tazocin (Piperacillin/Tazobactam, Injection)	PS		INTRAVENOUS	13.5 MG DAILY	10 DAY
	Torsade De Pointes	Other	Ciprofloxacin (Ciprofloxacin,)	SS		INTRAVENOUS	400 MG DAILY	5 DAY
			Cisapride (Cisapride,)	SS		INTRAVENOUS	30 MG DAILY	3 DAY
			Losec (Omeprazole,)	SS		INTRAVENOUS	40 MG DAILY	
			Maxolon (Metoclopramide Hydrochloride,)	SS		INTRAVENOUS	40 MG DAILY	5 DAY
			Nystatin (Nystatin)	C				

Date:12/08/03ISR Number: 4247216-5Report Type:Expedited (15-DaCompany Report #11003597
Age:60 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Aplasia		Etopophos For Inj	PS	Bristol-Myers Squibb Company	INTRAVENOUS		
Hospitalization - Initial or Prolonged	Coma Encephalopathy Hepatitis Cholestatic Hyperammonaemia Hyperbilirubinaemia Staphylococcal Sepsis		Kidrolase Chlorpromazine Cyamemazine Omeprazole	SS SS SS SS				
			Methotrexate	SS	Bristol-Myers Squibb Company		21-Mar:	dose=210mg
			Primperan Uricozyme	SS SS				

Date:12/10/03ISR Number: 4248893-5Report Type:Expedited (15-DaCompany Report #PHBS2003CH13653
Age:54 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Cardiac Arrest		Tegretol	PS	Novartis Sector: Pharma			
Hospitalization - Initial or Prolonged	Drug Interaction						UNKNOWN	600 mg/day
	Urinary Retention		Doryl	SS			SUBCUTANEOUS	0.25 mg 1440 MIN
			Metoclopramide	SS			UNKNOWN	60 mg/day
			Gutron	SS			UNKNOWN	7.5 mg/day

Date:12/11/03ISR Number: 4249586-0Report Type:Expedited (15-DaCompany Report #CH-BRISTOL-MYERS SQUIBB COMPANY-12423075
Age:35 YR Gender:Male I/FU:F

Outcome	PT
Death	Acute Prerenal Failure
Hospitalization - Initial or Prolonged	Anaemia Macrocytic
	Blood Alkaline Phosphatase Increased
	Cachexia
	Cardiovascular Disorder
	Cough
	Dizziness
	Dyspnoea
	Fatigue
	Haemoptysis
	Jaundice

		Muscular Weakness					
		Oedema Peripheral					
		Oral Pain	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
		Pancytopenia	Health	Atazanavir	PS	Bristol-Myers Squibb	
		Pneumocystis Jiroveci	Professional			Company	ORAL
		Pneumonia		Combivir	SS		ORAL
lamivudine							
		Pneumonia					
150 mg +							
		Pyrexia					
zidovudine							
		Somnolence					
300 mg = 1							
dosage form.							
				Paspertin	SS		ORAL
				Esomeprazole	SS		
				Methadone	SS		
				Co-Trimoxazole	SS		

Date:12/15/03ISR Number: 4251515-0Report Type:Expedited (15-DaCompany Report #WAES 0311USA00474
Age:68 YR Gender:Female I/FU:F

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Disability		Depressed Level Of	Health	Pepcid	PS	Merck & Co., Inc	
INTRAVENOUS		48 DAY					
Other		Consciousness	Professional	Primperan	SS		
INTRAVENOUS		55 DAY					
		Hypotension					
		Respiratory Depression					

Date:12/15/03ISR Number: 4251663-5Report Type:Expedited (15-DaCompany Report #JP-ROCHE-353847
Age:17 YR Gender:Female I/FU:I

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Disability		Dyspnoea	Health	Horizon	PS	Roche	
INTRAVENOUS	STOP DATED						
		Pharyngeal Oedema	Professional				
REPORTED AS							

DEC 2003.

		Gaster	SS	
INTRAVENOUS	STOP DATE			

REPORTED AS

DEC 2003.

Primperan	SS		
UNKNOWN			
Droleptan	SS		
UNKNOWN			

Date:12/15/03ISR Number: 4251665-9Report Type:Expedited (15-DaCompany Report #JP-ROCHE-353847
Age:17 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Disability	Dyspnoea	Health	Horizon	PS	Roche	
INTRAVENOUS	STOP DATED					
	Pharyngeal Oedema	Professional				

REPORTED AS

DEC 2003.

Gaster	SS		
INTRAVENOUS	STOP DATE		

REPORTED AS

DEC 2003.

Primperan	SS		
UNKNOWN			
Droleptan	SS		
UNKNOWN			

Date:12/17/03ISR Number: 4252748-XReport Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0316882A
Age:47 YR Gender:Female I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Blood Culture Positive
	Escherichia Infection
	Febrile Bone Marrow

	Aplasia Pneumocystis Jiroveci Infection Septic Shock	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Small Intestinal Obstruction		Zophren	PS	Glaxosmithkline	INTRAVENOUS	8MG Per day 5 DAY
	Streptococcal Infection		Primperan	SS	Glaxosmithkline	INTRAVENOUS	2UNIT Per day
			Efferalgan Codeine	SS		ORAL	3UNIT Per day 12 DAY
			Effexor	SS		ORAL	2UNIT Per day
			Vincristine	SS		INTRAVENOUS	2MG Cyclic
			Vogalene	SS		ORAL	15MG Per day 5 DAY
			Uromitexan	C			
			Endoxan	C			
			Aracytine	C			
			Methotrexate	C			
			Adriablastin	C			
			Prednisone	C			

Date:12/17/03ISR Number: 4253573-6Report Type:Expedited (15-DaCompany Report #DE-ROCHE-354050
Age:69 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Anorexia	Health Professional	Interferon Alfa-2a	PS	Roche	UNKNOWN	54 DAY
	Ascites		Proleukin	SS	Roche	UNKNOWN	26 DAY
	Atrioventricular Block First Degree		5-Fu	SS		UNKNOWN	50 DAY
			Mcp	SS		INTRAVENOUS	1 DAY
	Atrophy		Paracetamol	SS	Roche	UNKNOWN	
	Bowel Sounds Abnormal		Codeine	SS	Roche	UNKNOWN	
	Bundle Branch Block Left Deep Vein Thrombosis Endoscopy Upper Gastrointestinal Tract Abnormal						

Food Aversion
Gastritis
General Physical Health
Deterioration
Iliac Vein Occlusion
Iliac Vein Thrombosis
Klebsiella Bacteraemia
Malignant Neoplasm
Progression
Metastases To Bone
Metastases To Liver
Metastases To Lymph Nodes
Nausea
Qrs Axis Abnormal
Renal Cell Carcinoma
Stage Iv
Subcutaneous Nodule
Tachycardia
Urinary Tract Infection

Date:12/17/03ISR Number: 4268306-7Report Type:Periodic Company Report #USA-2003-0006530
Age:40 YR Gender:Male I/FU:I

Outcome	PT	Report Source
Death	Accidental Overdose	Health Professional
	Multiple Drug Overdose	Company Representative

Other

Product	Role	Manufacturer	Route	Dose	Duration
Oxycontin Tablets (Oxycodone Hydrochloride)	PS			20 MG, Q12H	
Reglan (Metoclopramide)	SS			10 MG, QID	PRN
Lexapro (Citalopram)	SS			10 UNK, DAILY	
Percocet (Paracetamol, Oxycodone Hydrochloride)	SS			5 MG, Q4H PRN	
Zantac (Ranitidine Hydrochloride)	SS			300 MG, BID,	PRN
Zanaflex (Tizanidine Hydrochloride)	SS				
Flagyl (Metronidazole)	SS			500 MG, BID	

Date:12/17/03ISR Number: 4269120-9Report Type:Periodic Company Report #USA-2003-0007058
Age:51 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Health Professional Other	Oxycodone Hydrochloride (Similar To Nda 20-553)	PS				
			Carisoprodol	SS				
			Meprobamate	SS				
			Caffeine	SS				
			Metoclopramide	SS				
			Dextromethorphan	SS				

			Epherdrine	SS		
			Nicotine	SS		
			Methsuximide	SS		
			Cannibis	SS		

Date:12/18/03ISR Number: 4255492-8Report Type:Expedited (15-DaCompany Report #FRWYE458812DEC03
Age:47 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Small Intestinal Obstruction	Health Professional	Effexor (Venlafaxine Hydrochloride,					
Other		Other	Unspec, 0)	PS		ORAL	2 DOSE 1X PER	1 DAY
			Efferalgan Codeine (Paracetamol/Codeine Phosphate)	SS		ORAL	3 DOSE 1X PER	1 DAY 12 DAY
			Primperan (Metoclopramide)	SS		INTRAVENOUS	2 DOSE 1X PER	1 DAY
			Vincristine Sulfate (Vincristine Sulfate)	SS		INTRAVENOUS	2 MG 1X PER 1	CYC

			Vogalene (Metopimazine)	SS		ORAL	15 MG 1X PER
1 DAY	5 DAY						
			Zophren (Ondansetron Hydrochloride)	SS			
INTRAVENOUS	8 MG 1X PER 1						
DAY	5 DAY						

Date:12/19/03ISR Number: 4255101-8Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0317633A
Age:50 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Anaemia	Consumer	Augmentin	PS	Glaxosmithkline	ORAL	6G Per day	8 DAY
	Dermatitis Bullous		Gardenal	SS				
UNKNOWN	800MG Per day	6 DAY						
	Erythema		Primperan	SS	Glaxosmithkline			
UNKNOWN		4 DAY						
	Genital Ulceration		Perfalgan	SS	Glaxosmithkline			
INTRAVENOUS	4G Per day	4 DAY						
	Inflammation		Duphalac	C		ORAL		
	Leukopenia		Phosphoneuros	C		ORAL		
	Pruritus Generalised		Acupan	C				
UNKNOWN								
	Pyrexia		Polaramine	C				
UNKNOWN								
	Staphylococcal		Vitamin B1-B6	C				
UNKNOWN								
	Bacteraemia		Heparine	C				
UNKNOWN								
	Toxic Epidermal		Fraxodi	C				
SUBCUTANEOUS								
	Necrolysis		Zovirax	C	Glaxosmithkline			
UNKNOWN								
	Vomiting		Solupred	C	Glaxosmithkline			
UNKNOWN								
			Solumedrol	C				
UNKNOWN								
			Clarityne	C				
UNKNOWN								

			Mydriaticum	C		
OPHTHALMIC						
			Cernevit	C		
UNKNOWN						
			Previscan	C		ORAL
			Vitamin C	C	Glaxosmithkline	
UNKNOWN						

Date:12/19/03ISR Number: 4255569-7Report Type:Expedited (15-DaCompany Report #WAES 0312USA01150
Age:17 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Dyspnoea	Health	Pepcid	PS	Merck & Co., Inc	
PARENTERAL						
	Pharyngeal Oedema	Professional	Horizon	SS		
PARENTERAL						
			Droleptan	SS		
			Primperan	SS		
			[Therapy Unspecified]	C		

Date:12/22/03ISR Number: 4256126-9Report Type:Expedited (15-DaCompany Report #DE-ROCHE-353822
Age:62 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Asthenia	Health	Interferon Alfa-2a	PS	Roche	
UNKNOWN						
Hospitalization -	Atrial Fibrillation	Professional	Proleukin	SS	Roche	
UNKNOWN						
Initial or Prolonged	Balance Disorder		5-Fu	SS		
UNKNOWN						
	Dehydration		Paracetamol	SS	Roche	
UNKNOWN						
	Dyspnoea		Mcp	SS		
UNKNOWN						
	Electrolyte Imbalance		Metamizol	SS		
UNKNOWN						
	Hypernatraemia		Omeprazol	SS		
UNKNOWN						
	Pulmonary Oedema					
	Speech Disorder					

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/22/03ISR Number: 4257746-8Report Type:Expedited (15-DaCompany Report #2003123783
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Colonic Polyp Feeling Abnormal	Consumer	Lipitor (Atorvastatin)	PS		ORAL	10 MG	
Other	Fibrosis							
	Gait Disturbance		Reglan (Metoclopramide)	SS		ORAL	(QID), ORAL	
	Haematochezia							
	Hepatitis Viral		Norvasc (Amlodipine)	C				
	Medication Error		Buspirone Hydrochloride (Buspirone Hydrochloride)	C				
	Movement Disorder		Sertraline Hydrochloride (Sertraline Hydrochloride)	C				
			Warfarin Sodium (Warfarin Sodium)	C				
			Omeprazole (Omeprazole)	C				

Date:12/23/03ISR Number: 4256992-7Report Type:Expedited (15-DaCompany Report #WAES 0311USA00474
Age:68 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Depressed Level Of Consciousness	Health	Pepcid	PS	Merck & Co., Inc	INTRAVENOUS		48 DAY
Disability		Professional	Primperan	SS		INTRAVENOUS		55 DAY
Other	Hypotension Respiratory Depression							

Date:12/23/03ISR Number: 4257014-4Report Type:Expedited (15-DaCompany Report #WAES 0312USA01150
Age:17 YR Gender: I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Apallic Syndrome	Health	Pepcid	PS	Merck & Co., Inc	PARENTERAL		
	Cardiac Arrest	Professional	Horizon	SS		PARENTERAL		
	Dyspnoea		Droleptan	SS				
	Loss Of Consciousness		Primperan	SS				
	Obstructive Airways Disorder		[Therapy Unspecified]	C				
	Pharyngeal Oedema							
	Respiratory Failure							

Date:12/23/03ISR Number: 4258133-9Report Type:Expedited (15-DaCompany Report #20031200122
Age:64 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Alcohol Use	Foreign	Temesta (Lorazepam)					
	Atherosclerosis	Literature	Baxter	PS				
	Brain Oedema	Other	Phenobarbital	SS				
	Completed Suicide		Ethanol	SS				
	Intentional Misuse		Nembutal (Pentobarbital)	SS				
	Pulmonary Oedema		Primperan (Metoclopramide)	SS				

Date:12/30/03ISR Number: 4261693-5Report Type:Expedited (15-DaCompany Report #03-00950
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Aphasia	Other	Metoclopramide					
Hospitalization - Initial or Prolonged	Asthenia		(Purepac)	PS	Purepac			
	Cerebrovascular Accident		Reglan	SS				
Disability	Depressed Mood		Vicodin	SS				
Other	Diabetic Neuropathy							
	Drug Toxicity							
	Dysarthria							
	Extrapyramidal Disorder							
	Facial Palsy							
	Hemiparesis							
	Immobile							
	Injury							
	Lacunar Infarction							
	Nervous System Disorder							
	Overdose							
	Pain							
	Suicide Attempt							
	Transient Ischaemic Attack							
	Tremor							

Date:12/30/03ISR Number: 4261707-2Report Type:Expedited (15-DaCompany Report #03-00950
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Cerebrovascular Accident	Other	Metoclopropamide					
Hospitalization - Initial or Prolonged	Depression		(Purepac)	PS	(Purepac)			
	Drug Toxicity		Reglan	SS				
Disability	Extrapyramidal Disorder		Vicodin	SS				
Other	Injury							
	Lacunar Infarction							
	Overdose							
	Suicide Attempt							
	Transient Ischaemic Attack							
	Tremor							

Date:01/07/04ISR Number: 4266060-6Report Type:Direct Company Report #CTU 209503
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Cardiovascular Disorder Chest Pain		5 Fu	PS		INTRAVENOUS	1840 MG 24 HRS CONT. IV	
Required Intervention to Prevent Permanent Impairment/Damage			Cisplatin	SS		INTRAVENOUS	37 MG 24 HRS. CONT. IV	
			5 Fu	SS		INTRAVENOUS	1800 MG 24 HRS. CONT IV	
			Cisplatin	SS		INTRAVENOUS	36 MG 24 HRS. CONT IV	
			Iressa	SS		ORAL	250 MG QD PO	
			Aciphex	SS		ORAL	20 MG QD PO	
			Reglan	SS		ORAL	10 MG QID PO	
			Ativan	SS		ORAL	1 MG TID PRN PO	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/07/04ISR Number: 4266291-5Report Type:Expedited (15-DaCompany Report #WAES 0311USA00474
Age:68 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Depressed Level Of	Health	Pepcid	PS	Merck & Co., Inc	INTRAVENOUS		48 DAY
Disability	Consciousness	Professional	Primperan	SS		INTRAVENOUS		55 DAY
Other	Hypotension							
	Respiratory Depression							

Date:01/08/04ISR Number: 4266736-0Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0317633A
Age:50 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Anaemia	Consumer	Augmentin	PS	Glaxosmithkline	ORAL	6G Per day	8 DAY
	Dermatitis Bullous		Gardenal	SS		UNKNOWN	800MG Per day	6 DAY
	Erythema		Primperan	SS	Glaxosmithkline	UNKNOWN		4 DAY
	Face Oedema		Perfalgan	SS	Glaxosmithkline	INTRAVENOUS	4G Per day	4 DAY
	Inflammation		Duphalac	C		ORAL		
	Leukopenia		Phosphoneuros	C		ORAL		
	Localised Oedema		Acupan	C		UNKNOWN		
	Pruritus Generalised		Polaramine	C		UNKNOWN		
	Pyrexia		Vitamin B1-B6	C		UNKNOWN		
	Staphylococcal Infection		Heparine	C		UNKNOWN		
	Toxic Epidermal		Fraxodi	C		SUBCUTANEOUS		
	Necrolysis		Zovirax	C	Glaxosmithkline	UNKNOWN		
	Vomiting		Solupred	C	Glaxosmithkline	UNKNOWN		
			Solumedrol	C		UNKNOWN		
			Clarityne	C		UNKNOWN		

			Mydriaticum	C		
OPHTHALMIC						
			Cernevit	C		
UNKNOWN						
			Previscan	C		ORAL
			Vitamin C	C	Glaxosmithkline	
UNKNOWN						

Date:01/13/04ISR Number: 4271737-2Report Type:Expedited (15-DaCompany Report #04P-062-0246399-00
Age:41 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hypoaesthesia Overdose Suicide Attempt Tachycardia	Foreign Health Professional	Klacid Filtmtabs (Biaxin) (Clarithromycin)	PS		ORAL	250 MG, 10 IN 1 D, PER ORAL	
			Agopton 30	SS		ORAL	1 TABLET, 14 IN 1 D, PER ORAL	
			Metoclopramide Hydrochloride	SS		ORAL	1 TABLET, 16 IN 1 D, PER ORAL	
			Ambroxol (Ambroxol Chloridrate)	SS		ORAL	1 TABLET, 3 IN 1 D, PER ORAL	
			Diazepam	SS		ORAL	1 TABLET, 7 IN 1 D, PER ORAL	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/14/04ISR Number: 4273667-9Report Type:Expedited (15-DaCompany Report #2003-BP-10862RO
Age:51 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Erythema Skin Exfoliation	Foreign Study Consumer Health Professional	Leucovorin Calcium Tablets Usp, 10 Mg (Calcium Folinate)	PS		ORAL	90 MG/CYCLE (NR), PO	
			Taxol (Paclitaxel)	SS		INTRAVENOUS	192 MG/CYCLE (NR), IV	
			Uft (Tegafur Uracil)	SS		ORAL	600 MG/CYCLE (NR), PO	
			Metoclopramide (Me-Toclopramide)	SS				

Date:01/15/04ISR Number: 4274360-9Report Type:Expedited (15-DaCompany Report #7052
Age:54 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Flushing Oedema Peripheral Pyrexia Rash Erythematous	Foreign Health Professional Professional Other	Metoclopramide	PS		ORAL	10 MG FREQ, PO	1 DAY
			Allopurinol	SS		ORAL	300 MG FREQ, PO	2 DAY
			Lansoprazole	SS		ORAL	30 MG FREQ, PO	2 DAY
			Co-Trimoxazole	SS		ORAL	960 MG BID, PO	2 DAY
			Fluconazole	SS		ORAL	50 MG, PO	2 DAY

				Fludarabine	C		
				Dexamethasone	C		
				Metoclopramide	C		

Date:01/20/04ISR Number: 4274097-6Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0317633A
Age:50 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Anaemia	Consumer	Augmentin	PS	Glaxosmithkline	ORAL	6G Per day	8 DAY
	Dermatitis Bullous		Gardenal	SS			UNKNOWN	800MG Per day 6 DAY
	Erythema		Primperan	SS	Glaxosmithkline		UNKNOWN	4 DAY
	Face Oedema		Perfalgan	SS	Glaxosmithkline		INTRAVENOUS	4G Per day 4 DAY
	Genital Ulceration		Previscan	SS		ORAL	3 DAY	
	Inflammation		Duphalac	C		ORAL		
	Leukopenia		Phosphoneuros	C		ORAL		
	Localised Oedema		Acupan	C			UNKNOWN	
	Pruritus Generalised		Polaramine	C			UNKNOWN	
	Pyrexia		Vitamin B1-B6	C			UNKNOWN	
	Rash		Heparine	C			UNKNOWN	
	Staphylococcal		Fraxodi	C			SUBCUTANEOUS	
	Bacteraemia		Zovirax	C	Glaxosmithkline		UNKNOWN	
	Toxic Epidermal		Solupred	C	Glaxosmithkline		UNKNOWN	
	Necrolysis		Solumedrol	C			UNKNOWN	
	Vomiting		Clarityne	C			UNKNOWN	
			Mydriaticum	C			OPHTHALMIC	
			Cernevit	C			UNKNOWN	
			Previscan	C		ORAL		
			Vitamin C	C	Glaxosmithkline		UNKNOWN	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/20/04ISR Number: 4276675-7Report Type:Expedited (15-DaCompany Report #04P-163-0246493-00
Age:52 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	Asthenia	Literature	Cyclosporine (Gengraf) (Cyclosporine) (Cyclosporine)	PS			150 MG, 2 IN	1 D
	Blindness Cortical	Health Professional						
	Coma							
	Confusional State							
	Convulsion							
	Dizziness		Metoclopramide (Metoclopramide)	SS				
	Drug Interaction		Azathioprine	C				
	Haemoglobin Decreased		Prednisone	C				
	Headache		Bactrim	C				
	Neurotoxicity		Ganciclovir	C				
	Staring		Nystatin	C				
	Tremor		Clarithromycin	C				
	Urinary Incontinence		Furosemide	C				
	Vision Blurred		Cisapride	C				
			Nizatidine	C				
			Folic Acid	C				
			Potassium Chloride	C				
			Losartan	C				
			Furosemide	C				

Date:01/21/04ISR Number: 4277528-0Report Type:Expedited (15-DaCompany Report #RB-162-2003
Age:33 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Nervous System Disorder	Health Professional	Suboxone	PS		SUBLINGUAL	8 MG DAILY SL	
	Restless Legs Syndrome		Metoclorpramide	SS		ORAL	10 MG DAILY	
	Restlessness					PO		
			Ativan	C				
			Prozac	C				
			Reglan	C				

Date:01/22/04ISR Number: 4279348-XReport Type:Expedited (15-DaCompany Report #04P-062-0246399-00
Age:41 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hypoaesthesia Multiple Drug Overdose Suicide Attempt Tachycardia	Foreign Health Professional	Klacid Filmtabs (Biaxin) (Clarithromycin) (Clarithromycin)	PS		ORAL	250 MG, 10 IN 1 D, PER ORAL	
			Agopton 30	SS		ORAL	1 TABLET, 14 IN 1 D, PER ORAL	
			Metoclopramide Hydrochloride	SS		ORAL	1 TABLET, 16 IN 1 D, PER ORAL	
			Ambroxol (Ambroxol Chloridrate) (Ambroxol Chloridrate)	SS		ORAL	1 T ABLET, 3 IN 1 D, PER ORAL	
			Diazepam	SS		ORAL	1 TABLET, 7 IN 1 D, PER	

ORAL

Date:01/22/04ISR Number: 4279837-8Report Type:Expedited (15-DaCompany Report #200410092DE
Age:75 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Drug Ineffective	Foreign	Lasix Solution For					
Life-Threatening	Haemoglobin Decreased	Study	Injection	PS				
INTRAVENOUS	IV						3	DAY
	Septic Shock	Health	Novalgin Drops	SS		ORAL		
20 DROP QD PO							4	DAY
	Staphylococcal Infection	Professional	Lasix Solution For					
	Stevens-Johnson Syndrome	Other	Injection	SS				
INTRAVENOUS	IV						3	DAY
	Toxic Epidermal		Nitrazepam Tablets	SS		ORAL		
PO							1	DAY
	Necrolysis		Nitrazepam Tablets	SS		ORAL		
PO							1	WK
	Toxic Shock Syndrome		Nitrazepam Tablets	SS		ORAL		
PO							1	DAY
			Nitrazepam Tablets	SS		ORAL		
PO							1	DAY
			Furorese Solution For Injection	SS				
INTRAVENOUS	IV						4	DAY
			Furorese Solution For Injection	SS				
INTRAVENOUS	IV						18	DAY
			Tramal Drops	SS		ORAL		
15 DROP/DAY								
PO							1	DAY
			Pcm Liquid	SS		ORAL		
PO							1	DAY
			Mcp	SS				
INTRAVENOUS	IV						1	DAY
			Mcp	SS				
INTRAVENOUS	IV						1	DAY
			Mcp	SS				
INTRAVENOUS	IV						5	DAY
			Prednison	SS		ORAL		
PO							6	DAY
			Pantozol	SS		ORAL		
40 MG QPM PO							6	DAY

Gentamicin	C
Spizef	C
Periplasmal	C
Orgaran	C
Clont	C
Vancomycin	C
Mst	C
Solu-Decortin H	C
Antra	C
Baldrian	C
Paspertin	C
Dimeticon	C
Multibionta	C

Date:01/26/04ISR Number: 4280151-5Report Type:Expedited (15-DaCompany Report #2004001329
Age:5 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anaphylactoid Reaction Anuria Asthma Therapeutic Product Ineffective Vomiting	Foreign Health Professional Company Representative	Zithromac (Azithromycin) Ceftriaxone Sodium (Ceftriaxone Sodium) Metoclopramide (Metoclopramide)	PS SS SS		ORAL ORAL INTRAVENOUS		

Date:01/26/04ISR Number: 4280435-0Report Type:Expedited (15-DaCompany Report #002#4#2004-00009
Age: Gender:Female I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Aphasia Asthenia
Disability	Cerebrovascular Accident

		Condition Aggravated Depression Diabetic Neuropathy	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
		Drug Toxicity Dysarthria	Consumer Other	Reglan-Dose-Unknown (Metoclopramide Hcl)	PS		ORAL
ORAL							
		Facial Palsy		Metoclopramide	SS		ORAL
ORAL							
		Lacunar Infarction Overdose Paralysis Suicide Attempt Transient Ischaemic Attack Tremor					

Date:01/28/04ISR Number: 4281948-8Report Type:Expedited (15-DaCompany Report #SGB1-2003-00673
Age:54 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Life-Threatening	Cardiac Arrest	Foreign	Midon 2.5mg ()			
Hospitalization -	Cardiomegaly	Health	Tablet	PS		ORAL
7.5 MG, ORAL						
Initial or Prolonged	Drug Interaction	Professional Other	Tegretol (Carbamazepine)	SS		ORAL
600 MG, ORAL	122 DAY					
			Metoclopramide Hydrochloride (Metoclopramide Hydrochloride)	SS		ORAL
60 MG, ORAL	5 DAY					
			Doryl (Carbachol)	C		

Date:01/28/04ISR Number: 4281989-0Report Type:Expedited (15-DaCompany Report #04P-163-0247509-00
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization -	Overdose	Other	Vicodin			
Initial or Prolonged	Suicide Attempt		(Hydrocodone/Acetami nophen)			

(Hydrocodone/Acetaminophen)	PS
Metoclopramide	SS
Reglan	SS

Date:01/29/04ISR Number: 4283076-4Report Type:Expedited (15-DaCompany Report #2004-01-1277
Age:38 YR Gender:Male I/FU:I

Outcome	PT
Death	Blood Ph Decreased
Life-Threatening	Blood Pressure Immeasurable
	Blood Pressure Increased
	Circulatory Collapse
	Coma
	Dilatation Atrial
	Dilatation Ventricular
	Hypotension
	Nausea
	Nodal Arrhythmia
	Pco2 Decreased
	Po2 Increased
	Pulse Absent

		Sinus Tachycardia Vomiting					
			Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
			Literature	Labetalol Injectable	PS		
INTRAVENOUS	10 MG						
			Health				
INTRAVENOUS,							
			Professional				
1 DOSE							
				Metoclopramide Injectable	SS		
INTRAVENOUS	10 MG						
INTRAVENOUS,							
1 DOSE							
				Lisinopril	SS		
				Mepivacaine	C		
				Bupivacaine	C		
				Midazolam	C		
				Propofol	C		

Date:02/02/04ISR Number: 4285019-6Report Type:Expedited (15-DaCompany Report #USA-2003-0007803
Age:75 YR Gender:Male I/FU:F

Outcome	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Dose							
Death		Benign Prostatic Hyperplasia Blood Ketone Body Present Bone Neoplasm Malignant Carcinoid Tumour Cardiomegaly Completed Suicide Coronary Artery Atherosclerosis Drug Screen Positive Gun Shot Wound Hepatic Steatosis Kyphoscoliosis Multiple Fractures Nephrosclerosis Skull Fractured Base Spinal Osteoarthritis	Health Professional Other	Oxycodone Hydrochloride (Similar To Nda 20-553) (Oxycodone Hydrochloride)	PS		
				Amitriptyline (Amitriptyline)	SS		
				Salicylic Acid (Salicylic Acid)	SS		
				Diphenhydramine (Diphenhydramine)	SS		
				Metoclopramide (Metoclopramide)	SS		
				Nortriptyline (Nortriptyline)	SS		
				Acetone (Acetone)	SS		

Date:02/02/04ISR Number: 4285290-0Report Type:Expedited (15-DaCompany Report #2004003879
Age:60 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agranulocytosis Asthenia	Foreign Health	Diflucan Injection (Ifluconazole)	PS			SEE IMAGE	
	Cd4 Lymphocytes Decreased Neutropenia	Professional	Ceftriaxone (Ceftriaxone)	SS		INTRAVENOUS	4 GRAM	(DAILY),
	Pyrexia							
			Metoclopramide Hydrochloride (Metoclopramide Hydrochloride)	SS		INTRAVENOUS	30 MG	(DAILY),
			Paracetamol (Paracetamol)	SS		INTRAVENOUS	4 GRAM	(DAILY),
			Ketorolac			INTRAVENOUS		

				Tromethamine (Ketorolac Tromethamine)	SS		
INTRAVENOUS	60 MG (DAILY), INTRAVENOUS						

Date:02/03/04ISR Number: 4284995-5Report Type:Direct Company Report #CTU 211453
Age:11 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Depression		Reglan Liquid	PS				
VRS								

Date:02/03/04ISR Number: 4285807-6Report Type:Expedited (15-DaCompany Report #002#8#2004-00017
Age:87 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Anorexia	Literature	Reglan-5mg-Tablet					
	Incontinence	Health	(Metoclopramide Hcl)	PS		ORAL	5MG, 4 IN 1	
	Mobility Decreased	Professional					D, ORAL	
	Muscle Contracture							
	Muscle Rigidity							
	Tremor							

Date:02/03/04ISR Number: 4285809-XReport Type:Expedited (15-DaCompany Report #002#28#2004-00015(0)
Age:84 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	Literature Health	Reglan-10mg-Tablet (Metoclopramide Hcl)	PS		ORAL	10MG, 3 IN 1	
Disability	Bradykinesia	Professional					D, ORAL	
	Cogwheel Rigidity							

	Confusional State						
	Depressive Symptom						
	Dysphagia						
	Incontinence						
	Weight Decreased						

Date:02/04/04ISR Number: 4284870-6Report Type:Expedited (15-DaCompany Report #PHBS2004JP01330
Age:74 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anaemia	Health Professional	Lochol	PS	Novartis Sector: Pharma	ORAL	20 mg/day	
	Platelet Count Decreased							
	Red Blood Cell Count Decreased		Berizym	SS		ORAL		
			Alinamin	SS		ORAL		
			Biofermin	SS		ORAL		
			Clotiazepam	SS		ORAL		
			Elieten	SS		ORAL		
			Sennoside A	SS		ORAL		

Date:02/04/04ISR Number: 4285114-1Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0319476A
Age:42 YR Gender:Female I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Disease Recurrence
	Empyema
	Meningioma

Thrombocytopenia

Dose	Duration	Report Source	Product	Role	Manufacturer	Route
			Zophren	PS	Glaxosmithkline	
INTRAVENOUS	8MG Twice per day					
			Claforan	SS		
INTRAVENOUS	2G Six times per day	6 DAY				
			Tiberal	SS		
INTRAVENOUS	1G Twice per day	6 DAY				
			Mopral	SS		ORAL
20MG Per day						
			Lovenox	SS		ORAL
40MG Per day	4 DAY					
			Perfalgan	SS	Glaxosmithkline	
INTRAVENOUS	1G Four times per day					
			Primperan	SS	Glaxosmithkline	
INTRAVENOUS	1G Four times per day					
			Depakine	SS		ORAL
500MG Four times per day						
			Morphine	SS		
			Vancomycine	C		
			Rifater	C		ORAL
			Danaparoide Sodique	C		

Date:02/09/04ISR Number: 4289971-4Report Type:Expedited (15-DaCompany Report #DE-ROCHE-357741
Age:60 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization -	Arthralgia	Consumer	Kevatril	PS	Roche	
INTRAVENOUS						

Initial or Prolonged	Myalgia		Taxotere	SS		
INTRAVENOUS						
	Oedema Peripheral		Fortecortin	SS		
INTRAVENOUS ROUTE IS						
	Parainfluenzae Virus					
REPORTED AS						
	Infection					
IV/ ORAL.						
	Pyrexia					
DOSING						
	Thrombophlebitis					
REGIMEN IS 3 DAY						
			Paspertin	SS		ORAL
4 DAY						
			Berodual	C		
			Berotec	C		
			Imap	C		
			Pantozol	C		

Date:02/10/04ISR Number: 4290555-2Report Type:Expedited (15-DaCompany Report #04-00046
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Depression	Consumer	Metoclopramide					
Hospitalization -	Gastrointestinal Injury		Tablets Usp, 10mg					
Initial or Prolonged	Intentional Self-Injury		(Purepac)	PS	Purepac	ORAL	10 MG, ORAL	
Required	Suicidal Ideation							
Intervention to	Suicide Attempt							
Prevent Permanent	Wound							
Impairment/Damage								

Date:02/10/04ISR Number: 4293301-1Report Type:Direct Company Report #CTU 211999
Age: Gender: I/FU:I

Outcome	PT
Other	Abnormal Behaviour
	Burning Sensation
	Pharmaceutical Product

Complaint

			Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
				Metoclopramide Injection, Usp 10mg/2ml	PS	Gensia Sicor Pharmaceuticals, Inc.	

Date:02/17/04ISR Number: 4299152-6Report Type:Direct Company Report #CTU 212486
Age:21 YR Gender:Female I/FU:I

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Other		Chest Discomfort		Reglan 5mg	PS		ORAL
5 MG TID ORAL							
		Confusional State		Zyprexa 2.5 Mg	SS		ORAL
3.75MG Q HS							
		Corneal Reflex Decreased					
ORAL							
		Lethargy					
		Movement Disorder					
		Parkinsonian Rest Tremor					
		Parkinsonism					
		Tongue Disorder					

Date:02/18/04ISR Number: 4300230-3Report Type:Expedited (15-DaCompany Report #20040100073
Age:66 YR Gender:Female I/FU:I

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Other		Medication Error	Health Professional	Reglan (Metoclopramide) Baxter	PS		
10 MG DAILY							

Date:02/19/04ISR Number: 4301416-4Report Type:Expedited (15-DaCompany Report #2004198784FR
Age:22 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	Solu-Medrol (Methylprednisolone)	PS				
	Aspartate Aminotransferase Increased	Professional Other	Azantac (Ranitidine Hydrochloride)	SS		ORAL	40 MG, QD, IV	
	Blood Bilirubin Increased		Visceralgine Forte (Metamizole Sodium, Tiemonium Methylsulphate)	SS		ORAL	1 DF, QD,	
	Cholestasis							
	Gamma-Glutamyltransferase Increased							
	Hepatocellular Damage							
	Jaundice		Zyloric(Allopurinol)	SS		ORAL	900 MG, ORAL	
			Ciflox (Ciprofloxacin)	SS			200 MG, BID,	IV
			Zophren (Ondansetron Hydrochloride)	SS			16 MG, BID,	IV
			Rocephin (Ceftriaxone Sodium)	SS				
			Zovirax(Aciclovir)	SS				
			Primperan(Metoclopramide)	SS				
			Duphalac(Lactulose)	SS				
			Acupan(Nefopam					

			Hydrochloride)	SS		
			Trimebutine (Trimebutine)	SS		
			Mopral	C		
			Oncovin	C		
			Endoxan	C		
			Cerubidine	C		
			Methotrexate	C		
			Aracytine	C		

Date:02/23/04ISR Number: 4301651-5Report Type:Expedited (15-DaCompany Report #200412214GDDC
Age:73 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Alanine Aminotransferase Increased	Health Professional	Lasix	PS	Aventis Pharmaceuticals Inc.	ORAL		
	Aspartate Aminotransferase Increased		Takepron	SS		ORAL		
			Primperan	SS		ORAL		
			Gaster	SS		ORAL		
	Hyperbilirubinaemia		Rocefin	SS		PARENTERAL		
			Selbex	SS		ORAL		
			Penicillin G	SS		PARENTERAL	dose: UNK	

Date:02/23/04ISR Number: 4302321-XReport Type:Expedited (15-DaCompany Report #WAES 0402DEU00054
Age:72 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Drug Interaction		Zocor	PS	Merck & Co., Inc	ORAL		
Other	Pancreatitis		Acetaminophen	SS				
	Post Procedural Complication		Amiodarone	SS				
			Amlodipine Maleate	SS				
	Rhabdomyolysis		Aspirin	SS				
			Atorvastatin Calcium	SS				
			Captopril	SS				
			Cefotiam	SS				
			Clonidine	SS				
			Dexamethasone	SS				
			Dexpanthenol	SS				
			Diazepam	SS				
			Dopamine					

Hydrochloride	SS
Enalapril Maleate	SS
Enoximone	SS
Epinephrine Hydrochloride	SS
Etomidate	SS
Fenoterol And Ipratropium Bromide	SS
Sufentanil	SS
Flunitrazepam	SS
Furosemide	SS
Isosorbide Dinitrate	SS
Lidocaine	SS
Lormetazepam	SS
Cozaar	SS
Metoclopramide	SS
Metoprolol	SS
Verapamil	SS
Molsidomine	SS
Neostigmine Bromide	SS

			Nifedipine	SS			
			Nitroglycerin	SS			
			Norepinephrine Hydrochloride	SS			
			Omeprazole	SS			
			Ondansetron	SS			
			Pancuronium Bromide	SS			
			Piperacillin Sodium And Tazobactam Sodium	SS			
			Piritramide	SS			
			Propofol	SS			
			Radiographic Contrast Medium (Unspecified)	SS			

Date:02/23/04ISR Number: 4303368-XReport Type:Expedited (15-DaCompany Report #04P-062-0246399-00
Age:41 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Asthenia Hypoaesthesia Intentional Misuse Multiple Drug Overdose Suicide Attempt Tachycardia	Foreign Health Professional	Klacid Filmtabs (Biaxin) (Clarithromycin)	PS		ORAL	250 MG, 10 IN 1 D, PER ORAL
			Agopton 30	SS		ORAL	1 TABLET, 14 IN 1 D, PER ORAL
			Metoclopramide Hydrochloride	SS		ORAL	1 TABLET, 16 IN 1 D, PER ORAL
			Ambroxol (Ambroxol Chloridrate)	SS		ORAL	1 TABLET, 3 IN 1 D, PER

ORAL

			Diazepam	SS		ORAL

1 TABLET, 7

IN 1 D, PER

ORAL

Date:02/23/04ISR Number: 4303411-8Report Type:Expedited (15-DaCompany Report #2004195147DE
Age:60 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Arthralgia Myalgia Nasopharyngitis	Foreign Study Health	Comparator-Docetaxel (Comparator-Docetaxel) Injection	PS		
INTRAVENOUS 75 MG/M2, DAILY, CYCLIC, IV	Oedema Peripheral Rheumatoid Arthritis Thrombophlebitis	Professional Other				
			Comparator - Dexamethasone (Dexamethasone) Injection	SS		
INTRAVENOUS 8MG, IV, IV						
			Comparator - Dexamethasone (Dexamethasone, Dexamethasone) Tablet	SS		ORAL

8 MG, ORAL,

ORAL

Kevatril

				(Granisetron Hydrochloride)	SS			
INTRAVENOUS	3 MG, QD, IV							
				Paspertin (Metoclopramide Hydrochloride)	SS			ORAL
40 MG, QID,								
ORAL								
				Pantozol (Pantoprazole Sodium)	C			
				Imap (Fluspirilene)	C			
				Begodural	C			

Date:02/24/04ISR Number: 4303506-9Report Type:Direct Company Report #CTU 212999
Age:24 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Extrapyramidal Disorder		Reglan 10 Mg	PS		ORAL	10 MG TID	
ORAL								

Date:02/26/04ISR Number: 4304986-5Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0495507A
Age: Gender: I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Convulsion		Wellbutrin	PS	Glaxosmithkline		300MG Per day	3 WK
			Reglan	SS	Glaxosmithkline		10MG Per day	

Date:02/26/04ISR Number: 4306975-3Report Type:Direct Company Report #CTU 213299
Age:61 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Drug Ineffective		Metoclopramide	PS			10 MG Q 3 HR	

Initial or Prolonged	Hallucination, Visual		Ondasertron	SS
INTRAVENOUS 4 MG IV X 2 DOSES	Hypnagogic Hallucination			
			Ampicillin	C
			Aspirin	C
			Metoprolol	C
			Hydromorphone	C
			Metoclopramide	C
			Pantoprazole	C
			Acetaminophen	C
			Gentamicin	C
			Glyburide	C
			Regular Insulin	C

Date:02/27/04ISR Number: 4307747-6Report Type:Direct Company Report #CTU 213352
Age:55 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Ventricular Fibrillation		Reglan	PS			10 MG TID	PTA
			Sotolol	SS			80 MG BID	

Date:02/27/04ISR Number: 4307759-2Report Type:Direct Company Report #CTU 213363
Age:48 YR Gender:Female I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Convulsion
	Malignant Neoplasm

	Progression Metastases To Central Nervous System Metastatic Malignant Melanoma	Report Source	Product	Role	Manufacturer	Route	Dose Duration
			Il-2 2 Mu Sq	PS		SUBCUTANEOUS	2 MU SQ
			Reglan	SS			10 MG Q 4 PRN
			Vicodin	SS			2 TABS Q4HRS PRN

Date:02/27/04ISR Number: 4308877-5Report Type:Expedited (15-DaCompany Report #2004001329
Age:5 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Anaphylactic Shock Anuria Asthma Condition Aggravated Drug Ineffective Vomiting	Foreign Health Professional Company Representative	Zithromac (Azithromycin)	PS		ORAL	200 MG (ONCE), ORAL
			Ceftriaxone Sodium (Ceftriaxone Sodium)	SS		INTRAVENOUS	1 GRAM (ONCE), INTRAVENOUS
			Metoclopramide (Metoclopramide)	SS			0.6 ML (ONCE), INTRAVITREOUS
			Theophylline (Theophylline)	C			
			Clemastine Fumarate (Clemastine Fumarate)	C			
			Tipepidine Hibenzate (Tipepidine Hibenzate)	C			

			Acetylcysteine (Acetylcysteine)	C		
			Procaterol Hyrochloride Iprocaterol Hydrochloride)	C		

Date:03/01/04ISR Number: 4308454-6Report Type:Expedited (15-DaCompany Report #JP-ROCHE-355374
Age:5 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Anaphylactoid Reaction	Health	Rocephin	PS	Roche	INTRAVENOUS	1	DAY
Initial or Prolonged	Asthma	Professional	Primperan	SS		INTRAVENOUS	1	DAY
	Vomiting		Zithromac	SS		ORAL	1	DAY
			Theodur	C		ORAL	1	DAY
			Telgin G	C		ORAL	1	DAY
			Asverin	C		ORAL		
			Mucosal Procaterol Hydrochloride	C		ORAL		

Date:03/02/04ISR Number: 4311023-5Report Type:Expedited (15-DaCompany Report #KII-2003-0007440
Age:41 YR Gender:Female I/FU:I

Outcome
Life-Threatening
Hospitalization -

Initial or Prolonged
Other

PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Arrhythmia	Study	Morphine Sulfate (Similar To Nda 19-516) (Morphine Sulfate)	PS		ORAL		ORAL
Blood Bicarbonate Decreased	Health Professional Other	Vistaril(Hydroxyzine Embonate)	SS				
Blood Calcium Decreased		Benadryl (Diphenhydramine Hydrochloride)	SS				
Blood Glucose Increased		Metformin (Metformin)	SS				
Blood Potassium Decreased		Lipitor (Atorvastatin)	SS				
Body Temperature Increased		Effexor (Venlafaxine Hydrochloride)	SS				
Depressed Level Of Consciousness		Lasix (Furosemide)	SS				
Drug Screen Positive		Potassium (Potassium)	SS				
Electrocardiogram Qt Corrected Interval Prolonged		Reglan (Metoclopramide)	SS				
Nausea		Amfetamine (Amfetamine)	SS				
Prothrombin Time Prolonged		Ambien (Zolpidem Tartrate)	SS				
Red Blood Cell Sedimentation Rate Increased		Acebutolol Hydrochloride (Acebutolol Hydrochloride)	SS				
Respiratory Arrest		Baclofen (Baclofen)	SS				
Syncope		Nexium (Esomeprazole)	SS				
Torsade De Pointes		Prilosec (Omeprazole)	SS				
Ventricular Extrasystoles		Quinine (Quinine)	SS				
Ventricular Tachycardia		Promethazine (Promethazine)	SS				
Vomiting		Klonopin (Clonazepam)	SS				
White Blood Cell Count Increased		Wellbutrin (Amfebutamone Hydrochloride)	SS				
		Celexa (Citalopram					

			Hydrobromide)	C			

Date:03/02/04ISR Number: 4313882-9Report Type:Periodic Company Report #002#1#2003-00557(0)
Age:70 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Fatigue	Health Professional Other	Reglan (Metoclopramide Hcl)	PS		ORAL	ORAL	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/02/04ISR Number: 4313883-0Report Type:Periodic Company Report #002#4#2003-00553-(0)
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Depression	Foreign	Reglan					
	Dyskinesia	Consumer	(Metoclopramide Hcl)	PS		ORAL		
ORAL								
	Extrapyramidal Disorder	Other						

Date:03/02/04ISR Number: 4313884-2Report Type:Periodic Company Report #002#4#2003-00285(0)
Age:52 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Depression	Distributor	Reglan-10mg-Tablet					
	Dystonia		(Metoclopramide Hcl)	PS		ORAL		
20 MG, 2 IN 1								
	Extrapyramidal Disorder							
D, ORAL								
	Hyperkinesia		Lansoprazole	C				
	Tardive Dyskinesia		Lisinopril	C				
			Fexofenadine	C				

Date:03/02/04ISR Number: 4313885-4Report Type:Periodic Company Report #002#2#2002-00047(0)
Age:58 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Back Pain	Consumer	Reglan-10mg-Tablet					
Initial or Prolonged	Dizziness		(Metoclopramide Hcl)	PS		ORAL		
10 MG, 2 IN 1								
	Headache							
D, ORAL								
	Muscle Contractions		Omeprazole	C				
	Involuntary		Pantoprazole	C				
	Paraesthesia		Conjugated-Estrogens	C				
	Tardive Dyskinesia							
	Tremor							

Date:03/02/04ISR Number: 4313886-6Report Type:Periodic Company Report #002#2#2002-00252(0)
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Cardiac Disorder	Consumer	Reglan-10mg-Tablet (Metoclopramide Hcl)	PS		ORAL	10 MG, 2 IN 1 D, ORAL	
	Depression							
	Dyspnoea							
	Erectile Dysfunction		Methadone	C				
	Fatigue		Alprazolam	C				
	Headache		Atorvastatin	C				
	Hepatic Enzyme Increased		Claritin-D	C				
	Hyperkinesia		Tamsulosin	C				
	Hypertension		Bisacodyl	C				
	Micturition Disorder		Tolmetin	C				
	Somnolence		Cyclobenzaprine	C				
			Unspecified Sleeping Medication	C				

Date:03/08/04ISR Number: 4314122-7Report Type:Direct Company Report #CTU 214006
Age:7 MON Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Extrapyramidal Disorder		Reglan 5mg/5ml Purepac	PS	Purepac	ORAL	.5 TID ORAL	
	Sedation							
	Sensory Disturbance		Zantac	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/15/04ISR Number: 4318456-1Report Type:Expedited (15-DaCompany Report #2004199814JP
Age:50 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anaphylactic Shock Cyanosis Feeling Abnormal Heart Rate Decreased Hypoaesthesia	Foreign Health Professional Other	Solu-Cortef (Hydrocortisone) Powder, Sterile Minopen (Minocycline Hydrochloride)	PS SS		INTRAVENOUS	100 MG, SINGLE, IV	
			Glunon (Glucose)	SS		INTRAVENOUS	100 MG, SINGLE, IV	
			C-Para (Vitamins Nos)	SS		INTRAVENOUS	2 ML, SINGLE, IV	
			Cravit (Levofloxacin)	C				
			Transamin	C				
			Biofermin (Bacillus Subtilis, Streptococcus Faecalis)	C				
			Cerekinon (Trimebutine Maleate	C				
			Celestamine (Betamethasone)	C				
			Primperan	C				
			Normal Saline	C				

Date:03/19/04ISR Number: 4319583-5Report Type:Expedited (15-DaCompany Report #JP-ROCHE-355374
Age:5 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Anaphylactoid Reaction		Rocephin	PS	Roche	INTRAVENOUS	1	DAY

Initial or Prolonged	Asthma			Primperan	SS		
INTRAVENOUS	1 DAY						
	Vomiting			Zithromac	SS		ORAL
1 DAY							
				Theodur	C		ORAL
1 DAY							
				Telgin G	C		ORAL
1 DAY							
				Asverin	C		ORAL
				Mucosal	C		ORAL
				Procaterol Hydrochloride	C		ORAL

Date:03/19/04ISR Number: 4322367-5Report Type:Expedited (15-DaCompany Report #F01200400483
Age:61 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Death	Cardiac Arrest	Study	Oxaliplatin -			
	Cyanosis	Health	Solution - 170 Mg	PS		
INTRAVENOUS	170 MG Q3W					
	Dyspnoea	Professional				
INTRAVENOUS						
NOS	1 DAY					
			Fluorouracil -			
			Solution - 2000 Mg	SS		
INTRAVENOUS	800 MG BOLUS					
+ 1200 MG						
CONTINUOUS						
INTRAVENOUS						
NOS	1 DAY					
			Leucovorin -			
			Solution - 400 Mg	SS		
INTRAVENOUS	400 MG Q2W					
INTRAVENOUS						

NOS	1	DAY						
					Maxeran (Metoclopramide Hydrochloride)	SS		
					Pantoloc (Pantoprazole Sodium)	C		
					Decadron (Dexamethasone)	C		
					Ondansetron	C		
					Lasix (Furosemide)	C		
					Robaxiret (Acetylsalicyclic Acid/Methocarbamol)	C		
					Vioxx (Rofecoxib)	C		

Date:03/22/04ISR Number: 4323073-3Report Type:Expedited (15-DaCompany Report #002#4#2004-00046 (0)
Age:55 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Grand Mal Convulsion	Health	Reglan-10mg-Tablet					
Required		Professional	(Metoclopramide Hcl)	PS		ORAL	10MG, 1 IN 1	
Intervention to		Other						
Prevent Permanent			Bupropion	SS		ORAL		
Impairment/Damage			Valsartan-Hct	C				
			Amlodipine	C				
			Simvastatin	C				
			Diflunisal	C				
			Doxepin	C				
			Levothyroxine	C				
			Omeprazole	C				
			Venlafaxine	C				
			Fluoxetine	C				
			Hydrochloroquine	C				
			Folic-Acid	C				

Date:03/23/04ISR Number: 4322241-4Report Type:Expedited (15-DaCompany Report #WAES 0403ITA00015
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abnormal Behaviour Anxiety Depression Drug Ineffective Headache Medication Error	Health Professional	Maxalt (Rizatriptan Benzoate) Aspirin Butalbital Metoclopramide Nonsteroidal Anti-Inflammatory Drug (Unspecified)	PS SS SS SS SS	Merck & Co., Inc	ORAL		

Date:03/23/04ISR Number: 4322246-3Report Type:Expedited (15-DaCompany Report #WAES 0403ITA00018
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abnormal Behaviour Anxiety Depression Headache Medication Error		Maxalt (Rizatriptan Benzoate) Aspirin Butalbital Metoclopramide	PS SS SS SS	Merck & Co., Inc	ORAL		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/23/04ISR Number: 4326017-3Report Type:Expedited (15-DaCompany Report #HQWYE605910SEP03
Age:58 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Abdominal Pain	Health Professional	Metoclopramide (Metoclopramide Hydrochloride, ESI LEDERLE), ORAL	PS		ORAL	SEE IMAGE	
	Asthenia							
	Burning Sensation							
	Cerebrovascular Accident							
	Diabetic Gastroparesis							
	Diabetic Neuropathy		Metoclopramide (Metoclopramide,) ORAL	SS		ORAL	SEE IMAGE	
	Drug Effect Decreased							
	Dry Mouth		Reglan (Metoclopramide Hydrochloride, Tablet) ORAL	SS		ORAL		
	Dysarthria							
	Dysphagia							
	Dystonia							
	Essential Tremor		Zantac (Ranitidine Hydrochloride)	C				
	Fall							
	Fatigue		Drixoral (Dexbrompheniramine Maleate/Pseudoephedrine Sulfate)	C				
	Gastric Polyps							
	Gastrooesophageal Reflux Disease							
	Hallucination		Bayer Children'S Aspirin (Acetylsalicylic Acid)	C				
	Hyperaesthesia							
	Hypersomnia		Ativan (Lorazepam)	C				
	Insomnia		Lithobid (Lithium Carbonate)	C				
	Social Avoidant Behaviour		Premarin (Conjugated Estrogens)	C				
	Tardive Dyskinesia		Senokot (Senna Fruit)	C				
	Throat Tightness		Humalog (Insulin Lispro)	C				
	Tongue Biting		Effexor Xr (Venlafaxine Hydrochloride)	C				
	Transient Ischaemic Attack		Verelan (Verapamil Hydrochloride)	C				
			Procardia Xl (Nifedipine)	C				

Lantus (Insulin Glargine)	C
Prevacid (Lansoprazole)	C
Zoloft (Sertraline Hydrochloride)	C
Detrol (Tolterodine L-Tartrate)	C
Neurontin (Gabapentin)	C
Cipro (Ciprofloxacin Hydrochloride)	C
Altace (Ramipril)	C
Prandin "Kuhn" (Repaglinide)	C
Maalox (Aluminum Hydroxide Gel/Magnesium Hydroxide)	C
Bentyl (Dicycloverine	

Hydrochloride) C

Date:03/24/04ISR Number: 4323021-6Report Type:Direct Company Report #CTU 215115
Age:76 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Neuroleptic Malignant Syndrome		Metoclopramide	PS				

Date:03/24/04ISR Number: 4325571-5Report Type:Expedited (15-DaCompany Report #2004-052
Age:17 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dystonia	Health Professional	Metoclopramide Tablets, Usp 10mg (Pliva)	PS			10MG PO 30MIN	AC & QHS

Date:03/25/04ISR Number: 4323540-2Report Type:Expedited (15-DaCompany Report #WAES 0311USA00474
Age:68 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Depressed Level Of Consciousness		Pepcid	PS	Merck & Co., Inc	INTRAVENOUS	48	DAY
Disability			Primperan	SS		INTRAVENOUS	55	DAY
Other	Drug Level Increased Hypotension Respiratory Depression							

Date:03/25/04ISR Number: 4327847-4Report Type:Expedited (15-DaCompany Report #AU-JNJFOC-20040304367
Age:23 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Life-Threatening	Anaphylactic Reaction	Foreign Health Professional	Tramadol (Tramadol Hydrochloride) Unspecified	PS
100 MG				
			Fentanyl (Fentanyl)	SS
100 MG				
			Suxamethonium Bromide (Suxamethonium Bromide)	SS
100 MG				
			Sevoflurane (Sevoflurane)	SS
			Metoclopramide Hydrochloride(Metoclopramide Hydrochloride)	SS
10 MG				
			Midazolam (Midazolam)	SS
2 MG				
			Propofol (Propofol)	SS
200 MG				

Date:03/26/04ISR Number: 4325327-3Report Type:Direct Company Report #CTU 215381
Age:2 DY Gender:Female I/FU:I

Outcome
Required
Intervention to
Prevent Permanent

Impairment/Damage

	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Medication Error		Zantac 75/5ml	PS		ORAL	2.48	3/DAY
			Reglan	SS		ORAL	1.5	3/DAY

Date:03/29/04ISR Number: 4325982-8Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0326788A
Age:62 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Death	Consumer	Zophren	PS	Glaxosmithkline	INTRAVENOUS	1AMP See dosage text	8 DAY
Life-Threatening	Hyperbilirubinaemia		Aracytine	SS		INTRAVENOUS	100MGM2 per day	6 DAY
			Primperan	SS	Glaxosmithkline	INTRAVENOUS		4 DAY
			Zavedos	SS		INTRAVENOUS	8MGM2 per day	1 DAY
			Belustine	SS		ORAL	200MGM2 per day	1 DAY
			Tenordate	C		ORAL	1UNIT per day	UNKNOWN
			Acupan	C				
			Lasilix	C	Glaxosmithkline			UNKNOWN

Date:03/29/04ISR Number: 4326261-5Report Type:Expedited (15-DaCompany Report #US-MERCK-0210USA00929
Age:57 YR Gender:Male I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Amnesia
Other	Apathy
	Balance Disorder
	Blood Cholesterol Increased
	Blood Pressure Increased
	Blood Triglycerides Increased
	Carotid Artery Stenosis
	Carpal Tunnel Syndrome
	Cerebellar Infarction
	Cerebrovascular Accident
	Cerebrovascular Disorder
	Chest Discomfort
	Cholecystectomy
	Cognitive Disorder
	Cogwheel Rigidity
	Coordination Abnormal
	Deafness Neurosensory
	Dementia
	Diabetes Mellitus
	Non-Insulin-Dependent
	Difficulty In Walking
	Dizziness
	Fall
	Fatigue
	Gallbladder Disorder
	Glossitis
	Haematochezia
	Hiatus Hernia
	High Density Lipoprotein

	Decreased Loss Of Consciousness Low Density Lipoprotein Increased	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Lumbar Radiculopathy		Vioxx	PS	Merck & Co., Inc	ORAL	696 DAY
	Major Depression		Reglan	SS			UNKNOWN
	Neuropathy Peripheral		Celebrex	C			UNKNOWN
	Orthostatic Hypotension		Catapres	C			UNKNOWN
	Pain In Extremity		Flonase	C			UNKNOWN
	Pseudodementia		Prilosec	C			UNKNOWN
	Radiculopathy		Lopid	C			UNKNOWN
	Sinusitis		Robaxin	C			UNKNOWN
	Sleep Apnoea Syndrome Somnolence Swollen Tongue Tongue Disorder Treatment Noncompliance Tremor						

Date:03/29/04ISR Number: 4330078-5Report Type:Expedited (15-DaCompany Report #HQWYE909417MAR04
Age:88 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged Other	Angioneurotic Oedema Dysphagia Dyspnoea Hyperhidrosis	Health Professional Other	Avlocardyl (Propranolol Hydrochloride, Tablet)	PS		ORAL	20 MG 2X PER 1 DAY; ORAL 1 YR
			Neutrogena (Castrol Oil/Coconut Oil/Stearic Acid/Trolamine Laurylsulfate,)	SS		TOPICAL	TOPICAL

				Nicergoline (Nicergoline,)	SS	ORAL
3 DOSE 1X PER						
1 DAY; ORAL	1	YR				
				Noctran 10 (Acepromazine/Acepro metazine/Clorazepate Dipotassium,)	SS	ORAL
10 MG 1X PER						
1 DAY; ORAL						
				Primperan "Synthelabo" (Metoclopramide,)	SS	ORAL
30 MG 1X PER						
1 DAY; ORAL	3	DAY				
				Seglor (Dihydroergotamine Mesilate,)	SS	ORAL
5MG 1X PER 1						
DAY; ORAL	1	YR				
				Tiorfan (Acetorphan,)	SS	ORAL
100 MG 3X PER						
1 DAY; ORAL	3	DAY				
				Triatec (Ramipril,)	SS	ORAL
2.5 MG 1X PER						
1 DAY; ORAL	1	YR				

Date:03/30/04ISR Number: 4327480-4Report Type:Direct Company Report #CTU 215565
Age:73 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dystonia		Reglan	PS				
	Hypoaesthesia							
	Paraesthesia							
	Tardive Dyskinesia							
	Tongue Disorder							
	Tremor							

Date:03/30/04ISR Number: 4331959-9Report Type:Expedited (15-DaCompany Report #B0326031A
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Congenital Anomaly	Anomaly Of External Ear	Literature	Zofran (Formulation					
	Congenital	Health	Unknown)					
	Apnoea	Professional	(Ondansetron					
	Asthenia		Hydrochloride)	PS				
	Body Height Below Normal							
	Bradycardia Neonatal		Zantac (Formulation					
	Cervical Spinal Stenosis		Unknown) (Ranitidine					
	Chondrodystrophy		Hydrochloride)	SS				
	Congenital							
	Musculoskeletal Anomaly		Compazine					
	Congenital Nose		(Formulation					
	Malformation		Unknown)					
	Finger Hypoplasia		(Prochlorperazine)	SS				
	Hyperreflexia							
	Maternal Drugs Affecting		Diphenhydramine					
	Foetus		Hydrochloride					
	Micrognathia		(Formulation					
	Movement Disorder		Unknown)					
	Multiple Congenital		(Diphenhydramine	SS				

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	Abnormalities		
RY			
	Neonatal Respiratory Distress Syndrome Premature Baby	Metoclopramide Hcl (Formulation Unknown) (Metoclopramide Hcl)	SS
TRANSPLACENTAL	TRANSPLACENTA		
RY			
		Emgel (Formulation Unknown) (Erythromycin)	SS
TRANSPLACENTAL	TRANSPLACENTA		
RY			
		Simethicone (Formulation Unknown) (Simethicone)	SS
TRANSPLACENTAL	TRANSPLACENTA		
RY			
		Promethazine Hcl (Formulation Unknown) (Promethazine Hcl)	SS
TRANSPLACENTAL	TRANSPLACENTA		
RY			
		Iron Supplements (Formulation Unknown) (Iron Supplements)	SS
TRANSPLACENTAL	TRANSPLACENTA		
RY			

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/01/04ISR Number: 4329749-6Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0321882A
Age:22 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Alanine Aminotransferase Increased	Consumer	Azantac	PS	Glaxosmithkline	ORAL	4	DAY
Hospitalization - Initial or Prolonged	Aspartate Aminotransferase Increased		Zyloric	SS	Glaxosmithkline	ORAL	900MG Per day	11 DAY
			Zophren	SS	Glaxosmithkline	INTRAVENOUS	8MG Twice per day	12 DAY
	Blood Bilirubin Increased		Zovirax	SS	Glaxosmithkline	UNKNOWN		
	Jaundice Cholestatic		Solumedrol	SS		INTRAVENOUS	40MG Per day	24 DAY
	Septic Shock		Visceralgine	SS		ORAL	1UNIT Per day	8 DAY
			Ciflox	SS		INTRAVENOUS	200MG Twice per day	14 DAY
			Rocephine	SS		UNKNOWN		12 DAY
			Primperan	SS	Glaxosmithkline	UNKNOWN		
			Duphalac	SS		UNKNOWN		
			Acupan	SS		UNKNOWN		4 DAY
			Debridat	SS		UNKNOWN		
			Mopral	C		UNKNOWN		3 DAY
			Oncovin	C		INTRAVENOUS		
			Endoxan	C		INTRAVENOUS		
			Cerubidine	C		INTRAVENOUS		3 DAY
			Methotrexate	C		INTRATRACHEAL		
			Aracytine	C		INTRATRACHEAL		
			Vancocine	C		UNKNOWN		

Oflocet C

UNKNOWN

Date:04/01/04ISR Number: 4329964-1Report Type:Expedited (15-DaCompany Report #US-MERCK-0210USA00929
Age:57 YR Gender:Male I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Amnesia
	Apathy
Disability	Balance Disorder
	Carotid Artery Stenosis
	Carpal Tunnel Syndrome
	Cerebellar Infarction
	Cerebrovascular Accident
	Cerebrovascular Disorder
	Chest Discomfort
	Cognitive Disorder
	Cogwheel Rigidity
	Coordination Abnormal
	Deafness Neurosensory
	Decreased Interest
	Dementia
	Diabetes Mellitus
	Non-Insulin-Dependent
	Diabetic Neuropathy
	Difficulty In Walking
	Dizziness
	Fall
	Fatigue
	Gait Disturbance
	Gallbladder Disorder
	Glossitis
	Haematochezia
	Headache
	Hiatus Hernia
	Loss Of Consciousness
	Major Depression

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Memory Impairment							
	Neuropathy Peripheral							
	Orthostatic Hypotension		Vioxx	PS	Merck & Co., Inc	ORAL	696	DAY
	Pseudodementia		Reglan	SS			UNKNOWN	
	Radiculopathy		Celebrex	C			UNKNOWN	
	Sensory Disturbance		Catapres	C			UNKNOWN	
	Sinusitis		Flonase	C			UNKNOWN	
	Sleep Apnoea Syndrome		Prilosec	C			UNKNOWN	
	Somnolence		Lopid	C			UNKNOWN	
	Subclavian Steal Syndrome		Robaxin	C			UNKNOWN	
	Treatment Noncompliance							
	Tremor							

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:04/02/04ISR Number: 4330435-7Report Type:Expedited (15-DaCompany Report #CH-BRISTOL-MYERS SQUIBB COMPANY-12423075
Age:35 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Anaemia Macrocytic	Health	Atazanavir	PS	Bristol-Myers Squibb			
Hospitalization - Initial or Prolonged	Death	Professional			Company	ORAL	lamivudine	
	General Physical Health		Combivir	SS		ORAL	150 mg +	
	Deterioration						zidovudine	
	Jaundice						300 mg = 1	
	Leukopenia						dosage form.	
	Muscular Weakness							
	Pancytopenia		Paspertin	SS		ORAL		
	Pneumonia		Esomeprazole	SS				
	Somnolence		Methadone	SS				
	Thrombocytopenia		Co-Trimoxazole	SS				

Date:04/08/04ISR Number: 4334941-0Report Type:Expedited (15-DaCompany Report #PHBS2003CH08887
Age:59 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Coma	Health	Zelmac	PS	Novartis Sector:			
	Status Epilepticus	Professional			Pharma		12 mg/day	14400MIN
Other			Paspertin	SS			6.7 mg, TID	
			Voltaren	SS			100 mg/day	
			Creon	C			900 mg/day	
			Clopamide	C				
			Pantozol	C			40 mg/day	
			Kalium	C		ORAL	3 tablet/day	
			Colpermin	C		ORAL	2 caps/day	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/09/04ISR Number: 4338298-0Report Type:Expedited (15-DaCompany Report #HQWYE291831MAR04
Age:83 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hyperventilation	Foreign	Effexor Xr	PS		ORAL	150 MG 1X PER	1 DAY
	Respiratory Alkalosis	Health Professional	Fludrocortisone (Fludrocortisone)	SS				
		Other	Metoclorpramide (Metoclopramide)	SS				
			Pantoprazole (Pantroprazole)	SS				
			Serepax (Oxazepam, Unspec)	SS				
			Sotalol (Sotalol)	SS				
			Trimethoprim (Trimethoprim)	SS				

Date:04/12/04ISR Number: 4339296-3Report Type:Expedited (15-DaCompany Report #HQWYE291831MAR04
Age:83 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Respiratory Alkalosis	Health Professional Other	Efexor Xr (Venlafaxine Hydrochloride, Capsule, Extended Release)	PS		ORAL	150 MG 1X PER	1 DAY
			Fludrocortisone (Fludrocortisone)	SS				
			Metoclopramide (Metoclopramide)	SS				
			Pantoprazole (Pantoprazole)	SS				
			Serepax (Oxazepam, Unspec)	SS				
			Sotalol (Sotalol)	SS				
			Trimethoprim (Trimethoprim)	SS				

			Warfarin (Warfarin)	C		

Date:04/12/04ISR Number: 4339471-8Report Type:Expedited (15-DaCompany Report #2004207481FR
Age:62 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death Life-Threatening	Hyperbilirubinaemia	Foreign Health Professional	Aracytine(Cytarabine) Powder, Sterile	PS		INTRAVENOUS	100 MG/M2, UNK, IV	
		Other	Zavedos (Idarubicin Hydrochloride) Powder, Sterile	SS		INTRAVENOUS	8 MG/M2, SINGLE, IV	
			Primperan (Metoclopramide)	SS		INTRAVENOUS	1 VIAL/8 HOURS MAX, IV	
			Belustine (Lomustine)	SS		ORAL	200 MG/M2, UNK, ORAL	
			Zophren (Ondansetron Hydrochloride)	SS		INTRAVENOUS	2 MG/ML, 1	

VIAL/12

HOURS, IV

			Tenordate	C		
			Acupan (Nefopam Hydrochloride)	C		
			Lasilix	C		

Date:04/12/04ISR Number: 4341367-2Report Type:Periodic Company Report #HQ4886828OCT2002
Age:49 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Pressure Increased	Other	Reglan	PS				
	Cardiac Disorder		Reglan	SS				
INTRAVENOUS							10 MG BID IV	
	Depression		Methadone	C				
	Erectile Dysfunction		Alprazolam	C				
	Fatigue		Atorvastatin	C				
	Headache		Loratadine/Pseudoephedrine Sulfate	C				
	Hepatitis B		Tamsulosin	C				
	Lethargy		Bisacodyl	C				
	Respiratory Disorder		Tolmetin	C				
	Restlessness		Cyclobenzaprine	C				
	Sedation							
	Urinary Tract Disorder							

Date:04/12/04ISR Number: 4341368-4Report Type:Periodic Company Report #HQWYE228624MAR03
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Convulsion	Health	Reglan	PS				
INTRAVENOUS							10 MG QD IV	
		Professional	Benadryl	SS				
		Other	Zantac	SS				

Date:04/12/04ISR Number: 4341369-6Report Type:Periodic Company Report #HQWYE937928APR03
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dyskinesia Tardive Dyskinesia	Consumer Other	Reglan	PS				

Date:04/12/04ISR Number: 4341370-2Report Type:Periodic Company Report #HQWYE983830APR03
Age:43 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Neuroleptic Malignant	Health	Metoclopramide	PS		ORAL	10 MG Q6HR PO	
Hospitalization - Initial or Prolonged	Syndrome	Professional Other	Metoclopramide Hdyrochloride	SS		INTRAVENOUS	10 MG Q6HR IV	
			Vanomycin	C				
			Gentamicin	C				
			Docusate	C				
			Senna	C				
			Lansoprazole	C				
			Fluoxetine Hydrochloride	C				
			Cyclobenzaprine	C				
			Phenobarbital	C				
			Nafcillin	C				
			Hydralazine	C				
			Ondansetron	C				

			Acetaminophen	C			
			Codeine	C			

Date:04/13/04ISR Number: 4340680-2Report Type:Expedited (15-DaCompany Report #2004-052
Age:17 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dystonia	Health Professional	Metoclopramide Tablets, Usp 10 Mg (Pliva)	PS	Pliva	ORAL	10 MG PO	30 MIN AC & QHS
			Zoloft	C				
			Depo-Provera	C				
			Ultram	C				

Date:04/13/04ISR Number: 4340733-9Report Type:Expedited (15-DaCompany Report #HQWYE605910SEP03
Age:58 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Abdominal Pain Apathy Asthenia Condition Aggravated Dry Mouth Dysphagia Dystonia Essential Tremor Fatigue Gastrooesophageal Reflux Disease Hallucination Hypersomnia Insomnia Mood Altered	Consumer	Metoclopramide (Metoclopramide Hydrochloride, Tablet)	PS		ORAL	ESI LABERLE, ORAL	
			Metoclopramide (Metoclopramide)	SS		ORAL	ORAL	
			Regland(Metoclopramide Hydrochloride, Tablet)	SS		ORAL	ORAL	
			Seroquel (Quetiapine)	SS			SEE IMAGE	
			Zantac (Ranitidine Hydrochloride)	C				
			Drixoral					

Social Avoidant Behaviour	(Dexbrompheniramine
Speech Disorder	Maleate/Pseudoephedr
Tardive Dyskinesia	ine Sulfate) C
Throat Tightness	Bayer Children'S
Tongue Disorder	Aspirin
Weight Loss Poor	(Acetylsalicylic
	Acid) C
	Ativan (Lorazepam) C
	Lithobid (Lithium
	Carbonate) C
	Premarin (Conjugated
	Estrogens) C
	Senokot (Senna
	Fruit) C
	Humalog (Insulin
	Lispro) C
	Effexor Xr
	(Venlafaxine
	Hydrochloride) C
	Verelan (Verpamil
	Hydrochloride) C
	Procardia Xl
	(Nifedipine) C
	Lantus (Insulin
	Glargine) C

Prevacid (Lansoprazole)	C
Zoloft (Sertraline Hydrochloride)	C
Detrol (Tolterodine L-Tartrate)	C
Neurontin (Gabapentin)	C
Cipro (Ciprofloxacin Hydrochloride)	C
Altace (Ramipril)	C
Prandin "Kuhn" (Repaglinide)	C
Maalox (Aluminium Hydroxide Gel/Magnesium Hydroxide)	C
Bentyl (Dicycloverine Hydrochloride)	C
Benadryl (Diphenhydramine Hydrochloride)	C

Date:04/14/04ISR Number: 4338504-2Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0328958A
Age:51 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Arterial Thrombosis	Consumer	Zophren	PS	Glaxosmithkline			
INTRAVENOUS								9 DAY
Initial or Prolonged	Creatinine Renal		Neulasta	SS				
SUBCUTANEOUS							6MG Per day	1 DAY
	Clearance Decreased		Largactil	SS				
INTRAVENOUS							12MG Per day	1 DAY
	Dehydration		Cisplatine	SS				
INTRAVENOUS							70MG Per day	4 DAY
	Leg Amputation		Etoposide	SS				
INTRAVENOUS							250MG Per day	4 DAY
	Neutrophil Count		Bleomycine	SS				
INTRAVENOUS							30MG Per day	4 DAY
	Decreased		Primperan	SS	Glaxosmithkline			
UNKNOWN								9 DAY
	Pancytopenia		Solumedrol	SS				
UNKNOWN								9 DAY

	Peripheral Ischaemia		Polaramine	SS			
UNKNOWN	2 DAY						
	Renal Failure		Loxen	SS			ORAL
1 DAY							
	Rhabdomyolysis						
	Sepsis						
	Thrombocytopenia						
	Vomiting						
	White Blood Cell Count Decreased						

Date:04/14/04ISR Number: 4340481-5Report Type:Expedited (15-DaCompany Report #002#2#2004-00070 (0)
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Anxiety	Consumer	Reglan-Dose-Unknown			
Initial or Prolonged	Depression	Other	(Metoclopramide Hcl)	PS		
	Suicidal Ideation		Antidepressants	C		
			Diazepam	C		
			Clonazepam	C		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/19/04ISR Number: 4344385-3Report Type:Expedited (15-DaCompany Report #2004198784FR
Age:22 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cholestasis	Foreign	Solu-Medrol (Methylprednisolone)					
Hospitalization - Initial or Prolonged	Cytolytic Hepatitis	Health Professional	Powder, Sterile	PS		INTRAVENOUS	SEE IMAGE	
	Hepatocellular Damage							
	Septic Shock	Other	Azantac (Ranitidine Hydrochloride)	SS		ORAL		
			Visceralgine Forte Tablets (Metamizole, Tiemonium Methylsulphate)	SS		ORAL	1 DF,	QD,
			Zyloric (Allopurinol)	SS		ORAL	900 MG,	QD,
			Ciflox (Ciprofloxacin)	SS		INTRAVENOUS	200 MG,	BID,
			Zophren (Ondansetron Hydrochloride)	SS		INTRAVENOUS	16 MG,	BID,
			Rocephin (Ceftriaxone Sodium)	SS		IV		
			Zovirax (Aciclovir)	SS				
			Primperan (Metoclopramide)	SS				
			Duphalac (Lactulose)	SS				
			Acupan (Nefopam Hydrochloride)	SS				
			Trimebutine (Trimebutine)	SS				
			Mopral	C				
			Oncovin	C				
			Endoxan	C				

Cerubidine	C
Methotrexate	C
Aracytine	C
Vancomycin	C
Ofloxacin	C

Date:04/21/04ISR Number: 4345433-7Report Type:Expedited (15-DaCompany Report #2004208897FR
Age:13 MON Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Haematuria Nephritis Interstitial Pyrexia Renal Failure Acute Renal Tubular Disorder Vomiting	Foreign Health Professional Other	Vantin (Cefpodoxime Proxetil) Suspension	PS		ORAL	70 MG, DAILY, ORAL	
			Aspegic (Acetylsalicylate Lysine)	SS		ORAL	UNK, ORAL	
			Primperan (Metoclopramide)	SS		ORAL	UNK, ORAL	
			Efferalgan (Paracetamol)	SS		ORAL	UNK, ORAL	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/21/04ISR Number: 4345606-3Report Type:Expedited (15-DaCompany Report #2004-01530
Age:87 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Failure To Thrive Muscle Rigidity Tremor	Literature Health Professional	Metoclopramide (Watson Laboratories)(Metoclopramide)Tablet, 10mg	PS	Watson Laboratories	ORAL	5 MG, QID,	ORAL

Date:04/21/04ISR Number: 4345607-5Report Type:Expedited (15-DaCompany Report #2004-01510
Age:69 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Activities Of Daily Living Impaired Failure To Thrive Muscle Rigidity	Literature Health Professional	Metoclopramide (Watson Laboratories)(Metoclopramide) Tablets, 10mg	PS	Watson Laboratories	ORAL	10 MG, QID,	ORAL

Date:04/21/04ISR Number: 4345608-7Report Type:Expedited (15-DaCompany Report #2004-01515
Age:84 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Failure To Thrive Parkinsonism	Literature Health Professional	Metoclopramide (Watson Laboratories)(Metoclopramide) Tablet, 10mg	PS	Watson Laboratories	ORAL	10 MG, TID,	ORAL

Date:04/23/04ISR Number: 4348596-2Report Type:Expedited (15-DaCompany Report #2004-01517
Age:71 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Failure To Thrive Parkinsonism	Literature Health Professional	Metoclopramide (Watson Laboratories) (Metoclopramide) Tablet, 10mg	PS		ORAL	10 MG, QID, ORAL	

Date:04/23/04ISR Number: 4348789-4Report Type:Expedited (15-DaCompany Report #2004US000433
Age:52 YR Gender:Female I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Drug Interaction Drug Level Above Therapeutic Drug Level Below Therapeutic Gastric Hypomotility Impaired Gastric Emptying Liver Transplant Rejection Nephropathy Toxic

Neurotoxicity

		Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
		Literature	Prograf (Tacrolimus)	PS		
7.00 MG, BID						
		Health Professional	Metoclopramide (Metoclopramide)	SS		
SEE IMAGE						
			Prednisone (Prednisone)	C		
			Sirolimus (Sirolimus)	C		

Date:04/27/04ISR Number: 4349119-4Report Type:Direct Company Report #CTU 217464
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization -	Drug Abuser		Metoclopramide 10 Mg	PS		ORAL
10 MG QID						
Initial or Prolonged	Ileus Paralytic					
ORAL						
			Senna 8.6 Mg	SS		ORAL
17.6 MG TID						
ORAL						
			Combivent	C		
			Albuterol	C		
			Colchicine	C		
			Simethicone	C		
			Atenolol	C		
			Omerazole	C		
			Maalox	C		
			Multivitamin	C		
			Iron Sulfate	C		
			Chlorpheniramine	C		

Date:04/29/04ISR Number: 4350116-3Report Type:Expedited (15-DaCompany Report #GB-ROCHE-324953
Age:16 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					

Hospitalization - Initial or Prolonged	Injection Site Reaction Medication Error	Midazolam Hydrochloride	PS	Roche
INTRA-ARTERIAL	REGIMEN Musculoskeletal Stiffness			
REPORTED AS	Oedema			
ONCE.	Oedema Peripheral	Propofol	SS	Roche
INTRA-ARTERIAL	REGIMEN Pain			
REPORTED AS	Pain In Extremity			
ONCE.	Rash Erythematous	Metoclopramide	SS	
INTRA-ARTERIAL	REGIMEN Skin Discolouration			
REPORTED AS				
ONCE.		Pethidine	SS	Roche
INTRA-ARTERIAL	REGIMEN			
REPORTED AS				
ONCE.		Glucose	C	
INTRAVENOUS				
		Sevoflurane	C	
RESPIRATORY				
(INHALATION)				

Date:05/03/04ISR Number: 4354329-6Report Type:Expedited (15-DaCompany Report #2002GB02751
Age:16 YR Gender:Female I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Erythema Injection Site Pain Medication Error

	Musculoskeletal Stiffness Oedema Pain	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
	Skin Discolouration	Foreign	Propofol	PS		
INTRA-ARTICULAR 5 ML ONCE IA						
		Health	Midazolam	SS		
INTRA-ARTICULAR 1.5 MG ONCE						
		Professional				
IA						
		Other	Pethidine	SS		
INTRA-ARTICULAR 50 MG ONCE IA						
			Metoclopramide	SS		
INTRA-ARTICULAR 10 MG ONCE IA						
			Glucose	C		
			Sevoflurane	C		

Date:05/05/04ISR Number: 4353569-XReport Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0326788A
Age:62 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Death		Zophren	PS	Glaxosmithkline	
INTRAVENOUS 1AMP See						
Life-Threatening	Hyperbilirubinaemia					
dosage text 8 DAY						
			Aracytine	SS		
INTRAVENOUS 100MGM2 per						
day 6 DAY						
			Primperan	SS	Glaxosmithkline	
INTRAVENOUS 4 DAY						
			Zavedos	SS		
INTRAVENOUS 8MGM2 per day 5 DAY						
			Belustine	SS		ORAL
200MGM2 per						
day 1 DAY						
			Tenordate	C		ORAL
1UNIT per day						
			Acupan	C		
UNKNOWN						
			Lasilix	C	Glaxosmithkline	
UNKNOWN						

Date:05/07/04ISR Number: 4356673-5Report Type:Expedited (15-DaCompany Report #20040400290
Age:66 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Blood Pressure Systolic Increased Cardiac Arrest Post Procedural Complication	Foreign Literature Health Professional Other	Metoclopramide (Baxter) Metoclopramide (Baxter) Fentanyl Thiopental Rocuronium Isoflurane	PS SS C C C C	Baxter Baxter	INTRAVENOUS IV INTRAVENOUS IV	10 MG	DAILY

Date:05/10/04ISR Number: 4355453-4Report Type:Expedited (15-DaCompany Report #JP-MERCK-0312USA01150
Age:17 YR Gender: I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Apallic Syndrome Cardiac Arrest Dyspnoea Obstructive Airways Disorder Pharyngeal Oedema Post Procedural Complication Respiratory Failure		Pepcid Horizon Droleptan Primperan [Therapy Unspecified]	PS SS SS SS C	Merck & Co., Inc	PARENTERAL INTRAVENOUS UNKNOWN UNKNOWN UNKNOWN		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/11/04ISR Number: 4358883-XReport Type:Expedited (15-DaCompany Report #HQWYE671603MAY04
Age:52 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Alanine Aminotransferase Increased	Literature	Metoclopramide (Metoclopramide Hydrochloride, Tablet)	PS			10 MG 4X PER	1 DAY; SEE IMAGE
	Aspartate Aminotransferase Increased							
	Asthenia							
	Diarrhoea		Tacrolimus (Tacrolimus,)	SS			7 MG 2X PER 1	DAY; SEE IMAGE
	Drug Interaction							
	Drug Level Above Therapeutic							
	Drug Level Below Therapeutic		Prednisone (Prednisone)	C				
	Drug Toxicity		Rapamune (Sirolimus)	C				
	Headache		Ursodiol (Ursodeoxycholic Acid)	C				
	Nausea							
	Nephropathy Toxic		Ondansetron (Ondansetron)	C				
	Neurotoxicity							
	Pain In Extremity		Mycophenolate Mofetil (Mycophenolate Mofetil)	C				
	Pyrexia							
	Renal Failure Acute		Ketoconazole (Ketoconazole)	C				
	Renal Tubular Necrosis							
	Transplant Rejection		Omeprazole (Omeprazole)	C				
	Tremor							
	Vomiting		Pantoprazole (Pantoprazole)	C				
			Levofloxacin (Levofloxacin)	C				
			Metronidazole (Metronidazole)	C				
			Ranitdine (Ranitidine)	C				

Date:05/11/04ISR Number: 4359433-4Report Type:Expedited (15-DaCompany Report #20040500294
Age:44 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Coma	Foreign	Metoclopramide	PS		INTRAMUSCULAR IM	10 MG DAILY	
Required Intervention to Prevent Permanent Impairment/Damage	Dystonia	Literature						
	Joint Dislocation	Other						
	Loss Of Consciousness							
	Musculoskeletal Stiffness							
	Opisthotonus							
	Pain In Extremity							
	Posturing							
	Tetany							

Date:05/12/04ISR Number: 4357065-5Report Type:Expedited (15-DaCompany Report #GB-ROCHE-324953
Age:16 YR Gender:Female I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Anaesthetic Complication
	Injection Site Pain
	Injection Site Reaction

		Medication Error Musculoskeletal Stiffness Oedema	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
		Oedema Peripheral Pain	Consumer	Midazolam Hydrochloride	PS	Roche	
INTRA-ARTERIAL	REGIMEN						
		Pain In Extremity					
REPORTED AS							
		Pitting Oedema					
ONCE.							
		Rash Erythematous		Propofol	SS	Roche	
INTRA-ARTERIAL	REGIMEN						
		Skin Discolouration					
REPORTED AS							
ONCE.							
				Metoclopramide	SS		
INTRA-ARTERIAL	REGIMEN						
REPORTED AS							
ONCE.							
				Pethidine	SS	Roche	
INTRA-ARTERIAL	REGIMEN						
REPORTED AS							
ONCE.							
				Glucose	C		
INTRAVENOUS							
				Sevoflurane	C		
RESPIRATORY							
(INHALATION)							

Date:05/12/04ISR Number: 4359736-3Report Type:Expedited (15-DaCompany Report #DSA_24312_2004
Age:68 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization -	Pancreatitis	Foreign	Orfidal	PS		ORAL
1 MG PO						
Initial or Prolonged		Health	Gemzar	SS		
INTRAVENOUS	1.2 G IV					

			Professional	Navelbine	SS		
INTRAVENOUS	40 MG IV						
			Other	Primperan	SS		
INTRAVENOUS	30 MG IV						
				Primperan	SS		ORAL
90 QD PO							
				Solu Moderin	SS		
INTRAVENOUS	45 MG IV						

Date:05/13/04ISR Number: 4359690-4Report Type:Expedited (15-DaCompany Report #2004212160FR
Age:31 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Dermatitis Exfoliative Eosinophilia	Foreign Health	Solu-Medrol (Methylprednisolone)	PS		
INTRAVENOUS 500 MG,	Toxic Skin Eruption	Professional				
CYCLIC, IV						
		Other	Endoxan (Cyclophosphamide)	SS		
INTRAVENOUS 1125 MG IN						
TOT 3 CYCLE,						
INTRAVENOUS						
			Uromitexan(Mesna)	SS		
INTRAVENOUS 675 MG IN						
TOT, 3 CYCLE,						
IV						
			Primperan(Metoclopramide)	SS		
INTRAVENOUS 25 MG,						
CYCLIC, IV						

Date:05/13/04ISR Number: 4360551-5Report Type:Expedited (15-DaCompany Report #USA-2004-0013536
Age:41 YR Gender:Female I/FU:I

Outcome	PT
Death	Accidental Overdose
	Cardiomegaly
	Chronic Obstructive Pulmonary Disease
	Coma

	Drug Toxicity Fall						
		Report Source	Product	Role	Manufacturer	Dose	Route Duration
		Consumer Health Professional Other	Oxycodone Hydrochloride (Similar To Nda 20-553)	PS			
			Hydrocodone Bitartrate (Similar To Ind 59,175)	SS			
			Fluoxetine (Fluoxetine)	SS			
			Caffeine (Caffeine)	SS			
			Alprazolam (Alprazolam)	SS			
			Citalopram (Citalopram)	SS			
			Metoclopramide (Metoclopramide)	SS			
			Nicotine (Nicotine)	SS			
			Gabapentin (Gabapentin)	SS			

Date:05/14/04ISR Number: 4360465-0Report Type:Expedited (15-DaCcompany Report #002#8#2004-00017
Age:87 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Dose	Route Duration
Disability	Abasia Anorexia	Literature Health	Reglan-5mg-Tablet (Metoclopramide Hcl)	PS			ORAL 5MG, 4 IN 1 D, ORAL
	Incontinence	Professional					
	Masked Facies		Cimetidine	C			
	Muscle Contracture		Levothyroxine-Sodium	C			
	Muscle Rigidity		Timolol-Maleate-Opthalmic-Solution	C			
	Parkinsonian Rest Tremor		Multivitamin	C			

Date:05/14/04ISR Number: 4360466-2Report Type:Expedited (15-DaCompany Report #002#8#2004-00015
Age:84 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Activities Of Daily Living Impaired	Literature Health	Reglan-10mg-Tablet (Metoclopramide Hcl)	PS		ORAL	10MG, 4 IN 1 D, ORAL	
Disability	Bradykinesia	Professional						
	Cognitive Disorder		Levothyroxine-Sodium	C				
	Cogwheel Rigidity		Dronabinol	C				
	Confusional State		Carbidopa 25mg And Levodopa 100mg	C				
	Dementia		Bupropion	C				
	Depressive Symptom							
	Dysphagia							
	Failure To Thrive							
	General Physical Health Deterioration							
	Incontinence							
	Mobility Decreased							
	Weight Decreased							

Date:05/14/04ISR Number: 4360691-0Report Type:Expedited (15-DaCompany Report #2004207481FR
Age:62 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Hyperbilirubinaemia	Foreign	Aracytine					
Life-Threatening		Health Professional	(Cytarabine) Powder, Sterile	PS		INTRAVENOUS	100 MG/M2, IV	
		Other	Zavedos (Idarubicin Hydrochloride) Powder, Sterile	SS		INTRAVENOUS	8 MG/M2,	SINGLE, IV
			Primperan (Metoclopramide)	SS		INTRAVENOUS	1 VIAL/8	HOURS MAX, IV
			Belustine (Lomustine)	SS		ORAL	200 MG/M2,	ORAL
			Zophren (Ondansetron Hydrochloride)	SS		INTRAVENOUS	2 MG/ML	VIAL/12 HOURS, IV
			Tenordate	C				
			Acupan (Nefopam Hydrochloride)	C				
			Lasilix	C				

Date:05/17/04ISR Number: 4362233-2Report Type:Expedited (15-DaCompany Report #20040500298
Age:83 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Carotid Artery Stenosis	Study	Reglan					
	Depressed Level Of Consciousness	Other	(Metoclopramide) Baxter	PS				

	Encephalopathy		Hydrochlorothiazide	C			
	Transient Ischaemic Attack		Isoptin Sr (Verapamil Hcl)	C			
			Mavik (Trandolopril) Abbott	C			
			Tarka (Trandolopril/Verapamil Hcl) Abbott	C			

Date:05/18/04ISR Number: 4362692-5Report Type:Expedited (15-DaCompany Report #002#4#2004-00104
Age:80 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Carotid Artery Stenosis	Health Professional	Reglan (Metoclopramide Hcl)	PS		ORAL	ORAL
	Depressed Level Of Consciousness	Other	Potassium Supplement	C			
	Encephalopathy		Lipid-Lowering Drug	C			
	Spinal Compression Fracture		Hormon Replacement	C			
	Transient Ischaemic Attack		Aspirin	C			
			Alpha-Blocker	C			

Date:05/18/04ISR Number: 4362695-0Report Type:Expedited (15-DaCompany Report #002#4#2004-00111
Age:61 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Glucose Increased	Other	Reglan (Metoclopramide Hcl)	PS		ORAL		
	Blood Pressure Diastolic Decreased		Levothyroxine	C				
	Dilatation Atrial		Atorvastatin	C				
	Medication Error		Calcium	C				
	Monocyte Percentage Increased		Glucosamine Chondroitin	C				
	Syncope							

Date:05/19/04ISR Number: 4360611-9Report Type:Expedited (15-DaCompany Report #US-MERCK-0210USA00929
Age:57 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Amnesia		Vioxx	PS	Merck & Co., Inc	ORAL	696	DAY
	Balance Disorder		Reglan	SS			UNKNOWN	
Disability	Blood Pressure Increased		Celebrex	C			UNKNOWN	
	Carpal Tunnel Syndrome		Catapres	C			UNKNOWN	
	Cerebellar Infarction		Flonase	C			UNKNOWN	
	Cerebrovascular Accident		Prilosec	C			UNKNOWN	
	Cerebrovascular Disorder		Lopid	C			UNKNOWN	
	Cognitive Disorder		Robaxin	C			UNKNOWN	
	Cogwheel Rigidity							
	Deafness Neurosensory							
	Diabetes Mellitus							
	Diabetes Mellitus Non-Insulin-Dependent							
	Diabetic Neuropathy							
	Dystonia							
	Fall							
	Fatigue							

	Gallbladder Disorder					
	Glossitis					
	Haematochezia					
	Hiatus Hernia					
	Loss Of Consciousness					
	Low Density Lipoprotein Increased					
	Major Depression					
	Neuropathy Peripheral					
	Orthostatic Hypotension					
	Pseudodementia					
	Radiculopathy					
	Sinusitis					
	Treatment Noncompliance					
	Tremor					

Date:05/19/04ISR Number: 4360813-1Report Type:Direct Company Report #CTU 219021
Age:36 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Agitation		Reglan	PS				
INTRAVENOUS							10 MG IV	
	Feeling Hot		Versed	C				
	Panic Attack		Zofran	C				
	Restlessness							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/19/04ISR Number: 4360824-6Report Type:Direct Company Report #CTU 219022
Age:30 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Agitation		Reglan 10 Mgm	PS		INTRAVENOUS	10 MGM IV	
	Dizziness							

Date:05/25/04ISR Number: 4369000-4Report Type:Expedited (15-DaCompany Report #002#8#2004-00115
Age:52 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Asthenia	Literature	Metoclopramide-Hydrochloride (Metoclopramide Hcl)	PS		ORAL	10 MG, 4 IN 1	
	Diarrhoea							
	Drug Interaction							
	Drug Level Below							
	Therapeutic		Tacrolimus	SS		ORAL	ORAL	
	Drug Toxicity		Ursodiol	C				
	Gastric Hypomotility		Levofloxacin	C				
	Headache		Metronidazole	C				
	Hepatic Enzyme Increased		Ranitidine	C				
	Liver Transplant		Omeprazole	C				
	Rejection		Pantoprazole	C				
	Nausea		Ketoconazole	C				
	Nephropathy Toxic		Sirolimus	C				
	Pain In Extremity		Mycophenolate-Mofetil	C				
	Pyrexia							
	Renal Failure Acute							
	Renal Tubular Necrosis							
	Tremor							
	Vomiting							

Date:05/26/04ISR Number: 4366854-2Report Type:Direct Company Report #USP 56532
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Other	Medication Error	Reglan	PS

TABLET

Date:05/26/04ISR Number: 4370663-8Report Type:Expedited (15-DaCompany Report #HQWYE876213MAY04
Age:18 YR Gender:Male I/FU:I

Outcome	PT
Life-Threatening	Asthenia
Hospitalization - Initial or Prolonged	Blood Immunoglobulin G Increased
Other	Cardiomegaly
	Chest X-Ray Abnormal
	Gastroenteritis
	Haematuria
	Haemolytic Anaemia
	Heart Rate Increased
	Kidney Enlargement
	Mumps
	Mycoplasma Serology Positive
	Normochromic Normocytic Anaemia
	Otitis Media
	Oxygen Saturation Decreased

Parkinson'S Disease Peritoneal Dialysis Renal Failure Acute Renal Tubular Necrosis Renal Vessel Disorder Thrombocytopenia	Report Source Health Professional Other	Product	Role	Manufacturer	Route	Dose Duration
		Children'S Advil (Ibuprofen, Suspension)	PS		ORAL	3 DAY
		Efferalgan (Paracetamol,)	SS		ORAL	
		Maxilase (Amylase,)	SS		ORAL	3 DAY
		Orelox (Cefpodoxime Profexil,)	SS		ORAL	1 DAY
		Panfurex (Nifuroxazide,)	SS		ORAL	3 DAY
		Pivalone (Tixocortol Pivalate,)	SS		ORAL	3 DAY
		Primperan (Metoclopramide,)	SS		NASAL	3 DAY

Date:05/27/04ISR Number: 4366565-3Report Type:Expedited (15-DaCompany Report #FR-BRISTOL-MYERS SQUIBB COMPANY-12590477
Age:82 YR Gender:Female I/FU:I

Outcome PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Life-Threatening Leukopenia	Health Professional	Amiklin Powder	PS	Geneva Pharmaceuticals Technology, Corp.		
						INTRAVENOUS 3 DAY
		Perfalgan Iv	SS	Regulatory Health Authority Denmark		
						INTRAVENOUS
		Polaramine	SS		ORAL	3 DAY
		Primperan	SS			
						INTRAVENOUS 1 DAY
		Rocephine	SS			
						INTRAVENOUS 3 DAY
		Mopral	SS			
						INTRAVENOUS

Date:06/02/04ISR Number: 4369003-XReport Type:Direct Company Report #CTU 219886
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Ineffective Pharmaceutical Product Complaint		Reglan	PS				

Date:06/02/04ISR Number: 4370736-XReport Type:Direct Company Report #CTU 219944
Age:59 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Tremor		Metoclopramide	PS				

Date:06/02/04ISR Number: 4371688-9Report Type:Expedited (15-DaCompany Report #002#0#2004-00121
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other Required Intervention to Prevent Permanent Impairment/Damage	Medication Error	Other	Reglan-10mg-Tablet (Metoclopramide Hcl)	PS		ORAL	10MG, 1 IN 1 D; ORAL	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/03/04ISR Number: 4370326-9Report Type:Periodic Company Report #US-BRISTOL-MYERS SQUIBB COMPANY-12532958
Age:55 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Dyskinesia		Abilify	PS	Otsuka Pharmaceutical Company, Ltd.	ORAL	2	MON
			Reglan	SS				
			Paxil	C				
			Valium	C				
			Multivitamin	C				

Date:06/07/04ISR Number: 4372222-XReport Type:Expedited (15-DaCompany Report #FR-BRISTOL-MYERS SQUIBB COMPANY-12599239
Age:82 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Leukopenia	Health Professional	Perfalgan	PS	Regulatory Health Authority Denmark	INTRAVENOUS		
			Amiklin	SS	Geneva Pharmaceuticals Technology, Corp.	INTRAVENOUS		
			Mopral	SS		INTRAVENOUS		
			Rocephine	SS		INTRAVENOUS	3	DAY
			Primperan	SS		INTRAVENOUS	1	DAY
			Polaramine	SS		ORAL	3	DAY

Date:06/07/04ISR Number: 4375486-1Report Type:Expedited (15-DaCompany Report #2004UW11073
Age:44 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Alcoholism Dependence Depression	Health Professional	Seroquel	PS				
			Alcohol	SS				
			Sustiva	SS				

Multiple Drug Overdose		Reglan	SS	
Myocardial Infarction		Phenergan	SS	
Suicide Attempt		Viread	SS	
		Trazodone	SS	
		Depakote	SS	
		3tc	SS	

Date:06/15/04ISR Number: 4377717-0Report Type:Expedited (15-DaCompany Report #GB-BRISTOL-MYERS SQUIBB COMPANY-12608071
Age:57 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Headache Restless Legs Syndrome		Paclitaxel	PS	Bristol-Myers Squibb Company	INTRAVENOUS		
			Metoclopramide	SS				
			Omeprazole	C				
			Beconase	C				
			Ferrous Sulfate	C				
			Atenolol	C	Geneva Pharmaceuticals Technology, Corp.	ORAL		
			Acetaminophen	C		ORAL		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/16/04ISR Number: 4382321-4Report Type:Expedited (15-DaCompany Report #HQWYE345008JUN04
Age:83 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Disease Recurrence Drug Interaction	Health Professional	Efexor (Venlafaxine Hydrochloride)	PS		ORAL	37.5 MG 1X	
Other	Drug Toxicity							PER 1 DAY
	Metabolic Syndrome Systemic Inflammatory Response Syndrome		Paspertin (Metoclopramide Hydrochloride,)	SS		ORAL	30 MG 1X PER	
	Urinary Tract Infection							1 DAY
			Recormon (Erythropoietin Human)	C				
			Liquemine (Heparin Sodium)	C				
			Dafalgan (Paracetamol)	C				
			Norvasc (Amlodipine Besilate)	C				
			Nexium (Esomeprazole)	C				
			Laxoberon (Sodium Picosulfate)	C				
			Stilnox (Zolpidem)	C				

Date:06/16/04ISR Number: 4382712-1Report Type:Expedited (15-DaCompany Report #002#4#2004-00046
Age:55 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Grand Mal Convulsion	Health Professional	Reglan-10mg-Tablet (Metoclopramide Hcl)	PS		ORAL	10MG, 1IN 1	
Intervention to		Other						D, ORAL
Prevent Permanent			Bupropion	SS		ORAL	300MG, 1 IN 1	
Impairment/Damage								D, ORAL

Valsartan-Hct	C
Amlodipine	C
Simvastatin	C
Diflunisal	C
Doxepin	C
Levothyroxine	C
Omeprazole	C
Venlafaxine	C
Fluoxetine	C
Hydrochloroquine	C
Folic-Acid	C
Vitamin B-12	C
Vitamin B-6	C

Date:06/17/04ISR Number: 4380067-XReport Type:Expedited (15-DaCompany Report #US-MERCK-0210USA00929
Age:57 YR Gender:Male I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Amnesia
Disability	Aortic Calcification
	Apathy
	Asthenia
	Balance Disorder
	Blood Cholesterol Increased

		Blood Pressure Increased Blood Triglycerides Increased	Report Source	Product	Role	Manufacturer	Route	Dose
Duration								
		Carotid Artery Stenosis		Vioxx	PS	Merck & Co., Inc	ORAL	696
DAY								
		Carpal Tunnel Syndrome		Reglan	SS			
UNKNOWN								
		Cerebellar Infarction		Celebrex	C			
UNKNOWN								
		Cerebrovascular Disorder		Catapres	C			
UNKNOWN								
		Chest Discomfort		Flonase	C			
UNKNOWN								
		Cholecystitis		Prilosec	C			
UNKNOWN								
		Cognitive Disorder		Lopid	C			
UNKNOWN								
		Cogwheel Rigidity		Robaxin	C			
UNKNOWN								
		Coordination Abnormal						
		Deafness Neurosensory						
		Decreased Interest						
		Dementia						
		Diabetes Mellitus Non-Insulin-Dependent						
		Diabetic Neuropathy						
		Difficulty In Walking						
		Dizziness						
		Dystonia						
		Fall						
		Fatigue						
		Gait Disturbance						
		Glossitis						
		Haematochezia						
		Headache						
		Hiatus Hernia						
		High Density Lipoprotein Decreased						
		Hyporeflexia						
		Loss Of Consciousness						
		Low Density Lipoprotein Increased						
		Major Depression						
		Memory Impairment						
		Neuropathy Peripheral						
		Orthostatic Hypotension						

Pseudodementia
Radiculopathy
Sensory Disturbance
Sinusitis
Sleep Apnoea Syndrome
Tongue Discolouration
Treatment Noncompliance
Tremor

Date:06/17/04ISR Number: 4381108-6Report Type:Direct Company Report #USP 56622
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Medication Error		Metoclopramide	PS	Pharmaceutical Associates, Inc		LIQUID	
			Docusate Sodium	SS	Pharmaceutical Associates, Inc		LIQUID	
			Guaifenesin	SS	Pharmaceutical Associates, Inc		LIQUID	
			Guaifenesin With Dextromethorphan Bromide	SS	Pharmaceutical			

						Associates, Inc	
LIQUID							
				Ferrous Sulfate	SS	Pharmaceutical Associates, Inc	
LIQUID							
				Diphenhydramine Hcl	SS	Pharmaceutical Associates, Inc	
LIQUID							

Date:06/17/04ISR Number: 4381417-0Report Type:Direct Company Report #CTU 220978
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Agitation		Metoclopramide 10mg			
	Hyperhidrosis		/ 2 Ml Baxter	PS	Baxter	
INTRAVENOUS 10MG ONCE						
	Hyperreflexia					
INTRAVENOUS						

Date:06/17/04ISR Number: 4381420-0Report Type:Direct Company Report #CTU 220977
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Agitation		Metoclopramide 10mg			
	Hyperhidrosis		/ 2ml Baxter	PS	Baxter	
INTRAVENOUS 10MG ONCE						
	Hyperreflexia					
INTRAVENOUS						

Date:06/21/04ISR Number: 4381053-6Report Type:Expedited (15-DaCompany Report #PHBS2004BR07763
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Malaise	Consumer	Syntocinon	PS	Novartis Sector:	
	Tachycardia				Pharma	
			Plasil	SS		

Date:06/21/04ISR Number: 4382400-1Report Type:Direct Company Report #CTU 221136
Age:53 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Bradyphrenia		Topamax 100 Mg	PS		ORAL	150 MG TWICEA	
	Mania						DAY ORAL	
	Paranoia		Metoclopramide	SS		ORAL	ORAL	
	Speech Disorder		Imitrex	C				
			Wellbutrin Sr	C				
			Flonase	C				
			Adderal Xr	C				
			Ambien	C				

Date:06/21/04ISR Number: 4396541-6Report Type:Periodic Company Report #USA-2003-0010313
Age:56 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Health Professional Other	Oxycodone Hydrochloride (Similar To Nda 20-553) (Oxycodone Hydrochloride)	PS				
			Metoclopramide (Metoclopramide)	SS				
			Diazepam (Diazepam)	SS				
			Oxazepam (Oxazepam)	SS				
			Temazepam					

			(Temazepam)	SS		
			Caffeine (Caffeine)	SS		
			Nicotine (Nicotine)	SS		

Date:06/23/04ISR Number: 4383977-2Report Type:Direct Company Report #CTU 221279
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Delusion		Cyclobenzapine 10 Mg	PS		ORAL	PO TID	
	Mental Status Changes		Dicyclomiine 10 Mg	SS		ORAL	PO AC HS	
	Psychotic Disorder		Metoclopramide 10 Mg	SS		ORAL	PO ACHS	
			Propranolol 40 Mg	SS		ORAL	PO TID	

Date:06/24/04ISR Number: 4388675-7Report Type:Expedited (15-DaCompany Report #002#4#2004-00138
Age:13 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Electrocardiogram Qt	Health	Reglan-Dose-Unknown					
Required	Prolonged	Professional	(Metoclopramide Hcl)	PS				
Intervention to	Overdose	Other	Fexofenadine	SS				
Prevent Permanent	Suicide Attempt		Acetaminophen	SS				
Impairment/Damage			Tramadol	SS				

Date:06/28/04ISR Number: 4386908-4Report Type:Direct Company Report #CTU 221722
Age:48 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Oxygen Saturation Decreased		Metoclopramide 15 Mg 4x/D Udl	PS	Udl	ORAL	PO	10 MON
	Sulphaemoglobinaemia		Amylase-Lipase-Protase	C				
			Divalproex	C				
			Beano	C				
			Etidronate	C				

Golytely	C
Levothyroxine	C
Oyster Calcium	C
Multiple Vitamin	C
Vioxx	C
Pantoprazole	C
Tegaserod	C
Acetaminophen	C

Date:06/28/04ISR Number: 4389233-0Report Type:Expedited (15-DaCompany Report #002#4#2004-00139
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Dystonia	Consumer	Reglan-Dose-Unknown					
	Tardive Dyskinesia	Other	(Metoclopramide Hcl)	PS		ORAL	ORAL	
	Tremor							

Date:06/29/04ISR Number: 4386664-XReport Type:Expedited (15-DaCompany Report #FR-BRISTOL-MYERS SQUIBB COMPANY-12599239
Age:82 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Leukopenia		Perfalgan	PS	Regulatory Health Authority Denmark	INTRAVENOUS		

			Amiklin	SS	Geneva Pharmaceuticals Technology, Corp.		
INTRAVENOUS							
			Mopral	SS			
INTRAVENOUS							
			Rocephine	SS			
INTRAVENOUS	3	DAY					
			Primperan	SS			
INTRAVENOUS	1	DAY					
			Polaramine	SS			ORAL
3 DAY							

Date:06/30/04ISR Number: 4389932-0Report Type:Direct Company Report #CTU 221855
Age:40 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Pharmaceutical Product		Metoclopramide 5 Mg	PS			5 MG BEFORE	
	Complaint							
MEALS								
	Vomiting							

Date:07/01/04ISR Number: 4388787-8Report Type:Expedited (15-DaCompany Report #US-MERCK-0210USA00929
Age:57 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Amnesia	Health	Vioxx	PS	Merck & Co., Inc	ORAL	696 DAY	
Initial or Prolonged	Aortic Calcification	Professional	Reglan	SS			UNKNOWN	
Disability	Blood Cholesterol		Celebrex	C			UNKNOWN	
	Increased		Catapres	C			UNKNOWN	
	Blood Pressure Increased		Flonase	C			UNKNOWN	
	Blood Triglycerides		Prilosec	C			UNKNOWN	
	Increased		Lopid	C			UNKNOWN	

	Carotid Artery Stenosis	Robaxin	C
UNKNOWN			
	Cerebellar Infarction		
	Cerebrovascular Disorder		
	Cholecystitis		
	Cognitive Disorder		
	Deafness Neurosensory		
	Diabetes Mellitus		
	Non-Insulin-Dependent		
	Diabetic Neuropathy		
	Dystonia		
	Fall		
	Glossitis		
	Haematochezia		
	Hiatus Hernia		
	High Density Lipoprotein		
	Decreased		
	Low Density Lipoprotein		
	Increased		
	Major Depression		
	Neuropathy Peripheral		
	Orthostatic Hypotension		
	Pseudodementia		
	Radiculopathy		
	Sinusitis		
	Sleep Apnoea Syndrome		
	Treatment Noncompliance		
	Tremor		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/07/04ISR Number: 4390771-5Report Type:Expedited (15-DaCompany Report #US-MERCK-0210USA00929
Age:57 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Amnesia		Vioxx	PS	Merck & Co., Inc	ORAL		696 DAY
Initial or Prolonged	Aortic Calcification		Reglan	SS				UNKNOWN
Disability	Blood Pressure Increased		Celebrex	C				UNKNOWN
	Cerebellar Infarction		Catapres	C				UNKNOWN
	Cholecystitis		Flonase	C				UNKNOWN
	Cognitive Disorder		Prilosec	C				UNKNOWN
	Deafness Neurosensory		Lopid	C				UNKNOWN
	Diabetes Mellitus		Robaxin	C				UNKNOWN
	Non-Insulin-Dependent Diabetic Neuropathy							
	Dystonia							
	Fall							
	Glossitis							
	Haematochezia							
	Haemorrhoids							
	Hiatus Hernia							
	Orthostatic Hypotension							
	Pseudodementia							
	Radiculopathy							
	Tremor							

Date:07/12/04ISR Number: 4422150-6Report Type:Periodic Company Report #TAP2003Q01776
Age:2 MON Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Drug Ineffective	Consumer	Prevacid					
Initial or Prolonged		Health	(Lansoprazole)	PS		ORAL		12 MG, 1 IN 1
		Professional						D; PER ORAL
			Reglan					

	(Metoclopramide)	SS	ORAL

5 MG/ML, 1 IN

1 D; PER ORAL

	Cara Cream [Sic]	C
	Tapioca-Based Infant Formula (Infant Formulas)	C

Date:07/20/04ISR Number: 4402477-4Report Type:Expedited (15-DaCompany Report #US-MERCK-0210USA00929
Age:57 YR Gender:Male I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Amnesia
Disability	Aortic Calcification
	Apathy
	Asthenia
	Blood Cholesterol Increased
	Blood Pressure Increased
	Blood Triglycerides Increased
	Carotid Artery Stenosis
	Carpal Tunnel Syndrome
	Cerebellar Infarction
	Cerebrovascular Accident
	Cerebrovascular Disorder
	Chest Discomfort
	Cholecystitis

		Cognitive Disorder Deafness Neurosensory Decreased Interest	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
		Diabetes Mellitus		Vioxx	PS	Merck & Co., Inc	ORAL
696	DAY						
		Diabetes Mellitus		Reglan	SS		
UNKNOWN							
		Non-Insulin-Dependent		Celebrex	C		
UNKNOWN							
		Diabetic Neuropathy		Catapres	C		
UNKNOWN							
		Dizziness		Flonase	C		
UNKNOWN							
		Dystonia		Prilosec	C		
UNKNOWN							
		Fall		Lopid	C		
UNKNOWN							
		Fatigue		Robaxin	C		
UNKNOWN							
		Glossitis Haematochezia Haemorrhoids Hiatus Hernia High Density Lipoprotein Decreased Hypoglycaemia Low Density Lipoprotein Increased Major Depression Neuropathy Peripheral Orthostatic Hypotension Pain In Extremity Pseudodementia Radiculopathy Sinusitis Sleep Apnoea Syndrome Somnolence Treatment Noncompliance Tremor					

Date:07/23/04ISR Number: 4407192-9Report Type:Direct Company Report #CTU 223416
Age:77 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Delirium		Metoclopramide	PS				
			Omeprazole	C				
			Insulin Nph	C				
			Simvastatin	C				
			Metoprolol Succinate	C				
			Fosinopril	C				
			Hydrochlorothiazide	C				
			Niacin Er	C				
			Ibuprofen	C				
			Gemfibrozil	C				
			Acetaminophen/Hydrocodone	C				

Date:07/28/04ISR Number: 4409827-3Report Type:Expedited (15-DaCompany Report #PHBS2004BR07763
Age: Gender:Female I/FU:F

Outcome	PT
Other	Drug Exposure Via Breast Milk
	Malaise
	Menstruation Irregular
	Palpitations
	Suppressed Lactation

Tachycardia

Dose	Duration	Report Source	Product	Role	Manufacturer	Route
		Consumer	Syntocinon	PS	Novartis Sector: Pharma	
			Plasil	SS		

Date:07/29/04ISR Number: 4443998-8Report Type:Periodic Company Report #USA-2002-0000869
Age:26 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Death	Accidental Overdose	Consumer	Morphine Sulfate (Similar To Nda 19-516) (Morphine Sulfate)	PS		
Other	Drug Abuser	Health Professional Other	Dihydrocodone/Caffeine/Acetaminophen (Similar To And A 88-584) (Dihydrocodone, Hydrocodone Bitartrate (Similar To Ind 59,175) (Hydrocodone Bitartrate)	SS		
	Multiple Drug Overdose		Cocaine (Cocaine)	SS		
			Ibuprofen (Ibuprofen)	SS		
			Caffeine (Caffeine)	SS		
			Metoclopramide "Cox" (Metoclopramide Hydrochloride)	SS		
			Acetaminophen (Paracetamol)	SS		
			Methadone (Methadone)	C		

Date:07/29/04ISR Number: 4444151-4Report Type:Periodic Company Report #USA-2003-0011953
Age:41 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose Multiple Drug Overdose	Health Professional Other	Morphine Sulfate (Similar To Nda-19-516) (Morphine Sulfate)	PS				
			Fentanyl (Fentanyl)	SS				
			Diazepam (Diazepam)	SS				
			Gabapentin (Gabapentin)	SS				
			Lorazepam (Lorazepam)	SS				
			Metoclopramide (Metoclopramide)	SS				
			Promethazine (Promethazine)	SS				
			Venlafaxine (Venlafaxine)	SS				

Date:07/30/04ISR Number: 4411990-5Report Type:Expedited (15-DaCompany Report #JP-ROCHE-375512
Age:77 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Blood Creatinine		Panaldine	PS	Roche	ORAL	3	DAY
	Increased		Atp	SS			UNKNOWN	
	Blood Urea Increased		Primperan	SS			UNKNOWN	
	Haematuria		Radicut	C		OTHER	ROUTE:	
	Liver Disorder						INJECTION.	
	Pyrexia							
	Thrombocytopenia							

Date:08/02/04ISR Number: 4413079-8Report Type:Direct Company Report #CTU 224021
Age:54 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Pyrexia		Metoclopramide 10 Mg Pai	PS	Pai	ORAL	10 MG BID	
							ORAL	

Date:08/05/04ISR Number: 4418173-3Report Type:Direct Company Report #CTU 224312
Age:48 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Convulsion		Il - 2 2mv Sq	PS			SUBCUTANEOUS	2 MU SQ
Initial or Prolonged	Malignant Neoplasm		Vicodin	SS			VICODIN 2	
	Progression						TABS Q 4 PRN	
	Metastases To Central		Reglan	SS			REGLAN 10 MG	

	Nervous System					
Q 4 PRN						
	Metastatic Malignant Melanoma					

Date:08/12/04ISR Number: 4427527-0Report Type:Expedited (15-DaCompany Report #2004-03402
Age:52 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Interaction Drug Level Increased Drug Toxicity	Literature Health Professional	Metoclopramide (Watson Laboratories) (Metoclopramide) Tablet, 10mg	PS		ORAL	10 MG, QID, ORAL : 20 MG, QID, ORAL : 20 MG QAC,	QHS 19 MIN
			Tacrolimus(Tacrolimus)	SS		ORAL	28 MG, BID, ORAL : 20 MG, BID	
			Cimetidine	C				
			Ketoconazole	C				
			Mycophenolate Mofetil	C				
			Ondansetron	C				
			Ursodiol (Ursodeoxycholic Acid)	C				
			Levofloxacin	C				
			Metronidazole	C				

Ranitidine	C
Omeprazole Sodium	C
Protonix "Wyeth-Ayers" (Pantoprazole Sodium)	C

Date:08/13/04ISR Number: 4425442-XReport Type:Expedited (15-DaCompany Report #JP-ROCHE-375512
Age:77 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Arthralgia	Health	Panaldine	PS	Roche	ORAL	3	DAY
Hospitalization -	Blood Creatinine	Professional	Radicut	SS		INTRAVENOUS		
Initial or Prolonged	Increased					DRIP	2	DAY
	Blood Urea Increased		Atp	SS		INTRAVENOUS		
	Haematuria					DRIP	2	DAY
	Injection Site Erythema		Primperan	SS		INTRAVENOUS		
	Injection Site Induration					DRIP	2	DAY
	Injection Site Pain							
	Injection Site Swelling							
	Leukocytosis							
	Liver Disorder							
	Polyarteritis Nodosa							
	Pulse Pressure Decreased							
	Pyrexia							
	Renal Disorder							
	Thrombocytopenia							

Date:08/16/04ISR Number: 4426722-4Report Type:Expedited (15-DaCompany Report #GB-ROCHE-376496
Age:60 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Anorexia	Health	Ibandronic Acid	PS	Roche	INTRAVENOUS	1	DAY

Initial or Prolonged	Diarrhoea	Professional	Ibandronic Acid	SS	Roche	ORAL
EACH MORNING 6 DAY						
	Duodenal Stenosis		Co-Dydramol	SS		ORAL
	Nausea		Tramadol	SS		ORAL
			Megestrol Acetate	SS	Roche	ORAL
			Bendroflumethiazide	SS		ORAL
			Amlodipine Besilate	SS		ORAL
			Losec	SS		ORAL
			Metoclopramide	SS		ORAL

Date:08/23/04ISR Number: 4433097-3Report Type:Expedited (15-DaCompany Report #USA-2004-0016080
Age:37 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Alcoholism	Consumer	Morphine Sulfate	PS		
MG						
	Cardiomegaly	Health	Oxycodone			
	Coma	Professional	Hydrochloride	SS		
	Drug Toxicity	Other	Ethanol (Ethanol)	SS		
	Hepatic Cirrhosis		Trazodone			
	Hepatic Steatosis		(Trazodone)	SS		
	Multiple Drug Overdose		Metoclopramide			
	Pulmonary Congestion		(Metoclopramide)	SS		
	Pulmonary Oedema		Nicotine (Nicotine)	SS		
			Acetaminophen			
			(Acetaminophen)	C		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/24/04ISR Number: 4433877-4Report Type:Direct Company Report #CTU 225480
Age:32 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Muscle Spasms		Reglan 10 Mg	PS		ORAL	4X DAY ORAL	
	Muscle Twitching							
	Nervous System Disorder							

Date:08/25/04ISR Number: 4433533-2Report Type:Expedited (15-DaCompany Report #1017687-2004-001
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Corneal Reflex Decreased	Consumer	Metoclopramide Hcl	PS	Pharmaceutical Associates,Inc.	ORAL	5MG (3 X DAILY) ORAL	
	Hyperhidrosis							
	Posturing							

Date:08/26/04ISR Number: 4435378-6Report Type:Expedited (15-DaCompany Report #2004228034FR
Age:18 MON Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Hospitalization - Initial or Prolonged	Cardiomegaly	Foreign Health Professional Other	Vantin(Cefpodoxime Proxetil) Suspension	PS		ORAL	ORAL	
	Chest X-Ray Abnormal		Bacitracin(Bacitracin) Powder, Sterile	SS		ORAL	ORAL	
	Chlamydial Infection		Maxilase-Bacitracine (Alpha-Amylase Bacterial)	SS		ORAL	ORAL	
	Conjunctival Disorder		Pivalone(Tixocortol Pivalate) Spray	SS		INTRA-AMNIOTIC	INTRA-AMNIOTIC	
	Coombs Direct Test Positive		Metoclopramide(Metoclopramide) Solution,					
	Dehydration							
	Gastroenteritis							
	Haematuria							
	Haemolytic Anaemia							
	Heart Rate Increased							
	Jaundice							

	Kidney Enlargement	Sterile	SS	ORAL
ORAL				
	Leukocytosis	Panfurex(Nifuroxazid		
	Mumps Antibody Test	e) Solution, Oral	SS	ORAL
ORAL				
	Positive	Ibupirac(Ibuprofen)		
	Normochromic Normocytic	Suspension, Oral	SS	ORAL
ORAL				
	Anaemia	Efferalgan	C	
	Otitis Media	Motilium		
	Oxygen Saturation	(Domperidone)	C	
	Decreased			
	Peritoneal Dialysis			
	Platelet Count Increased			
	Renal Failure Acute			
	Renal Tubular Necrosis			

Date:08/27/04ISR Number: 4437307-8Report Type:Expedited (15-DaCompany Report #USA-2004-0012715
Age:38 YR Gender:Female I/FU:F

Outcome	PT
Hospitalization -	Abdominal Distension
Initial or Prolonged	Abdominal Pain
Other	Ascites
	Faecal Volume Increased
	Flatulence
	Infrequent Bowel
	Movements
	Malignant Neoplasm
	Progression

		Pain Pleural Effusion Ultrasound Abdomen	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
		Abnormal	Study Health Professional Other	Oxycontin Tablets (Oxycodone Hydrochloride) Cr Tablet	PS		
				Morphine Sulfate (Morphine Sulfate)	SS		
20 MG,							
				Roxanol (Morphine Sulfate)	SS		
				Metoclopramide (Metoclopramide)	SS		
				Irinotecan (Irinotecan)	SS		
				Citalopram (Citalopram)	SS		
				Gemcitabine (Gemcitabine)	SS		
				Megace (Megestrol Acetate)	C		
				Dolasetron (Dolasetron)	C		
				Levofloxacin (Levofloxacin)	C		

Date:08/27/04ISR Number: 4437452-7Report Type:Expedited (15-DaCompany Report #HQWYE876213MAY04
Age:18 MON Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Life-Threatening Hospitalization - Initial or Prolonged	Blood Immunoglobulin G Increased Cardiomegaly	Health Professional Other	Children'S Advil (Ibuprofen Suspension)	PS		ORAL
ORAL	3 DAY					
Other	Chest X-Ray Abnormal		Maxilase (Amylase)	SS		ORAL
ORAL	3 DAY					
	Coombs Direct Test Positive		Orelox (Cefpodoxime Proxetil)	SS		ORAL
ORAL	1 DAY					
	Gastroenteritis Haemolytic Anaemia		Panfurex (Nifuroxazide)	SS		ORAL
ORAL						

			Heart Rate Increased Jaundice	Pivalone (Tixocortol Pivalate)	SS		NASAL
NASAL	3	DAY					
			Kidney Enlargement Mumps Antibody Test	Primperan (Metoclopramide)	SS		ORAL
ORAL	3	DAY					
			Positive Mycoplasma Serology Positive Otitis Media Oxygen Saturation Decreased Peritoneal Dialysis Platelet Count Increased Renal Failure Acute Renal Tubular Necrosis White Blood Cell Count Increased	Efferalgan (Paracetamol)	C		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/31/04ISR Number: 4439243-XReport Type:Expedited (15-DaCompany Report #20040800379
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Disability	Injury		Reglan (Metoclopramide)	PS				

Date:09/01/04ISR Number: 4439484-1Report Type:Direct Company Report #CTU 226045
Age:68 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dystonia		Reglan	PS				
			Imipenem	SS				
			Tigan	SS				

Date:09/02/04ISR Number: 4441082-0Report Type:Direct Company Report #CTU 226182
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dyskinesia Muscle Twitching		Metoclopramide Liquid Formulation	PS		ORAL	MAX DOSING Q 8 HRS ORAL	
			Prevacid	C				

Date:09/02/04ISR Number: 4441121-7Report Type:Direct Company Report #CTU 226239
Age:83 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Chorea		Reglan Oral 10.0 Mg	PS		ORAL	ORAL TID	

Date:09/03/04ISR Number: 4440218-5Report Type:Expedited (15-DaCompany Report #FR-BRISTOL-MYERS SQUIBB COMPANY-12590477
Age:82 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Leukopenia Neutropenia	Health Professional	Amiklin Powder	PS	Geneva Pharmaceuticals Technology, Corp.	INTRAVENOUS	3	DAY
			Perfalgan Iv	SS	Regulatory Health Authority Denmark	INTRAVENOUS	3	DAY
			Polaramine	SS		ORAL		
			Primperan	SS		INTRAVENOUS	1	DAY
			Rocephine	SS		INTRAVENOUS	3	DAY
			Mopral	SS		INTRAVENOUS		

Date:09/03/04ISR Number: 4441659-2Report Type:Expedited (15-DaCompany Report #2004-DE-04435GD
Age:48 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Multiple Drug Overdose	Foreign Literature	Codeine (Codeine)	PS				
			Olanzapine (Olanzapine)	SS				
			Venlafaxine (Venlafaxine)	SS				
			Flurazepam (Flurazepam)	SS				
			Metoclopramide					

(Metoclopramide) SS

Date:09/07/04ISR Number: 4443158-0Report Type:Direct Company Report #CTU 226454
Age:37 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Dyspnoea Muscular Weakness Restlessness Swollen Tongue		Metoclopramide 10 Mg Purepac	PS	Purepac	ORAL	10 MG Q6H ORAL	

Date:09/07/04ISR Number: 4446397-8Report Type:Expedited (15-DaCompany Report #2004059627
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Asthenia Balance Disorder Body Height Decreased Cerebrovascular Accident Difficulty In Walking Drug Level Increased Gastrointestinal Disorder Headache Irritability Nausea Parkinson'S Disease	Consumer	Navane (Capsules) (Thiothixene) Tikosyn (Dofetilide) Lithium (Lithium) Metoclopramide (Metoclopramide) Digoxin (Digoxin) Sinemet (Carbidopa, Levodopa) Entacapone (Entacapone) Famotidine (Famotidine) Penicillamine (Penicillamine) Levothyroxine Sodium (Levothyroxine Sodium) Lorazepam	PS SS SS SS SS SS C C C C		ORAL ORAL	1 MG (0.5 MG, 2 IN 1 D), ORAL 600 MG, ORAL	

				(Lorazepam)	C		
				Mesalazine (Mesalazine)	C		

Date:09/09/04ISR Number: 4448832-8Report Type:Expedited (15-DaCompany Report #2004-119916-NL
Age:90 YR Gender:Female I/FU:I

Outcome	Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Death			Anxiety		Mirtazapine (See			
Life-Threatening			Coagulopathy		Attached Pages For			
			Depression		Addtional Suspect			
			Gastritis		Drugs)	PS		ORAL
DF	ORAL	3 DAY						
			General Physical Health		Sulpiride	SS		ORAL
50 MG	ORAL	23 DAY						
			Deterioration		Metoclopramide	SS		
DF		18 DAY						
			Hepatic Failure		Doxepin			
			Hepatitis		Hydrochloride	SS		
DF		17 DAY						
			Pain		Omeprazole	SS		
DF		3 WK						
			Renal Failure Acute		Clopidogrel Sulfate	SS		
DF		27 DAY						
					Molsidomine	C		
					Oxybutynin Hydrochloride	C		
					Smectite	C		
					Metronidazole	C		

Ferrous Fumarate C

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 (Betamethasone)	PS				
	Brain Oedema	Literature	Augmentin (Amox.Trihyd+Pot.Clavulan.)	SS			1200 MG THREE TIMES PER DAY	
	Bronchopneumonia	Health Professional						
	Cachexia							
	Calcinosis							
	Cerebral Disorder							
	Enterococcal Infection		Sodium Rabeprazole (Sodium Rabeprazole)	SS				
	Hepatic Fibrosis							
	Lung Infiltration		Metoclopramide (Metoclopramide)	SS			4 ML THREE TIMES PER DAY	
	Lymphocytic Infiltration							
	Pseudomonas Infection		Calcium Lactate Gluconate (Calcium Lactate Gluconate)	SS				
	Renal Haemorrhage							
	Septic Shock							
	Staphylococcal Infection		Nystatin (Nystatin)	SS				
	Toxic Epidermal Necrolysis		Cefaclor (Cefaclor)	SS			25 MG TWICE PER DAY	
			Omeprazole (Omeprazole)	SS				
			Cortisone Acetate (Cortisone Acetate)	SS				
			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: 4446719-8Report Type:Expedited (15-DaCompany Report #2004CG01715
Age:90 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Anxiety	Foreign	Mopral	PS				
Life-Threatening	Coagulopathy	Health	Norset	SS				
	Depression	Professional	Dogmatil	SS		ORAL	50 MG BID PO	YR
	Gastritis	Other	Primperan	SS				
	Gastroduodenitis		Quitaxon	SS				
	Hepatitis		Plavix	SS				
	Iron Deficiency Anaemia		Corvasal	SS				
	Renal Failure Acute		Ditropan/Sch/	SS				
			Smecta "Ipsen"	SS				
			Flagyl "Aventis"	SS				
			Fumafer	SS				

Date:09/10/04ISR Number: 4448987-5Report Type:Expedited (15-DaCompany Report #2004PK01481
Age:67 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Chills	Foreign	Nexium	PS		ORAL	20 MG DAILY	
Initial or Prolonged	Diarrhoea	Health					PO	
	Neutropenia	Professional	Primperan	SS		ORAL	10 MG DAILY	
	Pyrexia	Other					PO	
			5-Fluorouracil					
			"Biosyn"	SS	Biosyn			
			Campto	SS				
			Ciproxine	SS		ORAL	1000 MG DAILY	
							PO	
			Citalopram	C				

Xatral	C
Aspirin Cardio	C
Lantus	C
Liquemine	C
Dafalgan	C
Stilnox	C

Date:09/13/04ISR Number: 4450679-3Report Type:Direct Company Report #CTU 226952
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Difficulty In Walking		Risperdal / Janssen Pharmaceuticals	PS	Janssen Pharmacenticals		0.5 MG BY MOUTH TWICE A DAY	
	Drug Interaction							
	Dyskinesia							
	Gait Disturbance							
			Reglan	SS			10 MG BY MOUTH DAILY	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/15/04ISR Number: 4450288-6Report Type:Expedited (15-DaCompany Report #002#4#2004-00177
Age:7 WK Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Convulsion	Consumer	Reglan-Dose-Unknown					
	Developmental Delay	Other	(Metoclopramide Hcl)	PS				

Date:09/15/04ISR Number: 4451979-3Report Type:Direct Company Report #CTU 227182
Age:61 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Blood Pressure Systolic		Metoclopramide	PS				
INTRAVENOUS							10 MG IV	
Initial or Prolonged	Decreased		Cardizem	C				
	Eye Rolling		Amiodarone	C				
	Heart Rate Decreased		Warfarin	C				
	Hyperhidrosis		Zocor	C				
	Loss Of Consciousness		Glucosamine	C				
	Nausea		Toradol	C				
	Syncope Vasovagal		Versed	C				
			Vioxx	C				
			Ancef	C				
			Morphine Pca	C				

Date:09/17/04ISR Number: 4455552-2Report Type:Expedited (15-DaCompany Report #20040900391
Age:1 MON Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Convulsion	Consumer	Reglan					
	Developmental Delay		(Metoclopramide)	PS				

Date:09/17/04ISR Number: 4455797-1Report Type:Expedited (15-DaCompany Report #04P-151-0272717-00
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required	Abortion Induced	Foreign	Akineton (Biperiden)					

Intervention to	Drug Exposure During	Health	(Biperiden)	PS
INTRAVENOUS 5 MG, ONCE,				
Prevent Permanent	Pregnancy	Professional		
INTRAVENOUS				
Impairment/Damage	Dyskinesia		Metoclopramide	SS
	Menstruation Irregular			
	Pregnancy			

Date:09/20/04ISR Number: 4455791-0Report Type:Expedited (15-DaCompany Report #S04-SWI-04094-01
Age:91 YR Gender:Female I/FU:I

Outcome	PT
Disability	Chest Pain
	Coma
	Depressed Level Of Consciousness
	Epilepsy
	Fall
	Haemorrhage
	Hemiplegia
	Hypertension
	Hyperthermia
	Hypokalaemia
	Myoclonus
	Prothrombin Time

	Prolonged Vomiting						
		Report Source	Product	Role	Manufacturer	Route	Dose
		Foreign Health	Seropram (Citalopram Hydrobromide)	PS		ORAL	20 MG QD PO
		Professional	Co-Dafalgan	SS		ORAL	30 MG QD PO
		Other	Dafalgan (Paracetamol)	SS		ORAL	500 MG QD PO
			Paspertin (Metoclopramide Hydrochloride)	SS			
SUBCUTANEOUS	30 MG ONCE SC		Temesta (Lorazepam)	C			
			Nitroderm (Glycertyl Trinitrate)	C			
			Corvaton "Aventis Pharma" (Molsidomine)	C	Aventis Pharma		
			Aldactone (Spironolactone)	C			
			Torem (Torasemide)	C			
			Nexium (Esomeprazole)	C			
			Imodium "Janssen" (Loperamide Hydrochloride)	C	Janssen		
			Recormon (Erythropoietin Human)	C			
			Vitarubin (Cyanocobalamin)	C			
			Enatec (Enalapril Maleate)	C			
			Aldosterone	C			
			Morphine	C			

Date:09/22/04ISR Number: 4457204-1Report Type:Expedited (15-DaCompany Report #002#4#2004-00183
Age:49 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose

Other Required Intervention to Prevent Permanent Impairment/Damage	Battered Wife Bronchitis Acute Chest Discomfort Chest Pain Condition Aggravated	Other	Reglan Dose (Metoclopramide Hcl) Peg-Intron	PS SS	SUBCUTANEOUS 150MCG, 1 IN 1 W, SUBCUTANEOUS
	Depression Dissociative Identity Disorder Drug Abuser Drug Intolerance Flat Affect Gastroenteritis Neurosis Personality Change Refusal Of Treatment By Patient Social Avoidant Behaviour		Ribavirin Oxycodone	SS SS	ORAL 1 IN 1 D, ORAL ORAL ORAL

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/22/04ISR Number: 4458033-5Report Type:Expedited (15-DaCompany Report #A02200402642
Age:90 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Asthenia Hepatic Failure Renal Failure Acute	Foreign Health Professional	Plavix - (Clopidogrel Sulfate) - Tablet - 75 Mg	PS		ORAL	ORAL	27 DAY
			Primperan - (Metoclopramide)	SS			18 DAY	
			Dogmatil - (Sulpiride)	SS		ORAL	50 MG BID	
			Ditropan - (Oxybutynin) - Tablet - 5 Mg	SS		ORAL	ORAL	23 DAY
			Fumafer - (Ferrous Fumarate)	SS		ORAL	ORAL	3 DAY
			Norset - (Mirtazapine)	SS		ORAL	ORAL	3 DAY
			Quitaxon - (Doxepin Hydrochloride)	SS			24 DAY	
			Mopral - (Omeprazole)	SS			3 WK	
			Corvasal - (Molsidomine)	SS				
			Smecta "Ipsen" - (Smectite) - Powder - 3 G	SS		ORAL	ORAL	13 DAY
			Flagyl "Aventis" - (Metronidazole)	SS			1 WK	

Date:09/23/04ISR Number: 4462372-1Report Type:Expedited (15-DaCompany Report #HQWYE098116SEP04
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Anaphylactoid Reaction Angioneurotic Oedema	Foreign Health Professional Other	Pantozol (Pantoprazole, Injection)	PS		INTRAVENOUS	40 MG 1X PER	1 DAY
						INTRAVENOUS	1	DAY
			Paspertin (Metoclopramide Hydrochloride)	SS		INTRAVENOUS	10 MG 1X PER	1 DAY
						INTRAVENOUS	1	DAY

Date:09/24/04ISR Number: 4462018-2Report Type:Direct Company Report #CTU 228013
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Constipation Pharmaceutical Product Complaint		Reglan	PS				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/28/04ISR Number: 4465071-5Report Type:Direct Company Report #CTU 228194
Age:32 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Fatigue		Metoclopramide 10mg					
	Gastrointestinal Disorder		Pliva, Inc	PS	Pliva, Inc	ORAL	10MG 3/DAY	
	Mood Swings							
ORAL								

Date:09/28/04ISR Number: 4465183-6Report Type:Direct Company Report #CTU 228133
Age:36 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Anxiety		Metoclopramide 10 Mg					
	Irritability		Tablets	PS	Goldline	ORAL	10 MG PO Q 6	
	Restlessness							
HRS/TOTAL 6								
DOSES								
			Ferrous Sulfate	C				
			Oscal 500 + Vitamin D	C				
			Famotidine	C				
			Nifedipine	C				

Date:10/01/04ISR Number: 4466817-2Report Type:Direct Company Report #CTU 228507
Age:20 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Agitation		Metoclopramide 10mg					
	Idiosyncratic Drug		/ 2ml Gensiasicor	PS	Gensiasicor	INTRAVENOUS	10 MG ONCE	
	Reaction							
INTRAVENOU								
	Screaming							

Date:10/08/04ISR Number: 4471130-3Report Type:Expedited (15-DaCompany Report #C-04-0053
Age:4.5 MON Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Dystonia Eye Rolling Musculoskeletal Stiffness	Consumer Other	Metoclopramide Oral Solution, Usp 5 Mg / Ml	PS	Usp	ORAL	1 ML ORALLY BEFORE MEALS	
			Prevacid	C			1ST DOSE ON 09/28/2004	

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	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
		Hepatic Fibrosis	Foreign	Amox/Clav	PS		
1200 MG							
		Hypokalaemia	Literature				
T.D.S.; TABLE							
		Hypotension					
OVER LEAF							
		Lung Infiltration		Rabeprazole	SS		
		Lymphocytic Infiltration		Metoclopramide	SS		
		Oliguria		Calcium Lactogluconate/Carbonate	SS		
		Onychomadesis					
		Ovarian Atrophy		Betametasone	SS		
		Pseudomonas Infection		Nystatin	SS		
		Rash Macular		Cefaclor	SS		
		Respiratory Distress		Omeprazole	SS		
		Septic Shock		Cortisone Acetate	SS		
20 MG							
		Staphylococcal Infection		Calcitriol	SS		
25 MG B.I.D.							
		Thyroid Atrophy		Aluminium/Magnesium Hydroxide	SS		
0.5 MCG AT 8							
		Toxic Epidermal Necrolysis		Fludrocortisone	SS		
A.M.							
		Vomiting		Amoxicillin/Clavulanic 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:10/15/04ISR Number: 4476678-3Report Type:Direct Company Report #CTU 229728
Age:48 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Coma		Zantac 50 Mg Per Cc	PS		INTRAVENOUS	25 MG ONE	
Hospitalization -	Hypotension					INTRAVENOU		
Initial or Prolonged	Infusion Related Reaction		Reglan 10mg	SS		INTRAVENOUS	10MG ONE	
	Syncope Vasovagal					INTRAVENOU		

Date:10/18/04ISR Number: 4478911-0Report Type:Expedited (15-DaCompany Report #2004AL000447
Age:71 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Akinesia	Literature	Metoclopramide					
	Condition Aggravated	Health Professional	Tablets Usp, 10 Mg (Purepac)	PS	Purepac	10 MG; QID;		
	Dysphagia							
	Dysphonia							
	Failure To Thrive							
	Parkinsonism							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/18/04ISR Number: 4478913-4Report Type:Expedited (15-DaCompany Report #2004AL000444
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	Activities Of Daily Living Impaired Bradykinesia Cogwheel Rigidity Confusional State Depression Dysphagia Failure To Thrive General Physical Health Deterioration Incontinence Weight Decreased	Literature Health Professional	Metoclopramide Tablets Usp, 10 Mg (Purepac)	PS	Purepac		10 MG; TID	

Date:10/18/04ISR Number: 4478914-6Report Type:Expedited (15-DaCompany Report #2004AL000445
Age:87 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Anorexia Extremity Contracture Failure To Thrive Incontinence Muscle Rigidity Tremor	Literature Health Professional	Metoclopramide Tablets Usp, 10 Mg (Purepac)	PS	Purepac		5 MG; QID;	

Date:10/18/04ISR Number: 4478915-8Report Type:Expedited (15-DaCompany Report #2004AL000446
Age:69 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Abasia Activities Of Daily Living Impaired Decubitus Ulcer Failure To Thrive	Literature Health Professional	Metoclopramide Tablets Usp, 10 Mg (Purepac)	PS	Purepac		10 MG; QID	

Muscle Rigidity

Date:10/18/04ISR Number: 4479968-3Report Type:Expedited (15-DaCompany Report #M2004-1514
Age:26 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dystonia	Foreign Consumer	Loperamide Hcl	PS				
			Metoclopramide	SS		ORAL	3 TABLETS,	ORAL
			Noroxine (Norfloxacin)	C				
			Doliprane (Paracetamol)	C				

Date:10/20/04ISR Number: 4482023-XReport Type:Direct Company Report #CTU 230124
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Convulsion		Metoclopramide 10mg/2ml Vials Gensiasenicor	PS	Gensiasenior	INTRAVENOUS	10MG X1	

INTRAVENOUS							
				Hydromorphone 2mg/Ml Amps Baxter	SS	Baxter	
INTRAVENOUS	1-2MG	X1					
INTRAVENOUS							
				Heplock Iv	C		
				Toradol	C		
				Ativan	C		

Date:10/22/04ISR Number: 4485080-XReport Type:Direct Company Report #CTU 230210
Age:38 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Abnormal Behaviour		Metoclopramide Inj					
	Formication		Mfd By Faulding	PS	Faulding			
INTRAVENOUS	10 MG IV X 1							
	Restlessness							
DOSE								
			Lactated Ringers Inj	C				
			Pepcid	C				

Date:10/25/04ISR Number: 4487720-8Report Type:Expedited (15-DaCompany Report #HQWYE877718OCT04
Age:76 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Amnesia	Health Professional Other	Efexor (Venlafaxine Hydrochloride, Tablet)	PS		ORAL	112.5 MG 2X	
	Blood Creatine Phosphokinase Increased						PER 1 DAY; 75	
	Blood Pressure Increased						MG 1X PER 1	
	C-Reactive Protein Increased						DAY	
	Clonus		Primperan (Metoclopramide,)	SS		ORAL	10 MG AS	
	Confusional State						NECESSARY	14 DAY
	Drug Interaction							

	Hyperreflexia	Zocor (Simvastatin)	C
	Pyrexia	Lexontanil	
	Serotonin Syndrome	(Bromazepam)	C
	Tachycardia	Digoxine (Digoxin)	C
	White Blood Cell Count Increased	Bioflorin (Lactobacillus Acidophilus)	C
		Imodium (Loperamide Hydrochloride)	C

Date:10/25/04ISR Number: 4487841-XReport Type:Expedited (15-DaCompany Report #S04-SWI-04094-01
Age:91 YR Gender:Female I/FU:F

Outcome	PT
Disability	Chest Pain
	Coma
	Depressed Level Of Consciousness
	Epilepsy
	Fall
	Haemorrhage
	Hemiplegia
	Hypertension
	Hyperthermia
	Hypokalaemia
	Myoclonus
	Prothrombin Time Prolonged

Vomiting

Dose	Duration	Report Source	Product	Role	Manufacturer	Route
20 MG QD PO		Foreign Health	Seropram (Citalopram Hydrobromide)	PS		ORAL
30 MG QD PO		Professional	Co-Dafalgan	SS		ORAL
		Other	Paspertin (Metoclopramide Hydrochloride)	SS		
SUBCUTANEOUS	30 MG ONCE SC					
			Temesta (Lorazepam)	C		
			Nitroderm (Glyceryl Trinitrate)	C		
			Corvaton "Aventis Pharma" (Molsidomine)	C		
			Aldactone (Spirinolactone)	C		
			Torem (Torasemide)	C		
			Nexium (Esomeprazole)	C		
			Imodium "Janssen" (Loperamide Hydrochloride)	C		
			Recormon (Erythropoietin Human)	C		
			Vitarubin (Cyanocobalamin)	C		
			Enatec (Enalapril Maleate)	C		
			Morphine	C		
			Dafalgan (Paracetamol)	C		

Date:10/29/04ISR Number: 4491765-1Report Type:Expedited (15-DaCompany Report #S04-ESP-06636-01
Age:64 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization -	Coma	Foreign	Esertia			

Initial or Prolonged	Confusional State	Health	(Escitalopram)	PS	ORAL
10 MG QD PO					
	Dystonia	Professional	Metoclopramide	SS	
	Hyponatraemia	Other	Lorazepam	C	
	Vomiting		Zopiclone	C	

Date:10/29/04ISR Number: 4492285-0Report Type:Expedited (15-DaCompany Report #USA-2004-0012715
Age:38 YR Gender:Female I/FU:F

Outcome	PT
Hospitalization -	Abdominal Distension
Initial or Prolonged	Abdominal Pain
Other	Ascites
	Constipation
	Disease Progression
	Flatulence
	Malignant Neoplasm
	Progression
	Neoplasm Malignant
	Pleural Effusion
	Ultrasound Abdomen

	Abnormal						
		Report Source	Product	Role	Manufacturer	Route	Dose Duration
		Study	Oxycontin				
		Health	Tablets(Oxycodone				
		Professional	Hydrochloride) Cr				
		Other	Tablet	PS			20 MG
			Roxanol (Morphine				
			Sulfate)	SS			
			Metoclopramide				
			(Metoclopramide)	SS			
			Irinotecan				
			(Irinotecan)	SS			
			Citalopram				
			(Citalopram)	SS			
			Gemcitabine				
			(Gemcitabine)	C			
			Megace (Megestrol				
			Acetate)	C			
			Dolasetron				
			(Dolasetron)	C			
			Levofloxacin				
			(Levofloxacin)	C			

Date:10/29/04ISR Number: 4492541-6Report Type:Expedited (15-DaCompany Report #2004GB02380
Age:29 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Death	Aspiration	Foreign	Heminevrin	PS			3 - 4 TDS PRN
	Vomiting	Health	Omeprazole	SS		ORAL	20 MG DAILY
		Professional					PO
		Other	Clonidine	SS		ORAL	0.1 MG PRN PO
			Diazepam	SS		ORAL	10 MG PRN PO
			Lorazepam	SS		ORAL	2.5 MG PRN PO
			Temazepam	SS		ORAL	20 MG HS PO

		Rohypnol	SS	ORAL
1 MG HS PO				
		Chlorpromazine	SS	ORAL
50 MG PRN PO				
		Octreotide	SS	
SUBCUTANEOUS	100 UG Q12H			
SQ				
		Metoclopramide	SS	
SUBCUTANEOUS	10 MG Q8H SQ			
		Buccastem	SS	
1 - 2 BD				
		Buscopan	SS	ORAL
10 MG PRN PO				
		Naltrexone	SS	
1/2 - 1 DAILY				
		Acupan	SS	
2 - 3 TDS PRN				
		Voltarol	SS	ORAL
25 MG TID PO				
		Zofran	SS	ORAL
8 MG PRN PO				

Date:11/08/04ISR Number: 4498761-9Report Type:Expedited (15-DaCompany Report #002#4#2004-00177
Age:7 WK Gender:Female I/FU:F

Outcome	PT
Disability	Convulsion
	Developmental Delay
	Diarrhoea
	Dyskinesia
	Dysuria
	Floppy Infant
	Hypersomnia
	Hypotonia

	Petit Mal Epilepsy						
	Posture Abnormal						
	Pupils Unequal	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Speech Disorder	Consumer	Reglan-5mg-Tablet				
		Other	(Metoclopramide Hcl)	PS			

Date:11/09/04ISR Number: 4498292-6Report Type:Direct Company Report #CTU 231611
Age:79 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Other	Tremor		Reglan	PS			

Date:11/10/04ISR Number: 4497545-5Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20040908820
Age:35 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Death	Cardiac Arrest		Ultram	PS			
OROPHARINGEAL							
	Completed Suicide		Citalopram	SS			
OROPHARINGEAL							
	Convulsion		Metoclopramide	SS			
	Hypotension		Omeprazole	SS			
	Hypoxic Encephalopathy		Gabapentin	SS			
OROPHARINGEAL							
	Intentional Misuse						

Date:11/10/04ISR Number: 4499627-0Report Type:Direct Company Report #CTU 231684
Age:78 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Required	Confusional State		Metoclopramide 10 Mg				
Intervention to			Goldline	PS	Goldline	ORAL	5 MG EVERY 6
Prevent Permanent							HOURS ORAL
Impairment/Damage							

Date:11/10/04ISR Number: 4499779-2Report Type:Direct Company Report #CTU 231745
Age:83 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Disability	Abasia Asthenia Cerebrovascular Accident Cogwheel Rigidity Gait Disturbance Hemiparesis		Metoclopramide 10 Mg	PS			10 MG TID	30 DAY

Date:11/11/04ISR Number: 4499066-2Report Type:Expedited (15-DaCompany Report #JP-BRISTOL-MYERS SQUIBB COMPANY-12747127
Age:11 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Pancreatitis	Health Professional	Ifomide	PS	Bristol-Myers Squibb Company	INTRAVENOUS DRIP	5	DAY
			Lastet	SS	Bristol-Myers Squibb Company	INTRAVENOUS		
			Uromitexan	SS	Bristol-Myers Squibb Company	INTRAVENOUS DRIP		
			Randa	SS		INTRAVENOUS		

							DRIP
5 DAY							
				Sandostatin	SS		
INTRAVENOUS							
							DRIP
5 DAY							
				Primperan	SS		
INTRAVENOUS							
							DRIP
				Zofran	C		
INTRAVENOUS							
							BOLUS
				Gaster	C		
INTRAVENOUS							
							BOLUS

Date:11/11/04ISR Number: 4499229-6Report Type:Expedited (15-DaCompany Report #GB-GLAXOSMITHKLINE-B0351135A
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Aspiration	Consumer	Zofran	PS	Glaxosmithkline	ORAL	8MG As	
required								
			Heminevrin	SS		ORAL		
			Omeprazole	SS		ORAL	20MG Per day	
			Clonidine	SS		ORAL	.1MG As	
required								
			Diazepam	SS		ORAL	10MG As	
required								
			Lorazepam	SS		ORAL	2.5MG As	
required								
			Temazepam	SS		ORAL	20MG As	
required								
			Rohypnol	SS		ORAL	1MG As	

				Chlorpromazine	SS	Glaxosmithkline	ORAL
50MG As required							
				Octreotide	SS		
SUBCUTANEOUS	100MCG See dosage text						
				Metoclopramide	SS	Glaxosmithkline	
SUBCUTANEOUS	10MG See dosage text						
				Buccastem	SS		ORAL
				Buscopan	SS		ORAL
10MG As required							
				Naltrexone	SS		ORAL
				Acupan	SS		ORAL
				Voltarol	SS	Glaxosmithkline	ORAL
25MG Three times per day							

Date:11/15/04ISR Number: 4501014-3Report Type:Expedited (15-DaCompany Report #GB-GLAXOSMITHKLINE-B0351135A
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Aspiration		Zofran	PS	Glaxosmithkline	ORAL	8MG As required	
	Foreign Body Aspiration							
			Heminevrin	SS		ORAL		
			Omeprazole	SS		ORAL	20MG Per day	
			Clonidine	SS		ORAL	.1MG As required	
			Diazepam	SS		ORAL	10MG As required	
			Lorazepam	SS		ORAL	2.5MG As required	

	Temazepam	SS	ORAL
20MG As required			
	Rohypnol	SS	ORAL
1MG As required			

				Chlorpromazine	SS	Glaxosmithkline	ORAL
50MG As required							
				Octreotide	SS		
SUBCUTANEOUS	100MCG See dosage text						
				Metoclopramide	SS	Glaxosmithkline	
SUBCUTANEOUS	10MG See dosage text						
				Buccastem	SS		ORAL
				Buscopan	SS		ORAL
10MG As required							
				Naltrexone	SS		ORAL
				Acupan	SS		ORAL
				Voltarol	SS	Glaxosmithkline	ORAL
25MG Three times per day							

Date:11/15/04ISR Number: 4503829-4Report Type:Expedited (15-DaCompany Report #2004083748
Age:71 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blood Glucose Decreased	Foreign	Atarax-P (Iv/Im)					
	Convulsion	Health	(Hydroxyzine					
	Fall	Professional	Hydrochloride)	PS			150 MG (50 MG, 3 IN 1 D)	
	Hepatic Function Abnormal	Company						
	Musculoskeletal Stiffness	Representative	Metoclopramide					
			(Metoclopramide)	SS				

Date:11/16/04ISR Number: 4501916-8Report Type:Expedited (15-DaCompany Report #PHFR2004GB04138
Age:29 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Death	Aspiration	Voltarol	PS	Novartis Sector:	
	Foreign Body Aspiration			Pharma	ORAL
25 mg, TID					
		Heminevrin	SS		ORAL
		Omeprazole	SS		ORAL
20 mg/day					
		Clonidine	SS		ORAL
.1 mg, PRN					
		Diazepam	SS		ORAL
10 mg, PRN					
		Lorazepam	SS		ORAL
2.5 mg, PRN					
		Temazepam	SS		ORAL
20 mg, PRN					
		Rohypnol	SS		ORAL
1 mg, PRN					
		Chlorpromazine	SS		ORAL
50 mg, PRN					
		Octreotide	SS		
SUBCUTANEOUS	100 ug Q12H				
		Metoclopramide	SS		
SUBCUTANEOUS	10 mg Q8H				
		Buccastem	SS		ORAL
		Buscopan	SS		ORAL
10 mg, PRN					
		Naltrexone	SS		ORAL
		Acupan	SS		ORAL
		Zofran	SS		ORAL
8 mg, PRN					

Date:11/17/04ISR Number: 4525340-7Report Type:Periodic Company Report #C-04-0053
Age:4.5 YR Gender:Female I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Dystonia
Other	Eye Rolling
	Hypertonia
	Muscle Spasms
	Musculoskeletal Stiffness
	Nervous System Disorder
	Neuropathy Peripheral

Oculogyration

Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Consumer Other	Metoclopramide Oral Solution, Usp 5 Mg/5ml	PS		ORAL	1 ML ORALLY	BEFORE MEALS AND AT BEDTIME
	Prevacid	C				

Date:11/18/04ISR Number: 4504325-0Report Type:Expedited (15-DaCompany Report #200414279FR
Age:69 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Condition Aggravated		Lovenox	PS	Aventis Pharmaceuticals Inc.	SUBCUTANEOUS		
			Primperan	SS		ORAL		
			Skenan	SS		ORAL		
			Effexor	SS		ORAL		
			Tracleer	SS		ORAL		
			Omeprazole	SS		ORAL		
			Movicol	SS				

Date:11/18/04ISR Number: 4507575-2Report Type:Expedited (15-DaCompany Report #2004-UK-01140UK
Age:29 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Foreign Body Aspiration	Foreign Health Professional Other	Catapres (0015/5009r) (Clonidine)	PS		ORAL	0.1 MG (0.1 MG, AS	

REQUIRED) PO			
	Buscopan (0015/5005r/0074r) (Hyoscine Butylbromide) (Nr)	SS	ORAL
10 MG AS REQUIRED (, AS REQUIRED) PO			
	Heminevrin (Clomethiazole Edisilate) (Nr)	SS	ORAL
PO			
	Omeprazole (Omeprazole) (Nr)	SS	ORAL
20 MG DAILY (NR) PO			
	Diazepam (Diazepam) (Nr)	SS	ORAL
10 MG AS REQUIRED (, AS REQUIRED) PO			
	Lorazepam (Lorazepam) (Nr)	SS	ORAL
2.5 MG AS REQUIRED (, AS REQUIRED) PO			
	Temazepam (Temazepam) (Nr)	SS	ORAL
20 MG AS REQUIRED (,			

AS REQUIRED) PO		Rohypnol (Flunitrazepam) (Nr)	SS	ORAL
1 MG AS REQUIRED (, AS REQUIRED) PO		Chlorpromazine (Chlorpromazine) (Nr)	SS	ORAL
50 MG AS REQUIRED PO		Octreotide (Octreotide) (Nr)	SS	
SUBCUTANEOUS	100 MCG EVERY 12 HOURS (, EVERY 12 HOURS) SC	Metoclopramide (Metoclopramide) (Nr)	SS	
SUBCUTANEOUS	10 MG EVERY 8 HOURS (, EVERY 8 HOURS) SC	Buccastem (Prochlorperazine Maleate) (Nr)	SS	ORAL
PO		Naltrexone (Naltrexone) (Nr)	SS	ORAL
PO		Acupan (Nefopam		

			Hydrochloride) (Nr)	SS		ORAL	PO
			Voltarol (Diclofenac Sodium) (Nr)	SS		ORAL	25 MG THREE TIMES DAILY (25 NR, THREE TIMES DAILY) PO
			Zofran (Ondansetron Hydrochloride) (Nr)	SS		ORAL	8 MG AS REQUIRED (, AS REQUIRED) PO

Date:11/19/04ISR Number: 4507265-6Report Type:Expedited (15-DaCompany Report #C-04-0053
Age:4.5 MON Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged Other	Dystonia Eructation	Consumer Other	Metoclopramide	PS	Mgp	ORAL	1 ML ORALLY BEFORE MEALS AND AT BEDTIME
			Prevacid	C			

Date:11/19/04ISR Number: 4509464-6Report Type:Expedited (15-DaCompany Report #002#4#2004-00270
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Death	Completed Suicide	Consumer Other	Reglan-10mg-Tablet (Metoclopramide Hcl)	PS		ORAL	10 MG, 2 IN 1 D, ORAL

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/19/04ISR Number: 4510575-XReport Type:Expedited (15-DaCompany Report #9187
Age:17 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agitation Caesarean Section Drug Exposure During Pregnancy Headache Hypertension Hypotension Medication Error Nausea Post Procedural Discomfort Somnolence Tachycardia Vision Blurred Vomiting	Literature Health Professional	Metoclopramide Bupivacaine	PS C				1 MIN

Date:11/22/04ISR Number: 4507683-6Report Type:Expedited (15-DaCompany Report #2004AL001317
Age:5 MON Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Convulsion Crying Dystonia Hypersensitivity Pallor Respiratory Rate Decreased Vision Blurred	Consumer Health Professional	Metoclopramide Oral Solution Usp, Eq. 5 Mg Base/5 Ml (Alpharma)	PS		ORAL	5 ML;X1;PO	

Date:11/22/04ISR Number: 4508015-XReport Type:Direct Company Report #CTU 232717
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Life-Threatening	Depression	Reglan	PS
4XDAY			
Disability	Impaired Work Ability	Zoloft	C
Required	Suicidal Ideation	Remeron	C
Intervention to			
Prevent Permanent			
Impairment/Damage			

Date:11/22/04ISR Number: 4508989-7Report Type:Direct Company Report #CTU 232598
Age:58 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Abdominal Pain		Metoclopramide	PS				
UNKNOWN								
Initial or Prolonged			Aspirin	C				
			Insulin	C				
			Pravastatin	C				
			Advair	C				
			Unithyroid	C				
			Esomeprazole	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/22/04ISR Number: 4510753-XReport Type:Expedited (15-DaCompany Report #FR-2004-034824
Age:67 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Erythema Multiforme	Foreign Other	Fludara (Fludarabine Phosphate) Ampule	PS		INTRAVENOUS	INTRAVENOUS	
			Endoxan (Cyclophosphamide) Ampule	SS		INTRAVENOUS	INTRAVENOUS	
			Primperan (Metoclopramide)	SS		ORAL	ORAL	
			Zophren (Ondansetron Hydrochloride)	SS		INTRAVENOUS	INTRAVENOUS	

Date:11/22/04ISR Number: 4511296-XReport Type:Expedited (15-DaCompany Report #12754727
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Foreign Body Aspiration	Foreign Health Professional Other	Naltrexone (Naltrexone Hcl)	PS		ORAL	ORAL	
			Diazepam	SS		ORAL	10 MILLIGRAM	
			Heminevrin (Chlormethiazole Edisylate)	SS		ORAL	ORAL	
			Omeprazole	SS		ORAL	20 MILLIGRAM	1 DAY ORAL
			Clonidine	SS		ORAL	.1 MILLIGRAM	ORAL
			Lorazepam	SS		ORAL	2.5 MILLIGRAM	

ORAL					
20 MILLIGRAM			Temazepam	SS	ORAL
ORAL					
			Rohypnol (Flunitrazepam)	SS	ORAL
1 MILLIGRAM					
ORAL					
			Chlorpromazine	SS	ORAL
50 MILLIGRAM					
ORAL					
			Octreotide (Octreotide Acetate)	SS	
SUBCUTANEOUS	100 MICROGRAM				
1/12 HOUR SC					
			Metoclopramide (Metoclopramide Hcl)	SS	
SUBCUTANEOUS	10 MILLIGRAM				
1/8 HOUR SC					
			Buccastem (Prochlorperazine Maleate)	SS	ORAL
ORAL					
			Buscopan (Hyoscine Butylbromide)	SS	ORAL
10 MILLIGRAM					
ORAL					
			Acupan (Nefopam Hcl)	SS	ORAL
ORAL					
			Voltarol (Diclofenac Sodium)	SS	ORAL
25 MILLIGRAM					
3/1 DAY ORAL					
			Zofran (Ondansetron Hcl)	SS	ORAL
8 MILLIGRAM					
ORAL					

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/23/04ISR Number: 4512356-XReport Type:Expedited (15-DaCompany Report #2004AC00779
Age:17 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Required	Agitation	Foreign	Bupivacaine	PS			15 MG ONCE
Intervention to	Discomfort	Literature	Metoclopramide	SS			GIVEN IN
Prevent Permanent	Drug Exposure During	Health					ERROR
Impairment/Damage	Pregnancy	Professional	Fentanyl	SS			25 [MU] G
	Headache	Other					
	Hypertension						
	Medication Error						
	Nausea						
	Somnolence						
	Tachycardia						
	Vision Blurred						
	Vomiting						

Date:11/23/04ISR Number: 4512390-XReport Type:Expedited (15-DaCompany Report #S04-ESP-06636-01
Age:64 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Coma	Foreign	Esertia				
Initial or Prolonged	Confusional State	Health	(Escitalopram)	PS		ORAL	10 MG QD PO
	Dystonia	Professional	Metoclopramide	SS			
	Hyponatraemia	Other	Lorazepam	C			
	Vomiting		Zopiclone	C			

Date:11/23/04ISR Number: 4527793-7Report Type:Periodic Company Report #ATO-04-0158(0)
Age:25 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Electrocardiogram Qt	Health	Trisenox (Arsnic				
Initial or Prolonged	Prolonged	Professional	Trioxide)	PS			9 MG (9

MG),IVI

Metoclopramide	SS
Amphotericine B, Liposome	C
Kytril	C
Ativan	C
Diphenhydramine	C
Ambien	C
Valaciclovir	C
Pantoprazole	C
Allopurinol	C
Leuprolide Acetate	C
Reglan	C
Cefepime	C

Date:11/24/04ISR Number: 4510466-4Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0357014A
Age:67 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Dermatitis Bullous	Consumer	Zophren	PS	Glaxosmithkline			
INTRAVENOUS							5	DAY
Initial or Prolonged	Erythema Multiforme		Endoxan	SS				
INTRAVENOUS							5	DAY
	Self-Medication		Fludara	SS				
INTRAVENOUS							5	DAY
			Primperan	SS	Glaxosmithkline	ORAL		
16 DAY								

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/24/04ISR Number: 4512413-8Report Type:Expedited (15-DaCompany Report #M2004-1695
Age:29 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Foreign Body Aspiration	Foreign	Chlorpromazine	PS		ORAL	50 MG PRN,	
		Other					ORAL	
			Clonidine	SS		ORAL	0.1 MG, PRN,	
							ORAL	
			Omeprazole (Omeprazole)	SS		ORAL	20 MG DAILY	
							ORAL	
			Temazepam (Temazepam)	SS			20 MG PRN	
			Voltarol (Diclofenac)	SS			25 MG TID	
			Diazepam (Diazepam)	SS			10 MG PRN	
			Heminevrin (Clomethiazole)	SS				
			Lorazepam (Lorazepam)	SS			2.5 MG PRN	
			Rohypnol (Flunitrazepam)	SS			1 MG PRN	
			Metoclopramide (Metoclopramide)	SS			10 MG Q8H	
			Buccastem (Prochlorperazine)	SS				
			Buscopan (Hyoscine)	SS			10 MG, PRN	
			Naltrexone (Naltrexone)	SS				
			Acupan (Nefopam Hydrochloride)	SS				
			Zofran (Ondansetron)	SS			8 MG, PRN	

				Octreotide (Octreotide)	SS		

100MCG Q12H

Date:11/26/04ISR Number: 4514679-7Report Type:Expedited (15-DaCompany Report #HQWYE876213MAY04
Age:18 MON Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Asthenia	Foreign	Children'S Advil					
Hospitalization - Initial or Prolonged	Blood Immunoglobulin M Increased	Health Professional	(Ibuprofen, Suspension)	PS		ORAL		
						ORAL	3	DAY
Other	Enteritis	Other	Maxilase (Amylase,)	SS		ORAL		
						ORAL	3	DAY
	Haematuria		Orelox (Cefpodoxime					
	Haemolytic Anaemia		Proxetil,)	SS		ORAL		
						ORAL	1	DAY
	Heart Rate Increased		Panfurex					
	Jaundice		(Nifuroxazide,)	SS		ORAL		
						ORAL	3	DAY
	Otitis Media		Pivalone (Tixocortol					
	Proteinuria		Pivalate,)	SS		NASAL		
						NASAL	3	DAY
	Renal Failure Acute		Primperan					
	Renal Tubular Necrosis		(Metoclopramide,)	SS		ORAL		
						ORAL	3	DAY
	Vomiting		Efferalgan					
	White Blood Cell Count Increased		(Paracetamol)	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/26/04ISR Number: 4515092-9Report Type:Expedited (15-DaCompany Report #DSA_25395_2004
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Aspiration	Foreign	Ativan	PS		ORAL	2.5 MG PRN PO	
	Vomiting	Health	Voltarol	SS		ORAL	25 MG TID PO	
		Professional	Acupan	SS		ORAL	DF PO	
		Other	Buccastem	SS		ORAL	DF PO	
			Buscopan	SS		ORAL	10 MG PRN PO	
			Chlorpromazine	SS		ORAL	50 MG PRN PO	
			Clonidine	SS		ORAL	1 MG PRN PO	
			Diazepam	SS		ORAL	10 MG PRN PO	
			Heminevrin	SS		ORAL	DF PO	
			Metoclopramide	SS			SUBCUTANEOUS	10 MG Q8HR SC
			Naltrexone	SS		ORAL	DF PO	
			Octreotide	SS			SUBCUTANEOUS	100 MCG Q12HR SC
			Omeprazole	SS		ORAL	20 MG PO	
			Rohypnol	SS		ORAL	1 MG PRN PO	
			Temazepam	SS		ORAL	20 MG PRN PO	
			Zofran	SS		ORAL	8 MG PRN PO	

Date:11/26/04ISR Number: 4515329-6Report Type:Expedited (15-DaCompany Report #2004083748
Age:71 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Other	Blood Glucose Decreased	Foreign	Atarax-P (Iv/ Im)				
	Convulsion	Health	(Hydroxyzine				
	Hepatic Function Abnormal	Professional	Hydrochloride)	PS			
150 MG (50							
	Musculoskeletal Stiffness	Company					
MG, 3 IN 1 D)							
		Representative	Metoclopramide				
			(Metoclopramide)	SS			

Date:11/29/04ISR Number: 4511738-XReport Type:Expedited (15-DaCompany Report #200414310FR
Age:84 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Alanine Aminotransferase		Lasilix	PS	Aventis			
Initial or Prolonged	Increased				Pharmaceuticals Inc.	ORAL		
	Aspartate		Di-Antalvic	SS		ORAL		
	Aminotransferase		Stablon	SS		ORAL		
	Increased		Cordarone	SS		ORAL		
	Blood Alkaline		Primperan	SS		ORAL		
	Phosphatase Increased		Temesta	C		ORAL		
	Hepatic Enzyme Increased		Tanakan	C		ORAL		
	Pneumonitis		Diafusor	C				
TRANSDERMAL								
	Pulmonary Toxicity		Previscan	C		ORAL		

Date:11/29/04ISR Number: 4515008-5Report Type:Direct Company Report #CTU 233096
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required	Depressed Level Of		Metoclopramide					
Intervention to	Consciousness		10mg	PS		ORAL		
5MG QAC AND								
Prevent Permanent	Drug Ineffective							
HS ORAL								
Impairment/Damage	Dystonia							
	Muscle Rigidity							
	Oculogyration							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/29/04ISR Number: 4515668-9Report Type:Expedited (15-DaCompany Report #12754727
Age:29 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Foreign Body Aspiration	Health Professional	Naltrexone (Naltrexone Hcl)	PS		ORAL		
		Other	Diazepam	SS		ORAL	10 MILLIGRAM	
			Omeprazole	SS		ORAL	20 MILLIGRAM	1 DAY
			Lorazepam	SS		ORAL	2.5 MILLIGRAM	
			Rohypnol (Flunitrazepam)	SS		ORAL	1 MILLIGRAM	
			Octreotide (Octreotide Acetate)	SS		SUBCUTANEOUS	100 MICROGRAM	1/12 HOUR
			Buccastem (Prochlorperazine Maleate)	SS		ORAL		
			Acupan (Nefopam Hcl)	SS		ORAL		
			Zofran (Ondansetron Hcl)	SS		ORAL	8 MILLIGRAM	
			Voltarol (Diclofenac Sodium)	SS		ORAL	25 MILLIGRAM	3/1 DAY
			Buscopan (Hyoscine					

			Butylbromide)	SS		ORAL	10 MILLIGRAM
							ORAL
			Metoclopramide (Metoclopramide Hcl)	SS			
SUBCUTANEOUS	10 MILLIGRAM						
							1/8 HOUR SC
			Chlorpromazine	SS		ORAL	50 MILLIGRAM
							ORAL
			Temazepam	SS		ORAL	20 MILLIGRAM
							ORAL
			Clonidine	SS		ORAL	.1 MILLIGRAM
							ORAL
			Heminevrin (Chlormethiazole Edisylate)	C		ORAL	
ORAL							

Date:11/30/04ISR Number: 4518104-1Report Type:Expedited (15-DaCompany Report #FRWYE225923NOV04
Age:69 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Condition Aggravated	Health Professional	Effexor (Venlafaxine Hydrochloride)	PS		ORAL		
Other	Unevaluable Event	Other	Lovenox (Heparin-Franction, Sodium Salt)	SS		ORAL		
			Omeprazole (Omeprazole)	SS		ORAL		
ORAL								
			Primperan (Metoclopramide)	SS		ORAL		
ORAL								
			Skenan (Morphine Sulfate)	SS		ORAL		
ORAL								
			Tracleer (Bosentan)	SS		ORAL	125 MG 2X PER	1 DAY

			Movicol (Macrogol/Potassium Chloride/Sodium Bicarbonate/Sodium Chloride)	C			

Date:12/01/04ISR Number: 4514944-3Report Type:Expedited (15-DaCompany Report #200414279FR
Age:69 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Condition Aggravated Pulmonary Hypertension		Lovenox	PS	Aventis Pharmaceuticals Inc.	SUBCUTANEOUS		
			Primperan	SS		ORAL		
			Skenan	SS		ORAL		
			Effexor	SS		ORAL		
			Tracleer	SS		ORAL		
			Omeprazole	SS		ORAL		
			Movicol	SS				

Date:12/01/04ISR Number: 4515357-0Report Type:Expedited (15-DaCompany Report #FR-ROCHE-383891
Age:78 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Acidosis		Rocephine	PS	Roche	INTRAMUSCULAR	73	DAY
	Anaemia		Pyostacine	SS		ORAL	43	DAY
	Anorexia		Pyostacine	SS		ORAL	30	DAY
	Dyspnoea Exertional		Phenergan	SS		ORAL	TAKEN DAILY.	
	General Physical Health Deterioration		Zyvoxid	SS		ORAL	73	DAY
	Nausea		Zoltum	SS		ORAL		
	Thrombocytopenia		Digoxine Nativelle	SS		ORAL	0.25	MG
			Celectol	SS		ORAL		
			Novonorm	SS		ORAL		
			Difrarel	SS		ORAL		
			Kardegic	SS		ORAL		

			Atarax	SS		ORAL
			Prokinyl Lp	SS		ORAL
			Imovane	SS		ORAL

Date:12/01/04ISR Number: 4515987-6Report Type:Expedited (15-DaCompany Report #M2004.1773
Age:66 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Anxiety	Foreign	Metoclopramide	PS			SINGLE DOSE	
Hospitalization - Initial or Prolonged	Blood Pressure Decreased	Literature						
	Cyanosis							
	Dyspnoea							
	Feeling Cold							
	General Physical Health Deterioration							
	Phaeochromocytoma							
	Sensation Of Heaviness							
	Shock							
	Wheezing							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/01/04ISR Number: 4517804-7Report Type:Direct Company Report #CTU 233373
Age:59 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Pruritus Generalised		Reglan 10mg	PS			10 MG	
	Rash		Levaquin 500 Mg/100 Ml Nss	SS		INTRAVENOUS		
	Urticaria		Zantac 50 Mg Ivpb 50ml Nss	SS		INTRAVENOUS		

Date:12/02/04ISR Number: 4518364-7Report Type:Expedited (15-DaCompany Report #TAP2004Q01510
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Vision Blurred	Consumer	Prevacid (Lansoprazole)	PS				
			Hydrocodone (Hydrocodone)	SS				
			Reglan (Metoclopramide Hydrochloride)	SS				

Date:12/03/04ISR Number: 4517536-5Report Type:Expedited (15-DaCompany Report #JP-ABBOTT-04P-087-0281479-00
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Hepatitis Fulminant		Cefzon Capsule	PS		ORAL		
	Multi-Organ Failure		Cefzon Capsule	SS				
			Fructlact	SS		INTRAVENOUS		
			Metamizole Sodium	SS		DRIP INTRAVENOUS		
			Metoclopramide	SS		DRIP INTRAVENOUS		
			Minocycline			DRIP		

			Hydrochloride	SS			
INTRAVENOUS							
							DRIP
			Brufen	SS			ORAL
1 DAY							
			Huscode	SS			ORAL
1 DAY							
			Metamizole Sodium	SS			ORAL
1 DAY							

Date:12/03/04ISR Number: 4519729-XReport Type:Direct Company Report #CTU 233568
Age:75 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Diarrhoea Muscle Spasms		Metoclopramide 10 Mg Gensiascior	PS	Gensiascior	INTRAVENOUS INTRAVENOU	10 MG	EVERY 12 HOUR

Date:12/06/04ISR Number: 4520409-5Report Type:Direct Company Report #CTU 233676
Age:31 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Congenital Anomaly	Congenital Pulmonary Valve Atresia Drug Exposure During Pregnancy		Reglan	PS		SUBCUTANEOUS SUBCUTANEOUS		

Date:12/06/04ISR Number: 4521077-9Report Type:Expedited (15-DaCompany Report #2004AC00779
Age:17 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Agitation	Foreign	Bupivacaine	PS			15 MG ONCE	
	Discomfort	Literature	Metoclopramide	SS			GIVEN IN ERROR	
	Headache	Health						
	Hypertension	Professional	Fentanyl	SS			25 [MU] G	
	Medication Error	Other						
	Nausea							
	Somnolence							
	Tachycardia							
	Vision Blurred							
	Vomiting							

Date:12/06/04ISR Number: 4521736-8Report Type:Expedited (15-DaCompany Report #M2004-1805
Age:38 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Bradycardia	Foreign	Lisinopril	PS				
	Post Procedural Complication	Literature	Metoclopramide	SS			INTRAVENOUS	SINGLE DOSE OF 10 MG IV
			Mepivacaine	C				
			Bupivacaine	C				
			Midazolam	C				
			Propofol	C				

Date:12/06/04ISR Number: 4522114-8Report Type:Expedited (15-DaCompany Report #2004228034FR
Age:18 MON Gender:Male I/FU:F

Outcome	PT
Life-Threatening	Autoimmune Disorder
	Cardiomegaly
	Chlamydia Serology Positive

Coombs Direct Test
Positive
Dehydration
Gastroenteritis
Haematuria
Haemolytic Anaemia
Heart Rate Increased
Hepato-Lenticular
Degeneration
Jaundice
Kidney Enlargement
Leukocytosis
Mycoplasma Serology
Positive
Normochromic Normocytic
Anaemia
Otitis Media
Oxygen Saturation
Decreased
Pallor
Peritoneal Dialysis
Proteinuria
Renal Failure Acute
Renal Tubular Necrosis
Spherocytic Anaemia

		Virus Serology Test Positive					
			Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
			Foreign Health Professional	Vantin Suspension (Cefpodoxime Proxetil)	PS		ORAL
ORAL							
				Metoclopramide Hydrochloride (Metoclopramide Hydrochloride)	SS		ORAL
ORAL							
				Ibuprofen (Ibuprofen)	SS		ORAL
ORAL							
				Nifuroxazide (Nifuroxazide)	C		ORAL
ORAL							
				Maxilase-Bacitracine (Alpha-Amylase Bacterial, Bacitracin)	C		
				Tixocortol Pivalate (Tixocortol Pivalate)	C		
				Paracetamol (Paracetamol)	C		
				Domperidone (Domperidone)	C		
				Smecta / Old Form / (Aluminium Hydroxide-Magnesium Carbonate Gel, Aluminium Magnesium	C		

Date:12/07/04ISR Number: 4522117-3Report Type:Expedited (15-DaCompany Report #002#2#2004-00283
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Disability	Dyskinesia	Consumer	Reglan-Dose-Unknown			
	Dystonia		(Metoclopramide Hcl)	PS		ORAL
ORAL						
	Muscle Spasms					

	Opisthotonus

Date:12/07/04ISR Number: 4522695-4Report Type:Expedited (15-DaCompany Report #M2004-1814
Age:72 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Serotonin Syndrome	Foreign	Metoclopramide	PS			10 MG ON ALL	
		Literature					OCCASIONS	
		Health	Sertraline	SS			100 MG	
		Professional	Celecoxib	C				
			Hydrocortisone	C				
			Acetaminophen	C				
			Morphine Sulphate	C				

Date:12/07/04ISR Number: 4522699-1Report Type:Expedited (15-DaCompany Report #M2004-1813
Age:32 YR Gender:Female I/FU:I

Outcome	PT
Other	Mydriasis
	Nystagmus

Serotonin Syndrome

Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Foreign	Metoclopramide	PS		INTRAVENOUS	10 MG (2 DOSES) IV	
Literature	Venlafaxine	SS			150MG O.M. & 75MG O.N.	
	Acetaminophen (Acetaminophen)	C				
	Indomethacin (Indomethacin)	C				
	Morphine (Morphine)	C				

Date:12/07/04ISR Number: 4523199-5Report Type:Direct Company Report #CTU 233805
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dyspepsia		Reglan 10 Mg Ac	PS		ORAL	10 MG BEFORE	
	Nausea							
ORAL							1	WK
	Pharmaceutical Product		Phenergan	SS		ORAL	25 MG 6 HRS	
	Complaint							
ORAL							1	WK

Date:12/08/04ISR Number: 4521286-9Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0359079A
Age:56 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Ascites		Augmentin Iv	PS	Glaxosmithkline			
INTRAVENOUS							3G per day	9 DAY
Life-Threatening	C-Reactive Protein		Debridat	SS				
INTRAVENOUS							6UNIT per day	7 DAY
	Increased		Noradrenaline	SS				
UNKNOWN								11 DAY

		Enterobacter Infection		Primperan	SS	Glaxosmithkline	
INTRAVENOUS	3UNIT per day	6 DAY					
		Hyperbilirubinaemia		Soludactone	SS		
INTRAVENOUS	200MG per day	4 DAY					
		Jaundice		Surbronc	SS	Glaxosmithkline	
UNKNOWN		7 DAY					
		Liver Disorder		Rocephine	SS		
INTRAVENOUS	2G per day	6 DAY					
		Pyrexia		Ciflox	SS		
INTRAVENOUS	400MG Three						
		Thrombocytopenia					
times per day	6 DAY						
				Lasilix	SS	Glaxosmithkline	
INTRAVENOUS		4 DAY					
				Insuline	SS		
INTRAVENOUS		6 DAY					
				Hypnovel	C		
UNKNOWN							
				Fentanyl	C		
UNKNOWN							
				Ephedrine	C		
UNKNOWN							

Date:12/09/04ISR Number: 4521809-XReport Type:Expedited (15-DaCompany Report #200414531FR
Age:50 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization - Initial or Prolonged	Cytolytic Hepatitis		Claforan	PS	Aventis Pharmaceuticals Inc.	
INTRAVENOUS						
			Primperan	SS		ORAL
			Augmentin	SS		
INTRAVENOUS						
			Burinex	SS		
INTRAVENOUS						
			Inexium	SS		ORAL
			Perfalgan	SS		
INTRAVENOUS						
			Ciflox	SS		
			Surbronc	SS		
			Eupressyl	SS		ORAL

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/10/04ISR Number: 4524879-8Report Type:Expedited (15-DaCompany Report #M2004-1805
Age:38 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Bradycardia	Foreign	Lisinopril	PS				
		Literature	Metoclopramide	SS		INTRAVENOUS	SINGLE DOSE OF 10MG IV	
			Mepivacaine	C				
			Midazolam	C				
			Propofol	C				

Date:12/10/04ISR Number: 4524896-8Report Type:Expedited (15-DaCompany Report #M2004-1814
Age:72 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Serotonin Syndrome	Foreign	Metoclopramide	PS			10 MG ON ALL OCCASIONS	
		Literature	Sertraline	SS			100 MG	
			Celecoxib	C				
			Hydrocortisone	C				
			Acetaminophen	C				
			Morphine Sulphate	C				

Date:12/10/04ISR Number: 4524905-6Report Type:Expedited (15-DaCompany Report #M2004-1813
Age:32 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Serotonin Syndrome	Foreign	Metoclopramide	PS		INTRAVENOUS	10MG (2 DOSE) IV	
		Literature	Venlafaxine	SS			150MG O.M. & 75MG O.N	

Acetaminophen	C	
Indomethacin	C	
Morphine	C	

Date:12/14/04ISR Number: 4527250-8Report Type:Direct Company Report #CTU 234310
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dyspepsia		Metoclopramide	PS	Pliva		10 MG AC AND	
	Nausea						H.S.	
	Pharmaceutical Product Complaint							

Date:12/14/04ISR Number: 4527309-5Report Type:Direct Company Report #CTU 234267
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dyspepsia		Reglan 6 Mg Ac	PS			10 MG BEFORE	
	Nausea						MEALS	
	Pharmaceutical Product		Phenergan	SS		ORAL	25 MG EVERY	
	Complaint						6HRS ORAL	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/15/04ISR Number: 4530410-3Report Type:Expedited (15-DaCompany Report #2004CG02417
Age:50 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Cytolytic Hepatitis	Foreign Health Professional Other	Nexium Claforan Primperan Augmentin /Sch/ Burinex Perfalgan Ciflox Surbronc Eupressyl	PS SS SS SS SS SS SS SS		ORAL	1 DF QD PO 1 G QID IV	

Date:12/16/04ISR Number: 4528825-2Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0359079A
Age:56 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Arterial Disorder		Augmentin Iv	PS	Glaxosmithkline	INTRAVENOUS	3G per day	9 DAY
Life-Threatening	Ascites		Debridat	SS		INTRAVENOUS	6UNIT per day	7 DAY
	Enterobacter Infection		Noradrenaline	SS		UNKNOWN		11 DAY
	Haemangioma Of Liver		Primperan	SS	Glaxosmithkline	INTRAVENOUS	3UNIT per day	6 DAY
	Hyperbilirubinaemia		Soludactone	SS		INTRAVENOUS	200MG per day	4 DAY
	Jaundice		Surbronc	SS	Glaxosmithkline	UNKNOWN		7 DAY
	Retroperitoneal Haematoma		Rocephine	SS		INTRAVENOUS	2G per day	6 DAY
	Thrombocytopenia		Ciflox	SS		INTRAVENOUS	400MG Three times per day	6 DAY
			Lasilix	SS	Glaxosmithkline	INTRAVENOUS		4 DAY
			Insuline	SS		INTRAVENOUS		6 DAY

			Hypnovel	C		
UNKNOWN						
			Fentanyl	C		
UNKNOWN						
			Ephedrine	C		
UNKNOWN						

Date:12/16/04ISR Number: 4529508-5Report Type:Expedited (15-DaCompany Report #2004AL001761
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Disease Progression	Company	Metoclopramide					
	Dyskinesia	Representative	Tablets Usp, 10 Mg					
	Dystonia	Other	(Purepac)	PS		ORAL	PO	
	Injury							
	Mental Disorder							
	Muscle Spasms							
	Nervous System Disorder							
	Pain							

Date:12/16/04ISR Number: 4530597-2Report Type:Expedited (15-DaCompany Report #2004228034FR
Age:18 MON Gender:Male I/FU:F

Outcome	PT
Life-Threatening	Cardiomegaly
	Chlamydial Infection
	Coombs Direct Test Positive
	Dehydration
	Gastroenteritis
	Haematuria
	Haemoglobinuria
	Haemolysis

		Haemolytic Anaemia Heart Rate Increased Hepato-Lenticular Degeneration Jaundice Kidney Enlargement Leukocytosis Mumps Mycoplasma Infection Normochromic Normocytic Anaemia Otitis Media Pallor Peritoneal Dialysis Pleural Disorder Polyuria Proteinuria Renal Failure Acute Renal Tubular Necrosis Respiratory Disorder Reticulocyte Count Abnormal Serology Positive Spherocytic Anaemia	Report Source Foreign Health Professional	Product Vantin Suspension (Cefpodoxime Proxetil) Metoclopramide Hydrochloride (Metoclopramide Hydrochloride) Ibuprofen (Ibuprofen) Nifuroxazide (Nifuroxazide) Maxilase-Bacitracine (Alpha-Amylase Bacterial, Bacitracin) Tixocortol Pivalate (Tixocortol Pivalate) Paracetamol (Paracetamol) Domperidone (Domperidone) Smecta/Old Form/ (Aluminium Hydroxide-Magnesium Carbonate Gel, Aluminium Magnesium	Role PS SS SS SS C C C C	Manufacturer	Route ORAL ORAL ORAL ORAL
Dose	Duration						

Date:12/20/04ISR Number: 4536665-3Report Type:Expedited (15-DaCompany Report #USA-2004-0013363
Age:62 YR Gender:Female I/FU:F

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Death		Adhesion Asthma Cardiomegaly	Health Professional Other	Oxycontin Tablets (Oxycodone Hydrochloride) Cr			

	Coronary Artery	Tablet	PS
20 MG, Q12H			
	Atherosclerosis	Percocet	
	Depression	(Paracetamol,	
	Dilatation Ventricular	Oxycodone	
	Drug Ineffective	Hydrochloride)	SS
	Hypertensive Heart	Flexeril	
	Disease	(Cyclopbenzaprine	
	Lung Disorder	Hydrochloride)	SS
	Pulmonary Oedema	Acetaminophen	
	Smoker	(Paracetamol)	SS
	Somnolence	Propoxyphene	
	Treatment Noncompliance	(Dextropropoxyphene)	SS
	Ventricular Hypertrophy	Metoclopramide	SS
		Promethazine	SS
		Diazepam	SS
		Bupropion	
		(Amfebutamone)	C
		Fosamax (Alendronate	
		Sodium)	C
		Prilosec	
		(Omeprazole)	C

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/21/04ISR Number: 4533727-1Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0361800A
Age:88 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Acute Pulmonary Oedema		Augmentin Iv	PS	Glaxosmithkline	INTRAVENOUS	3G per day	6 DAY
Hospitalization - Initial or Prolonged	Neutropenia		Oflocet	SS		ORAL	200MG Twice per day	5 DAY
			Inexium	SS		ORAL	40MG per day	
			Primperan	SS	Glaxosmithkline		10MG Three times per day	6 DAY
			Hydrocortisone	C	Glaxosmithkline		200MG per day	

Date:12/27/04ISR Number: 4539271-XReport Type:Direct Company Report #CTU 235135
Age:50 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Arrhythmia		Reglan 5mg	PS		ORAL	HS QD	
Hospitalization - Initial or Prolonged	Tachycardia							
Required Intervention to Prevent Permanent Impairment/Damage								

Date:12/27/04ISR Number: 4539311-8Report Type:Direct Company Report #CTU 235137
Age:4 MON Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Dystonia		Metaclopramide	PS		ORAL	0.8CC TID	
Required	Torticollis							
ORAL								

Intervention to
Prevent Permanent
Impairment/Damage

Date:12/28/04ISR Number: 4540863-2Report Type:Expedited (15-DaCompany Report #2004GB03151
Age:29 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Cyanosis	Foreign	Diprivan	PS		INTRAVENOUS	200 MG	DAILY
	Electrocardiogram St	Health				IV		
	Segment Depression	Professional	Metoclopramide	SS		INTRAVENOUS	10 MG	DAILY
	Hypotension	Other				IV		
	Hypoxia		Fentanyl	SS		INTRAVENOUS	50 UG	DAILY
						IV		
			Atracurium	SS		INTRAVENOUS	25 UG	DAILY
						IV		

Date:12/28/04ISR Number: 4540968-6Report Type:Expedited (15-DaCompany Report #2004CG02529
Age:88 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Acute Pulmonary Oedema	Foreign	Nexium	PS		ORAL	40 MG	QD PO
Initial or Prolonged	Neutropenia	Health	Oflocet	SS		ORAL	200 MG	BID PO
		Professional	Augmentin Injection	SS			3 G + 600 MG	
		Other					QD	
			Primperan	SS			1O MG	TID
			Hydrocortisone	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/29/04ISR Number: 4540942-XReport Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0362672A
Age:64 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Arterial Thrombosis Limb		Zophren	PS	Glaxosmithkline			
INTRAVENOUS								5 DAY
Initial or Prolonged	Injection Site Erythema		Solumedrol	SS				
INTRAVENOUS								5 DAY
	Injection Site Thrombosis		Primperan	SS	Glaxosmithkline			
INTRAVENOUS								5 DAY
	Neutropenia		Cisplatine	SS				
INTRAVENOUS							220MG per day	1 DAY
	Renal Failure		Fluorouracil	SS				
INTRAVENOUS							2200MG per day	5 DAY
			Mopral	C	Glaxosmithkline			
UNKNOWN								
			Stilnox	C				
UNKNOWN								

Date:01/03/05ISR Number: 4543576-6Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0317633A
Age:50 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Anaemia		Augmentin	PS	Glaxosmithkline	ORAL	6G Per day	8 DAY
	Dermatitis Bullous		Gardenal	SS				
UNKNOWN							800MG Per day	6 DAY
	Erythema		Primperan	SS	Glaxosmithkline			
UNKNOWN								4 DAY
	Face Oedema		Perfalgan	SS	Glaxosmithkline			
INTRAVENOUS							4G Per day	4 DAY
	Genital Ulceration		Previscan	C		ORAL	3	DAY
	Inflammation		Duphalac	C		ORAL		
	Leukopenia		Phosphoneuros	C		ORAL		
	Pruritus Generalised		Acupan	C				
UNKNOWN								
	Pyrexia		Polaramine	C				
UNKNOWN								
	Rash		Vitamin B1-B6	C				
UNKNOWN								

	Staphylococcal Infection		Heparine	C			
UNKNOWN							
	Toxic Epidermal		Fraxodi	C	Glaxosmithkline		
SUBCUTANEOUS							
	Necrolysis		Zovirax	C	Glaxosmithkline		
UNKNOWN							
	Vomiting		Solupred	C	Glaxosmithkline		
UNKNOWN							
			Solumedrol	C			
UNKNOWN							
			Clarityne	C			
UNKNOWN							
			Mydriaticum	C			
OPHTHALMIC							
			Cernevit	C			
UNKNOWN							
			Previscan	C			ORAL
			Vitamin C	C	Glaxosmithkline		
UNKNOWN							

Date:01/03/05ISR Number: 4543916-8Report Type:Expedited (15-DaCompany Report #GXKR2003GB00518
Age:51 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Akathisia	Foreign	Metoclopramide (Ngx)					
	Anaemia	Health	(Metoclopramide)	PS		ORAL	10 MG, TID,	
Disability	Coordination Abnormal	Professional				ORAL		
Other	Leukopenia	Other	Olanzapine					
	Muscle Rigidity		(Olanzapine)	SS		ORAL	15 MG, QD,	
	Somnolence					ORAL		
	Thrombocytopenia		Ritonavir (Ritonavir)	C				
			Lamivudine (Lamivudine)	C				
			Azithromycin (Azithromycin)	C				
			Fluconazole (Fluconazole)	C				
			Methadone (Methadone)	C				
			Lansoprazole (Lansoprazole)	C				

Lactulose (Lactulose)	C
Thiamine (Thiamine)	C
Tenofovir Disoproxil Fumarate (Tenofovir Disoproxil Fumarate)	C
Fosamprenavir (Fosamprenavir)	C

Date:01/03/05ISR Number: 4543918-1Report Type:Expedited (15-DaCompany Report #GXKR2003GB00504
Age:53 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Hypotension	Foreign	Metoclopramide (Ngx)					
Other		Health	(Metoclopramide)	PS			10 MG/DAY	
		Professional						
		Other						

Date:01/04/05ISR Number: 4544096-5Report Type:Expedited (15-DaCompany Report #JP-JNJFOC-20041205300
Age:88 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Acute Pulmonary Oedema		Ofloxacin	PS		OROPHARINGEAL		
Hospitalization - Initial or Prolonged	Neutropenia		Inexium	SS		OROPHARINGEAL		
			Augmentin	SS		INTRAVENOUS		
			Augmentin	SS		INTRAVENOUS		
			Primperan	SS		UNKNOWN		

Date:01/04/05ISR Number: 4545787-2Report Type:Direct Company Report #USP 57036
Age:3 WK Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Hospitalization - LIQUID Initial or Prolonged	Medication Error		Reglan	PS		

Date:01/04/05ISR Number: 4545794-XReport Type:Direct Company Report #USP 57032
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Medication Error		Metoclopramide Injection Usp	PS	Gensia Sicor	INJECTABLE		
			Phenylephrine Hcl Injection	SS	Baxter	INJECTABLE		

Date:01/05/05ISR Number: 4546679-5Report Type:Expedited (15-DaCompany Report #9532
Age:29 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Anaesthetic Complication	Foreign	Fentanyl	PS		INTRAVENOUS	50 MICROGRAM	
	Cyanosis					IV	1	DAY
	Electrocardiogram St		Atracurium	SS		INTRAVENOUS	25 MICROGRAM	
	Segment Depression					IV	1	DAY
	Hypotension		Propofol	SS		INTRAVENOUS	200 MG	IV 1 DAY
	Hypoxia		Metoclopramide	SS		INTRAVENOUS	10 MG	IV 1 DAY

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/07/05ISR Number: 4550061-4Report Type:Expedited (15-DaCompany Report #KII-2004-0014452
Age:24 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anion Gap Increased Blood Bicarbonate Decreased Blood Chloride Increased	Study Consumer Health Professional	Oxycontin Tablets (Oxycodone Hydrochloride) Cr Tablet	PS		ORAL	UNK, ORAL	
	Blood Potassium Decreased Dysarthria Dystonia Electrocardiogram Pr Prolongation	Other	Excedrin Extra Strength (Acetylsalicylic Acid, Cafeine, Paracetamol)	SS		ORAL	UNK, ORAL	
	Flat Affect Gait Disturbance		Metoclopramide (Metoclopramide)	SS		ORAL	UNK, ORAL	
	Gaze Palsy Heart Rate Increased Hypoxia Lethargy Multiple Drug Overdose Nausea Pancreatitis Respiratory Rate Increased Tremor							

Date:01/10/05ISR Number: 4551848-4Report Type:Expedited (15-DaCompany Report #6838
Age:82 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Anaphylactoid Reaction	Foreign	Etoposide	PS		ORAL	PO	1 DAY
Hospitalization - Initial or Prolonged	Cardiac Failure Congestive	Health Professional	Cyclophosphamide Metoclopramide	SS SS		ORAL	PO 10 MG TID	1 DAY 1 DAY
		Other	Morphine Fentanyl Dexamethasone Rofecoxib	C C C C				

Date:01/10/05ISR Number: 4585478-5Report Type:Direct Company Report #USP 57071
Age:1 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Medication Error		Reglan	PS	Mgp	LIQUID		

Date:01/10/05ISR Number: 4585504-3Report Type:Direct Company Report #USP 57065
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Accidental Overdose		Phenylephrine					
	Medication Error		(Phenylephrine)	PS	Baxter	INJECTABLE		
			Metoclopramide					
			(Metoclopramide)	SS	Baxter	INJECTABLE		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/11/05ISR Number: 4553840-2Report Type:Direct Company Report #CTU 236123
Age:29 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Anxiety		Metoclopramide					
	Restlessness		Autonomic Medications	PS				

Date:01/12/05ISR Number: 4550042-0Report Type:Expedited (15-DaCompany Report #200510077FR
Age:62 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Abnormal Sensation In Eye		Lovenox	PS	Aventis Pharmaceuticals Inc.			
Hospitalization - Initial or Prolonged	Cholestasis							
	Coma		Topalgic	SS		ORAL		
	Confusional State		Sectral	SS				
	Convulsion		Zyrtec	SS		ORAL		
	Drug Toxicity		Primperan	SS				
	Extrapyramidal Disorder		Amlor	SS				
	Eye Disorder		Atarax					
	Feeling Abnormal							
	Klebsiella Infection		/Can/	SS				
	Metabolic Encephalopathy		Prograf	SS		ORAL		
	Nervous System Disorder		Mopral	SS		ORAL		
	Nosocomial Infection		Cortancyl	SS		ORAL		
	Photopsia							
	Renal Failure Chronic							
	Retinopathy Hypertensive							
	Sepsis							
	Visual Disturbance							
	Vitreous Floaters							

Date:01/14/05ISR Number: 4554478-3Report Type:Expedited (15-DaCompany Report #PHFR2004GB04138
Age:29 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Aspiration	Foreign	Voltarol (Diclofenac					
	Drug Withdrawal Syndrome	Health	Sodium)	PS		ORAL	25 MG, TID,	

Professional

ORAL

Other

Octreotide (Octreotide Acetate) SS

SUBCUTANEOUS 100 UG Q12H,

SUBCUTANEOUS

Heminevrin (Clomethiazole Edisilate) SS ORAL

ORAL

Omeprazol (Ngx) (Omeprazole) SS ORAL

20 MG/DAY,

ORAL

Clonidine (Ngx) (Clonidine Hydrochloride) SS ORAL

0.1 MG, PRN,

ORAL

Diazepam (Ngx) (Diazepam) SS ORAL

10 MG, PRN,

ORAL

Lorazepam (Ngx) (Lorazepam) SS ORAL

2.5 MG, PRN,

ORAL

Temazepam (Ngx) (Temazepam) SS ORAL

20 MG, PRN,

ORAL							
				Rohypnol (Flunitrazepam)	SS		ORAL
1 MG, PRN,							
ORAL							
				Chlorpromazine (Chlorpromazine)	SS		ORAL
50 MG, PRN,							
ORAL							
				Metoclopramide (Metoclopramide)	SS		
SUBCUTANEOUS	10 MG Q8H,						
SUBCUTANEOUS							
				Buccastem (Prochlorperazine Maleate)	SS		ORAL
ORAL							
				Buscopan (Hyoscine Butylbromide)	SS		ORAL
10 MG, PRN,							
ORAL							
				Naltrexone (Naltrexone)	SS		ORAL
ORAL							
				Acupan (Nefopam Hydrochloride)	SS		ORAL
ORAL							
				Zofran (Ondansetron Hydrochloride)	SS		ORAL
8 MG, PRN,							
ORAL							

Date:01/14/05ISR Number: 4554800-8Report Type:Expedited (15-DaCompany Report #GXKR2003GB00516
Age:12 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Coordination Abnormal	Foreign	Metoclopramide					
Other	Muscle Spasms	Health	(Ngx)(Metoclopramide					
	Musculoskeletal Stiffness	Professional	) Unknown	PS				

	Tongue Disorder	Other				

Date:01/14/05ISR Number: 4556647-5Report Type:Expedited (15-DaCompany Report #2005CG00085
Age:45 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Alveolitis	Foreign	Mopral	PS				
Hospitalization -	Anaemia	Health	Largactil	SS				
Initial or Prolonged	Bronchoalveolar Lavage	Professional	Largactil	SS				
	Abnormal	Other	Largactil	SS				
	Chest X-Ray Abnormal		Vepeside	SS				
INTRAVENOUS							170 MG	DAILY
	Creatinine Renal							
IV								
	Clearance Decreased		Vepeside	SS				
INTRAVENOUS							170 MG	DAILY
	Depressed Level Of							
IV								
	Consciousness		Vepeside	SS				
INTRAVENOUS							170 MG	DAILY
	General Physical Health							
IV								
	Deterioration		Cisplatin "Qualimde"	SS	Qualimed			
INTRAVENOUS							50 MG	DAILY
	Leukocytosis							
IV								
	Pneumonia		Cisplatin "Qualimed"	SS	Qualimed			
INTRAVENOUS							50 MG	DAILY
	Septic Shock							
IV								
	Vomiting		Cisplatin "Qualimed"	SS	Qualimed			
INTRAVENOUS							50 MG	DAILY
IV								
			Lexomil	SS				
			Zophren	SS				
INTRAVENOUS							16 MG	T1WK
IV								
			Zophren	SS				
INTRAVENOUS							16 MG	T1WK
IV								
			Zophren	SS				
INTRAVENOUS							16 MG	T1WK
IV								
			Calcium Carbonate W/Colecalciferol	SS				
			Solupred	SS				

Solupred	SS
Solupred	SS
Solupred	SS
Stilnox/Fra/	SS
Primperan	SS
Primperan	SS
Primperan	SS
Solu-Medrol	SS
Solu-Medrol	SS
Solu-Medrol	SS
Deroxat	SS
Durogesic	SS
Actiskenan	SS

Date:01/18/05ISR Number: 4557685-9Report Type:Expedited (15-DaCompany Report #6838
Age:82 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Anaphylactoid Reaction		Etoposide	PS		ORAL	PO	1 DAY
Initial or Prolonged	Bronchospasm		Metoclopramide	SS			10 MG TID	1 DAY
	Cardiac Failure		Cyclophosphamide	SS		ORAL	PO	1 DAY
	Congestive		Morphine	C				
	Malignant Neoplasm		Fentanyl	C				
	Progression		Dexamethasone	C				
	Small Cell Lung Cancer		Rofecoxib	C				
	Stage Unspecified							
	Swelling Face							
	Urticaria							
	Wheezing							

Date:01/18/05ISR Number: 4582349-5Report Type:Periodic Company Report #378837
Age:82 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Leukopenia	Other	Rocephin					
	Neutropenia		(Ceftriaxone Sodium)	PS				
INTRAVENOUS	2 GRAM DAILY							

INTRAVENOUS				
		Polaramine (Dexchlorpheniramine)	SS	ORAL
2 MG 3 PER 1 DAY	ORAL			
		Amiklin (Amikacin)	SS	
INTRAVENOUS	480 MG DAILY			
INTRAVENOUS				
		Primperan (Metoclopramide)	SS	
INTRAVENOUS	2 PER 1 DAY			
INTRAVENOUS				
		Mopral (Omeprazole)	C	
		Perfalgan (Acetaminophen)	C	

Date:01/21/05ISR Number: 4560717-5Report Type:Expedited (15-DaCompany Report #2005CG00115
Age:62 YR Gender:Male I/FU:I

Outcome	PT
Death	Angiopathy
	Cholestasis
	Coma
	Condition Aggravated

	Convulsion					
	Drug Toxicity					
	Extrapyramidal Disorder	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
	Hepatitis	Foreign	Mopral	PS		ORAL
40 MG QD PO						
	Metabolic Encephalopathy	Health	Topalgic "Houde"	SS		ORAL
150 MG QD PO						
	Nosocomial Infection	Professional	Cortancyl	SS		ORAL
5 MG QD PO						
	Pathogen Resistance	Other	Zyrtec	SS		ORAL
1 DF QD PO						
	Pneumonia Klebsiella		Prograf	SS		ORAL
2 MG QD PO						
	Renal Failure Chronic		Tigecycline	SS		
INTRAVENOUS	50 MG BID IV					
	Retinopathy Hypertensive		Lovenox	SS		
	Sepsis		Primperan	SS		
			Atarax/Can/	SS		
			Sectral "Aventis"	SS		
			Amlor	SS		

Date:01/24/05ISR Number: 4562673-2Report Type:Expedited (15-DaCompany Report #2005015418
Age:64 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization -	Arterial Thrombosis Limb	Foreign	Solu-Medrol			
Initial or Prolonged	Injection Site Erythema	Health	(Methylprednisolone			
	Injection Site Thrombosis	Professional	Sodium Succinate)	PS		
	Neutropenia	Other	Cisplatin	SS		
220 MG (220						
	Renal Failure					
MG, 1 IN 1 D)						
			Metoclopramide	SS		
			Fluorouracil	SS		
2.2 GRAM (2.2						
GRAM, 1 IN 1						
			Zophren (Ondansetron			
			Hydrochloride)	SS		
			Omeprazole	C		
			Zolpidem	C		

Date:01/26/05ISR Number: 4560794-1Report Type:Expedited (15-DaCompany Report #JP-SOLVAY-00305000185
Age:24 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Aggression		Fluvoxamine Maleate	PS		ORAL	Daily dose: 250 milligram(s), Frequency: once	
	Drug Toxicity							
	Loss Of Consciousness							
	Multiple Drug Overdose							
	Neuroleptic Malignant Syndrome		Metoclopramide	SS		ORAL	Daily dose: 50 milligram(s), Frequency: once	
	Pulmonary Congestion							
	Pulmonary Oedema							
	Respiratory Arrest							
	Snoring							
			Propericiazine	SS		ORAL	Daily dose: 200 milligram(s), Frequency: once	
			Promethazine Hydrochloride	SS		ORAL	Daily dose: 1125 milligram(s), Frequency: once	
			Levomepromazine					

	Maleate	SS	ORAL

Daily dose:

50

milligram(s),

Frequency:

once

	Levomepromazine Maleate	SS	ORAL

Daily dose:

350

milligram(s),

Frequency:

once

	Sulpiride	SS	ORAL

Daily dose:

1450

milligram(s),

Frequency:

once

	Brotizoram	SS	ORAL

Daily dose:

12.5

milligram(s),

Frequency:

once

Date:01/26/05ISR Number: 4561170-8Report Type:Expedited (15-DaCompany Report #200510077FR
Age:62 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Abnormal Sensation In Eye		Lovenox	PS	Aventis			
Hospitalization -	Cholestasis				Pharmaceuticals Inc.			
Initial or Prolonged	Coma		Topalgic	SS		ORAL		
	Complications Of		Sectral	SS				
	Transplanted Liver		Zyrtec	SS		ORAL		
	Confusional State		Primperan	SS				
	Convulsion		Amlor	SS				
	Disease Recurrence		Atarax					
	Drug Toxicity							
	Extrapyramidal Disorder		/Can/	SS				
	Hepatitis		Prograf	SS		ORAL		
	Klebsiella Infection		Mopral	SS		ORAL		
	Metabolic Encephalopathy		Cortancyl	SS		ORAL		
	Nosocomial Infection							
	Pathogen Resistance							
	Photopsia							
	Renal Failure Chronic							
	Retinopathy Hypertensive							
	Sepsis							
	Visual Disturbance							
	Vitreous Floaters							

Date:01/26/05ISR Number: 4565687-1Report Type:Expedited (15-DaCompany Report #20050100003
Age:25 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Abdominal Pain Upper	Health	Reglan					
Initial or Prolonged	Hypertension	Professional	(Metoclopramide)	PS				
INTRAVENOUS	10 MG ONCE IV							
Other	Myocardial Infarction		Antibiotic	C				
Required	Rash							
Intervention to								
Prevent Permanent								
Impairment/Damage								

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/27/05ISR Number: 4570241-1Report Type:Direct Company Report #CTU 238352
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Facial Pain		Reglan	PS				
REGLAN								
	Muscle Twitching							
	Tongue Oedema							

Date:01/31/05ISR Number: 4567987-8Report Type:Expedited (15-DaCompany Report #2005-BP-00783AU
Age:83 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blood Creatinine Increased	Other	Atrovent (Ipratropium					
	Blood Urea Increased		Bromide)	PS				
RESPIRATORY								
	Hypokalaemia							
(INHALATION)							500 MCG IH	4 DAY
	Renal Impairment		Ceftriaxone (Ceftriaxone)	SS				
INTRAVENOUS							1G DAILY	
INTRAVENOUS								
			Rulide (Roxithromycin) (Ta)	SS		ORAL		
300 MG (300								
MG ORALLY								
DAILY) PO							1	DAY
			Ventolin	SS				
RESPIRATORY								
(INHALATION)							5 MG INHALED	
AS NECESSARY							4	DAY
			Frusemide (Furosemide)	SS				
INTRAVENOUS							240 MG (240	
MG DAILY) IV							2	DAY

INTRAVENOUS	40 MG (40 MG DAILY) IV	2	DAY	Losec	SS	
INTRAVENOUS	400 MG (400 MG DAILY) IV	6	DAY	Ciprofloxacin	SS	
INTRAVENOUS	300 MG (300 MG DAILY) IV	4	DAY	Hydrocortisone (Hydrocortisone)	SS	
	10 MG, 10 MG AS NECESSARY)	6	DAY	Maxolon (Metoclopramide Hydrochloride)	SS	
SUBCUTANEOUS	100 MG (100 MG DAILY) SC	2	DAY	Clexane (Heparin-Fraction, Sodium Salt)	SS	
	4 DOSES DAILY PO			Slow-K (Potassium Chloride) (Ta)	SS	ORAL
	2 DOSES DAILY PO			Caltrate (Calcium Carbonate) (Ta)	SS	ORAL
	5 MG WEEKLY PO			Folic Acid	SS	ORAL
	30 MG (30 MG DAILY)			Prednisolone	SS	
	5 MG, 300 MG DAILY PO			Zantac (Ranitidine Hydrochloride) (Ta)	SS	ORAL

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/31/05ISR Number: 4568254-9Report Type:Expedited (15-DaCompany Report #2005CG00115
Age:62 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Abnormal Sensation In Eye	Foreign	Mopral	PS		ORAL	40 MG QD PO	
Hospitalization -	Angiopathy	Health	Topalgic "Houde"	SS		ORAL	150 MG QD PO	
Initial or Prolonged	Cholestasis	Professional	Cortancyl	SS		ORAL	5 MG QD PO	
	Coma	Other	Zyrtec	SS		ORAL	1 DF QD PO	
	Condition Aggravated		Prograf	SS		ORAL	2 MG QD PO	
	Confusional State		Tigecycline	SS				
INTRAVENOUS							50 MG BID IV	
	Convulsion		Lovenox	SS				
	Drug Toxicity		Primperan	SS				
	Extrapyramidal Disorder		Atarax /Can/	SS				
	Hepatic Function Abnormal		Sectral "Aventis"	SS				
	Hepatitis		Amlor	SS				
	Metabolic Encephalopathy							
	Nosocomial Infection							
	Photopsia							
	Pneumonia Klebsiella							
	Renal Failure Chronic							
	Retinopathy Hypertensive							
	Sensory Disturbance							
	Sepsis							
	Visual Disturbance							

Date:01/31/05ISR Number: 4570668-8Report Type:Expedited (15-DaCompany Report #2005010453
Age:72 YR Gender:Male I/FU:F

Outcome	PT
Death	Activated Partial
Hospitalization -	Thromboplastin Time
Initial or Prolonged	Prolonged
Other	Adverse Drug Reaction
	Agitation
	Anaemia
	Anorexia
	Aortic Calcification
	Arrhythmia

Supraventricular
Arthralgia
Asthenia
Back Pain
Blood Albumin Decreased
Blood Calcium Decreased
Blood Glucose Increased
Blood Sodium Decreased
Blood Urine Present
Candida Sepsis
Cardiac Failure
Congestive
Cardiac Tamponade
Cardiomegaly
Carpal Tunnel Syndrome
Choreoathetosis
Chronic Obstructive
Pulmonary Disease
Coma
Confusional State
Constipation
Csf Protein Increased
Dehydration

Diastolic Dysfunction Dysarthria Dyspepsia	Report Source	Product	Role	Manufacturer	Route
Dysuria Encephalopathy	Consumer	Lipitor (Atorvastatin)	PS		
Fluid Overload					
Gastrointestinal		Celebrex (Celecoxib)	SS		
Haemorrhage					
Gravitational Oedema Haemodialysis		Fenofibrate (Fenofibrate)	SS		
Haemodynamic Instability					
Haemolysis Headache		Nabumetone (Nabumetone)	SS		
Heparin-Induced					
Thrombocytopenia Hypoxia Ileus Interstitial Lung Disease		Paroxetine Hydrochloride (Paroxetine Hydrochloride)	SS		
Joint Swelling					
Logorrhoea Lymphocyte Count		Metoclopramide (Metoclopramide)	SS		
Decreased					
Mental Status Changes Metabolic Acidosis Micturition Urgency Mitral Valve Calcification Mitral Valve Incompetence Mobility Decreased Multi-Organ Failure Muscle Twitching Myositis Nausea Pericardial Effusion		All Other Therapeutic Products Valsartan (Valsartan) Furosemide Metoprolol (Metoprolol) Felodipine (Felodipine) Hyzaar (Hydrochlorothiazide , Losartan	SS C C C C		

Dose	Duration
10 MG, 1 IN	1 D
200 MG, 1 IN	1 D
160 MG, 1 IN	1 D
750 G, 1 IN	2 D
12.5 MG, 1 IN	1 D
10 MG, 1 IN	3 D

Pericarditis	Potassium)	C
Platelet Count Increased	Anusol-Hc (Benzyl	
Pleural Effusion	Benzoate, Bismuth	
Pneumonia	Hydroxide, Bismuth	
Pneumonia Aspiration	Subgallate,	
Polyneuropathy	Hydrocortisone	C
Procedural Hypotension	Orphenadrine	
Prothrombin Time	(Orphenadrine)	C
Prolonged	Lorazepam	
Pulmonary Congestion	(Lorazepam)	C
Renal Failure	Prochlorperazine	
Renal Failure Acute	Edisylate	
Renal Failure Chronic	(Prochlorperazine	
Respiratory Failure	Edisylate)	C
Retching	Lansoprazole	
Rhabdomyolysis	(Lansoprazole)	C
Thrombophlebitis	Hydrochlorothiazide	
Ventricular Hypertrophy	(Hydrochlorothiazide	
Vomiting	)	C
Weight Decreased	Ultracet	
Weight Increased	(Paracetamol,	
	Tramadol	
	Hydrochloride)	C
	Metaxalone	
	(Metaxalone)	C

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/01/05ISR Number: 4566463-6Report Type:Expedited (15-DaCompany Report #FR-BRISTOL-MYERS SQUIBB COMPANY-12842746
Age:59 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Convulsion		Aprovel	PS	Bristol-Myers Squibb Company	ORAL		
	Demyelination							
	Headache		Tanganil	SS		ORAL	1	DAY
	Hyponatraemia		Vastarel	SS		ORAL	1	DAY
	Inappropriate Antidiuretic Hormone Secretion		Primperan	SS		ORAL		
	Lung Neoplasm Malignant		Primperan	SS		ORAL		
	Multiple Sclerosis							
	Nausea							
	Vertigo Positional							
	Vomiting							

Date:02/04/05ISR Number: 4570605-6Report Type:Expedited (15-DaCompany Report #SGB1-2005-00005
Age:39 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Chills		Ondansetron	PS	Glaxosmithkline	UNKNOWN		
	Dizziness		Metoclopramide	SS	Glaxosmithkline	UNKNOWN		
	Dyspnoea		Zometa	SS		INTRAVENOUS	4MG	Cyclic
	Feeling Cold		Epirubicin	C		UNKNOWN		
	Headache							
	Oedema Peripheral							
	Oral Candidiasis							
	Pain In Extremity							
	Photosensitivity Reaction							

Date:02/07/05ISR Number: 4578511-8Report Type:Direct Company Report #CTU 239387
Age:8 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Catheter Related Complication		Metoclopramide 5mg/5ml Syrup	PS		ORAL	3 TIMES A DAY	
Disability	Constipation					ORAL		
Required Intervention to Prevent Permanent Impairment/Damage	Contraindication To Medical Treatment		Metoclopramide Tablet	5mg SS		ORAL	3 TIMES A DAY	
	Crying					ORAL		
	Faecaloma		Reglan	C				
	Gastric Disorder		Zantac	C				
	Intestinal Functional Disorder		Advair	C				
	Painful Defaecation		Albuterol	C				
	Vomiting		Singulair	C				

Date:02/07/05ISR Number: 4578794-4Report Type:Direct Company Report #CTU 239412
Age:68 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Bursitis		Reglan	PS				
	Influenza Immunisation							
	Pain In Extremity							
	Polymyalgia Rheumatica							
	Therapeutic Response Decreased							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/08/05ISR Number: 4575106-7Report Type:Expedited (15-DaCompany Report #PHFR2005GB00747
Age:39 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dizziness Dyspnoea		Zometa	PS	Novartis Sector: Pharma	INTRAVENOUS	4 mg every 2	weeks
	Feeling Cold							
	Headache		Metoclopramide	SS		UNKNOWN		
	Oedema Peripheral		Ondansetron	SS		UNKNOWN		
	Oral Candidiasis		Epirubicin	C		UNKNOWN		
	Pain In Extremity							
	Photosensitivity Reaction							

Date:02/09/05ISR Number: 4575481-3Report Type:Expedited (15-DaCompany Report #JP-SOLVAY-00305000185
Age:24 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Aggression		Fluvoxamine Maleate	PS		ORAL	Daily dose:	
	Body Temperature						250	
	Increased						milligram(s),	
	Completed Suicide						Frequency:	
	Conjunctival Hyperaemia						once	
	Drug Toxicity		Metoclopramide	SS		ORAL	Daily dose:	
	Hepatic Steatosis						50	
	Intentional Misuse						milligram(s),	
	Neuroleptic Malignant						Frequency:	
	Syndrome						once	

	Pulmonary Congestion Pulmonary Oedema Respiratory Arrest Scar	Propericiazine	SS	ORAL
Daily dose: 200 milligram(s), Frequency: once				
		Promethazine Hydrochloride	SS	ORAL
Daily dose: 1125 milligram(s), Frequency: once				
		Levomepromazine Maleate	SS	ORAL
Daily dose: 50 milligram(s), Frequency: once				
		Levomepromazine Maleate	SS	ORAL
Daily dose: 350 milligram(s), Frequency: once				
		Sulpiride	SS	ORAL
Daily dose: 1450 milligram(s), Frequency: once				

Brotizoram SS ORAL

Daily dose:

12.5

milligram(s),

Frequency:

once

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/10/05ISR Number: 4577101-0Report Type:Expedited (15-DaCompany Report #GB-ROCHE-391917
Age:29 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Aspiration		Diazepam	PS	Roche	ORAL		
REGIMEN								
REPORTED AS								
PRN								
			Rohypnol	SS	Roche	ORAL		
REGIMEN								
REPORTED AS								
PRN								
			Heminevrin	SS		ORAL		
			Omeprazole	SS		ORAL		
			Clonidine	SS		ORAL		
REGIMEN								
RPEORTED AS								
PRN								
			Lorazepam	SS		ORAL		
REGIMEN								
REPORTED AS								
PRN								
			Temazepam	SS	Roche	ORAL		
REGIMEN								
REPORTED AS								
PRN								
			Chlorpromazine	SS		ORAL		
REGIMEN								
REPORTED PRN								
			Octreotide	SS				
SUBCUTANEOUS								
			Metoclopramide	SS				
SUBCUTANEOUS								
			Buccastem	SS		ORAL		

			Buscopan	SS	ORAL

REGIMEN

REPORTED AS

PRN

			Naltrexone	SS	ORAL
			Acupan	SS	ORAL
			Voltarol	SS Roche	ORAL
			Zofran	SS	ORAL

REGIMEN

REPORTED AS

PRN

Date:02/10/05ISR Number: 4580136-5Report Type:Expedited (15-DaCompany Report #2005AP00981
Age:8 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Apnoea	Foreign	Propofol	PS		INTRAVENOUS	70 MG DAILY	
	Muscle Twitching	Health				IV		
	Pulse Absent	Professional	Maxolon	SS		INTRAVENOUS	5 MG DAILY IV	
	Restlessness	Other	Pethidine Hydrochloride	SS			35 MG DAILY	
			Midazolam	C				
			Paracetamol	C				

Date:02/14/05ISR Number: 4580076-1Report Type:Expedited (15-DaCompany Report #FR-JNJFOC-20050202176
Age:62 YR Gender:Male I/FU:I

Outcome	PT
Death	Cholestasis
Hospitalization - Initial or Prolonged	Coma
	Confusional State
	Convulsion
	Disease Recurrence
	Drug Resistance
	Drug Toxicity
	Extrapyramidal Disorder

	Eye Disorder Metabolic Encephalopathy Nosocomial Infection	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Photopsia		Topalgic	PS		OROPHARINGEAL	
	Pneumonia Klebsiella		Cortancyl	SS		OROPHARINGEAL	
	Renal Failure Chronic		Lovenox	SS		UNKNOWN	
	Sepsis		Sectral	SS		UNKNOWN	
	Visual Disturbance		Mopral	SS		OROPHARINGEAL	
	Vitreous Floaters		Zyrtec	SS		OROPHARINGEAL	
			Prograf	SS		OROPHARINGEAL	
			Tigecycline	SS		INTRAVENOUS	
			Primperan	SS		UNKNOWN	
			Atarax	SS		UNKNOWN	
			Amlor	SS		UNKNOWN	

Date:02/15/05ISR Number: 4604287-1Report Type:Periodic Company Report #138728USA
Age:51 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Hospitalization - Initial or Prolonged	Bronchospasm Hypersensitivity	Health Professional	Propofol Kefzol Reglan	PS SS SS		

Date:02/16/05ISR Number: 4585806-0Report Type:Expedited (15-DaCompany Report #2005AL000020
Age:59 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Other	Anhedonia Anxiety	Other	Metoclopramide Tablets Usp, 10 Mg			

	Dystonia		(Purepac)	PS		
	Emotional Distress		Metoclopramide Oral			
	Injury		Solutoin Usp, Eq. 5			
	Nerve Injury		Mg Base/5 Ml			
	Tardive Dyskinesia		(Alpharma)	SS	Alpharma	
	Tongue Disorder		Reglan	SS		

Date:02/22/05ISR Number: 4588539-XReport Type:Expedited (15-DaCompany Report #200414531FR
Age:50 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Citrobacter Infection		Claforan	PS	Aventis Pharmaceuticals Inc.			
	Cytolytic Hepatitis						INTRAVENOUS	
	Pneumonia		Primperan	SS		ORAL		
			Augmentin	SS			INTRAVENOUS	
			Burinex	SS			INTRAVENOUS	
			Inexium	SS		ORAL		
			Perfalgan	SS			INTRAVENOUS	
			Ciflox	SS				
			Surbronc	SS				
			Eupressyl	SS		ORAL		

Date:02/22/05ISR Number: 4590964-8Report Type:Direct Company Report #CTU 240899
Age: Gender:Female I/FU:I

Outcome	PT
	Pharmaceutical Product Complaint

Unevaluable Event

		Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
			Reglan 10 Mg	PS		
1 TABLET 15						
MINUTES						
BEFORE MEALS						
AND AT						
BEDTIME						

Date:02/22/05ISR Number: 4591339-8Report Type:Expedited (15-DaCompany Report #2005AL000612
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Other	Dyskinesia	Company	Metoclopramide			
	Injury	Representative	Tablets Usp, 10 Mg			
	Mental Disorder	Other	(Purepac)	PS		
	Nervous System Disorder		Metoclopramide Oral			
	Pain		Solution Usp, Eq. 5			
	Tardive Dyskinesia		Mg Base/5	SS		
			Reglan	SS		

Date:02/23/05ISR Number: 4595055-8Report Type:Expedited (15-DaCompany Report #105515ISR
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Other	Disturbance In Attention	Foreign	Fluorouracil	PS		
INTRAVENOUS	INTRAVENOUS					
	Memory Impairment	Health				
(NOS)						
	Vertigo	Professional	Metoclopramide	SS		
		Other				

Date:02/24/05ISR Number: 4594921-7Report Type:Expedited (15-DaCompany Report #GXKR2004US00731
Age:52 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Asthenia	Literature	Metoclopramide (Ngx) (Metoclopramide) 10mg	PS			40-80 MG	
	Diarrhoea	Health Professional						
	Drug Interaction		Tacrolimus (Tacrolimus)	SS			2-56 MG	
	Drug Level Increased							
	Headache		Ondansetron (Ondansetron)	C				
	Nausea		Sirolimus (Sirolimus)	C				
	Nephropathy Toxic		Mycophenolate Mofetil (Mycophenolate Mofetil)	C				
	Neurotoxicity		Prednisolone (Prednisolone)	C				
	Pain In Extremity		Ursodiol (Ursodeoxycholic Acid)	C				
	Renal Failure Acute		Ketoconazole (Ketoconazole)	C				
	Renal Tubular Necrosis		Omeprazole (Omeprazole)	C				
	Tremor		Ketoconazol (Ketoconazole)	C				
	Vomiting							

				Pantoprazole (Pantoprazole)	C		

Date:03/01/05ISR Number: 4609094-1Report Type:Periodic Company Report #20040800385
Age:67 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Disability	Tardive Dyskinesia	Health Professional	Reglan (Metoclopramide) (Baxter)	PS	Baxter	

Date:03/01/05ISR Number: 4609097-7Report Type:Periodic Company Report #20041100486
Age:30 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Disability	Dystonia	Consumer	Reglan (Metoclopramide) (Baxter)	PS	Baxter	
Other	Muscle Twitching		Paxil	C		

Date:03/01/05ISR Number: 4609099-0Report Type:Periodic Company Report #20050100013
Age:59 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Disability	Tardive Dyskinesia	Consumer	Reglan (Metoclopramide) (Baxter)	PS	Baxter	

Date:03/01/05ISR Number: 4609102-8Report Type:Periodic Company Report #20040300245
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Disability	Dyskinesia	Consumer	Metoclopramide (Non-Baxter)	PS		

Date:03/01/05ISR Number: 4609103-XReport Type:Periodic Company Report #20040400274
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization - Initial or Prolonged	Anxiety Depression Suicidal Ideation	Other	Reglan (Metoclopramide) (Baxter)	PS	Baxter	

Date:03/01/05ISR Number: 4609105-3Report Type:Periodic Company Report #20040200191
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Other	Convulsion	Health Professional	Reglan (Metoclopramide)			
		Other	(Baxter)	PS	Baxter	
10 MG DAILY						
			Wellbutrin Xl (Bupropion Hcl) Tablets Glaxo Smith Kline	SS	Glaxo Smith Kline	ORAL
300 MG DAILY						
PO	3 WK					

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/01/05ISR Number: 4609107-7Report Type:Periodic Company Report #20040200145
Age:25 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Liver Function Test Abnormal	Foreign Other	Reglan (Metoclopramide) (Baxter)	PS	Baxter	INTRAVENOUS	10 MG TID IV	
			Protium (Pantoprazole)	SS		ORAL	30 MG DAILY	PO
			Cyclizine	C				
			Warfarin	C				
			Epilin (Valproate Sodium)	C				

Date:03/01/05ISR Number: 4609131-4Report Type:Periodic Company Report #002#1#2004-00229
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other Required Intervention to Prevent Permanent Impairment/Damage	Dystonia Tachycardia	Consumer Health Professional	Reglan-10mg-Tablet (Metoclopramide Hcl)	PS		ORAL	10MG, 4 IN 1 D; ORAL	

Date:03/01/05ISR Number: 4609134-XReport Type:Periodic Company Report #002#2#2004-00237
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Tardive Dyskinesia	Consumer	Reglan-Dose-Unknown (Metoclopramide Hcl)	PS		ORAL	ORAL	

Date:03/01/05ISR Number: 4609177-6Report Type:Periodic Company Report #002#4#2004-00264
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Tardive Dyskinesia	Consumer	Reglan-Dose-Unknown					
		Other	(Metoclopramide Hcl)	PS		ORAL		
			Generic					
			Metoclopramide	SS				

Date:03/01/05ISR Number: 4609182-XReport Type:Periodic Company Report #002#4#2004-00150
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Tardive Dyskinesia	Other	Reglan-Dose-Unknown					
			(Metoclopramide Hcl)	PS		ORAL		

Date:03/01/05ISR Number: 4609185-5Report Type:Periodic Company Report #002#2#2004-00133
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Depression	Consumer	Reglan-10mg-Tablet					
	Tardive Dyskinesia		(Metoclopramide Hcl)	PS		ORAL	10MG, 3 IN 1	
							D; ORAL	
			Esomeprazole	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/01/05ISR Number: 4609189-2Report Type:Periodic Company Report #002#4#2004-00126
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Hyperkinesia	Consumer	Reglan-Dose-Unknown					
	Tardive Dyskinesia	Other	(Metoclopramide Hcl)	PS		ORAL	ORAL	

Date:03/01/05ISR Number: 4609194-6Report Type:Periodic Company Report #002#1#2004-00124
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Tardive Dyskinesia	Consumer	Reglan-10mg-Tablet					
		Health	(Metoclopramide Hcl)	PS		ORAL	3 IN 1 D;	
		Professional					ORAL	

Date:03/01/05ISR Number: 4609254-XReport Type:Periodic Company Report #002#2#2004-00054
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Dyskinesia		Reglan-Dose-Unknown					
			(Metoclopramide Hcl)	PS		ORAL	ORAL	

Date:03/01/05ISR Number: 4609274-5Report Type:Periodic Company Report #002#4#2004-00029
Age:65 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Tardive Dyskinesia	Health	Reglan-Dose-Unknown					
		Professional	(Metoclopramide Hcl)	PS		ORAL	ORAL	
		Other	Gabapentin	C				

Date:03/01/05ISR Number: 4609277-0Report Type:Periodic Company Report #002#4#2004-00031
Age:67 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Tardive Dyskinesia	Other	Reglan-Dose-Unknown (Metoclopramide Hcl)	PS		ORAL	ORAL	

Date:03/01/05ISR Number: 4609286-1Report Type:Periodic Company Report #002#4#2003-00480
Age:62 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Tardive Dyskinesia	Consumer	Reglan-10mg-Tablet					
		Other	(Metoclopramide Hcl)	PS		ORAL	4 IN 1 D;	
							ORAL	
			Asa	C				

Date:03/01/05ISR Number: 4609290-3Report Type:Periodic Company Report #002#2#2002-00047
Age:58 YR Gender:Female I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Back Pain
	Dizziness
	Headache
	Muscle Contractions Involuntary
	Paraesthesia

	Tardive Dyskinesia Tremor					
		Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
		Consumer	Reglan-10mg-Tablet (Metoclopramide Hcl)	PS		ORAL
10MG, 2 IN 1						
D; ORAL						
			Omeprazole	C		
			Pantoprazole	C		
			Conjugated-Estrogens	C		

Date:03/04/05ISR Number: 4598361-6Report Type:Expedited (15-DaCompany Report #200414279FR
Age:69 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization - Initial or Prolonged	Condition Aggravated Pulmonary Hypertension		Lovenox	PS	Aventis Pharmaceuticals Inc.	
SUBCUTANEOUS						
			Tracleer	SS		ORAL
			Primperan	SS		ORAL
			Skenan	SS		ORAL
			Effexor	SS		ORAL
			Omeprazole	SS		ORAL
			Movicol	SS		

Date:03/07/05ISR Number: 4602557-4Report Type:Expedited (15-DaCompany Report #2005034566
Age:94 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Life-Threatening Hospitalization - Initial or Prolonged	Alanine Aminotransferase Increased Aspartate Aminotransferase Increased Hepatic Function Abnormal Hyperbilirubinaemia	Foreign Health Professional Company Representative	Sulperazon (Sulbactam, Cefoperazone) Bromhexine Hydrochloride (Bromhexine	PS		
INTRAVENOUS	2 GRAM					
(INTRAVENOUS)						

		Hydrochloride)	SS	ORAL
ORAL				
		Minocycline Hydrochloride (Minocycline Hydrochloride)	SS	
INTRAVENOUS	200 MG,			
INTRAVENOUS				
		Metoclopramide		
		(Metoclopramide)	SS	ORAL
ORAL				
		Lactec (Calcium Chloride Anhydrous, Potassium Chloride, Sodium Chloride, Sodium Lactate)	SS	
INTRAVENOUS	INTRAVENOUS			
		Teicoplanin (Teicoplanin)	SS	
INTRAVENOUS	INTRAVENOUS			
		Amino Acids/Electrolytes /Glucose/Vitamins (Amino Acids Nos, Electrolytes Nos,	C	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/10/05ISR Number: 4606840-8Report Type:Expedited (15-DaCompany Report #C-04-0053
Age:4.5 MON Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Dystonia Eye Rolling Regurgitation Of Food	Consumer Other	Metoclopramide Oral Solution, Usp 5 Mg / 5 Ml	PS			1 ML ORALLY BEFORE MEALS AND AT BEDTIME	

Date:03/11/05ISR Number: 4606031-0Report Type:Expedited (15-DaCompany Report #FR-ROCHE-397179
Age:51 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Aplasia Lymphangioleiomyomatosis Myeloid Leukaemia		Kytril	PS	Roche	INTRAVENOUS	DOSAGE REGIMEN REPORTED AS 6 DOSES TOTAL. 102	DAY
			Methylprednisolone	SS		INTRAVENOUS	DOSAGE REGIMEN REPORTED AS 6 DOSES TOTAL. 102	DAY
			Cardioxane	SS		INTRAVENOUS	DOSAGE REGIMEN REPORTED AS 6 DOSES TOTAL. 102	DAY

				Primperan	SS		
INTRAVENOUS	DOSAGE						
REGIMEN							
REPORTED AS 6							
DOSES TOTAL.	102 DAY						
				Endoxan	SS		
INTRAVENOUS	DOSAGE						
REGIMEN							
REPORTED AS 6							
DOSES TOTAL.	102 DAY						
				Unknown Study Drug	SS		
INTRAVENOUS	DRUG NAME						
REPORTED AS							
EPIADRIAMYCIN							
E. DOSAGE							
REGIMEN	102 DAY						

Date:03/14/05ISR Number: 4617467-6Report Type:Expedited (15-DaCompany Report #8360
Age:78 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Parkinsonism		Metoclopramide	PS				

Date:03/15/05ISR Number: 4613241-5Report Type:Expedited (15-DaCompany Report #2005034566
Age:94 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Alanine Aminotransferase	Foreign	Sulperazon					
Life-Threatening	Increased	Health	(Sulbactam,					
Hospitalization -	Aspartate	Professional	Cefoperazone)	PS				
INTRAVENOUS	2 GRAM,							
Initial or Prolonged	Aminotransferase	Company						
INTRAVENOUS								
	Increased	Representative	Bromhexine					
	Hepatic Function Abnormal		Hydrochloride					
	Hyperbilirubinaemia		(Bromhexine					

	Hydrochloride)	SS	ORAL

ORAL

				Minocycline Hydrochloride (Minocycline Hydrochloride)	SS			
INTRAVENOUS	200 MG,							
INTRAVENOUS								
				Metoclopramide (Metoclopramide)	SS			ORAL
ORAL								
				Lactec (Calcium Chloride Anhydrous, Potassium Chloride, Sodium Chloride, Sodium Lactate)	SS			
INTRAVENOUS	INTRAVENOUS							
				Teicoplanin (Teicoplanin)	SS			
INTRAVENOUS	INTRAVENOUS							
				Amino Acids/Electrolytes/Glucose/Vitamins (Amino Acids Nos, Electrolytes Nos,	C			

Date:03/17/05ISR Number: 4613446-3Report Type:Direct Company Report #CTU 243502
Age:67 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Electrocardiogram Qt		Risperidol 1 Mg	PS			1 MG PER PEG	
Initial or Prolonged	Prolonged						TUBE DAILY	
	Ventricular Tachycardia		Trazodone 50 Mg	SS			50 MG PER PEG	
TUBE QHS								
			Fluconazole 200 Mg -1100 Ml D5w	SS				
INTRAVENOUS	200 MG IVPB							
Q24 H								
			Clotrimazole 10 Mg	SS				
10 MG PO TID								

	Dopamine 400 Mg/250 Ml D5w	SS
TITRATED TO BLOOD PRESSURE		
	Metoclopramide 5 Mg	SS
2.5 MG PER PEG TUBE TID		
	Ondansetron 2 Mg/Ml	C
INTRAVENOUS 2 MG IV Q 6H PRN N/V		
	Ns Flush	C
	Cactinex	C
	Nystatin Topical Powder	C
	Vit C	C
	Baclofen	C
	Remeron	C
	Nystatin Cream	C
	Phenergan	C
	Albuterol Nebulized	C
	Atrovent	C
	Tpn	C
	Ativan	C
	Vancomycin	C
	Amiodarone	C
	Fentanyl Pca	C
	Primaxin	C
	Depacon	C
	Lipids	C
	Cetacaine	C

				Morphine	C		
				Tylenol	C		
				Lactated Ringers	C		

Date:03/17/05ISR Number: 4615239-XReport Type:Expedited (15-DaCompany Report #2005-DE-00918GD
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Congenital Anomaly	Congenital Hip Deformity	Foreign	Paracetamol					
	Drug Exposure During	Literature	(Paracetamol)	PS		INTRA-UTERINE	IU	
	Pregnancy		Amoxycillin					
			(Amoxicillin)	SS		INTRA-UTERINE	IU	
			Metoclopramide					
			(Metoclopramide)	SS		INTRA-UTERINE	IU	
			Sulfacetamide					
			(Sulfacetamide)	SS		INTRA-UTERINE	IU	

Date:03/18/05ISR Number: 4617233-1Report Type:Expedited (15-DaCompany Report #L04-USA-07403-12
Age:35 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardiac Arrest	Literature	Citalopram	PS				
	Coma	Health	Tramadol	SS				
	Completed Suicide	Professional	Gabapentin	SS				
	Convulsion		Metoclopramide	SS				
	Hypotension		Omeprazole	SS				
	Hypoxic Encephalopathy							
	Intentional Misuse							

Date:03/21/05ISR Number: 4616857-5Report Type:Expedited (15-DaCompany Report #5733
Age:44 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Hospitalization -	Coma	Literature	Metoclopramide	PS			
INTRAMUSCULAR 10 MG ONCE							
Initial or Prolonged	Dystonia	Health					
	Joint Dislocation	Professional					
	Opisthotonus						
	Pain In Extremity						

Date:03/22/05ISR Number: 4615171-1Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0375005A
Age:47 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Alanine Aminotransferase		Zophren	PS	Glaxosmithkline			
INTRAVENOUS								
Initial or Prolonged	Increased		Largactil	SS				
INTRAVENOUS								
	Aspartate		Primperan	SS	Glaxosmithkline			
INTRAVENOUS								
	Aminotransferase		Solumedrol	SS				
INTRAVENOUS								
	Increased		Navelbine	SS	Glaxosmithkline			
INTRAVENOUS	55MG Cyclic	1 DAY						
	Gamma-Glutamyltransferase		Cisplatine	SS				
INTRAVENOUS	220MG Cyclic	1 DAY						
	Increased		Tranxene	SS		ORAL	20MG per day	7 DAY
	White Blood Cell Count Decreased							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/23/05ISR Number: 4621318-3Report Type:Direct Company Report #CTU 244063
Age:8 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Pruritus		Reglan	PS		INTRAVENOUS	10 MG /NS 25 ML IV TID	

Date:03/25/05ISR Number: 4621046-4Report Type:Expedited (15-DaCompany Report #2005046980
Age:47 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	Solu-Medrol (Methylprednisolone Sodium Soccinate)	PS		INTRAVENOUS	INTRAVENOUS	
	Aminotransferase Increased		Chlorpromazine (Chlorpromazine)	SS		INTRAVENOUS	INTRAVENOUS	
	Asthenia Gamma-Glutamyltransferase Increased		Metoclopramide (Metoclopramide)	SS		INTRAVENOUS	INTRAVENOUS (CYCLICAL), INTRAVENOUS	
			Vinorelbine (Vinorelbine)	SS		INTRAVENOUS	(CYCLICAL), INTRAVENOUS	
			Cisplatin (Cisplatin)	SS		INTRAVENOUS	(CYCLICAL), INTRAVENOUS	
			Ondansetron Hydrochloride (Ondansetron Hydrochloride)	SS		INTRAVENOUS	INTRAVENOUS	
			Clorazepate Dipotassium (Clorazepate Dipotassium)	C				

Date:03/28/05ISR Number: 4621210-4Report Type:Expedited (15-DaCompany Report #2005015418
Age:64 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Arterial Thrombosis Limb	Foreign	Solu-Medrol					
	Injection Site Erythema	Health Professional	(Methylprednisolone Sodium Succinate)	PS			220 MG (220 MG, 1 IN 1 D)	
	Injection Site Thrombosis		Cisplatin	SS			2.2 GRAM (2.2 GRAM, 1 IN 1	
	Neutropenia	Other	Metoclopramide	SS				
	Phlebothrombosis		Fluorouracil	SS				
	Renal Failure		Zophren (Ondansetron Hydrochloride)	SS				
			Omeprazole	C				
			Zolpidem	C				

Date:04/01/05ISR Number: 4627708-7Report Type:Expedited (15-DaCompany Report #5557
Age:66 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Cardiac Arrest	Literature	Metoclopramide	PS		INTRAVENOUS	10 MG ONCE	
		Health Professional	Fentanyl	C				
			Thiopental	C				
			Rocuronium	C				

			Isoflurane	C		

Date:04/04/05ISR Number: 4625761-8Report Type:Expedited (15-DaCompany Report #PHBS2005JP04370
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Platelet Count Decreased		Lopresor	PS	Novartis Sector: Pharma	ORAL		
			Warfarin	SS		ORAL		
			Digoxin	SS		ORAL		
			Vasolan	SS				
			Ferromia	SS				
			Nitorol	SS		ORAL		
			Primperan	SS				

Date:04/05/05ISR Number: 4627160-1Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0376424A
Age:69 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abnormal Dreams		Zophren	PS	Glaxosmithkline	ORAL	8MG per day	12 DAY
	Cognitive Disorder		Zovirax	SS	Glaxosmithkline	INTRAVENOUS	2250MG per day	6 DAY
	Confusional State							
	Disorientation		Polaramin	SS		INTRAVENOUS	15MG per day	12 DAY
	Hallucination, Visual		Mopral	SS	Glaxosmithkline	ORAL	20MG Per day	14 DAY
	Hypersomnia		Primperan	SS	Glaxosmithkline	INTRAVENOUS	60MG per day	
	Incoherent		Neurontin	SS		ORAL	4	DAY
	Metabolic Encephalopathy		Fraxodi	C	Glaxosmithkline	SUBCUTANEOUS		
	Psychomotor Retardation		Fungizone	C		UNKNOWN		
	Retrograde Amnesia		Chemotherapy	C		UNKNOWN		

Date:04/05/05ISR Number: 4627301-6Report Type:Expedited (15-DaCompany Report #US-BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.-2005-BAge:2 MON Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Insomnia		Metoclopramide	PS	Roxane Laboratories, Inc.	ORAL	37.5 mg q6h (dosing error)	17 DAY
	Irritability							
	Medication Error							
	Refusal Of Treatment By Relative		Metoclopramide	SS	Roxane Laboratories, Inc.	ORAL	7.5 mg q6h (corrected dose)	17 DAY
	Tardive Dyskinesia							
			Ranitidine	C		ORAL	2.5 mL, bid, of 75 mg/5mL syrup	7 DAY

Date:04/05/05ISR Number: 4630257-3Report Type:Direct Company Report #CTU 245387
Age:12 MON Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Chills		Metoclopramide Syrup	PS		ORAL	0.5 QID PO	17 DAY
	Insomnia		Ranitidine	C				
	Irritability							
	Medication Error							
	Overdose							
	Tardive Dyskinesia							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/07/05ISR Number: 4631375-6Report Type:Expedited (15-DaCompany Report #2005-BP-05433RO
Age:2 MON Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Back Pain	Literature	Metoclopramide					
	Chills	Health	(Metoclopramide)	PS		ORAL	37.5 MG Q6H	
	Feeding Disorder	Professional					(DOSING	
	Grimacing						ERROR) (SEE	
	Hyperhidrosis						TEXT), PO;	
	Insomnia						SEE IMAGE	8 DAY
	Irritability		Ranitidine					
	Repetitive Speech		(Ranitidine)	C				
	Tardive Dyskinesia							

Date:04/07/05ISR Number: 4631469-5Report Type:Expedited (15-DaCompany Report #3472
Age:62 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Interaction	Literature	Metoclopramide	PS			6.67 MG	
	Dystonia	Health					ONCE/20 MG	
	Pleurothotonus	Professional					ONCE	
			Clozapine	C				
			Valproate Sodium	C				
			Zolpidem	C				

Date:04/08/05ISR Number: 4633284-5Report Type:Expedited (15-DaCompany Report #2005CG00637
Age:69 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Abnormal Dreams	Foreign	Mopral	PS		ORAL	20 MG QD PO	

Initial or Prolonged	Confusional State	Health	Polaramine	SS				
INTRAVENOUS	15 MG QD IV							
	Decreased Activity	Professional	Primperan	SS				
INTRAVENOUS	60 MG QD IV							
	Disorientation	Other	Zovirax	Glaxo				
	Hallucination, Visual		Wellcome	SS	Glaxo Wellcome			
INTRAVENOUS	2250 MG QD IV							
	Hypersomnia		Neurontin	SS			ORAL	
300 MG QD PO								
	Incoherent		Neurontin	SS			ORAL	
400 MG QD PO								
	Metabolic Encephalopathy		Neurontin	SS			ORAL	
200 MG QD PO								
	Retrograde Amnesia		Zophren	SS				
8 MG QD								
	Somnolence		Fraxodi	C				
			Fungizone	C				

Date:04/08/05ISR Number: 4633314-0Report Type:Expedited (15-DaCompany Report #5314
Age:33 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dysarthria	Health	Metoclopramide	PS				
INTRAVENOUS	10 MG DAILY							
	Muscle Spasms	Professional						
IV								
	Torticollis		Ketamine	C				
	Vision Blurred		Versed	C				
	Wisdom Teeth Removal		Fentanyl	C				

Date:04/11/05ISR Number: 4634297-XReport Type:Expedited (15-DaCompany Report #2927
Age:10 YR Gender:Male I/FU:I

Outcome	PT
Life-Threatening	Drug Ineffective
Hospitalization -	Dystonia
Initial or Prolonged	Respiratory Distress

Stridor

		Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
		Literature	Metoclopramide	PS		ORAL
30 MG; PO	1 DAY					
		Health Professional				

Date:04/12/05ISR Number: 4634479-7Report Type:Expedited (15-DaCompany Report #HQWYE600531MAR05
Age:57 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Life-Threatening	Angioneurotic Oedema	Foreign	Pantoloc			
Hospitalization - Initial or Prolonged	Generalised Oedema	Health Professional	(Pantoprazole, Injection)	PS		
INTRAVENOUS	"SOME TIME					
		Other				
(S) 40 MG"						
INTRAVENOUS						
			Metoclopramide (Metoclopramide,)	SS		
INTRAVENOUS	"SOME TIME					
(S) SOME DF"						
INTRAVENOUS						
			Insulatard (Insulin Human Injection, Isophane)	C		
			Xanor (Alprazolam)	C		
			Topamax (Topiramate)	C		
			Norvasc (Amlodipine Besilate)	C		

Date:04/13/05ISR Number: 4633818-0Report Type:Expedited (15-DaCompany Report #PHBS2005JP04370
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Other	Platelet Count Decreased		Lopresor	PS	Novartis Sector:	

			Pharma	ORAL
Warfarin	SS			ORAL
Digoxin	SS			ORAL
Vasolan	SS			
Ferromia	SS			
Nitorol	SS			ORAL
Primperan	SS			

Date:04/18/05ISR Number: 4639134-5Report Type:Expedited (15-DaCompany Report #2004GB03151
Age:29 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Anaesthetic Complication	Foreign	Diprivan	PS		INTRAVENOUS	200 MG	DAILY
	Cyanosis	Health				IV		
	Electrocardiogram St	Professional	Metoclopramide	SS		INTRAVENOUS	10 MG	DAILY
	Segment Depression	Other				IV		
	Hypotension		Alfentanil	SS		INTRAVENOUS	50 UG	DAILY
	Hypoxia					IV		
			Atracurium	SS		INTRAVENOUS	25 UG	DAILY
						IV		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/18/05ISR Number: 4639432-5Report Type:Expedited (15-DaCompany Report #2005AL001354
Age:2 MON Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Circumstance Or Information Capable Of Leading To Medication Error	Literature Health Professional	Metoclopramide Oral Solution Usp, Eq. 5 Mg Base/5 Ml (Alpharma)	PS		ORAL	2.5 ML; QID;	
	Drug Dispensing Error							
PO								17 DAY
	Feeding Problem In Child		Ranitidine	C				
	Hyperhidrosis							
	Insomnia							
	Irritability							
	Opisthotonus							
	Overdose							
	Refusal Of Treatment By Relative							
	Staring							
	Tardive Dyskinesia							

Date:04/19/05ISR Number: 4640740-2Report Type:Expedited (15-DaCompany Report #9532
Age:29 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Anaesthetic Complication		Atracurium	PS			INTRAVENOUS	25 MICROGRAM
	Cyanosis							
FREQ IV								1 DAY
	Electrocardiogram St		Propofol	SS			INTRAVENOUS	200 MG FREQ
	Segment Depression							
UNK IV								1 DAY
	Hypotension		Metoclopramide	SS			INTRAVENOUS	10 MG FREQ IV 1 DAY
	Hypoxia		Alfentanil	SS			INTRAVENOUS	60 MICROGRAM
FREQ UNK IV								1 DAY

Date:04/20/05ISR Number: 4642587-XReport Type:Expedited (15-DaCompany Report #9187
Age:17 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Accidental Exposure	Foreign	Metoclopramide	PS		INTRADISCAL (INTRASPINAL)	ISP	1 MIN
	Agitation	Literature						
	Anaesthetic Complication	Health Professional Other	Bupivacaine	C				
	Drug Exposure During Pregnancy							
	Headache							
	Hypertension							
	Nausea							
	Somnolence							
	Tachycardia							
	Vision Blurred							
	Vomiting							
	Wrong Drug Administered							

Date:04/22/05ISR Number: 4645338-8Report Type:Expedited (15-DaCompany Report #2005059237
Age:83 YR Gender:Male I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Alkalosis
	Blood Alkaline Phosphatase Increased
	Blood Glucose Increased
	Blood Potassium Increased

	Blood Uric Acid Decreased Confusional State Dystonia	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Hypotension Impaired Gastric Emptying Renal Failure Acute Somnolence Tetanus Vomiting	Foreign Literature Health Professional	Spironolacton (Spironolactone) Metoclopramide (Metoclopramide) Captopril (Captopril)	PS SS C			

Date:04/26/05ISR Number: 4647589-5Report Type:Expedited (15-DaCompany Report #FRWYE225923NOV04
Age:69 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged Other	Condition Aggravated Pulmonary Hypertension	Foreign Health Professional Other	Effexor (Venlafaxine Hydrochloride, , 0) Lovenox (Heparin-Fraction, Sodium Salt, , 0) Omeprazole (Omeprazole, , 0) Primperan (Metoclopramide, , 0) Skenan (Morphine Sulfate, , 0) Tracleer (Bosentan, , 0) Movicol (Macrogol/Potassium Chloride/Sodium Bicarbonate/Sodium Chloride)	PS SS SS SS SS SS C		ORAL ORAL ORAL ORAL ORAL ORAL	ORAL ORAL ORAL ORAL ORAL SEE IMAGE 34 DAY

Date:04/27/05ISR Number: 4649816-7Report Type:Expedited (15-DaCompany Report #CA-SHR-04-023322
Age:44 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Asthenia	Foreign	Betaseron	PS		SUBCUTANEOUS	8 MIU, EVERY 2D,	
Other	Burning Sensation	Consumer						
	Cholelithiasis	Other						
	Condition Aggravated		Metoclopramide (Metoclopramide)	SS		ORAL	1 TAB (S), 4X/DAY	
	Corrective Lens User							
	Decreased Appetite							
	Gastrooesophageal Reflux Disease		Bentylol (Dicycloverine Hydrochloride)	C				
	Haemangioma		Ventolin	C				
	Hypotension		Flovent (Fluticasone Propionate)	C				
	Injection Site Reaction		Valproic Acid (Ratio-) (Valproic Acid)	C				
	Irritable Bowel Syndrome		Clobazam (Ratio-) (Clobazam)	C				
	Multiple Sclerosis		Pariet (Rabeprazole Sodium)	C				
	Nausea		Emla Cream (Prilocaine) Cream	C				
	Oral Intake Reduced							
	Pneumonia							
	Post Procedural Complication							
	Reading Disorder							
	Weight Decreased							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/03/05ISR Number: 4655075-1Report Type:Expedited (15-DaCompany Report #2005AP02516
Age:73 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Cerebrovascular Accident	Foreign	Propofol	PS				
		Health	Maxolon	SS				
		Professional	Morphine Sulfate	SS				
		Other	Dynastat	SS				
			Rocuronium Bromide	SS				
			Sevoflurane	SS				
			Sodium	SS				

Date:05/05/05ISR Number: 4653278-3Report Type:Expedited (15-DaCompany Report #GB-BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.-2005-
UAge: 76UK Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Lung Neoplasm Malignant		Combivent (00015/0191)	PS	B.I. Pharmaceuticals,Inc. /Ridgefield			
RESPIRATORY								
(INHALATION)								
			Spiriva (14598/0062)	SS	B.I. Pharmaceuticals,Inc. /Ridgefield			
RESPIRATORY								
(INHALATION)								
			Salbutamol	SS				
RESPIRATORY								
(INHALATION)								
			Aspirin	SS				
			Atorvastatin	SS				
			Beclometasone	SS				
RESPIRATORY								
(INHALATION)								
			Co-Amilofruse	SS				
			Dexamethasone	SS				
			Diltiazem Hydrochloride	SS				

	Dosulepin	SS	
	Furosemide	SS	
	Gaviscon	SS	
	Lactulose	SS	
3.35 g/5 ml			
	Lansoprazole	SS	
	Metoclopramide Hydrochloride	SS	
	Nitrolingual	SS	
RESPIRATORY (INHALATION)			
	Nozinan	SS	
	Oxycodone Hydrochloride	SS	
	Oxycodone Hydrochloride	SS	ORAL
10mg/ml			
	Oxycodone Hydrochloride	SS	ORAL
5mg/5ml			
	Oxygen	SS	
RESPIRATORY (INHALATION)			
	Spironolactone	SS	
	Symbicort	SS	
RESPIRATORY (INHALATION) 200/6 mcg/inhalatio n			
	Temazepam	SS	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/05/05ISR Number: 4653282-5Report Type:Expedited (15-DaCompany Report #GB-BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.-2005-
UAge: 76UK Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Lung Neoplasm Malignant		Combivent (00015/0191)	PS	B.I. Pharmaceuticals,Inc. /Ridgefield	RESPIRATORY (INHALATION)		
			Spiriva (14598/0062)	SS	B.I. Pharmaceuticals,Inc. /Ridgefield	RESPIRATORY (INHALATION)		
			Salbutamol	SS		RESPIRATORY (INHALATION)		
			Aspirin	SS				
			Atorvastatin	SS				
			Beclometasone	SS		RESPIRATORY (INHALATION)		
			Co-Amilofruse	SS				
			Dexamethasone	SS				
			Diltiazem Hydrochloride	SS				
			Dosulepin	SS				
			Furosemide	SS				
			Gaviscon	SS				
			Lactulose	SS			3.35 g/5 ml	
			Lansoprazole	SS				
			Metoclopramide Hydrochloride	SS				
			Nitrolingual	SS		RESPIRATORY (INHALATION)		
			Nozinan	SS				
			Oxycodone Hydrochloride	SS				

			Oxycodone Hydrochloride	SS		ORAL 10mg/ml
			Oxycodone Hydrochloride	SS		ORAL 5mg/5ml
			Oxygen	SS		RESPIRATORY (INHALATION)
			Spironolactone	SS		
			Symbicort	SS		RESPIRATORY (INHALATION) 200/6 mcg/inhalation
			Temazepam	SS		

Date:05/05/05ISR Number: 4655386-XReport Type:Expedited (15-DaCompany Report #USA-2004-0018134
Age:26 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Accidental Death	Consumer	Oxycontin					
	Anoxic Encephalopathy	Health	Tablets(Oxycodone					
	Blood Sodium Increased	Professional	Hdyrochloride) Cr					
	Depressed Level Of	Other	Tablet	PS			MG	
	Consciousness		Percocet (Oxycocone					
	Polysubstance Abuse		Hydrochloride,					
			Paracetamol)	SS				
			Fentanyl (Fentanyl)	SS				
			Metoclopramide					

			(Metoclopramide)	SS		
			Papaverine (Papaverine)	SS		
			Lorazepam (Lorazepam)	SS		
			Fluconazole (Fluconazole)	SS		

Date:05/09/05ISR Number: 4656163-6Report Type:Expedited (15-DaCompany Report #FR-ROCHE-403724
Age:51 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Acute Myeloid Leukaemia		Kytril	PS	Roche			
INTRAVENOUS								93 DAY
Initial or Prolonged	Bone Marrow Depression		Cardioxane	SS				
INTRAVENOUS								102 DAY
			Endoxan	SS				
UNKNOWN								102 DAY
			Primperan	SS				
UNKNOWN								102 DAY
			Methylprednisolone	SS				
UNKNOWN								102 DAY
			4'-Epiadriamycin	SS				
UNKNOWN								

Date:05/10/05ISR Number: 4659397-XReport Type:Expedited (15-DaCompany Report #HQWYE600531MAR05
Age:57 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Angioneurotic Oedema	Health	Pantoloc					
Hospitalization -	Diabetic Nephropathy	Professional	(Pantoprazole,					
Initial or Prolonged		Other	Injection)	PS				
INTRAVENOUS							40 MG	1X PER
Other								1 DAY
			Plasil (Metoclopramide Hydrochloride)	SS				
INTRAVENOUS							10 MG	2X PER
1 DAY								3 DAY
			Insulatard (Insulin					

Human Injection, Isophane)	C
Xanor (Alprazolam)	C
Topamax (Topiramate)	C
Norvasc (Amlodipine Besilate)	C
Motilium (Domperidone)	C
Duspatalin (Mebeverine Hydrochloride)	C

Date:05/11/05ISR Number: 4659024-1Report Type:Expedited (15-DaCompany Report #2005-UK-00676UK
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Lung Neoplasm Malignant		Salbutamol	PS	Glaxosmithkline	RESPIRATORY (INHALATION)	100MCG See dosage text	
			Beclomethasone	SS	Glaxosmithkline		50MCG Twice per day	
			Aspirin	SS	Glaxosmithkline	UNKNOWN	75MG Unknown	
			Combivent	SS		RESPIRATORY (INHALATION)		
			Spiriva	SS		RESPIRATORY (INHALATION)	18MCG Unknown	
			Atorvastatin	SS		UNKNOWN	10MG per day	

		Frumil	SS	
UNKNOWN				
		Dexamethasone	SS	
UNKNOWN	2MG Unknown			
		Diltiazem	SS	Glaxosmithkline
UNKNOWN	60MG Per day			
		Dosulepin	SS	
UNKNOWN	75MG At night			
		Furosemide	SS	Glaxosmithkline
UNKNOWN				
		Gaviscon	SS	Glaxosmithkline
UNKNOWN	10ML Four			
times per day				
		Lactulose	SS	
UNKNOWN				
		Lansoprazole	SS	
UNKNOWN	30MG Per day			
		Metoclopramide	SS	Glaxosmithkline
UNKNOWN	10MG Three			
times per day				
		Nitrolingual	SS	Glaxosmithkline
UNKNOWN	400MG Unknown			
		Nozinan	SS	
UNKNOWN	25MG Four			
times per day				
		Oxycodone	SS	
UNKNOWN	20MG Twice			
per day				
		Oxygen	SS	
		Spironolactone	SS	
UNKNOWN	50MG Unknown			
		Symbicort	SS	
RESPIRATORY				
(INHALATION)	2PUFF Twice			
per day				
		Temazepam	SS	
UNKNOWN	10MG See			
dosage text				

Date:05/11/05ISR Number: 4659510-4Report Type:Expedited (15-DaCompany Report #GB-MERCK-0505GBR00060
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Lung Neoplasm Malignant		Decadron Tablets	PS	Merck & Co., Inc	UNKNOWN		
			Albuterol Sulfate And Ipratropium Bromide	SS		RESPIRATORY	(INHALATION)	
			Tiotropium Bromide	SS		RESPIRATORY	(INHALATION)	
			Albuterol	SS		RESPIRATORY	(INHALATION)	
			Aspirin	SS		UNKNOWN		
			Atorvastatin Calcium	SS		UNKNOWN		
			Beclomethasone Dipropionate	SS		RESPIRATORY	(INHALATION)	
			Furosemide	SS		UNKNOWN		
			Diltiazem Hydrochloride	SS		UNKNOWN		
			Dothiepin Hydrochloride	SS		UNKNOWN		
			Aluminum Hydroxide And Magnesium Trisilicate	SS		UNKNOWN		
			Lactulose	SS		UNKNOWN		
			Lansoprazole	SS		UNKNOWN		
			Metoclopramide	SS		UNKNOWN		
			Nitroglycerin	SS		UNKNOWN		
			Levomepromazine	SS		UNKNOWN		

UNKNOWN

RESPIRATORY

(INHALATION)

UNKNOWN

Oxycodone	SS
Oxygen	SS
Spironolactone	SS
Budesonide And	

				Formoterol Fumarate	SS		
RESPIRATORY							
(INHALATION)							
				Temazepam	SS		
UNKNOWN							
				Amiloride Hydrochloride And Furosemide	SS		
UNKNOWN							

Date:05/11/05ISR Number: 4661466-5Report Type:Direct Company Report #CTU 248271
Age:50 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Anaphylactic Reaction		Metoclopramide 10mg Tab	PS				

Date:05/12/05ISR Number: 4660394-9Report Type:Expedited (15-DaCompany Report #FR-SANOFI-SYNTHELABO-A02200501200
Age:15 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Neuropathy Peripheral		Stilnox	PS		ORAL		
	Oedema Peripheral		Primperan	SS				
UNKNOWN							UNK	
	Paraesthesia		Flagyl	SS				
INTRAVENOUS								
			Vfend	SS		ORAL		
			Cancidas	SS				
INTRAVENOUS								
			Bactrim	SS		ORAL		
			Xanax	SS		ORAL		
0.75 mg								
			Levocarnil	SS				
UNKNOWN							UNK	
			Zestril	SS		ORAL		
UNK								
			Motilium	SS		ORAL		
UNK								

			Lacteol	SS		ORAL
UNK						
			Mopral	SS		
UNKNOWN	UNK					
			Spasfon	SS		
UNKNOWN	UNK					
			Vitamines B1-B6	SS		
UNKNOWN	UNK					
			Vitamine K	SS		
UNKNOWN	UNK					
			Cernevit	SS		
INTRAVENOUS	UNK					
			Tracutil	SS		
INTRAVENOUS	UNK					
			Dipeptiven	SS		
INTRAVENOUS	UNK					
			Elvorine	SS		
INTRAVENOUS	UNK					

Date:05/12/05ISR Number: 4660405-0Report Type:Expedited (15-DaCompany Report #200514051GDDC
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Lung Neoplasm Malignant		Frumil	PS	Aventis Pharmaceuticals Inc.	
Other	Sudden Death		Furosemide	SS	Aventis Pharmaceuticals Inc.	
			Combivent	SS		
RESPIRATORY						
(INHALATION)						
			Tiotropium Bromide "Spiriva"	SS		
RESPIRATORY						
(INHALATION)						
			Salbutamol	SS		
RESPIRATORY						
(INHALATION)	dose: 100					
MCG, BID						
			Aspirin	SS		
			Atorvastatin	SS		
			Beclomethasone	SS		
RESPIRATORY						

(INHALATION) dose: 50 MCG,

2 BID

Dexamethasone	SS
Diltiazem	SS
Dosulepin	SS
Gaviscon	SS
Lactulose	SS

dose: 3.35 G/

5 ML

Lansoprazole	SS
Metoclopramide	SS
Nitrolingual	SS
Nozinan	SS
Oxycodone	SS
Oxygen	SS

RESPIRATORY

(INHALATION)

Spironolactone	SS
Symbicort	SS

RESPIRATORY

(INHALATION) dose: 200/6

UG, 1-2 PUFFS

Temazepam	SS

dose: 10 MG,

1-2

Date:05/12/05ISR Number: 4661350-7Report Type:Expedited (15-DaCompany Report #05-05-0769
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Lung Neoplasm Malignant	Foreign	Albuterol Sulfate					
Other		Other	Unknown	PS				

RESPIRATORY

(INHALATION) 100MCG, BD

INHALATION

Beclomethasone	

		Dipropionate	SS
RESPIRATORY			
(INHALATION)	50MCG, 2BD		
INHALATION			
RESPIRATORY			
(INHALATION)	18MCG		
INHALATION			
75MG		Aspirin	SS
10MG		Atorvastatin	SS
RESPIRATORY			
(INHALATION)	QDS		
INHALATION			
		Frumil	SS
		Dexamethasone	SS
2MG			
60MG, 1BD		Diltiazem	SS
75MG, 1NOCTE		Dosulepin	SS
80MG		Furosemide	SS
10ML, QDS		Gaviscon	SS
3.35G/5ML		Lactulose	SS
30MG, OD		Lansoprazole	SS
10MG TDS		Metoclopramide	SS
400MG		Nitrolingual	SS
25MG QDS		Nozinan	SS
20MG BD		Oxycodone	SS
RESPIRATORY			
(INHALATION)	INHALATION		
50MG		Spironolactone	SS
200/6MCG		Symbicort	SS

INHALATION

Temazepam SS

10MG, 1-2NOCT

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/12/05ISR Number: 4662054-7Report Type:Direct Company Report #CTU 248402
Age:51 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Asthenia Extrapyramidal Disorder		Metoclopramide 10mg	PS			10MG	INJECTION

Date:05/13/05ISR Number: 4662995-0Report Type:Expedited (15-DaCompany Report #THQ2005A00413
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Lung Neoplasm Malignant	Health Professional Other	Zoton Capsules (Lansoprazole) (Capsules)	PS		ORAL	30 MG (30 MG, 1 IN 1 D)	
			Combivent Metered Aerosol Inhaler (Combivent) (Inhalant)	SS			RESPIRATORY (INHALATION)	4 IN 1 D
			Spiriva (Tiotropium Bromide)(Inhalant)	SS			RESPIRATORY (INHALATION)	18 MCG
			Salbutamol (Inhalant)	SS			100 MCG, TWICE DAILY	WHEN REQUIRED
			Aspirin (Acetylsalicylic Acid)	SS			75 MG	

10 MG			
RESPIRATORY (INHALATION)	100 MCG (50 MCG, 2 IN 1 D)		
2 MG			
120 MG (60 MG, 2 IN 1 D)			
75 MG, ONCE EVERY EVENING			
80 MG			
40 ML (10 ML, 4 IN 1 D)			
3.35 G/5 ML			
30 MG (10 MG, 3 IN 1 D)			
400 MG			
100 MG (25 MG, 4 IN 1 D)			
10 MG, 1-2 EVERY EVENING			
RESPIRATORY (INHALATION)	200/6 UG 1-2		

Atorvastatin	SS	
Beclometasone (Inhalant)	SS	
Prumil	SS	
Dexamethasone	SS	
Diltiazem	SS	
Dosulepin	SS	
Furosemide	SS	
Gaviscon	SS	
Lactulose	SS	
Metoclopramide	SS	
Nitrolingual (Glyceryl Trinitrate)	SS	
Nozinan (Levomepromazine)	SS	
Temazepam	SS	
Symbicort (Symbicort Turbuhaler "Draco") (Inhalant)	SS	Draco

PUFFS TWICE

DAILY			Spironolactone	SS			
50 MG			Oxycodone	SS			
40 MG (20 MG, 2 IN 1 D)			Oxygen (Inhalant)	C			

Date:05/16/05ISR Number: 4663166-4Report Type:Expedited (15-DaCompany Report #002#1#2004-00292
Age:62 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other Required Intervention to Prevent Permanent Impairment/Damage	Bruxism Dystonia Oral Soft Tissue Disorder Tardive Dyskinesia Trismus	Health Professional	Hyoscyamine-Sulfate-Extended-Release-0.375mg-Tablets (Hyoscyamine Sulfate)	PS		ORAL	.375 MG, 1 IN 1 D, ORAL	
			Sertraline	SS		ORAL	100 MG, ORAL	
			Metoclopramide	SS		ORAL	ORAL	
			Esomeprazole	C				
			Atorvastatin-Calcium	C				
			Famotidine	C				
			Acetylsalicylic-Acid	C				
			Docusate	C				
			Multivitamin	C				

Date:05/17/05ISR Number: 4663529-7Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0376424A
Age:69 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abnormal Dreams Cognitive Disorder		Zophren	PS	Glaxosmithkline	ORAL	8MG per day	12 DAY
			Zovirax	SS	Glaxosmithkline	INTRAVENOUS	2250MG per	

		Confusional State					
day	6 DAY						
		Disorientation	Polaramin	SS			
INTRAVENOUS	15MG per day 12 DAY						
		Hallucination, Visual	Mopral	SS	Glaxosmithkline	ORAL	
20MG Per day	14 DAY						
		Hypersomnia	Primperan	SS	Glaxosmithkline		
INTRAVENOUS	60MG per day						
		Incoherent	Neurontin	SS		ORAL	
4 DAY							
		Metabolic Encephalopathy	Fraxodi	C	Glaxosmithkline		
SUBCUTANEOUS							
		Psychomotor Retardation	Fungizone	C			
UNKNOWN							
		Retrograde Amnesia	Chemotherapy	C			
UNKNOWN							

Date:05/17/05ISR Number: 4664856-XReport Type:Expedited (15-DaCompany Report #2005-127999-NL
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Lung Neoplasm Malignant		Dexamethasone	PS			2 MG	
			Ipratropim Bromide W/Salbutamol	SS				
RESPIRATORY								
(INHALATION)	RESPIRATORY							
(INHALATION)								
			Tiotropium Bromide	SS				
RESPIRATORY								
(INHALATION)	18 UG							
RESPIRATORY								
(INHALATION)								
			Salbutamol	SS				
RESPIRATORY								
(INHALATION)	200 UG BID							
RESPIRATORY								
(INHALATION)								
			Acetysalicylic Acid	SS			75 MG	
			Atorvastatin	SS				

		Beclomethasone Dipropionate	SS
100 UG BID			
RESPIRATORY			
(INHALATION)			
		Frumil	SS
		Diltiazem	SS
60 MG QD			
75 MG QD		Dosulepin	SS
80 MG		Furosemide	SS
10 ML QID		Gaviscon	SS
670 MG/ML		Lactulose	SS
30 MG QD		Lansoprazole	SS
10 MG TID		Metoclopramide	SS
400 MG		Glyceryl Trinitrate	SS
25 MG QID		Levomepromazine	SS
20 MG BID		Oxycodone	SS
RESPIRATORY		Oxygen	SS
(INHALATION)	DF		
RESPIRATORY			
(INHALATION)			
		Spironolactone	SS
50 MG			
RESPIRATORY		Symbicort	SS
(INHALATION)	2 PUFF BID		
RESPIRATORY			
(INHALATION)			

				Temazepam	SS		
10 MG BID							

Date:05/18/05ISR Number: 4664596-7Report Type:Expedited (15-DaCompany Report #234733
Age:60 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Blister		Dilatrend	PS	Glaxosmithkline	ORAL	6.25MG Twice	
	Cardiac Failure						per day	
	Hypertension		Unat	SS		ORAL	40MG Per day	
	Lip Erosion		Euglucon	SS		ORAL	1U Per day	
	Nausea		Heparin Calcium	SS				
SUBCUTANEOUS	Pain						7500IU Twice per day	8 DAY
	Pneumonia		Digimerck Minor	SS		ORAL	1U Per day	
	Rash Maculo-Papular		Paspertin	SS	Glaxosmithkline	ORAL	20DROP Three times per day	
	Septic Shock							
SUBCUTANEOUS	Shock		Fragmin Forte	SS			1U Per day	
	Toxic Epidermal Necrolysis		Xanef	SS		ORAL	5MG Twice per day	
			Isoket Retard	SS		ORAL	60MG Per day	
INTRAVENOUS			Benzylpenicillin Sodium	SS	Glaxosmithkline		10IU6 Twice per day	6 DAY
			Vancomycin	SS				
INTRAVENOUS			Lasix	SS	Glaxosmithkline	ORAL	6 DAY 1U Per day	
			Aquaphor	SS		ORAL	40MG Per day	11 DAY
			Novalgin	SS		ORAL	20DROP per day	1 DAY
			Pres	SS		ORAL	5MG Twice per	

day 7 DAY

100MG Per day

Ass	SS	Glaxosmithkline	ORAL
Lopirin Cor	C	Glaxosmithkline	
Eryfer	C	Glaxosmithkline	
Novodigal	C		
Antra	C	Glaxosmithkline	
Irenat	C		
Depot Insulin	C		

					Carbimazol	C		
					Zocor	C		
16	DAY							
					Dopamine Hydrochloride	C		
1	DAY							
					Paspertin	C	Glaxosmithkline	
19	DAY							
					Tutofusin	C		
7	DAY							
					Kalium Duriles	C		
7	DAY							
					Kaliumchloride	C	Glaxosmithkline	
					Kalinor	C	Glaxosmithkline	
					Sterofundin	C		
INTRAVENOUS		1	DAY					
					Glucose	C		
1	DAY							
					Tavegil	C		
1	DAY							
					Solu-Decortin	C		
1	DAY							
					Tagamet	C	Glaxosmithkline	
INTRAVENOUS		1	DAY					
					Paracetamol	C	Glaxosmithkline	
					Sortis	C		
					Zienam	C		
					Dexpanthenol	C		
1	DAY							

Date:05/19/05ISR Number: 4669170-4Report Type:Expedited (15-DaCompany Report #11049
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Lung Neoplasm Malignant		Dexamethasone	PS				
			Diltiazem	SS				
60 MG BID;								
			Furosemide	SS				
80 MG								
			Metoclopramide	SS				
10 MG								
			Tiotropium Bromide	SS				
18 MICROGRAM								

FREQ UNK		
	Salbutamol/Ipratropium	SS
	Atorvastatin	SS
	Beclomethasone	SS
50 MICROGRAM		
BID		
	Dosulepin	SS
75 MG		
	Magnesium Trisilicate	SS
10 ML		
	Lactulose	SS
3.35 G FREQ		
UNK		
	Lansoprazole	SS
30 MG		
	Glyceryl Trinitrate	SS
400 MG FREQ		
UNK		
	Methotrimeprazine	SS
20 MG BID		
	Oxycodone	SS
	Oxygen	SS
	Spironolactone	SS
50 MG FREQ		
UNK		
	Budesonide/Eformoterol	SS
200 MICROGRAM		
BID		
	Temazepam	SS
10MG NOCTE		
	Aspirin	SS
75 MG FREQ		
UNK		
	Salbutamol	SS
100 MICROGRAM		
PRN		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/20/05ISR Number: 4667761-8Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0559031B
Age: Gender: I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Drug Exposure During		Zofran	PS	Glaxosmithkline			4 DAY
	Pregnancy		Reglan	SS	Glaxosmithkline			4 DAY
	Drug Interaction							

Date:05/20/05ISR Number: 4669743-9Report Type:Expedited (15-DaCompany Report #GXKR2005GB01031
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Lung Neoplasm Malignant	Foreign Health Professional Other	Acetylsalicylic Acid (Ngx) (Acetylsalicylic Acid	PS			75 MG, QD	
			Beclomethasone (Ngx)(Bleclomethasone) Unknown	SS			RESPIRATORY (INHALATION)	50 UG; 2 BID,
			Lactulose Concentration (Ngx)(Lactulose Concentrate) Unknown	SS			RESPIRATORY	
			Temazepam (Ngx)(Temazepam) Unknown	SS			10 MG, 1-2	NOCTE
			Furosemide (Ngx)(Metoclopramide)	SS				
			Metoclopramide (Ngx)(Metoclopramide					

			) Unknown	SS
10 MG, TID				
			Diltiazem (Ngx)(Diltiazem) Unkown	SS
60 MG, BID				
			Combivent /Gfr(Ipratropium Bromide, Salbutamol Sulfate)Inhaler	SS
RESPIRATORY				
(INHALATION)	QID,			
RESPIRATORY				
			Spiriva (Tiotropium Bromide)	SS
RESPIRATORY				
(INHALATION)	18 MCG,			
RESPIRATORY				
			Salbutamol (Salbutamol)	SS
RESPIRATORY				
(INHALATION)	100 UG, BID			
PRN,				
RESPIRATORY				
			Atorvastatin (Atorvastatin)	SS
10 MG				
			Frumil (Amiloride Hydrochloride, Furosemide)	SS
			Dexamethasone (Dexamethasone)	SS
2 MG				
			Dosulepin	

(Dosulepin) SS

75 MG, 1

NOCTE

Gaviscon /Gfr/(Sodium Alginate, Sodium Bicarbonate0 SS

10 ML, QID

Lansoprazole (Lansoprazole) SS

30 MG, QD

Nitrolingual (Glyceryl Trinitrate SS

400 MG

Nozinan / Net (Levomepromazine) SS

25 MG, QID

Oxycodone (Oxycodone) SS

20 MG, BID

Oxygen (Oxygen) SS

RESPIRATORY

(INHALATION) RESPIRATORY

Spironolactone (Spironolactone) SS

50 MG

Symbicort Turbuhaler (Budesonide, Formoterol Fumarate) SS

RESPIRATORY

(INHALATION) 200/6 MCG 1-

2 PUFFS, BID,

RESPIRATORY

Date:05/20/05ISR Number: 4672366-9Report Type:Expedited (15-DaCompany Report #2005-05-0672
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Lung Neoplasm Malignant	Foreign Health	Salbutamol Sulphate "Like Proventil Hfa"					

		Professional	Oral Aerosol	PS	
RESPIRATORY					
		Other			
(INHALATION)	100 MCG BID				
ORAL AER INH					
			Beclomethasone Dipropionate Oral Aerosol	SS	
RESPIRATORY					
(INHALATION)	100 MCG BID				
ORAL AER INH					
			Combivent Oral Aerosol	SS	
RESPIRATORY					
(INHALATION)	4 PUFFS QID				
ORAL AER INH					
			Tiotropium Bromide	SS	
RESPIRATORY					
(INHALATION)	18 MCG ORAL				
AER INH					
			Aspirine	SS	ORAL
75 MG ORAL					
			Atorvastatin Calcium Tablets	SS	ORAL
10 MG ORAL					
			Frumil	SS	
			Dexamethasone	SS	
2 MG					
			Diltiazem Tablets	SS	ORAL
60 MG BID					
ORAL					
			Dosulepin	SS	
75 MG QD					
			Furosemide Tablets	SS	ORAL
80 MG ORAL					
			Gaviscon	SS	
10 ML QID					
			Lactulose	SS	
			Lansoprazole	SS	
30 MG QD					
			Metoclopramide	SS	
10 MG TID					
			Nitrolingual	SS	
400 MG					

Nozinan SS

25 MG QID

			Oxycodone	SS		
20 MG BID						
			Oxygen	SS		
RESPIRATORY						
(INHALATION)	INHALATION					
			Spironolactone Tablets	SS		ORAL
50 MG ORAL						
			Symbicort Oral Aerosol (Budesonide/Formoterol)	SS		
RESPIRATORY						
(INHALATION)	1-2 PUFFS BID					
ORAL AER INH						
			Temazepam Tablets	SS		ORAL
1-2 PM QD						
ORAL						

Date:05/20/05ISR Number: 4672375-XReport Type:Expedited (15-DaCompany Report #10602
Age:21 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Local Swelling	Health Professional	Vincristine	PS		INTRAVENOUS	25 MG	Q21DAYS, IV
			Metoclopramide	SS				
			Rituximab	C				
			Doxorubicin	C				
			Prednisolone	C				
			Chlorphenamine	C				
			Ondansetron	C				

Date:05/23/05ISR Number: 4668988-1Report Type:Expedited (15-DaCompany Report #CH-GLAXOSMITHKLINE-B0381643A
Age:65 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Alanine Aminotransferase Increased		Avandia	PS	Glaxosmithkline	ORAL	4MG	Unknown
	Aspartate Aminotransferase Increased		Fraxiparine	SS	Glaxosmithkline	SUBCUTANEOUS	1U per day	
	Blood Alkaline Phosphatase Increased		Furosemide	SS	Glaxosmithkline	ORAL	40MG	See dosage text
	Blood Bilirubin Increased		Pantoprazole Sodium	SS		ORAL	40MG	Per day
	C-Reactive Protein Increased		Paracetamol	SS	Glaxosmithkline	ORAL	2TAB	Four times per day
	Cholestasis Gamma-Glutamyltransferase Increased		Ciprofloxacin Hydrochloride	SS	Glaxosmithkline	ORAL	1TAB	Per day
	Jaundice		Metronidazole	SS	Glaxosmithkline	ORAL	500MG	Per day
			Pipamperone Hydrochloride	SS		ORAL	.5U	Per day
			Ciprofloxacin	SS		ORAL	500MG	Per day
			Levocetirizine Hydrochloride	SS		ORAL	1U	Per day
			Dimetindene Maleate	SS		ORAL	4MG	per day
			Metoclopramide Hydrochloride	SS	Glaxosmithkline	ORAL	15DROP	Three times per day
			Tramadol Hydrochloride	SS		ORAL	20DROP	Per day
			Levothyroxine Sodium	C	Glaxosmithkline	ORAL	.075MG	Per day
			Magnesium Aspartate Hydrochloride	C		ORAL	1.23G	Three times per day
			Torasemide	C		ORAL	.5TAB	Per day

			Lormetazepam	C		ORAL	2U Per day
			Metformin Hydrochloride	C		ORAL	850MG Per day

Date:05/23/05ISR Number: 4673074-0Report Type:Expedited (15-DaCompany Report #2005-05-0270
Age:43 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dehydration	Foreign	Peg-Intron Alfa-2b Injectable Powder	PS		SUBCUTANEOUS	100 UG Q WK	
Other	Diarrhoea	Health						
	Disease Recurrence	Professional				SUBCUTANEOUS		
	Drug Dependence		Ribavirin Capsules	SS		ORAL	1000 MG ORAL	
	Drug Screen Positive		Maxeran	SS				
	Faeces Discoloured		Fluticasone Propionate	C				
	Nausea		Gabapentin	C				
	Pancytopenia		Ibuprofen	C				
	Vomiting		Salbutamol (Albuterol)	C				
			Sodium Fusidate/Hydrocortisone Butyrate	C				
			Trazodone	C				

Date:05/23/05ISR Number: 4673163-0Report Type:Direct Company Report #CTU 249231
Age:58 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Aggression		Reglan	PS				
Hospitalization - Initial or Prolonged	Aphonia							
	Constipation							
Disability	Homicidal Ideation							
Congenital Anomaly	Mental Disorder							
Other	Paralysis							
Required Intervention to	Parkinsonism							
	Starvation							

Prevent Permanent Impairment/Damage	Suicidal Ideation Suicide Attempt					

Date:05/24/05ISR Number: 4672488-2Report Type:Expedited (15-DaCompany Report #200511244EU
Age:65 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Cholestasis Hepatitis Cholestatic Jaundice		Lasix	PS	Aventis Pharmaceuticals Inc.	ORAL		
			Flagyl "Aventis"	SS	Aventis Pharmaceuticals Inc.	ORAL		
			Zurcal	SS		ORAL		
			Dafalgan	SS				
			Ciproxin	SS		ORAL		
			Dipiperon	SS				
			Ciprofloxacin	SS		ORAL		
			Xyzal	SS		ORAL		
			Fenistil	SS		ORAL		
			Paspertin	SS		ORAL		
			Tramal Tropfen	SS		ORAL		
			Fraxiparin	SS				
SUBCUTANEOUS								
			Avandia	SS		ORAL		

Euthyrox	C		ORAL
Magnesiocard	C		ORAL
Torem	C		ORAL
Noctamid	C		ORAL
Glucophage	C		ORAL

Date:05/24/05ISR Number: 4674528-3Report Type:Expedited (15-DaCompany Report #20050500125
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Death Neonatal	Consumer	Reglan			
Life-Threatening	Drug Exposure During Pregnancy		(Metoclopramide) Baxter	PS	Baxter	
	Foetal Heart Rate Abnormal		Zofran (Ondansetron)	SS		
	Stillbirth					

Date:05/25/05ISR Number: 4675854-4Report Type:Expedited (15-DaCompany Report #GBR-2005-0001686
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Lung Neoplasm Malignant	Foreign Health Professional Other	Oxycodone Hydrochloride(Oxycodone Hydrochloride)			
29 MG, BID;			Unknown	PS		
60 MIG, BID;			Diltiazem Hcl (Diltiazem Hydrochloride)	SS		
10 MG, TID;			Metoclopramide (Metoclopramide, Metoclopramide)	SS		
RESPIRATORY (INHALATION) UNK, QID,			Combivent (Ipratropium Bromide, Salbutamol Sulfate)	SS		

INHALATION			
		Spiriva (Tiotropium Bromide)	SS
RESPIRATORY			
(INHALATION)	18 MCG, UNK,		
INHALATION			
		Salbutamol (Salbutamol)	SS
RESPIRATORY			
(INHALATION)	100 MCG, BIG		
PRN,			
INHALATION			
		Acetylsalicylic Acid (Acetylsalicylic Acid)	SS
75 MG, DAILY,			
UNKNOWN			
		Atorvastatin (Atorvastatin)	SS
10 MG, DAILY,			
		Beclometasone (Beclometasone)	SS
RESPIRATORY			
(INHALATION)	50 MCG, BID;		
INHALATION			
		Frumil (Amiloride Hydrochloride, Furosemide)	SS
UNK			

		Dexamethasone (Dexamethasone)	SS
2 MG, DAILY;			
		Dosulepin (Dosulepin)	SS
75 MG, NOCTE;			
		Furosemide (Furosemide)	SS
80 MG, DAILY,			
		Gaviscon (Sodium Alginate, Sodium Bicarbonate)	SS
10 ML, QID,			
		Lactulose (Lactulose)	SS
3.35 G/5 ML,			
DAILY,			
		Lansoprazole (Lansoprazole)	SS
30 MG, DAILY			
		Nitrolingual (Glyceryl Trinitrate)	SS
400 MG,			
		Nozinan (Levomepromazine)	SS
25 MG, QID;			
		Oxygen (Oxygen)	SS
		Spironolactone (Spironolactone)	SS
50 MG,			
		Symbicort (Formoterol)	SS
RESPIRATORY			
(INHALATION)	1-2 PUFF'S		
BID,			
INHALATION			
		Temazepam (Temazepam)	SS
10 MG 1-2			
NOCTE,			

Date:05/26/05ISR Number: 4675222-5Report Type:Expedited (15-DaCompany Report #2005-05-0001
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Lung Neoplasm Malignant	Foreign	Beclomethasone Dipropionate	PS				
Other		Health Professional						
RESPIRATORY								
(INHALATION)		Other					50MCG, 2BD	
INHALATION								
			Albuterol Sulfate	SS				
RESPIRATORY								
(INHALATION)							100MCG, BD	
INHALATION								
			Spiriva	SS				
RESPIRATORY								
(INHALATION)							18MCG	
INHALATION								
			Aspirin	SS			75MCG	
			Atorvastatin	SS			10MG	
			Combivent	SS				
RESPIRATORY								
(INHALATION)							QDS	
INHALATION								
			Frumil	SS				
			Dexamethasone	SS			2MG	
			Diltiazem	SS			60MG, 1BD	
			Dosulepin	SS			75MG, 1NOCTE	
			Furosemide	SS			80MG	
			Gaviscon	SS			10MG, QDS	
			Lactulose	SS			3.35G/5ML	
			Lansoprazole	SS			30MG, OD	
			Metoclopramide	SS			10MG TDS	

Nitrolingual SS
400MG

					Nozinan	SS		
100MG								
					Oxycodone	SS		
20MG BD								
					Oxygen	SS		
RESPIRATORY								
(INHALATION)	INHALATION							
					Spironolactone	SS		
50MG								
					Symbicort	SS		
RESPIRATORY								
(INHALATION)	1-2 PUFFS							
BID								
INHALATION								
					Temazepam	SS		
10MG, 1-2PM								

Date:05/27/05ISR Number: 4676506-7Report Type:Expedited (15-DaCompany Report #CH-JNJFOC-20050503523
Age:65 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Cholestasis		Tramal	PS				
OROPHARINGEAL							7	DAY
Initial or Prolonged	Jaundice		Dipiperon	SS				
OROPHARINGEAL							8	DAY
			Lasix	SS				
OROPHARINGEAL								
			Zurcal	SS				
OROPHARINGEAL								
			Dafalgan	SS				
OROPHARINGEAL								
			Ciproxin	SS				
OROPHARINGEAL								
			Flagyl	SS				
OROPHARINGEAL								
			Ciprin	SS				
OROPHARINGEAL	500							
millicuries.								

			Xyzal	SS		
OROPHARINGEAL						
			Fenistil	SS		
OROPHARINGEAL						
			Paspertin	SS		
OROPHARINGEAL						
			Fraxiparine	SS		
SUBCUTANEOUS						
			Avandia	SS		
OROPHARINGEAL						
			Euthyrox	C		
OROPHARINGEAL						
			Magnesiocard Citron	C		
OROPHARINGEAL						
			Torem	C		
OROPHARINGEAL						
			Noctamid	C		
OROPHARINGEAL						
			Glucophage	C		
OROPHARINGEAL						

Date:05/27/05ISR Number: 4677398-2Report Type:Direct Company Report #USP 57175
Age:58 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Dispensing Error		Mercaptopurine	PS	Ivax Pharmacy			
	Medication Error		Metoclopramide	SS			50MG TID	30
	Wrong Drug Administered							MIN AC

Date:05/27/05ISR Number: 4677849-3Report Type:Direct Company Report #CTU 249871
Age:79 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Asthenia		Metoclopramide 10 Mg					
Hospitalization -	Dysstasia		1000s Mfg Pliva	PS	Pliva		3X DAILY	
Initial or Prolonged	Masked Facies						BEFORE MEALS	
Disability	Muscle Spasms							
	Parkinson'S Disease							
	Peripheral Coldness							
	Tremor							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/31/05ISR Number: 4679677-1Report Type:Expedited (15-DaCompany Report #ACC000043
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardiac Flutter	Consumer	Reglan	PS		INTRAVENOUS	INTRAVENOUS	
	Drug Exposure During		Zofran	SS		INTRAVENOUS	INTRAVENOUS	
	Pregnancy							
	Intra-Uterine Death							
	Neonatal Disorder							

Date:05/31/05ISR Number: 4679982-9Report Type:Expedited (15-DaCompany Report #B0381643A
Age:65 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Alanine Aminotransferase Increased	Foreign	Nadroparine Calcium (Nadroparine Calcium)	PS		SUBCUTANEOUS	SUBCUTANEOUS	
	Aminotransferase Increased		Avandia Tablet (Rosiglitazone					
	Blood Alkaline Phosphatase Increased		Maleate0	SS		ORAL	4 MG/ORAL	
	C-Reactive Protein Increased		Frosemide Tablet (Furosemide)	SS		ORAL	SEE IMAGE	
	Cholestasis		Pantoprazole Tablet (Patoprazole)	SS		ORAL	40 MG /PER DAY / ORAL	
	Gamma-Glutamyltransferase Increased		Paracetamol Tablet (Acetaminophen)	SS		ORAL	2 TABLET / FOUR TIMES PER DAY/ ORAL	
			Ciprofloxacin Hcl Tablet (Ciprofloxacin Hcl)	SS		ORAL	1 TABLET /	

PER DAY / ORAL			
	Metronidazole Tablet (Metronidazole)	SS	ORAL
500 MG / PER DAY / ORAL			
	Pipamperone (Pipamperone)	SS	ORAL
5 UNKNOW/ PER DAY / ORAL			
	Ciprofloxacin Tablet Iciprofloxacin)	SS	ORAL
500 MG/ PER DAY / ORAL			
	Levocetirizine Hcl (Lievocetirizine Hcl)	SS	ORAL
1 UNKNOWN / PER DAY / ORAL			
	Dimethindene Maleate (Dimethindene Maleate)	SS	ORAL
ORAL			
	Metoclopramide Hcl Drop (S) (Metoclopramide Hcl)	SS	ORAL
15 DROPS (S) THREE TIMES PER DAY/ ORAL			
	Tramadol Hydrochloride Drop(S) (Tramadol Hydrochloride)	SS	ORAL
20 DROP(S) /			

PER DAY /

ORAL

			Thyroxine Sodium	C		
			Magnesium Aspartate	C		
			Torasemide	C		
			Lormetazepam	C		
			Metformin Hydrochloride	C		

Date:06/02/05ISR Number: 4681546-8Report Type:Expedited (15-DaCompany Report #2005078279
Age:53 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abnormal Dreams Choking Drug Dose Omission Dyspnoea Gastrooesophageal Reflux Disease Headache Hyperhidrosis	Consumer	Bextra (Valdecoxib) Reglan (Metoclopramide) Tagamet Oral (Cimetidine) Daricet (Dextropropoxyphene Napsilate,Paracetamol)	PS SS C C			30 MG (10 MG 3 IN 1 D)	

Date:06/02/05ISR Number: 4681938-7Report Type:Expedited (15-DaCompany Report #2005078139
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Jaundice Cholestatic	Foreign Health Professional	Flagyl Tablet (Metronidazole)	PS		ORAL	500 MG (500 MG, DAILY INTERVAL: DAILY), ORAL	

			Ciprin			

	(Ciprofloxacin)	SS	ORAL
500 MG (500 MG, DAILY INTERVAL: DAILY), ORAL			
	Lasix (Furosemide)	SS	ORAL
20 MG (40 MG, DAILY INTERVAL: DAILY), ORAL			
	Pantoprazole Sodium (Pantoprazole Sodium)	SS	ORAL
40 MG (40 MG, DAILY INTERVAL: DAILY), ORAL			
	Dafalgan, Paracetamol (Paracetamol)	SS	ORAL
QID INTERVAL: DAILY, ORAL			
	Dipiperon (Pipamperone)	SS	ORAL
ORAL			
	Xyzal (Levocetirizine Dihydrochloride)	SS	ORAL
ORAL			
	Fenistil (Dimetindene Maleate)	SS	ORAL
ORAL			

			Metoclopramide (Metoclopramide)	SS			ORAL
ORAL							
			Tramal (Tramadol Hydrochloride)	SS			ORAL
ORAL							
			Fraxiparine (Heparin-Fraction, Calcium Salt)	SS			
SUBCUTANEOUS	SUBCUTANEOUS						
			Avandia 4 Mg (Rosiglitazone Maleate)	SS			ORAL
ORAL							
			Euthyrox (Levothyroxine Sodium)	C			
			Magnesiocard (Magnesium Aspartate Hydrochloride)	C			
			Torem (Torasemide)	C			
			Noctamid (Lormetazepam)	C			
			Glucophage (Metformin Hydrochloride)	C			

Date:06/02/05ISR Number: 4681954-5Report Type:Expedited (15-DaCompany Report #HQWYE879023MAY05
Age:65 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Cholestasis	Foreign	Zurcal (Pantoprazole, Tablet, Delayed					
Other	Hepatocellular Damage	Health Professional Other	Release)	PS		ORAL	40 MG 1X PER	1 DAY ORAL
			Avandia (Rosiglitazone Maleate,)	SS		ORAL	4 MG - "SOME	TIME (S) SOME

DF" ORAL

500 MG 1X PER

1 DAY ORAL 9 DAY

500 - "1DF 1

TIME (S) PER

DAY" ORAL 2 DAY

2 DOSAGE FORM

4X PER 1 DAY

ORAL 13 DAY

0.5 DOSAGE

FORM 1X PER 1

DAY ORAL 8 DAY

500 MG 1X PER

1 DAY ORAL 11 DAY

SUBCUTANEOUS 1 DOSAGE FORM

1X PER 1 DAY

SC

Ciprine (Ciprofloxacin,)	SS	ORAL
Ciproxin (Ciprofloxacin,)	SS	ORAL
Dafalgan (Paracetamol,)	SS	ORAL
Dipiperon (Pipamperone,)	SS	ORAL
Flagyl (Metronidazole,)	SS	ORAL
Fraxiparine (Heparin-Fraction, Calcium Salt,)	SS	

			Lasix (Furosemide,)	SS	ORAL
20 MG 1X PER					
1 DAY ORAL					
			Paspertin (Metoclopramide Hydrochloride,)	SS	ORAL
4 MG - 15 GTT					
- 3 TIMES PER					
DAY ORAL	8	DAY			
			Tramal (Tramadol Hydrochloride,)	SS	ORAL
100 MG - 20					
GTT 1 TIME					
PER DAY ORAL	7	DAY			
			Xyzal (Levocetirizine,)	SS	ORAL
1 DOSAGE FORM					
1X PER 1 DAY					
ORAL	11	DAY			
			Fenistil (Dimetindene Maleate)	C	
			Euthyrox (Levothyroxine Sodium)	C	
			Magnesiocard (Magnesium Aspartate Hydrochloride)	C	
			Torem (Torasemide)	C	
			Noctamid (Lormetazepam)	C	
			Glucophage (Metformin Hydrochloride)	C	

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dyspnoea		Reglan	PS				
	Throat Tightness		Monopril	SS				
			Atenolol	C				
			Hctz	C				
			Verapamil	C				
			Lipitor	C				
			Actos	C				
			Insulin	C				
			Asa	C				

Date:06/06/05ISR Number: 4685868-6Report Type:Direct Company Report #CTU 250417E
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Distension		Iressa	PS		ORAL	250 MG DAILY	
	Back Pain						PO	
	Diarrhoea		Protonix	SS		ORAL	40 MG BID PO	
	Febrile Neutropenia		Lopressor	SS		ORAL	50 MG BID PO	
	Flatulence		Reglan	SS		ORAL	10 MG TID PO	
	Osteomyelitis		Cisplatin	SS			INTRAVENOUS	38 MG DAILY
	Post Procedural Complication		5fu	SS			IV	
	Streptococcal Bacteraemia						INTRAVENOUS	1900 MG DAILY
							IV	

Date:06/06/05ISR Number: 4686384-8Report Type:Expedited (15-DaCompany Report #2005080728
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Anorexia	Foreign	Doxorubicin					
	Anuria	Consumer	Hydrochloride For					
	Asthenia		Injection					
	Burns Second Degree		(Doxorubicin					
	Chest Pain		Hydrochloride)	PS		INTRAVENOUS	(INTERVAL: 3	WEEKS),
	Chills							
	Chromaturia					INTRAVENOUS		
	Faeces Discoloured		Cyclophosphamide					
	Feeling Abnormal		(Cyclophosphamide)	SS		INTRAVENOUS	(INTERVAL: 3	WEEKS),
	Feeling Cold							
	Hyperhidrosis					INTRAVENOUS		
	Joint Stiffness		Dexamethasone					
	Local Swelling		(Dexamethasone)	SS		(INTERVAL: 3		WEEKS),
	Malaise							
	Movement Disorder		Metoclopramide					
	Nail Disorder		Hydrochloride					
	Pain		(Metoclopramide					
	Skin Disorder		Hydrochloride)	SS				
	Spinal Osteoarthritis		Catapres (Clonidine)	C				
	Swelling							
	Swelling Face							
	Tremor							

Date:06/08/05ISR Number: 4685209-4Report Type:Expedited (15-DaCompany Report #GB-BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.-2005-
UAge:77 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Small Cell Lung Cancer		Combivent					
	Stage Unspecified		(00015/0191)	PS	B.I. Pharmaceuticals,Inc.			

			/Ridgefield
RESPIRATORY			
(INHALATION)			
	Spiriva (14598/0062)	SS	B.I. Pharmaceuticals,Inc. /Ridgefield
RESPIRATORY			
(INHALATION)			
	Salbutamol	SS	
RESPIRATORY			
(INHALATION)			
	Aspirin	SS	
	Atorvastatin	SS	
	Beclometasone	SS	
RESPIRATORY			
(INHALATION)			
	Co-Amilofruse	SS	
	Dexamethasone	SS	
	Diltiazem Hydrochloride	SS	
	Dosulepin	SS	
	Furosemide	SS	
	Gaviscon	SS	
	Lactulose	SS	
3.35 g/5 ml			
	Lansoprazole	SS	
	Metoclopramide Hydrochloride	SS	
	Nitrolingual	SS	
RESPIRATORY			
(INHALATION)			
	Nozinan	SS	
	Oxycodone		

				Hydrochloride	SS		
				Oxycodone Hydrochloride	SS		ORAL 10mg/ml
				Oxycodone Hydrochloride	SS		ORAL 5mg/5ml
				Oxygen	SS		RESPIRATORY (INHALATION)
				Spironolactone	SS		
				Symbicort	SS		RESPIRATORY (INHALATION) 200/6 mcg/inhalation
				Temazepam	SS		

Date:06/08/05ISR Number: 4685652-3Report Type:Expedited (15-DaCompany Report #US-MERCK-0506USA00627
Age:54 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Eye Disorder		Emend	PS	Merck & Co., Inc	ORAL	1	DAY
	Feeling Abnormal		Emend	SS	Merck & Co., Inc	ORAL	1	DAY
	Visual Disturbance		Reglan	SS		UNKNOWN		
	Vomiting		Atacand	C		UNKNOWN		
			Decadron (Dexamethasone)	C		ORAL		
			Antineoplastic (Unspecified)	C		UNKNOWN		

Date:06/17/05ISR Number: 4694602-5Report Type:Expedited (15-DaCompany Report #HQWYE879023MAY05
Age:65 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Wall Abscess C-Reactive Protein Increased Cholestasis Impaired Healing Postoperative Abscess	Foreign Health Professional Other	Zurcal (Pantoprazole) Avandia (Rosiglitazone Maleate) Ciprine (Ciprofloxacin,) Ciproxin (Ciprofloxacin) Dafalgan (Paracetamol,) Dipiperon (Pipamperone,) Flagyl	PS SS SS SS SS SS		ORAL ORAL ORAL ORAL ORAL ORAL	40 MG 1X PER 1 DAY 4 MG - "SOME TIME (S) SOME DF" 500 MG 1X PER 1 DAY 500 - "1DF 1 TIME (S) PER DAY" 2 DOSAGE FORM 4X PER 1 DAY 0.5 DOSAGE FORM 1X PER 1 DAY	ORAL 24 DAY ORAL ORAL 9 DAY ORAL 2 DAY ORAL 13 DAY ORAL 8 DAY

			(Metronidazole,)	SS		ORAL
500 MG 1X PER						
1 DAY ORAL	11	DAY				
			Fraxiparine			
			(Heparin-Fraction, Calcium Salt,)	SS		
SUBCUTANEOUS	1	DOSAGE FORM				
1X PER 1 DAY						
SC						
			Lasix (Furosemide,)	SS		ORAL
20 MG 1X PER						
1 DAY ORAL						
			Paspertin (Metoclopramide Hydrochloride,)	SS		ORAL
4 MG - 15 GTT						
- 3 TIMES PER						
DAY ORAL	8	DAY				
			Tramal (Tramadol Hydrochloride,)	SS		ORAL
100 MG - 20						
GTT 1 TIME						
PER DAY ORAL	7	DAY				
			Xyzal (Levocetirizine,)	SS		ORAL
1 DOSAGE FORM						
1X PER 1 DAY						
ORAL	11	DAY				
			Fenistil (Dimetindene Maleate)	C		
			Euthrox (Levothyroxine Sodium)	C		
			Magnesiocard			

(Magnesium Aspartate Hydrochloride)	C	
Torem (Torasemide)	C	
Noctamid (Lormetazepam)	C	
Glucophage (Metformin Hydrochloride)	C	

Date:06/21/05ISR Number: 4697203-8Report Type:Direct Company Report #CTU 251562
Age:1.5 MON Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Abdominal Pain		Reglan	PS		ORAL	.5 ML	Q 4 HOURS
	Abnormal Behaviour							
	Drug Ineffective							
	Musculoskeletal Stiffness							
	Neonatal Disorder							
	Pharmaceutical Product Complaint							
	Staring							

Date:06/22/05ISR Number: 4696745-9Report Type:Expedited (15-DaCompany Report #200515632GDDC
Age:77 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Mesothelioma		Frumil	PS	Aventis Pharmaceuticals Inc.			

	Furosemide	SS	Aventis Pharmaceuticals Inc.
	Nozinan	SS	
	Combivent	SS	
RESPIRATORY (INHALATION)			
	Tiotropium Bromide "Spiriva"	SS	
RESPIRATORY (INHALATION)			
	Salbutamol	SS	
RESPIRATORY (INHALATION)			
	Aspirin	SS	
	Atorvastatin	SS	
	Beclomethasone	SS	
RESPIRATORY (INHALATION)			
	Dexamethasone	SS	
	Gaviscon	SS	
	Diltiazem	SS	
	Dosulepin	SS	
	Lactulose	SS	
dose: 3.35 G/5ML			
	Lansoprazole	SS	
	Metoclopramide	SS	
	Nitrolingual	SS	
	Oxycodone	SS	
	Oxygen	SS	
RESPIRATORY (INHALATION)			
	Spironolactone	SS	
	Symbicort	SS	
RESPIRATORY (INHALATION) dose: 200/6 MCG 1-2 PUFFS			
	Temazepam	SS	
dose: 10 MG,			

1-2 NOCTE

Date:06/22/05ISR Number: 4697223-3Report Type:Expedited (15-DaCompany Report #2005-UK-00676UK
Age:77 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Mesothelioma		Salbutamol	PS	Glaxosmithkline	RESPIRATORY	(INHALATION)	100MCG See dosage text
			Beclomethasone	SS	Glaxosmithkline	RESPIRATORY	(INHALATION)	50MCG Twice per day
			Aspirin	SS	Glaxosmithkline	UNKNOWN		75MG Unknown
			Combivent	SS		RESPIRATORY	(INHALATION)	
			Spiriva	SS		RESPIRATORY	(INHALATION)	18MCG Unknown
			Atorvastatin	SS		UNKNOWN		10MG per day
			Frumil	SS		UNKNOWN		
			Dexamethasone	SS		UNKNOWN		2MG Unknown
			Diltiazem	SS	Glaxosmithkline	UNKNOWN		60MG Per day
			Dosulepin	SS		UNKNOWN		75MG At night
			Furosemide	SS	Glaxosmithkline	UNKNOWN		
			Gaviscon	SS	Glaxosmithkline	UNKNOWN		10ML Four times per day
			Lactulose	SS		UNKNOWN		
			Lansoprazole	SS		UNKNOWN		30MG Per day

Metoclopramide SS Glaxosmithkline

UNKNOWN 10MG Three

times per day

			Nitrolingual	SS	Glaxosmithkline
UNKNOWN	400MG Unknown		Nozinan	SS	
UNKNOWN	25MG Four times per day		Oxycodone	SS	
UNKNOWN	20MG Twice per day		Oxygen	SS	
RESPIRATORY (INHALATION)			Spironolactone	SS	
UNKNOWN	50MG Unknown		Symbicort	SS	
RESPIRATORY (INHALATION)	2PUFF Twice per day				
UNKNOWN	10MG See dosage text		Temazepam	SS	

Date:06/22/05ISR Number: 4697496-7Report Type:Expedited (15-DaCompany Report #GB-MERCK-0505GBR00060
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Mesothelioma		Decadron Tablets	PS	Merck & Co., Inc			
UNKNOWN			Albuterol Sulfate And Ipratropium Bromide	SS				
RESPIRATORY (INHALATION)			Tiotropium Bromide	SS				
RESPIRATORY (INHALATION)								

RESPIRATORY (INHALATION)	Albuterol	SS
UNKNOWN	Aspirin	SS
UNKNOWN	Atorvastatin Calcium	SS
RESPIRATORY (INHALATION)	Beclomethasone Dipropionate	SS
UNKNOWN	Furosemide	SS
UNKNOWN	Diltiazem Hydrochloride	SS
UNKNOWN	Dothiepin Hydrochloride	SS
UNKNOWN	Aluminum Hydroxide And Magnesium Trisilicate	SS
UNKNOWN	Lactulose	SS
UNKNOWN	Lansoprazole	SS
UNKNOWN	Metoclopramide	SS
UNKNOWN	Nitroglycerin	SS
UNKNOWN	Levomepromazine	SS
UNKNOWN	Oxycodone	SS
UNKNOWN	Oxygen	SS
RESPIRATORY (INHALATION)	Spironolactone	SS
UNKNOWN	Budesonide And Formoterol Fumarate	SS
RESPIRATORY (INHALATION)	Temazepam	SS
UNKNOWN	Amiloride Hydrochloride And	

Furosemide SS

UNKNOWN

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/22/05ISR Number: 4699540-XReport Type:Expedited (15-DaCompany Report #THQ2005A00524
Age:77 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Lung Neoplasm Malignant Mesothelioma Malignant	Health Professional Other	Zoton Capsules (Lansoprazole) (Capsules)	PS		ORAL	1 IN 1 D	ORAL
			Combivent (Salbutamol W/ Ipratropium	SS			RESPIRATORY (INHALATION)	4 IN 1 D
			Spiriva (Tiotropium Bromide)	SS			INHALATION RESPIRATORY (INHALATION)	INHALATION
			Salbutamol	SS			RESPIRATORY (INHALATION)	2 IN 1 AS
			Aspirin (Acetylsalicylic Acid)	SS			REQUIRED INHALATION	
			Atorvastatin	SS				
			Beclomethasone (Beclomtasone Dipropionate)	SS			RESPIRATORY (INHALATION)	2 IN 2 D
			Frumil (Frumil)	SS			INHALATION	
			Dexamethasone	SS				
			Temazepam	SS			2 IN 1 D	

				Symbicort (Foraseq)	SS		
2 IN 1							
				Spironolactone	SS		
				Oxygen	SS		
RESPIRATORY							
(INHALATION)	INHALATION						
				Oxycodone	SS		
2 IN 1 D							
				Diltiazem	SS		
2 IN 1 D							
				Dosulepin (Dosulepin)	SS		
				Furosemide (Furosemide)	SS		
1 IN 1 D							
				Gaviscon	SS		
4 IN 1 D							
				Lactulose	SS		
3.35 G/5 ML							
				Metoclopramide	SS		
3 IN 1 D							
				Nitrolingual (Glyceryl Trinitrate)	SS		
1 IN 1 D							
				Nozinan (Levomepromazine)	C		
4 IN 1 D							

Date:06/23/05ISR Number: 4698811-0Report Type:Expedited (15-DaCompany Report #05-05-0769
Age:77 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Lung Neoplasm Malignant	Foreign	Albuterol Sulfate	PS				
RESPIRATORY								
Other	Mesothelioma	Other						
(INHALATION)	100MCG, BD							
	Sudden Death							
INHALATION								
			Beclomethasone Dipropionate	SS				
RESPIRATORY								
(INHALATION)	50MCG, 2BD							
INHALATION								

		Spiriva	SS
RESPIRATORY			
(INHALATION)	18MCG		
INHALATION			
75MG			
10MG			
RESPIRATORY			
(INHALATION)	QDS		
INHALATION			
		Frumil	SS
		Dexamethasone	SS
2MG			
60MG, 1BD			
75MG, 1NOCTE			
80MG			
10ML, QDS			
3.35G/5ML			
30MG, OD			
10MG TDS			
400MG			
25MG QDS			
20MG BD			
RESPIRATORY			
(INHALATION)	INHALATION		
50MG			
RESPIRATORY			

Aspirin	SS
Atorvastatin	SS
Combivent	SS
Diltiazem	SS
Dosulepin	SS
Furosemide	SS
Gaviscon	SS
Lactulose	SS
Lansoprazole	SS
Metoclopramide	SS
Nitrolingual	SS
Nozinan	SS
Oxycodone	SS
Oxygen	SS
Spironolactone	SS
Symbicort	SS

(INHALATION) 200/6MCG

INHALATION

Temazepam SS

10MG, 1-2NOCT

Date:06/24/05ISR Number: 4700501-2Report Type:Expedited (15-DaCompany Report #2005-127999-NL
Age:77 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Lung Neoplasm Malignant		Dexamethasone	PS			2 MG	
	Mesothelioma		Ipratropium Bromide W/Salbutamol (See Attached Pages For Additional Suspect Drugs)	SS				
RESPIRATORY (INHALATION)			Tiotropium Bromide (See Attached Pages For Additional Suspect Drugs)	SS			18 UG,	
RESPIRATORY (INHALATION)			Salbutamol (See Attached Pages For Additional Suspect Drugs)	SS			200 UG BID,	
RESPIRATORY (INHALATION)			Acetylsalicylic Acid (See Attached Pages For Additional Suspect Drugs)	SS			75 MG	
			Atorvastatin (See Attached Pages For Additional Suspect Drugs)	SS			10 MG	
			Beclomethasone					

		Dipropionate (See Attached Pages For Additional Suspect Drugs)	SS
100 UG BID, RESPIRATORY (INHALATION)			
		Frumil (See Attached Pages For Additional Suspect Drugs)	SS
DF			
		Diltiazem (See Attached Pages For Additional Suspect Drugs)	SS
60 MG QD			
		Dosulepin (See Attached Pages For Additional Suspect Drugs)	SS
75 MG QD			
		Furosemide (See Attached Pages For Additional Suspect Drugs)	SS
80 MG			
		Gaviscon (See Attached Pages For Additional Suspect Drugs)	SS
10 ML QID			
		Lactulose (See Attached Pages For Additional Suspect Drugs)	SS
670 MG/ML			
		Lansoprazole (See Attached Pages For Additional Suspect Drugs)	SS
30 MG QD			
		Metoclopramide (See Attached Pages For Additional Suspect Drugs)	SS
10 MG TID			

	Glyceryl Trinitrate (See Attached Pages For Additional Suspect Drugs)	SS
400 MG		
	Levomepromazine (See Attached Pages For Additional Suspect Drugs)	SS
25 MG QID		
	Oxycodone (See Attached Pages For Additional Suspect Drugs)	SS
20 MG BID		
	Oxygen (See Attached Pages For Additional Suspect Drugs)	SS
DF,		
RESPIRATORY		
(INHALATION)		
	Spironolactone (See Attached Pages For Additional Suspect Drugs)	SS
50 MG		
	Symbicort (See Attached Pages For Additional Suspect Drugs)	SS
2 PUFF BID,		

RESPIRATORY

(INHALATION)

			Temazepam	SS

10 MG BID

Date:06/24/05ISR Number: 4701120-4Report Type:Expedited (15-DaCompany Report #B0384392A
Age:35 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Activated Partial Thromboplastin Time Prolonged Anaphylactic Reaction Blood Pressure Decreased Drug Ineffective Erythema Fibrinolysis Heart Rate Increased Hypercoagulation	Foreign Literature Health Professional Other	Zantac (Ranitidine Hydrochloride) Metoclopramide (Metoclopramide) Remifentanil Hcl Cephazolin Sodium (Cefazolin Sodium) Midazolam (Midazolam) Propofol (Propofol) Rocuronium Bromide (Rocuronium Bromide) Sevoflurane (Sevoflurane) Temazepam (Temazepam)	PS SS SS SS SS SS SS SS		

Date:06/27/05ISR Number: 4700704-7Report Type:Expedited (15-DaCompany Report #GBR-2005-0001758
Age:77 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Mesothelioma	Foreign Health Professional	Oxycodone Hydrochloride (Oxycodone			

		Other	Hydrochloride)	PS
20 MG, BID				
			Metoclopramide (Metoclopramide)	SS
10 MG, TID				
			Diltiazem Hcl (Diltiazem Hydrochloride)	SS
60 MG, BID				
			Combivent (Ipratropium Bromide, Salbutamol Sulfate)	SS
RESPIRATORY				
(INHALATION)	QID ,			
INHALATION				
			Spiriva (Tiotropium Bromide)	SS
RESPIRATORY				
(INHALATION)	18 MCG,			
DAILY,				
INHALATION				
			Salbutamol (Salbutamol)	SS
RESPIRATORY				
(INHALATION)	100 MCG, BID			
PRN,				
INHALATION				

		Acetylsalicylic Acid(Acetylsalicylic Acid)	SS
75 MG, DAILY			
		Atorvastatin (Atorvastatin)	SS
10 MG, DAILY			
		Beclometasone (Beclometasone)	SS
RESPIRATORY			
(INHALATION)	100 MCG, BID,		
INHALATION			
		Frumil (Amiloride Hydrochloride, Furosemide)	SS
		Dexamethasone (Dexamethasone)	SS
2 MG, DAILY			
		Dosulepin (Dosulepin)	SS
75 MG,NOCTE			
		Furosemide (Furosemide)	SS
80 MG , DAILY			
		Gaviscon (Sodium Alginate, Sodium Bicarbonate)	SS
10 ML, QID			
		Lactulose (Lactulose)	SS
3.35G/5ML			
		Lansoprazole (Lansoprazole)	SS
30 MG, DAILY			
		Nitrolingual (Glyceryl Trinitrate)	SS
400 MG, DAILY			
		Nozinan (Levomepromazine)	SS
25 MG, QID			
		Oxygen (Oxygen)	SS
RESPIRATORY			
(INHALATION)	INHALATION		

				Spironolactone (Spironolactone)	SS		
50 MG, DAILY							
				Symbicort (Formoterol)	SS		
RESPIRATORY							
(INHALATION)	1-2 PUFF,						
BID,							
INHALATION							
				Temazepam (Temazepam)	SS		
1-2 AT NIGHT							

Date:06/27/05ISR Number: 4701435-XReport Type:Expedited (15-DaCompany Report #2005-05-0001
Age:77 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Lung Neoplasm Malignant	Foreign	Beclomethasone			
Other		Health	Dipropionate	PS		
RESPIRATORY						
		Professional				
(INHALATION)	50MCG, 2BD					
		Other				
INHALATION						
			Albuterol	SS		
RESPIRATORY						
(INHALATION)	100MCG, BD					
INHALATION						
			Spiriva	SS		
RESPIRATORY						
(INHALATION)	18 MCG					
INHALATION						
			Aspirin	SS		
75MCG						
			Atorvastatin	SS		
10 MG						
			Combivent	SS		
RESPIRATORY						
(INHALATION)	QDS					

INHALATION

2MG

60MG, 1BD

75MG, 1NOCTE

80MG

10MG, QDS

3.35G/5ML

30MG, OD

10 MG TDS

400MG

100MG

20MG BD

RESPIRATORY

(INHALATION) INHALATION

50MG

RESPIRATORY

(INHALATION) 1-2 PUFFS BID

INHALATION

10MG, 1-2PM

Frumil	SS
Dexamethasone	SS
Diltiazem	SS
Dosulepin	SS
Furosemide	SS
Gaviscon	SS
Lactulose	SS
Lansoprazole	SS
Metoclopramide	SS
Nitrolingual	SS
Nozinan	SS
Oxycodone	SS
Oxygen	SS
Spironolactone	SS
Symbicort	SS
Temazepam	SS

Date:06/27/05ISR Number: 4701750-XReport Type:Expedited (15-DaCompany Report #2005078279
Age:53 YR Gender:Male I/FU:F

Outcome PT Report Source Product Role Manufacturer Route
Dose Duration

Hospitalization - 30 MG (10 MG, Initial or Prolonged 3 IN 1 D)	Abnormal Dreams Choking Dyspnoea Gastrooesophageal Reflux Disease Headache Hyperhidrosis	Consumer Health Professional	Bextra (Valdecoxib) Reglan (Metoclopramide) Tagament Oral (Cimetidine) Darvocet (Dextropropoxyphene Napsilate, Paracetamol)	PS SS C C			

Date:06/28/05ISR Number: 4702787-7Report Type:Direct Company Report #CTU 252132
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Abnormal Behaviour Anxiety Hyperhidrosis		Metoclopramide Injection Mfd By Gensia Sicor	PS	Mfd By Gensia Sicor	INTRAVENOUS	10 MG IV - 1	DOSE ONLY
			Tylenol #3	C			(08:20)	

Date:06/28/05ISR Number: 4705214-9Report Type:Expedited (15-DaCompany Report #11049
Age:77 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Pleural Mesothelioma	Foreign Health	Dexamethasone Diltiazem	PS SS			60 MG BID	
		Professional	Furosemide	SS			80 MG	
		Other	Metoclopramide	SS			10 MG	
			Tiotropium Bromide	SS			RESPIRATORY (INHALATION)	18 MICROGRAM IH
			Salbutamol/Ipratropi					

		um	SS
RESPIRATORY			
(INHALATION)	IH		
		Atorvastatin	SS
		Beclomethasone	SS
RESPIRATORY			
(INHALATION)	50 MICROGRAM		
BID IH			
75 MG			
		Dosulepin	SS
		Magnesium Trisilicate	SS
10 ML			
3.35 G		Lactulose	SS
30 MG		Lansoprazole	SS
400 MG		Glyceryl Trinitrate	SS
25 MG QID		Methotrimeprazine	SS
20 MG BID		Oxycodone	SS
RESPIRATORY		Oxygen	SS
(INHALATION)	IH		
50 MG		Spironolactone	SS
		Budesonide/Eformoterol	SS
RESPIRATORY			
(INHALATION)	200 MICROGRAM		
BID IH			
10 MG NOCTE		Temazepam	SS
75 MG		Aspirin	SS
RESPIRATORY		Salbutamol	SS
(INHALATION)	100 MICROGRAM		

PRN IH

Date:06/29/05ISR Number: 4704704-2Report Type:Expedited (15-DaCompany Report #B0384404A
Age:22 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Drug Exposure During Pregnancy	Foreign Literature	Zantac (Ranitidine Hydrochloride)	PS		ORAL	150 MG/TWICE PER DAY/ORAL	
	Operative Haemorrhage	Health Professional	Remifentanil Hcl (Remifentanil Hcl)	SS			SEE DOSAGE TEXT	
			Metoclopramide (Metoclopramide)	SS			10 MG/SINGLE DOSE	
			Suxamethonium (Succinylcholine Chloride)	SS			1.5 MG/KG	
			Sodium Citrate (Sodium Citrate)	SS			30 ML	
			Etomidate (Etomidate)	SS				
			Isoflurane+Nitr.Ox+Oxygen(Isoflurane+Nitr.Ox+Oxygen)	SS				
			Vencuronium Bromide (Vecuronium Bromide)	SS				
			Hartmann'S Solution (Hartmann'S Solution)	SS				
			Morphine	C				
			Glycopyrronium+Neostigmin	C				
			Paracetamol	C				
			Diclofenac	C				
			Oxytocin	C				

			Gentamicin Sulphate	C		
			Cefuroxime Sodium	C		

Date:06/29/05ISR Number: 4704709-1Report Type:Expedited (15-DaCompany Report #B0384406B
Age:27 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Blood Pressure Systolic Abnormal Drug Exposure During Pregnancy Operative Haemorrhage	Foreign Literature Health Professional	Zantac (Ranitidine Hydrochloride) Remifentanil Hcl (Remifentanil Hcl) Metoclopramide (Metoclopramide) Suxamethonium (Succinylcholine Chloride) Hartmann'S Solution (Hartmann'S Solution) Sodium Citrate (Sodium Citrate) Etomidate (Etomidate) Isoflurane+Nitr.Ox+Oxygen(Isoflurane+Nitr.Ox+Oxygen) Vencuronium Bromide (Vecuronium Bromide) Metaraminol (Metaraminol) Morphine Clycopyrronium+Neostigmin Paracetamol	PS SS SS SS SS SS SS SS SS SS C C C		ORAL INTRAVENOUS	150 MG/TWICE PER DAY/ORAL 10 MG/SINGLE DOSE 1.5 MG/KG 30 ML 1 MG/KG	INTRAVENOUS

Diclofenac	C
Oxytocin	C
Gentamicin Sulphate	C
Cefuroxime Sodium	C

Date:06/29/05ISR Number: 4704711-XReport Type:Expedited (15-DaCompany Report #B0384406A
Age: Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Apgar Score Low Drug Exposure During Pregnancy Neonatal Disorder Respiratory Disorder	Foreign Literature Health Professional	Zantac (Ranitidine Hydrochloride) Remifentanil Hcl (Remifentanil Hcl)	PS SS			150 MG/TWICE PER DAY/ SEE DOSGE	

TRANSPLACENTAL

TEXT/TRANSPLA

C

			Metoclopramide (Metoclopramide)	SS				

TRANSPLACENTAL 10 MG/SINGLE

DOSE/TRANSPLA

CENTA

			Suxamethonium (Succinylcholine					

		Chloride)	SS
TRANSPLACENTAL	1.5 MG/KG/TRANSPL ACENTARY		
		Hartmann'S Solution (Hartmann'S Solution)	SS
TRANSPLACENTAL	TRANSPLACENTA RY		
		Sodium Citrate (Sodium Citrate)	SS
TRANSPLACENTAL	30 ML / TRANSPLACENTA RY		
		Etomidate (Etomidate)	SS
TRANSPLACENTAL	TRANSPLACENTA RY		
		Isoflurane+Nitr.Ox+Oxygen(Isoflurane+Nitr.Ox+Oxygen)	SS
TRANSPLACENTAL	TRANSPLACENTA RY		
		Vencuronium Bromide (Vecuronium Bromide)	SS
TRANSPLACENTAL	.1 ,G/KG/TRANSPL ACENTARY		
		Metaraminol (Metaraminol)	SS
TRANSPLACENTAL	TRANSPLACENTA RY		

Date:06/29/05ISR Number: 4705351-9Report Type:Expedited (15-DaCompany Report #GXKR2005GB01031
Age:77 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Mesothelioma	Foreign Health Professional Other	Acetylsalicylic Acid (Ngx) (Acetysalicylic Acid) Unknown	PS			75 MG, QD	
			Belcomethasone (Ngx)(Belcomethasone)	SS			RESPIRATORY (INHALATION)	50 UG, 2 BID, RESPIRATORY
			Lactulose Concentrate (Ngx) (Lactulose Concentrate)	SS			3.35 G/5 ML	
			Temazepam (Ngx)(Temazepam)	SS			10 MG, 1-2	NOCTE
			Furosemide (Ngx) (Furosemide)	SS				
			Metoclopramide (Ngx) (Metoclopramide)	SS			10 MG, TID	
			Diltiazem (Ngx)(Diltiazem)	SS			60 MG, BID	
			Combivent /Gfr(Ipratropium Bromide,Salbutamol Sulfate) Inhaler	SS			RESPIRATORY (INHALATION)	QID, RESPIRATORY
			Spiriva(Tiotropium Bromide)	SS			RESPIRATORY (INHALATION)	18 MCG,

RESPIRATORY			
		Salbutamol (Salbutamol)	SS
RESPIRATORY			
(INHALATION)	100 UG, BID,		
PRN,			
RESPIRATORY			
		Atorvastatin(Atorvastatin)	SS
10 MG			
		Frumil (Amiloride Hydrochloride, Furosemide)	SS
		Dexamethasone(Dexamethasone)	SS
2 MG			
		Dosulepin(Dosulepin)	SS
75 MG, 1			
NOCTE			
		Gaviscon /Gfr/(Sodium Alginate, Sodium Bicarbonate)	SS
10 ML, QID			
		Lansoprazole(Lansoprazole)	SS
30 MG, QD			
		Nitrolingual(Glyceryl Trintrate)	SS
400 MG			
		Nozinan/Net/(Levomepromazine)	SS
25 MG, QID			
		Oxycodone(Oxycodone)	SS
20 MG, BID			
		Oxygen(Oxygen)	SS
RESPIRATORY			
(INHALATION)	RESPIRATORY		
		Spironolactone(Spironolactone)	SS
50 MG			
		Symbicort	

				Turbuhaler(Budesonide, Formoterol Fumarate)	SS		

RESPIRATORY

(INHALATION) 200/6 MCG 102

PUFFS, BID,

RESPIRATORY

Date:06/29/05ISR Number: 4705358-1Report Type:Expedited (15-DaCompany Report #05-05-0769
Age:77 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Mesothelioma	Foreign	Albuterol Sulfate	PS		

RESPIRATORY

Other	Sudden Death	Health				

(INHALATION) 200MCG

Professional

INHALATION

		Other	Beclomethasone Dipropioante	SS		

RESPIRATORY

(INHALATION) 200MCG

INHALATION

			Spiriva	SS		

RESPIRATORY

(INHALATION) 18MCG

INHALATION

			Aspirin	SS		

75 MG

			Atorvastatin	SS		

10 MG

			Combivent	SS		

RESPIRATORY

(INHALATION) QDS

INHALATION

			Frumil	SS		
			Dexamethasone	SS		

2MG

			Diltiazem	SS		

120MG

	Dosulepin	SS

75 MG, 1NOCTE

80 MG		Furosemide	SS
40 ML, QDS		Gaviscon	SS
3.35G/5ML		Lactulose	SS
30 MG, OD		Lansoprazole	SS
30MG		Metoclopramide	SS
400MG		Nitrolingual	SS
100MG		Nozinan	SS
40MG		Oxycodone	SS
RESPIRATORY (INHALATION)	UNKNOWN	Oxygen	SS
INHALATION 50 MG		Spironolactone	SS
1-2 PUFFS BID INHALATION		Symbicort	SS
10MG, 1-2NOCT		Temazepam	SS

Date:06/30/05ISR Number: 4704085-4Report Type:Expedited (15-DaCompany Report #US-MERCK-0506USA00627
Age:54 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Eye Disorder		Emend	PS	Merck & Co., Inc	ORAL	1	DAY
	Feeling Abnormal		Emend	SS	Merck & Co., Inc	ORAL	1	DAY
	Stevens-Johnson Syndrome		Reglan	SS			UNKNOWN	
	Visual Disturbance		Atacand	C			UNKNOWN	
	Vomiting		Decadron					

			(Dexamethasone)	C		ORAL
			Antineoplastic (Unspecified)	C		

UNKNOWN

Date:06/30/05ISR Number: 4704775-3Report Type:Expedited (15-DaCompany Report #2005-05-0672
Age:77 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Mesothelioma	Foreign Health Professional Other	Salbutamol Sulphate Oral Aerosol (Like Proventil Hfa)	PS		
RESPIRATORY (INHALATION) 100 MCG BID ORAL AER INH						
			Beclomethasone Dipropionate Oral Aerosol	SS		
RESPIRATORY (INHALATION) 100 MCG BID ORAL AER INH						
			Combivent Oral Aerosol	SS		
RESPIRATORY (INHALATION) 4 PUFFS QID ORAL AER INH						
			Tiotropium Bromide	SS		
RESPIRATORY (INHALATION) 18 MCG ORAL AER INH						
			Aspirine	SS		ORAL
75 MG ORAL						
			Atorvastatin Calcium Tablets	SS		ORAL
10 MG ORAL						
			Frumil	SS		
			Dexamethasone	SS		
2 MG						
			Diltiazem Tablets	SS		ORAL
60 MG BID ORAL						

Dosulepin	SS	
Furosemide Tablets	SS	ORAL

75 MG QD

80 MG ORAL

			Gaviscon	SS			
10 ML QID							
			Lactulose	SS			
			Lansoprazole	SS			
30 MG QD							
			Metoclopramide	SS			
10 MG TID							
			Nitrolingual	SS			
400 MG							
			Nozinan	SS			
25 MG QID							
			Oxycodone	SS			
20 MG BID							
			Oxygen	SS			
RESPIRATORY							
(INHALATION)	INHALATION						
			Spironolactone Tablets	SS			ORAL
50 MG ORAL							
			Symbicort (Budesonide/Formoterol) Oral Aerosol	SS			
1-2 PUFFS BID							
ORAL AER I							
			Temazepam Tablets	SS			ORAL
1-2 PM QD							
ORAL							

Date:07/05/05ISR Number: 4708972-2Report Type:Expedited (15-DaCompany Report #2005092061
Age:77 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Death	Lung Neoplasm Malignant Mesothelioma	Foreign Health Professional	Atorvastatin (Atorvastatin)	PS		
10 M G						
			Nitroglicerina (Glyceryl Trinitrate)	SS		
			Spironolacton (Spironolactone)	SS		
50 MG						

		Frumil (Furosemide, Amiloride)	SS
		Furosemide (Furosemide)	SS
80 MG			
		Levomepromazine (Levomepromazine)	SS
100 MG			
		Ipratropium Bromide (Ipratropium Bromide)	SS
RESPIRATORY			
(INHALATION)	4 TIMES A		
DAY,			
INHALATION			
		Spiriva (Tiotropium Bromide)	SS
RESPIRATORY			
(INHALATION)	18 UG,		
INHALATION			
		Salbutamol (Salbutamol)	SS
RESPIRATORY			
(INHALATION)	100 UG AS		
NEEDED,			
INHALATION			
		Acetylsalicylic Acid (Acetylsalicylic Acid)	SS
75 MG			
		Beclomethasone (Beclomethasone)	SS
RESPIRATORY			
(INHALATION)	50 UG TWICE A		
DAY,			
INHALATION			
		Dexamethasone (Dexamethasone)	SS
2 MG			

		Gaviscon (Sodium Alginate, Sodium Bicarbonate)	SS
40 ML			
		Diltiazem (Diltiazem)	SS
120 MG			
		Dosulepin (Dosulepin)	SS
75 MG			
		Lactulose (Lactulose)	SS
3.35 G/5ML			
		Lansoprazole (Lansoprazole)	SS
30 MG			
		Metoclopramide (Metoclopramide)	SS
30 MG			
		Oxycodone (Oxycodone)	SS
40 MG			
		Oxygen (Oxygen)	SS
RESPIRATORY (INHALATION)	INHALATION		
		Symbicort (Budesonide, Formoterol Fumarate)	SS
RESPIRATORY (INHALATION)	200/6 MCG 1-2 PUFFS (TWICE A DAY), INHALATION		
		Temazepam (Temazepam)	SS
10 MG 1-2 NOCTE			

Date:07/06/05ISR Number: 4708366-XReport Type:Expedited (15-DaCompany Report #KII-2005-0017246
Age:20 MON Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Accidental Exposure Agitation Somnolence Vomiting	Study Health Professional Other	Oxycodone Hydrochloride (Similar To Nda 20-533)(Oxycodone Hydrochloride)	PS		ORAL	ORAL	
			Theophylline (Similar To 40-086) (Theophilline)	SS		ORAL	ORAL	
			Potassium Chloride (Potassium Chloride)	SS		ORAL	ORAL	
			Methadone (Methadone)	SS		ORAL	ORAL	
			Furosemide (Furosemide)	SS		ORAL	ORAL	
			Lovastatin (Lovastatin)	SS		ORAL	ORAL	
			Lisinopirl (Lisinopril)	SS		ORAL	ORAL	
			Folic Acid (Folic Acid)	SS		ORAL	ORAL	
			Metoclopramide (Metoclopramide)	SS				
			Trazodone (Trazodone)	SS		ORAL	ORAL	
			Sildenafil (Sildenafil)	SS		ORAL	ORAL	
			Bisacodyl (Bisacodyl)	SS		ORAL	ORAL	

			Hyoscyamine (Hyoscyamine)	SS		ORAL
ORAL						
			Gemfibrozil (Gemfibrozil)	SS		ORAL
ORAL						
			Omeprazole (Omeprazole)	SS		ORAL
ORAL						
			Glipizide (Glipizide)	SS		ORAL
ORAL						
			Promethazine (Promethazine)	SS		
			Clonazepam (Clonazepam)	C		ORAL
ORAL						
			Prednisone (Prednisone)	C		

Date:07/07/05ISR Number: 4710577-4Report Type:Expedited (15-DaCompany Report #2005-05-0001
Age:77 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Mesothelioma	Foreign	Beclomethasone			
Other		Health	Dipropionate	PS		
RESPIRATORY						
		Professional				
(INHALATION) 200MCG, 2BD						
		Other				
INHALATION						
			Albuterol	SS		
RESPIRATORY						
(INHALATION) 200MCG, BD						
INHALATION						
			Spiriva	SS		
RESPIRATORY						
(INHALATION) 18 MCG						
INHALATION						

75 MCG		
10MG		
RESPIRATORY		
(INHALATION)	QDS	
INHALATION		
2MG		
120MG		
75MG, 1NOCTE		
80MG		
40ML		
3.35G/5ML		
30MG, OD		
30MG TDS		
400MG		
100MG		
40MG BD		
RESPIRATORY		
(INHALATION)	INHALATION	
50MG		
RESPIRATORY		
(INHALATION)	1-2 PUFF BID	
INHALATION		
10MG, 1-2PM		

Aspirin	SS
Atorvastatin	SS
Combivent	SS
Frumil	SS
Dexamethasone	SS
Diltiazem	SS
Dosulepin	SS
Furosemide	SS
Gaviscon	SS
Lactulose	SS
Lansoprazole	SS
Metoclopramide	SS
Nitrolingual	SS
Nozinan	SS
Oxycodone	SS
Oxygen	SS
Spironolactone	SS
Symbicort	SS
Temazepam	SS

Date:07/08/05ISR Number: 4709803-7Report Type:Expedited (15-DaCompany Report #US-MERCK-0506USA00627
Age:54 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Eye Disorder		Emend	PS	Merck & Co., Inc	ORAL	1	DAY
	Feeling Abnormal		Emend	SS	Merck & Co., Inc	ORAL	1	DAY
	Visual Disturbance		Reglan	SS			UNKNOWN	
	Vomiting		Atacand	C			UNKNOWN	
			Decadron (Dexamethasone)	C		ORAL		
			Antineoplastic (Unspecified)	C			UNKNOWN	

Date:07/08/05ISR Number: 4710182-XReport Type:Direct Company Report #CTU 252787
Age:76 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Anorexia		Metoclopramide					
	Anxiety		Reglan	PS			10 MG TABLETS	
	Difficulty In Walking						ONE BEFORE	
	Dizziness						EACH MEAL	
	Drooling		Vicodin	C				
	Dyskinesia		Milk Of Mag	C				
	Dysphagia		Protonix	C				
	Malaise		Pheneragan	C				
	Nervousness		Tylenol/Codine	C				
	Speech Disorder		Valium	C				
	Tremor		Senakot Stool Softener	C				
	Weight Decreased							

Date:07/08/05ISR Number: 4711067-5Report Type:Expedited (15-DaCompany Report #2005093261
Age:52 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Toxic Epidermal Necrolysis	Foreign Health Professional	Solu-Medrol (Methylprednisolone Sodium Succinate)	PS		INTRAVENOUS	80 MG,	
						INTRAVENOUS		
			Metoclopramide (Metoclopramide)	SS		ORAL	1 DOSE FORM,	
						ORAL		
			Cisplatin (Cisplatin)	SS		INTRAVENOUS	50 MG,	
						INTRAVENOUS		
			Zophren (Ondansetron Hydrochloride)	SS		ORAL	8 MG, ORAL	
			Ethyol (Amifostine)	SS		INTRAVENOUS	400 MG,	
						INTRAVENOUS		

Date:07/13/05ISR Number: 4714231-4Report Type:Direct Company Report #CTU 253153
Age:39 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Drug Exposure During Pregnancy Foetal Distress Syndrome Intra-Uterine Death		Zofran Reglan	PS SS				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/13/05ISR Number: 4714611-7Report Type:Direct Company Report #CTU 253178
Age:74 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Abnormal Behaviour		Metoclopramide					
Disability	Amnesia		(Generic Reglan) 10					
Required	Confusional State		Mgm Mfg: Teva	PS	Teva	ORAL	1-10 MG TAB	
Intervention to	Depression						PO 4 X ADAY	
Prevent Permanent	Tardive Dyskinesia							
Impairment/Damage	Tremor							

Date:07/14/05ISR Number: 4715618-6Report Type:Expedited (15-DaCompany Report #GXKR2005GB01295
Age:33 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Bradycardia	Foreign	Ranitidine (Ngx)					
	Drug Exposure During	Literature	Ranitidine					
	Pregnancy	Health	Hydrochloride)					
	Haemorrhage	Professional	Unknown	PS		ORAL	300 MG, ORAL	
	Hypotension	Other	Metoclopramide (Ngx)					
	Postpartum Haemorrhage		(Metoclopramide)					
	Retained Placenta Or		Tablet	SS			10 MG, UNK	
	Membranes		Remifentanl					
	Uterine Atony		(Remifentanil)	SS			2.4 MCG/KG,	
							UNK (SEE	
							IMAGE)	
			Suxamethonium					
			(Suxamethonium)	SS			1.5 MG/KG,	
							UNK	
			Sodium Citrate					
			(Sodium Citrate)	SS				
			Etomidate					
			(Etomidate)	SS			0.1 -0.2	

MG/KG, UNK			
		Isoflurane (Isoflurane)	SS
RESPIRATORY			
(INHALATION)	1-2%,		
RESPIRATORY			
		Nitrous Oxide (Nitrous Oxide)	SS
RESPIRATORY			
(INHALATION)	RESPIRATORY		
		Oxygen (Oxygen)	SS
RESPIRATORY			
(INHALATION)	RESPIRATORY		
		Vecuronium Bromide (Vecuronium Bromide)	SS
0.1 MG/KG,			
UNK			
		Oxytocin (Oxytocin)	SS
INFUSION (SEE			
IMAGE)			
		Gentamicin (Gentamicin)	SS
		Cefuroxime (Cefuroxime)	SS
		Hartmann'S Solution (Calcium Chloride Dihydrate, Potassium Chloride, Sodium Chloride, So..)	SS
		Morphine	C
		Glycopyrronium Bromide	C
		Sodium Chloride	C

Analgesics (No Ingredients/Substances)	C
Prostaglandins (No Ingredients/Substances)	C

Date:07/18/05ISR Number: 4716586-3Report Type:Expedited (15-DaCompany Report #05-07-1179
Age:27 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Exposure During Pregnancy	Foreign	Ranitidine Unknown	PS		ORAL	300MG	ORAL
		Literature	Remifentanil	SS			2-4UG/KG	
		Other	Metoclopramide	SS			10MG	
			Suxamethonium	SS			1.5MG/KG	
			Sodium Citrate	SS				
			Etomidate	SS			0.1MG-0.2MG/K	
			Isoflurane	SS			RESPIRATORY (INHALATION)	1-2%
			Nitrous Oxide	SS			INHALATION RESPIRATORY (INHALATION)	INHALATION
			Oxygen	SS			RESPIRATORY (INHALATION)	INHALATION
			Vecuronium Bromide	SS			RESPIRATORY (INHALATION)	0.1MG/KG
			Morphine	C			INHALATION	
			Glycopyrronium					

			Bromide	C			
			Neostigmine	C			
			Paracetamol	C			
			Diclofenac	C			
			Oxytocin	C			
			Gentamicin	C			
			Cefuroxime	C			

Date:07/18/05ISR Number: 4716588-7Report Type:Expedited (15-DaCompany Report #05-07-1174
Age:22 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Exposure During	Foreign	Ranitidine Unknown	PS		ORAL	300MG ORAL	
	Pregnancy	Literature	Remifentanil Unknown	SS			2-4MCG/KG	
		Other	Metoclopramide Unknown	SS			10MG	
			Suxamethonium	SS			1.5MG/KG	
			Sodium Citrate Unknown	SS				
			Etomidate Unknown	SS			0.1-0.2MG/KG	
			Isoflurane Unknown	SS			RESPIRATORY (INHALATION)	1-2%
			Nitrous Oxide Unknown	SS			INHALATION RESPIRATORY (INHALATION)	INHALATION
			Oxygen Unknown	SS			RESPIRATORY (INHALATION)	INHALALTION
			Vecuronium Bromide Unknown	SS			0.1MG/KG	

Morphine	C
Paracetamol	C
Glycopyrronium Bromide	C
Diclofenac	C
Gentamicin	C
Cefuroxime	C
Oxytocin	C
Metaraminol	C

Date:07/21/05ISR Number: 4719599-0Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0508176A
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Adverse Event		Avandia	PS	Glaxosmithkline	ORAL		
			Reglan	SS	Glaxosmithkline		INTRAVENOUS	10MG Four times per day
			Norvasc	C		ORAL	10MG Per day	
			Toprol Xl	C		ORAL	200MG Per day	
			Zestoretic	C		ORAL	20MG Per day	
			Advair	C	Glaxosmithkline		RESPIRATORY (INHALATION)	
			Albuterol	C	Glaxosmithkline		RESPIRATORY (INHALATION)	
			Singulair	C		ORAL	10MG At night	
			Asa	C	Glaxosmithkline	ORAL	81MG Per day	
			Ambien	C		ORAL	10MG At night	
			Ntg	C	Glaxosmithkline		TOPICAL	
			Prilosec	C	Glaxosmithkline	ORAL	40MG Per day	

				Humalog Mix	C		
SUBCUTANEOUS	7 DAY						
				Lipitor	C		ORAL
20MG At night							
				Premarin	C		ORAL
.625MG Per day							
				Zestril	C		ORAL
20MG In the morning							
				Nitrostat	C	Glaxosmithkline	
SUBLINGUAL	.4MG As required						
				Minoxidil	C		ORAL
2.5MG Twice per day							

Date:07/21/05ISR Number: 4723996-7Report Type:Expedited (15-DaCompany Report #2005100086
Age:63 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Acute Myocardial Infarction	Consumer	Celebrex (Celecoxib)	PS			200 MG (200 MG, 1 IN 1 D)	
Hospitalization - Initial or Prolonged	Coronary Artery Atherosclerosis		Reglan (Metoclopramide)	SS			10 MG (10 MG, 1 IN 1 D)	
Other	Coronary Artery Disease							
Required Intervention to Prevent Permanent Impairment/Damage	Coronary Artery Occlusion Ejection Fraction Decreased Ventricular Dysfunction Ventricular Hypokinesia							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/22/05ISR Number: 4722109-5Report Type:Expedited (15-DaCompany Report #US-BRISTOL-MYERS SQUIBB COMPANY-13036991
Age:53 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Eyelid Ptosis Facial Pain		Paraplatin Inj	PS	Bristol-Myers Squibb Company	INTRAVENOUS		
Other	Hypoaesthesia Visual Disturbance		Taxol	SS	Bristol-Myers Squibb Company	INTRAVENOUS		
			Taxotere	SS				
			Reglan	SS				

Date:07/22/05ISR Number: 4724309-7Report Type:Direct Company Report #CTU 253982
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Blood Pressure		Reglan (Metoclopramide Hcl) 5mg/Ml Inj	PS		INTRAVENOUS	5 MG IV	
Other	Immeasurable Cardiac Arrest Infusion Related Reaction		Vancomycin	C				
			Zosyn	C				
			Bacitracin Zinc Oint	C				
			Docusate Sodium	C				
			Sennosides	C				

Date:07/22/05ISR Number: 4725011-8Report Type:Expedited (15-DaCompany Report #2005102690
Age:37 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Suicide Attempt	Foreign Consumer	Atarax (Tablet) (Hydroxyzine Hydrochloride)	PS		ORAL	200 MG, ORAL	
			Zyrtec (Tablets) (Cetirizine)	SS		ORAL	20 MG, ORAL	
			Metoclopramide					

			(Metoclopramide)	SS		ORAL	ORAL
			Valeriana Officinalis (Valeriana Officinalis)	SS		ORAL	ORAL

Date:07/26/05ISR Number: 4725997-1Report Type:Direct Company Report #CTU 254303
Age:58 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product		Role	Manufacturer	Route	Dose	Duration
Death	Loss Of Consciousness		Reglan	10mg	PS		ORAL	15MG	4X DAILY
	Neuroleptic Malignant Syndrome						ORAL		
	Pyrexia								

Date:07/26/05ISR Number: 4727041-9Report Type:Expedited (15-DaCompany Report #002#4#2005-00227
Age:80 YR Gender:Male I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Alanine Aminotransferase Increased
	Aspartate Aminotransferase Increased

	Blood Alkaline Phosphatase Increased						
	Cerebral Atrophy	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Cerebral Ischaemia	Health	Reglan				
	Confusional State	Professional	(Metoclopramide Hcl)	PS		ORAL	ORAL
	Dysarthria	Other	Lorazepam	SS		ORAL	ORAL
			Ondansetron	C			
			Pancrelipase	C			
			Erythropoietin	C			
			Docusate Sodium	C			
			Ranitidine	C			
			Glucosamine/Chondroitine	C			
			Levofloxacin	C			
			Sertraline	C			
			Gemcitabine	C			
			Megestrol	C			
			Atenolol	C			
			Simvastatin	C			
			Metformin	C			
			Acetyl-Salicylic-Acid	C			
			Dexamethasone	C			

Date:07/27/05ISR Number: 4728207-4Report Type:Expedited (15-DaCompany Report #11816
Age:4 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Urinary Retention	Foreign	Metoclopramide	PS			
		Literature					
		Health Professional					
		Other					

Date:07/28/05ISR Number: 4727649-0Report Type:Direct Company Report #CTU 254634
Age:18 MON Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration

Hospitalization -	Anaesthetic Complication	Reglan	PS	ORAL
1 MG/DAY PO				
Initial or Prolonged	Bronchospasm			
DIVIDED DO				
Required	Convulsion	Ranitadine	C	
Intervention to	Dacryostenosis Acquired	Sevoflurane	C	
Prevent Permanent	Dyskinesia	Nitrous Oxide	C	
Impairment/Damage	Dystonia	Atropine	C	
	Electroencephalogram	Albu	C	
	Abnormal			
	Gaze Palsy			
	Heart Rate Increased			
	Movement Disorder			
	Muscle Rigidity			
	Respiration Abnormal			

Date:07/28/05ISR Number: 4727662-3Report Type:Expedited (15-DaCompany Report #FR-ABBOTT-05P-056-0306276-00
Age:86 YR Gender:Female I/FU:I

Outcome	PT
Hospitalization -	Asthenia
Initial or Prolonged	Atrioventricular Block

		First Degree Bradycardia Pulmonary Embolism Purpura	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
		Thrombocytopenic Purpura		Tarka	PS		ORAL
141	DAY						
				Diosmine	SS		ORAL
1	YR						
				Paracetamol	SS		ORAL
				Metoclopramide	SS		ORAL
				Morphine Sulfate	SS		ORAL
1	YR						
				Nebivolol	SS		ORAL
79	DAY						
				Anastrozole	C		
				Macrogol	C		
				Paracetamol	C		

Date:07/28/05ISR Number: 4728123-8Report Type:Direct Company Report #CTU 254639
Age:18 MON Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization -	Anaesthetic Complication		Reglan	PS		
1MG/DAY PO						
Initial or Prolonged	Bronchospasm					
DIVIDED DOSES						
Required	Dacryostenosis Acquired		Ranitadine	C		
Intervention to	Dyskinesia		Sevoflurane	C		
Prevent Permanent	Dystonia		Nitrous Oxide	C		
Impairment/Damage	Electroencephalogram		Im Atropine	C		
	Abnormal		Albuterol	C		
	Gaze Palsy					
	Heart Rate Increased					
	Muscle Contractions Involuntary					
	Muscle Rigidity					
	Muscle Twitching					
	Oculogyration					
	Respiration Abnormal					

Date:08/01/05ISR Number: 4730192-6Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0388282A
Age:52 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blister		Zophren	PS	Glaxosmithkline	ORAL	8MG Cyclic	29 DAY
	Pruritus		Primperan	SS	Glaxosmithkline	ORAL	1UNIT Cyclic	7 DAY
	Pyrexia		Solumedrol	SS		INTRAVENOUS	80MG Cyclic	29 DAY
	Rash Maculo-Papular		Cisplatine	SS		INTRAVENOUS	50MG Cyclic	29 DAY
	Skin Disorder		Ethyol	SS		INTRAVENOUS	400MG Cyclic	32 DAY
	Toxic Epidermal Necrolysis							

Date:08/03/05ISR Number: 4735767-6Report Type:Direct Company Report #CTU 255349
Age:53 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability Required Intervention to Prevent Permanent Impairment/Damage	Activities Of Daily Living Impaired		Reglan 10mg Metoclopramide	PS				
	Anxiety							
	Depression							
	Drug Withdrawal Syndrome							
	Insomnia							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/09/05ISR Number: 4737796-5Report Type:Expedited (15-DaCompany Report #2005CG01350
Age:68 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Creatinine Increased		Inexium	PS	Astrazeneca Pharmaceuticals	ORAL		23 DAY
	Encephalopathy		Primperan	SS		ORAL		5 DAY
			Deroxat	C		ORAL		64 DAY

Date:08/09/05ISR Number: 4737959-9Report Type:Expedited (15-DaCompany Report #PHRM2005FR00813
Age:76 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Coma		Zometa	PS	Novartis Sector: Pharma	INTRAVENOUS		
	Deterioration		Sintrom 4	SS		ORAL	1 mg/day	4320 MIN
	Lung Infection		Sintrom 4	SS		ORAL	2 mg/day	5760 MIN
	Neutrophil Count Decreased Pancytopenia		Vincristine + Adriamycin + Dexamethasone	SS		INTRAVENOUS	30 mg/day	1440 MIN
	Platelet Count Decreased		Skenan	SS		ORAL	5 mg/day	17280MIN
	Pseudomonal Sepsis		Levothyrox	SS		ORAL	75 A?g on even days, 100 mg on odd days	
	Pyrexia Red Blood Cell Count Decreased White Blood Cell Count Decreased							
			Temesta	SS		ORAL	0.5 mg/day	
			Speciafoldine	SS		ORAL	1 tab/day	
			Magne B6	SS		ORAL		

			Furosemide	SS		ORAL
100 mg/day	2880 MIN					
			Durogesic	SS		
TRANSDERMAL	25 ug, QH	1440 MIN				
			Actiskenan	SS		ORAL
10 mg, PRN	1440 MIN					
			Primperan	SS		ORAL
30 mg, PRN	2880 MIN					
			Primperan	SS		ORAL
30 mg/day	4320 MIN					
			Pariet	SS		ORAL
1 tab/day						
			Diffu K	SS		ORAL
1200 mg/day						
			Effexor - Slow Release	SS		ORAL
			Dexamethasone	SS		ORAL
40 mg/day	17280MIN					
			Thalidomide	SS		ORAL
200 mg/day	5760 MIN					
			Thalidomide	SS		ORAL
100 mg/day	1440 MIN					
			Solupred	SS		ORAL
20 mg/day						

Date:08/12/05ISR Number: 4743605-0Report Type:Expedited (15-DaCompany Report #200515632GDDC
Age:77 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Death	Mesothelioma		Frumil	PS	Aventis Pharmaceuticals Inc.	
			Furosemide	SS	Aventis Pharmaceuticals Inc.	
			Nozinan	SS		
			Combivent	SS		
RESPIRATORY						
(INHALATION)						
			Tiotropium Bromide "Spiriva"	SS		
RESPIRATORY						
(INHALATION)						
			Salbutamol	SS		
RESPIRATORY						
(INHALATION)						
			Aspirin	SS		
			Atorvastatin	SS		

				Beclomethasone	SS		
RESPIRATORY							
(INHALATION)							
				Dexamethasone	SS		
				Gaviscon	SS		
				Diltiazem	SS		
				Dosulepin	SS		
				Lactulose	SS		
dose: 3.35							
G/5ML							
				Lansoprazole	SS		
				Metoclopramide	SS		
				Nitrolingual	SS		
				Oxycodone	SS		
				Oxygen	SS		
RESPIRATORY							
(INHALATION)							
				Spironolactone	SS		
				Symbicort	SS		
RESPIRATORY							
(INHALATION)	dose: 200/6						
MCG 1-2 PUFFS							
				Temazepam	SS		
dose: 10 MG,							
1-2 NOCTE							

Date:08/12/05ISR Number: 4743606-2Report Type:Expedited (15-DaCompany Report #200514051GDDC
Age:77 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Lung Neoplasm Malignant		Frumil	PS	Aventis Pharmaceuticals Inc.			
Other	Mesothelioma							
			Furosemide	SS	Aventis Pharmaceuticals Inc.			
			Combivent	SS				
RESPIRATORY								
(INHALATION)								

		Tiotropium Bromide "Spiriva"	SS
RESPIRATORY (INHALATION)			
		Salbutamol	SS
RESPIRATORY (INHALATION)	dose: 100 MCG, BID		
		Aspirin	SS
		Atorvastatin	SS
		Beclomethasone	SS
RESPIRATORY (INHALATION)	dose: 50 MCG, 2 BID		
		Dexamethasone	SS
		Diltiazem	SS
		Dosulepin	SS
		Gaviscon	SS
		Lactulose	SS
dose: 3.35 G/ 5 ML			
		Lansoprazole	SS
		Metoclopramide	SS
		Nitrolingual	SS
		Nozinan	SS
		Oxycodone	SS
		Oxygen	SS
RESPIRATORY (INHALATION)			
		Spironolactone	SS
		Symbicort	SS
RESPIRATORY (INHALATION)	dose: 200/6 UG, 1-2 PUFFS		
		Temazepam	SS
dose: 10 MG,			

Date:08/17/05ISR Number: 4747261-7Report Type:Expedited (15-DaCompany Report #US-MERCK-0506USA00627
Age:54 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Eye Disorder		Emend	PS	Merck & Co., Inc	ORAL	1	DAY
	Feeling Abnormal		Emend	SS	Merck & Co., Inc	ORAL	1	DAY
	Visual Disturbance		Reglan	SS			UNKNOWN	
	Vomiting		Atacand	C			UNKNOWN	
			Decadron (Dexamethasone)	C		ORAL		
			Antineoplastic (Unspecified)	C			UNKNOWN	

Date:08/18/05ISR Number: 4747990-5Report Type:Expedited (15-DaCompany Report #US-SANOFI-SYNTHELABO-A03200500832
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Abdominal Discomfort		Ambien	PS		ORAL	UNK	
	Gastrointestinal		Plavix	SS		ORAL	UNK	
	Haemorrhage		Carafate	SS		ORAL	UNK	
			Metoclopramide	SS		ORAL	UNK	
			Darvocet	SS		ORAL	UNK	
			Mycelex	SS			UNKNOWN	UNK
			Promethazine	SS		ORAL	UNK	
			Lasix	SS		ORAL	UNK	

			Tizanidine	SS		ORAL
UNK						

Date:08/18/05ISR Number: 4748066-3Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0388282A
Age:52 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Blister		Zophren	PS	Glaxosmithkline	ORAL	8MG Cyclic	29 DAY
Initial or Prolonged	Pruritus		Primperan	SS	Glaxosmithkline	ORAL	1UNIT Cyclic	7 DAY
	Pyrexia		Solumedrol	SS		INTRAVENOUS	80MG Cyclic	29 DAY
	Rash Maculo-Papular		Cisplatine	SS		INTRAVENOUS	50MG Cyclic	29 DAY
	Skin Disorder		Ethyol	SS		INTRAVENOUS	400MG Cyclic	32 DAY
	Toxic Epidermal Necrolysis							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Summary report for FOI selections:

Selection by inexact search of active ingredient: METOCLOPRAMIDE%

Selection by inexact search of Tradename/Verbatim: REGLAN%

Total number of reports: 1,719

From: 01-NOV-1997 To: Present