FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/03/97ISR Number: 100000145Report Type:Expedited (15-DaCompany Report #COU971063
Age:47 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Prothrombin Time Prolonged	Health Professional	Coumadin (Crystalline Warfarin Sodium)	PS		ORAL	UNKNOWN;ORAL	
			Lithium (Lithium)	SS			UNKNOWN	UNKNOWN
			Digoxin (Digoxin)	C			UNK/UNK	;UNKNOWN

Date:11/05/97ISR Number: 100000167Report Type:Expedited (15-DaCompany Report #97024471-1
Age:77 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Creatinine Increased	Foreign Literature	Lithium	PS		ORAL	625 MILLIGRAMS	DAILY
	Confusional State	Health						
	Coordination Abnormal	Professional	Diazepam	C				
	Drug Interaction		Losartan	C				
	Dysarthria		Nicardipine	C				
	Therapeutic Agent		Nifedipine	C				
	Toxicity		Tamoxifen	C				

Date:11/05/97ISR Number: 3008545-6Report Type:Periodic Company Report #M072320
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Interaction	Health	Glucophage	PS		ORAL	ORAL	

	Hypoglycaemia	Professional	Lithium	SS			
			Procardia	SS			
			Elavil	SS			

Date:11/07/97ISR Number: 100000186Report Type:Expedited (15-DaCompany Report #USA/97/01958/LEX
Age:68 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Delirium	Health	Clozaril (Clozapine)	PS		ORAL		2 YR
Initial or Prolonged	Overdose	Professional	Eskalith (Lithium Carbonate)	SS				
Other Required Intervention to Prevent Permanent Impairment/Damage			Flagyl (Metronidazole)	C				
			Erythromcin	C				
			Amitriptyline	C				
			Temazepam	C				
			Wellbutrin (Amfebutamone)	C				
			Synthroid (Levothyroxine Soduim)	C				
			Pepcid	C				

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Freedom Of Information (FOI) Report

Date:11/07/97ISR Number: 100000196Report Type:Expedited (15-DaCompany Report #D/97/03283/LEX
Age:60 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Cutaneous Vasculitis	Foreign	Leponex	PS		ORAL	25 MG ORAL
Initial or Prolonged	Dermatitis	Health	Quilonum Retard	SS		ORAL	1350 MG ORAL
Other	Vasculitis Necrotising	Professional	Dociton	SS		ORAL	120 MG ORAL
			Melleretten	C			

Date:11/10/97ISR Number: 3019695-2Report Type:Periodic Company Report #JAUSA-26957
Age:63 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Other	Drug Level Above	Health	Sporanox	PS	Janssen	ORAL	400 MG PULSE
	Therapeutic	Professional					ORAL;

COMMENTS: 200

MG BID, ONE

WEEK ON,

			Lithium	SS		ORAL	300 MG 1

DAILY ORAL;

COMMENTS: 600

MG TAKEN AT

BEDTIME.

			Tegretol	C			

Date:11/13/97ISR Number: 3005998-4Report Type:Direct Company Report #
Age:70 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dehydration		Lithium	PS		ORAL	300 MG BID PO	(MANY YEARS)
	Diarrhoea							
	Dizziness							
	Drug Toxicity		Lisinopril	C				
	Gastritis							
	Influenza							
	Nausea							
	Vision Blurred							
	Vomiting							

Date:11/17/97ISR Number: 3005746-8Report Type:Direct Company Report #
Age:48 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hepatic Cirrhosis		Lithium	PS			LONG TERM	
Required Intervention to Prevent Permanent Impairment/Damage	Hepatitis C							

Date:11/17/97ISR Number: 3005851-6Report Type:Direct Company Report #
Age:45 YR Gender:Male I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Blood Creatinine Increased
	Condition Aggravated
	Confusional State

	Drug Level Above Therapeutic						
	Drug Toxicity	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Renal Impairment		Lithum	PS			
	Urinary Incontinence						

Date:11/18/97ISR Number: 3001367-1Report Type:Expedited (15-DaCompany Report #LIT/97/00315/MEL
Age:30 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Anxiety	Literature	Thioridazine Hydrochloride	PS		ORAL	400 MG ORAL 3 DAY
	Confusional State	Health					
	Dysarthria	Professional	Lithium Carbonate	SS		ORAL	1800 MG ORAL 6 DAY
	Gait Disturbance						
	Insomnia						
	Nausea						
	Speech Disorder						
	Tremor						

Date:11/18/97ISR Number: 3001547-5Report Type:Expedited (15-DaCompany Report #EL U830101 (83900792-1)
Age:51 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Disability	Burning Sensation	Consumer	Eskalith	PS		ORAL	ORAL
Other	Disability		Thorazine (Chlorpromazine Hcl)	SS			
	Nephrogenic Diabetes Insipidus						
	Polydipsia						
	Polyuria						
	Urine Abnormality						
	Vomiting						

Date:11/18/97ISR Number: 3001563-3Report Type:Expedited (15-DaCompany Report #WAES 96096115
Age:77 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Creatinine Increased Confusional State Drug Interaction Drug Level Above Therapeutic Dysarthria Hypothyroidism	Foreign Literature Health Professional	Cozaar Lithium Carbonate Nifedipine Tamoxifen Citrate	PS SS C C		ORAL ORAL	50 MG 629 MG	5 WK
Disability								

Date:11/18/97ISR Number: 3001570-0Report Type:Expedited (15-DaCompany Report #97021136-1
Age:45 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Renal Failure	Consumer Health Professional	Lithium Haldol (Haloperidol) Depakote (Divalproex Sodium)	PS C C		ORAL ORAL		

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Freedom Of Information (FOI) Report

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

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

Date:11/20/97ISR Number: 3001875-3Report Type:Expedited (15-DaCompany Report #97025232-1
Age:82 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Apathy Blood Osmolarity Hypothyroidism Lethargy Nephrogenic Diabetes Insipidus Neurotoxicity Sedation Urinary Incontinence	Foreign Literature Other	Lithium Carbonate Carbamazepine Fluvoxamine Haloperidol	PS C C C	Smithkline Beecham		600MG

Date:11/20/97ISR Number: 3002046-7Report Type:Expedited (15-DaCompany Report #D/97/03283/LEX
Age:60 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Vasculitis Necrotising	Foreign	Leponex	PS		ORAL	25 MG ORAL

Initial or Prolonged		Health	Quilonum Retard	SS		ORAL
1350 MG ORAL						
Other		Professional	Dociton	SS		ORAL
120 MG ORAL						
Required			Melleretten	SS		ORAL
20 MG ORAL						
Intervention to Prevent Permanent Impairment/Damage						

Date:11/20/97ISR Number: 3006023-1Report Type:Direct Company Report #
Age:40 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Bradycardia Coordination Abnormal Dysarthria	Health Professional	Lithium Carbonate	PS		ORAL	600 MG AM & HS	

Date:11/21/97ISR Number: 3002039-XReport Type:Expedited (15-DaCompany Report #9721825
Age:58 YR Gender:Female I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Asthenia Diabetes Insipidus Electrocardiogram Abnormal Mania Peripheral Motor

	Neuropathy Renal Failure Acute						
		Report Source	Product	Role	Manufacturer	Route	Dose Duration
		Foreign	Lithane	PS		ORAL	ORAL TAB
		Health Professional	Herbal Medicine	C			

Date:11/21/97ISR Number: 3002092-3Report Type:Expedited (15-DaCompany Report #LITH002970032
Age:77 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Confusional State Coordination Abnormal Drug Toxicity Dysarthria	Foreign Literature	Lithium Losartan	PS SS		ORAL ORAL	625 MG PER DAY PER ORAL 50MG PER DAY PER ORAL

Date:11/21/97ISR Number: 3002329-0Report Type:Expedited (15-DaCompany Report #9721825
Age:58 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Asthenia Diabetes Insipidus Electrocardiogram Abnormal Mania Peripheral Motor Neuropathy Renal Failure Acute	Foreign Health Professional	Lithane Tablets Herbal Medicine Levothyroxine	PS C C		ORAL	ORAL

Date:11/21/97ISR Number: 3006582-9Report Type:Direct Company Report #
Age:55 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Drug Interaction		Lithium	PS		ORAL	900 MG QD	
	Drug Level Above						PO;LONGTERM	
	Therapeutic		Aspirin	C				
	Drug Toxicity		Chlorpronaze	C				
	Hypotension		Pepcid	C				
			Hctz	C				
			Quinspril	C				
			Ofloxacin	C				

Date:11/21/97ISR Number: 3006666-5Report 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	Drug Toxicity		Lithium	PS		ORAL	750 MG PO Q AM 900 Q PM	
	Medication Error							

Date:12/02/97ISR Number: 3003744-1Report Type:Expedited (15-DaCompany Report #D/97/03283/LEX
Age:60 YR Gender:Male I/FU:F

Outcome
Hospitalization - Initial or Prolonged

Other Required Intervention to	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Prevent Permanent	Aortic Valve Stenosis	Health	Leponex	PS		ORAL	25 MG	
Impairment/Damage	Dermatitis	Professional	Quilonum Retard	SS		ORAL	1350 MG	
	Gangrene		Melleretten	SS		ORAL	20 MG	
	Vasculitis Necrotising		Dociton	C				

Date:12/04/97ISR Number: 3007144-XReport Type:Direct Company Report #
Age:65 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Toxicity	Health	Lithium	PS			300MG QAM &	
	Therapeutic Agent	Professional					600MG QHS	
	Toxicity							

Date:12/04/97ISR Number: 3007234-1Report Type:Direct Company Report #
Age:53 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blood Pressure Decreased		Lithium	PS		ORAL	300MG PO TID	
	Confusional State		Lisinopril	SS			10MG BID	
	Gait Disturbance		Ibuprofen	C				
			Albuterol	C				
			Lorazepam	C				

Date:12/05/97ISR Number: 3004407-9Report Type:Expedited (15-DaCompany Report #9725392
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Hospitalization - Initial or Prolonged	Cardiac Disorder	Foreign Health Professional	Zoloft	PS		ORAL ORAL
	Mania		Lithium	SS		ORAL ORAL
	Muscle Rigidity					

Date:12/08/97ISR Number: 3018299-5Report Type:Direct Company Report #
Age:50 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Hospitalization - Initial or Prolonged	Confusional State		Lithium Carbonate	PS		ORAL 600 MG BID
	Diarrhoea		Lopid	C		
	Drug Toxicity		Hydrochlorothiazide	C		
	Dysarthria		Metoprolol	C		
	Hyperthyroidism		Risperidal	C		
	Nausea		Depakote	C		
	Tremor		Clonazepam	C		
	Vomiting					
	Weight Decreased					

Date:12/09/97ISR Number: 3007541-2Report Type:Direct Company Report #
Age:58 YR Gender:Male I/FU:I

Outcome
Life-Threatening
Disability
Congenital Anomaly
Other

Required Intervention to Prevent Permanent Impairment/Damage	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Toxicity	Health	Lithobid	PS	Solvay		1200 MG DAILY	
	Psychotic Disorder	Professional	Lithonate	SS				
			Synthroid	C				

Date:12/10/97ISR Number: 3006129-7Report Type:Expedited (15-DaCompany Report #9725562
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Accidental Overdose	Foreign	Lithane	PS		ORAL		
Other	Convulsion	Consumer						
	Dyspepsia							
	Pancreatic Carcinoma							

Date:12/12/97ISR Number: 3006734-8Report Type:Expedited (15-DaCompany Report #971204-008013330
Age:52 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dermatitis Exfoliative	Foreign	Serinase	PS		ORAL	10 MG, QD, ORAL	
	Tardive Dyskinesia							
			Litarex	SS		ORAL	ORAL	
			Lysantin	C				

Date:12/15/97ISR Number: 3007102-5Report Type:Expedited (15-DaCompany Report #9725928
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Abnormal Behaviour	Foreign	Lithane	PS		ORAL	ORAL	

Initial or Prolonged	Arachnoiditis	Consumer	Doxepin	SS		ORAL
ORAL						
	Eye Rolling		Benztropine	C		
	Hallucination					
	Headache					
	Hypersomnia					
	Muscle Twitching					
	Pain					
	Schizophrenia					
	Suicide Attempt					
	Tinnitus					

Date:12/16/97ISR Number: 3008218-XReport Type:Direct Company Report #
Age:57 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Arrhythmia	Health	Lithium	PS		
300 MG 1/ DAY						
	Dyspepsia	Professional				
	Face Oedema					
	Memory Impairment					
	Muscle Twitching					
	Tremor					
	Vision Blurred					

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

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

Date:12/22/97ISR Number: 3015233-9Report Type:Expedited (15-DaCompany Report #9726288
Age:13 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Drug Interaction	Foreign	Zoloft	PS		ORAL	50 MG DAILY	
Initial or Prolonged	Hyperhidrosis	Health					ORAL	
	Serotonin Syndrome	Professional	Lithium	SS			1500 MG TOTAL	
	Therapeutic Agent						TID	
	Toxicity		Pericyazine	C				
	Tremor		Benzhexol	C				
	Vomiting							

Date:12/23/97ISR Number: 3011970-0Report Type:Expedited (15-DaCompany Report #LITH002970035
Age:45 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Eosinophilia Myalgia	Health	Lithonate	PS	Solvay			
Initial or Prolonged	Syndrome	Professional			Pharmaceuticals Usa	ORAL	900 MG. PER	
	Eosinophilic Pneumonia							
ORAL							10 YR	

			Ativan	C		
			Imuran	C		

Date:12/30/97ISR Number: 3015311-4Report Type:Direct Company Report #
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Electrocardiogram Qt Prolonged		Lithium	PS		ORAL	600 MG QD PO/ORAL
Other	Nausea		N/A	SS			
	Nervousness		N/A	C			
	Tremor						

Date:12/31/97ISR Number: 3013432-3Report Type:Expedited (15-DaCompany Report #8-97357-001D
Age:15 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Accidental Overdose	Foreign	Trihexyphenidyl	PS		ORAL	4 MG ORAL
	Blood Pressure Decreased	Health	Levomepromazine	SS		ORAL	60 MG ORAL
	Coma	Professional	Lithium Carbonate	SS		ORAL	600 MG ORAL
	Hypothermia						
	Miosis						
	Neurological Symptom						

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Date:12/31/97ISR Number: 3013474-8Report Type:Expedited (15-DaCompany Report #8-97329-006T
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Cardiac Failure	Foreign	Asendin	PS		ORAL	50 MG DAILY	
Hospitalization - Initial or Prolonged		Health Professional	Bromazepam	SS		ORAL	15 MG DAILY	
Other			Lithium Carbonate	SS		ORAL	600 MG DAILY	
			Maprotiline Hydrochloride	SS		ORAL	30 MG DAILY	
			Sodium Valproate	SS		ORAL	100 MG ;	DAILY ; ORAL

Date:12/31/97ISR Number: 3069833-0Report Type:Periodic Company Report #9705125
Age:69 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Confusional State	Health Professional	Zithromax	PS		ORAL	250.00 MG	TOTAL:DAILY:O
	Drug Interaction							
	Drug Level Above Therapeutic	Company Representative	Lithium	SS		ORAL	1.00 GRAM	TOTAL:DAILY:O
								RAL

Date:01/05/98ISR Number: 3016361-4Report Type:Expedited (15-DaCompany Report #9711748
Age:74 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Amnesia	Foreign	Lithane	PS		ORAL	1200.00MG	
Hospitalization -	Blood Glucose Increased	Consumer						TOTAL:DAILY:O
Initial or Prolonged	Coma							RAL
Other	Drug Ineffective		Amitryptyline	C				
	Eczema							
	Lethargy							
	Memory Impairment							
	Muscle Twitching							
	Polyuria							
	Thirst							
	Tremor							

Date:01/08/98ISR Number: 3017427-5Report Type:Expedited (15-DaCompany Report #97030338-1
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Blood Creatinine	Health	Eskalith	PS	Smithkline Beecham	ORAL		ORAL
Initial or Prolonged	Increased	Professional	Clozaril	C				
Other	Dehydration		Moban	C				
	Hypotension							
	Neuroleptic Malignant Syndrome							
	Pyrexia							
	Renal Failure Acute							
	Urinary Tract Infection							

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Date:01/08/98ISR Number: 3087373-XReport Type:Periodic Company Report #9725041
Age:35 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Toxicity	Health	Zyrtec	PS		ORAL	10.00 MG	
	Hyperhidrosis	Professional						TOTAL:DAILY
	Nervousness		Lithium	SS		ORAL		
	Tremor		Erythromycin Ointment	C				
			Restoril	C				
			Akineton	C				
			Haldol Deconoate	C				
			Elavil	C				
			Anaprox Ds	C				
			Beconase	C				

Date:01/09/98ISR Number: 3016776-4Report Type:Expedited (15-DaCompany Report #LBID002970039
Age:58 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Confusional State	Other	Lithobid	PS		ORAL	1200 MG, PER	
	Dementia						ORAL	
	Disability		Elavil	C				
	Emotional Disorder		Synthroid	C				
	Gait Disturbance		Xanax	C				

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

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Atrial Septal Defect	Foreign	Haldol	PS		INTRA-UTERINE	100 MG, 1X/3WK,	
	Complications Of Maternal	Health						
	Exposure To Therapeutic	Professional						INTRAUTERINE 49 DAY

	Drugs		Lithium Acetate	SS		
INTRA-UTERINE	450 MG, QD,					
	Foetal Growth Retardation					
INTRAUTERINE	49 DAY					
	Neonatal Aspiration					
	Patent Ductus Arteriosus					

Date:01/12/98ISR Number: 3016611-4Report Type:Expedited (15-DaCompany Report #EL U830101 (83900792-1)
Age:51 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Burning Sensation	Consumer	Eskalith	PS	Smithkline Beecham			
Other	Dizziness	Health			Pharm	ORAL		
ORAL	16 YR							
	Headache	Professional	Thorazine	SS			100	
	Nephrogenic Diabetes						MILLIGRAMS	
	Insipidus		Lorazepam	C				
	Nocturia		Zantac	C				
	Polydipsia		Serzone	C				
	Polydipsia Psychogenic							
	Polyuria							
	Renal Disorder							
	Urine Abnormality							
	Vomiting							
	Weight Increased							

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Date:01/13/98ISR Number: 3015473-9Report Type:Expedited (15-DaCompany Report #98000342-1
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Creatinine Increased	Health Professional	Eskalith	PS	Smithkline Beecham	ORAL	450 ML/ 2.0 DAILY ORAL/20	
	Hypertension							YEARS 20 YR
	Tremor		Eskalith	SS	Smithkline Beecham	ORAL	2.0 DAILY/ ORAL	

Date:01/13/98ISR Number: 3095823-8Report Type:Direct Company Report #
Age:43 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Asthenia		Lithium	PS			200MG TID	
	Blood Creatine Phosphokinase Increased							
	Convulsion							
	Difficulty In Walking							
	Dizziness							
	Drug Toxicity							
	Hypertension							
	Neuroleptic Malignant Syndrome							
	Tremor							

Date:01/14/98ISR Number: 3016777-6Report Type:Expedited (15-DaCompany Report #LITH002970034
Age:58 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Balance Disorder	Other	Lithonate	PS		ORAL	PER ORAL	
	Confusional State		Elavil	C				
	Disorientation		Synthroid	C				

	Emotional Disorder		Xanax	C		
	Visual Disturbance					

Date:01/15/98ISR Number: 3018405-2Report Type:Direct Company Report #
Age:51 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Coma		Lithium Carbonate	PS		
900MG PO BID						
Initial or Prolonged	Drug Level Above					
Required	Therapeutic					
Intervention to	Lethargy					
Prevent Permanent	Mental Impairment					
Impairment/Damage	Oedema Peripheral					

Date:01/15/98ISR Number: 3018422-2Report Type:Direct Company Report #
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Life-Threatening	Asthenia		Olanzapine	PS		ORAL
15MG QD PO						
Required	Lethargy		Lithium	SS		
600 MG BID						
Intervention to			Deponovera	C		
Prevent Permanent			Bentotropine	C		
Impairment/Damage			Prophxdol	C		
			Nifedipine	C		
			Phetz	C		

			Metzltestzolerod	C		
			Malox	C		
			Tylenol	C		
			Trazadae	C		
			Vitamins E	C		
			Halolol	C		

Date:01/15/98ISR Number: 3018670-1Report Type:Direct Company Report #
Age:29 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Cyanosis		Imitrex	PS				
	Drug Interaction		Nardil	SS				
	Dyspnoea		Lithobid	SS				
	Pharyngeal Oedema		Epinephrine	C				
			Benadryl	C				

Date:01/20/98ISR Number: 3018830-XReport Type:Direct Company Report #
Age:51 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Decreased Activity		Lithium	PS		ORAL	300 MG BID PO	
	Poverty Of Speech							
	Therapeutic Agent Toxicity							

Date:01/21/98ISR Number: 3018900-6Report Type:Direct Company Report #
Age:64 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Coma		Lithionate	PS			300MG BID	12 YR
Hospitalization - Initial or Prolonged	Drug Toxicity		Enalapril	C				
Required Intervention to Prevent Permanent			Levothyroxine	C				

Impairment/Damage

Date:01/22/98ISR Number: 3017818-2Report Type:Direct Company Report #
Age:66 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Depressed Level Of Consciousness Mental Impairment		Lithium	PS			300MG BID 150HS	LONG TERM
			Perphenzxime	C				
			Valproic Acid	C				

Date:01/26/98ISR Number: 3019308-XReport Type:Expedited (15-DaCompany Report #9800488
Age:19 YR Gender:Male I/FU:I

Outcome	PT
Death	Abdominal Pain
Hospitalization - Initial or Prolonged	Bipolar Disorder
	Blood Lactate Dehydrogenase Decreased

	Blood Sodium Decreased					
	Completed Suicide					
	Crystalluria	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
	Cystitis	Health	Zoloft	PS		ORAL
50.00 MG						
	Depression	Professional				
TOTAL:DAILY:O						
	Drug Interaction					
RAL						
	Potentiation		Xanax	SS		
	Dyskinesia		Lithium	SS		ORAL
900.00 MG						
	Electroencephalogram					
TOTAL:TID:ORA						
	Abnormal					
L						
	Eye Movement Disorder		Risperidone	SS		ORAL
9.00 MG						
	Haematuria					
TOTAL:TID:ORA						
	Intentional Misuse					
L						
	Ketonuria		Cogentin	C		
	Nervous System Disorder		Ativan	C		
	Urinary Tract Infection		Restoril	C		
	Urine Analysis Abnormal		Haldol Decanoate	C		
			Haldol	C		

Date:01/27/98ISR Number: 3021391-2Report Type:Direct Company Report #
Age:61 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization -	Confusional State		Lithium	PS		
Initial or Prolonged	Coordination Abnormal		Atenolol	C		
			Hctz	C		
			Haloperidol	C		
			Risperidone	C		
			Benztropine	C		

Date:01/29/98ISR Number: 3021790-9Report Type:Expedited (15-DaCompany Report #B0052903
Age:36 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hepatic Enzyme Increased Hepatitis	Foreign	Epivir Thioridazine Lithium Salt Indianavir Stavudine	PS SS SS SS SS		ORAL ORAL ORAL ORAL ORAL	300MG PER DAY/ ORAL 100MG PER DAY / ORAL 1200MG PER DAY/ ORAL 800MG PER DAY / ORAL 40MG PER DAY/ ORAL	

Date:01/29/98ISR Number: 3111907-XReport Type:Periodic Company Report #8-97299-122K
Age:47 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Amnesia Anxiety Confusional State Thinking Abnormal	Consumer	Redux Eskalith	PS SS		ORAL ORAL	600MG	14 YR

Date:01/30/98ISR Number: 3021558-3Report Type:Expedited (15-DaCompany Report #EL U830101-(8900792-1)
Age:51 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Disability								

Other

	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Burn Oesophageal	Consumer	Eskalith	PS	Smithkline Beecham			
	Dizziness	Health			Pharm	ORAL	150	
	Headache	Professional					MILLIGRAMS	
	Nephrogenic Diabetes						ORAL DAILY	
	Insipidus		Thorazine	SS		ORAL	500	
	Nocturia						MILLIGRAMS	
	Pollakiuria						1.0 DAILY	
	Polydipsia						ORAL	
	Polyuria		Lorazepam	C				
	Renal Impairment		Zantac	C				
	Sedation		Serzone	C				
	Urine Analysis Abnormal							
	Vomiting							
	Weight Increased							

Date:02/02/98ISR Number: 3022576-1Report Type:Expedited (15-DaCompany Report #98000342-1
Age:41 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Blood Creatinine	Health	Eskalith	PS	Smithkline Beecham	ORAL	450	
Initial or Prolonged	Increased	Professional					MILLIGRAMS	
	Blood Thyroid Stimulating						2.0 DAILY	
	Hormone Increased						ORAL; 300	
	Diarrhoea						MILLIGRAMS	19 DAY
	Drug Level Above		Fluphenazine	C				
	Therapeutic		Carbamazepine	C				
	Drug Toxicity							
	Hypertension							

Hypothyroidism
Mania
Muscle Rigidity
Tremor
Urinary Incontinence

Date:02/03/98ISR Number: 3028985-9Report Type:Direct Company Report #
Age:58 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Mental Disorder		Lithonate	PS				
Other								
Required								
Intervention to								
Prevent Permanent								
Impairment/Damage								

Date:02/10/98ISR Number: 3027038-3Report Type:Expedited (15-DaCompany Report #LBID002980003
Age:49 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Blood Potassium Decreased	Consumer	Lithobid	PS		ORAL		
ORAL								
Initial or Prolonged			Prozac	C				

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

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

Date:02/10/98ISR Number: 3027145-5Report Type:Expedited (15-DaCompany Report #LITH000980001
Age:56 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Blood Parathyroid Hormone Increased Bradycardia Cardiovascular Disorder Dermatitis Drug Level Above Therapeutic Hypercalcaemia Hypertension Hypomania Parathyroid Disorder	Literature	Lithium Carbonate Thiothixene	PS C		ORAL	PER ORAL

Date:02/17/98ISR Number: 3029847-3Report Type:Expedited (15-DaCompany Report #8-98040-037D
Age:47 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Hypotension Overdose	Foreign Health	Effexor Diazepam	PS SS		ORAL ORAL	900MG ORAL 90 ORAL

Other	Sedation	Professional	Estrogen	SS		ORAL
6 ORAL						
			Lithium	SS		ORAL
3.6 G ORAL						
			Procyclidine	SS		ORAL
90 MG ORAL						

Date:02/17/98ISR Number: 3030593-0Report Type:Direct Company Report #
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Drug Level Above		Lithium Carbonate	PS		
Initial or Prolonged	Therapeutic		Haloperidol	C		
	Intentional Misuse		Trazodone	C		
			Benztropine	C		

Date:02/17/98ISR Number: 3030662-5Report Type:Direct Company Report #
Age:39 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Congenital Anomaly	Abortion Spontaneous		Lithium	PS		
	Complications Of Maternal		Trilafon	SS		
8 MG BID						
	Exposure To Therapeutic		Klonipin	C		
	Drugs		Zoloft	C		
	Foetal Disorder		Atenolol	C		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/17/98ISR Number: 3247642-7Report Type:Periodic Company Report #8-97357-005S
Age:41 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Interaction	Consumer	Duract	PS		ORAL	50 MG TWICE	
	Tremor						DAILY ORAL	
			Lithium	SS			1500 MG DAILY	
			Clonidine Patch	C				

Date:02/18/98ISR Number: 3031911-XReport Type:Direct Company Report #
Age:54 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Decreased Appetite		Lithium	PS		ORAL	PO	20 YR
	Mental Disorder							
	Nausea							
	Vomiting							

Date:02/19/98ISR Number: 3032009-7Report Type:Expedited (15-DaCompany Report #93968
Age:40 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Coma	Health	Posicor	PS		ORAL	50.0000 MG	
	Convulsion	Professional					DAILY ORAL	
	Drug Toxicity		Lithium	SS		ORAL	900.0000 MG	
	Electrocardiogram Qt						DAILY ORAL	
	Prolonged		Cogentin	C				
			Risperdal	C				

Date:02/19/98ISR Number: 3032300-4Report Type:Expedited (15-DaCompany Report #8-98040-023D
Age:45 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Dysarthria	Foreign	Efexor Tablets	PS		ORAL	750 MG ORAL	
Initial or Prolonged	Overdose	Health	Etoh	SS				
Other	Sedation	Professional	Lithium	SS			19.2 G	
			Thyroxine	SS			125 MCG	

Date:02/20/98ISR Number: 3032159-5Report Type:Expedited (15-DaCompany Report #8-98040-003D
Age:36 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Coma	Foreign	Efexor	PS		ORAL	ORAL	
Initial or Prolonged	Dry Mouth	Health	Alcohol	SS		ORAL	ORAL	
Other	Hypotension	Professional	Buprenorphine	SS				
	Overdose		Lithium	SS				
	Tachycardia		Paracetamol	SS				
			Thioridazine	SS				
			...	C				
			...	C				
			...	C				
			...	C				
			...	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/20/98ISR Number: 3032982-7Report Type:Expedited (15-DaCompany Report #EL U830101 (83900792-1)
Age:51 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Aggression Blood Creatinine Increased	Consumer Health Professional	Eskalith	PS	Smithkline Beecham Pharm	ORAL	600 MILLIGRAMS	3.0 DAILY
	Chest Pain							
	Dermatitis							
	Diarrhoea							
	Dizziness		Thorazine	SS		ORAL	200 MILLIGRAMS	3.0 DAILY
	Erectile Dysfunction							
	Flushing							
	Hallucinations, Mixed							
	Headache		Thorazine	SS		ORAL	100 MILLIGRAMS	1.0 DAILY
	Hostility							
	Nephrogenic Diabetes Insipidus							
	Nocturia							
	Oesophagitis		Eskalith	SS	Smithline Beecham Pharm	ORAL	1500 MILLIGRAMS	
	Paranoia							
	Polydipsia							
	Polydipsia Psychogenic							
	Polyuria							
	Renal Disorder							
	Schizophrenia		Lorazepam	C				
	Sedation		Serzone	C				

	Suicidal Ideation		Imipramine	C		
	Thirst		Klonopin	C		
	Throat Irritation					
	Urine Abnormality					
	Vomiting					
	Weight Increased					

Date:02/23/98ISR Number: 3036317-5Report Type:Expedited (15-DaCompany Report #8-98044-005D
Age:38 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Drug Interaction	Foreign	Efexor	PS		ORAL	
Initial or Prolonged	Potentiation	Health	Chlordiazepoxide	SS			
Other	Loss Of Consciousness	Professional	Lithium	SS			
	Mydriasis		Paracetamol	SS			
	Overdose		Promethazine	SS			
	Vomiting		Thiordidazine	SS			

Date:02/23/98ISR Number: 3036440-5Report Type:Expedited (15-DaCompany Report #9802883
Age:75 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Confusional State	Foreign	Zoloft	PS		ORAL	100.00MG
Initial or Prolonged	Disturbance In Attention	Health					TOTAL DAILY
	Drug Interaction	Professional					ORAL
	Therapeutic Agent	Company	Lithium	SS		ORAL	84.00MG TOTAL
	Toxicity	Representative					BID ORAL
		Other					

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/23/98ISR Number: 3036667-2Report Type:Direct Company Report #
Age:53 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Atrioventricular Block		Lithium	PS			450MG Q AM 900MG Q PM	3 MON
	First Degree							
	Depression		Olanzapine	C				
	Diarrhoea		Asa Ec	C				
	Drug Toxicity		Erythromycin	C				
	Suicidal Ideation							

Date:02/23/98ISR Number: 3036817-8Report Type:Direct Company Report #
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Abdominal Pain		Lithium	PS		ORAL	300 MG PO QD	
	Anorexia							
	Confusional State		Carbamazepine	C				
	Drug Toxicity							
	Dysarthria							
	Nausea							
	Tremor							

Date:02/23/98ISR Number: 3036824-5Report Type:Direct Company Report #
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Toxicity		Lithium	PS		ORAL	600 MG PO BID	
	Sedation						LESS THAN ONE YR	1 YR

Date:02/23/98ISR Number: 3037819-8Report Type:Expedited (15-DaCompany Report #93968
Age:40 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Coma	Health	Posicor	PS		ORAL	50.00 MG	
Initial or Prolonged	Convulsion	Professional					DAILY ORAL	
	Electrocardiogram Qt		Lithium	SS		ORAL	900.00 MG	
	Prolonged						DAILY ORAL	
	Therapeutic Agent		Cogentin	C				
	Toxicity		Risperdal	C				
	Ventricular Hypertrophy							

Date:02/23/98ISR Number: 3037910-6Report Type:Expedited (15-DaCompany Report #WAES 98020028
Age:60 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Drug Toxicity	Health	Fosamax	PS		ORAL	10	
Initial or Prolonged	Hypoglycaemia	Professional					MG/DAILY/PO	
	Syncope		Lithiumco3	SS			UNKNOWN	1500-1800
							MG/DAILY	
			Artane	C				
			Buspar	C				
			Depakote	C				
			Haldol	C				
			Os-Cal	C				
			Aspirin	C				
			Digoxin	C				

			Docusate Sodium	C			
			Lithium Carbonate	C			
			Vitamin E	C			

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

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

Date:02/25/98ISR Number: 3038292-6Report Type:Direct Company Report #
Age:60 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Coordination Abnormal		Phenytion	PS			200 MG Q AM + HS, 100 MG Q	
Required Intervention to Prevent Permanent Impairment/Damage	Nystagmus		Lithium	SS			600 MG Q AM + HS &300	
			Sertraline	C				
			Lisinopril	C				

Date:03/02/98ISR Number: 3128640-0Report Type:Periodic Company Report #9721690
Age:22 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Anorexia	Consumer	Zoloft	PS		ORAL	ORAL	
	Depression		Antibiotic	SS		ORAL	ORAL	
	Hostility		Lithium	SS		ORAL	1200 MG TOTAL	
	Increased Appetite						BID ORAL	
	Neurosis		Redux	SS		ORAL	ORAL	
	Weight Increased		Ritalin	C				
			Tegretol	C				
			Serzone	C				

Date:03/02/98ISR Number: 3129649-3Report Type:Periodic Company Report #9713237
Age:68 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Interaction	Health	Zoloft	PS		ORAL	50.00MG TOTAL	
	Nausea	Professional					DAILY ORAL	
	Sedation		Lithium	SS		ORAL	600.00MG TOTAL BID ORAL	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/02/98ISR Number: 3130209-9Report Type:Periodic Company Report #9618742
Age:83 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Ineffective	Health	Zoloft	PS		ORAL	200 MG TOTAL	
	Drug Level Below	Professional					DAILY ORAL	
	Therapeutic		Lithium	SS		ORAL	450 MG TOTAL	
	Tremor						ORAL	
			Aminophylline	C				
			Atrovent	C				
			Proventil	C				
			Vancenase	C				
			Synthroid	C				

Date:03/02/98ISR Number: 3130728-5Report Type:Periodic Company Report #9703016
Age:50 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Mania	Consumer	Zoloft Tablets	PS		ORAL	75.00 MG	
Initial or Prolonged	Tremor	Health					TOTAL;DAILY;O	
		Professional					RAL	
			Mellaril	SS		ORAL	ORAL	
			Lithium	SS				
			Klonopin	C				
			Restoril	C				

Date:03/02/98ISR Number: 3130964-8Report Type:Periodic Company Report #9724608
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Depression	Consumer	Zoloft	PS		ORAL	ORAL	

	Hangover		Lithium	SS		ORAL
DAILY: ORAL						
	Mania					

Date:03/02/98ISR Number: 3141572-7Report Type:Periodic Company Report #9722228
Age:36 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Depression	Consumer	Zoloft	PS		ORAL
150.00 MG						
	Ejaculation Disorder					
TOTAL:DAILY:O						
	Erectile Dysfunction					
RAL						
	Libido Decreased		Lithium	SS		ORAL
ORAL						
	Personality Disorder					

Date:03/02/98ISR Number: 3145014-7Report Type:Periodic Company Report #9703873
Age:19 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Confusional State	Health	Zoloft	PS		ORAL
100.00 MG						
	Delirium	Professional				
TOTAL: DAILY:						
	Drug Interaction					
ORAL						
	Vomiting		Lithium	SS		ORAL
600.00 MG						
TOTAL: DAILY:						
ORAL						
			Monosodium Glutamate	SS		ORAL
ORAL						

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/02/98ISR Number: 3145032-9Report Type:Periodic Company Report #9703875
Age:20 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Confusional State	Health	Zoloft	PS		ORAL	100.00 MG	
	Delirium	Professional					TOTAL: DAILY:	
	Drug Interaction					ORAL		
			Monosodium Glutamate	SS		ORAL		
			Lithium	SS		ORAL	600.00 MG	
							TOTAL: DAILY:	
						ORAL		

Date:03/02/98ISR Number: 3147552-XReport Type:Periodic Company Report #9709868
Age:38 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Chills	Consumer	Zoloft	PS		ORAL	TID ORAL	
	Confusional State	Health	Redux	SS		ORAL	30 MG TOTAL	
	Coordination Abnormal	Professional					BID ORAL	
	Depression		Lithium	SS		ORAL	300 MG TOTAL	
							DAILY ORAL	
			Eskalith	C				
			Glucophage	C				
			Glucotrol Xl	C				

Date:03/02/98ISR Number: 3149180-9Report Type:Periodic Company Report #9708927
Age:19 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Confusional State	Health	Zoloft Tablets	PS		ORAL	DAILY; ORAL	
	Vomiting	Professional	Lithonate	SS		ORAL	DAILY; ORAL	
			Monosodium Glutamate	SS		ORAL	ORAL	

Date:03/04/98ISR Number: 3040500-2Report Type:Expedited (15-DaCompany Report #1998004061-1
Age:56 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Anxiety	Literature	Lithuim	PS	Smithkline Beecham		900 MG	
Initial or Prolonged	Aphasia		Flupenthixol	C				
	Apraxia		Haloperidol	C				
	Chills		Perazine	C				
	Depression							
	Disorientation							
	Elevated Mood							
	Mania							
	Muscle Rigidity							
	Parkinson'S Disease							
	Reflexes Abnormal							
	Restlessness							
	Sleep Disorder							
	Tremor							

Date:03/04/98ISR Number: 3128786-7Report Type:Periodic Company Report #9726378
Age:57 YR Gender:Male I/FU:I

Outcome	PT
Other	Drug Interaction
	Drug Level Below

	Therapeutic						
	Hostility						
	Mania						
		Report Source	Product	Role	Manufacturer	Route	Dose Duration
		Health	Cardura	PS		ORAL	DAILY ORAL
		Professional	Lithium	SS		ORAL	1350.00MG TOTAL TID ORAL

Date:03/04/98ISR Number: 3131235-6Report Type:Periodic Company Report #9726378
Age:57 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Other	Drug Interaction	Health	Cardura	PS		ORAL	DAILY; ORAL
	Drug Level Below Therapeutic	Professional	Lithium	SS		ORAL	1350.00 MG TOTAL; TID; ORAL
	Hostility						
	Mania						

Date:03/06/98ISR Number: 3048757-9Report Type:Expedited (15-DaCompany Report #9803770
Age:51 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Confusional State	Foreign	Minipress Xl	PS		ORAL	ORAL
	Dysarthria	Health	Lithium Carbonate	SS			
	Sinus Bradycardia	Professional	Haloperidol	C			
	Therapeutic Agent Toxicity		Clobazam	C			
			Carbamazepine	C			
	Tremor		Disulfirame	C			

Date:03/06/98ISR Number: 3139756-7Report Type:Periodic Company Report #8-97162-003B
Age:43 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Abnormal Dreams	Health	Effexor	PS		ORAL	37.5MG THREE	
	Agitation	Professional					TIMES DAILY	
	Amnesia						ORAL,75MG	
	Anxiety						TWICE	
	Confusional State						DAILY,75MG	
	Coordination Abnormal		Codeine Cough Syrup	SS				
	Drug Withdrawal Syndrome		Fastin	SS		ORAL	ORAL	
	Gait Disturbance		Lithium	SS		ORAL	900MG DAILY	
	Pharyngitis						ORAL	
	Speech Disorder		Pondimin Tablets	SS		ORAL	ORAL	
			Sinequan	C				

Date:03/06/98ISR Number: 3145898-2Report Type:Periodic Company Report #8-97065-002J
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Agitation	Health	Effexor	PS		ORAL	300 MG THREE	
Initial or Prolonged	Hostility	Professional					TIMES DAILY	
	Psychotic Disorder						ORAL/ 300 MG	
							FOUR TIMES	
							DAILY / 100	
			Cogentin	SS		ORAL	0.5 MG AT	
							BEDTIME ORAL	
			Lithium	SS		ORAL	600 MG AT	

BEDTIME ORAL						
			Tranxene	SS		
75 MG THREE						
TIMES DAILY						
			Trilafon	SS		ORAL
2 MG AT						
BEDTIME ORAL						
			Cogentin	C		
			Lithium	C		
			Tranxene	C		
			Trilafon	C		

Date:03/06/98ISR Number: 3146564-XReport Type:Periodic Company Report #8-96346-001J
Age:30 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Condition Aggravated	Health	Effexor	PS		ORAL		
ORAL							2	MON
	Depression	Professional	Lithium	SS				
2 MON								
	Ecchymosis		Lithium	C				
	Menorrhagia							

Date:03/09/98ISR Number: 3051619-4Report Type:Expedited (15-DaCompany Report #9802883
Age:75 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Bipolar I Disorder	Foreign	Zoloft	PS		ORAL		
100.00 MG								
Initial or Prolonged	Blood Thyroid Stimulating	Health						
TOTAL:DAILY:O								
	Hormone Decreased	Professional						
RAL								
	Confusional State	Company	Lithium	SS		ORAL		
84.00 MG								
	Disturbance In Attention	Representative						
TOTAL:BID:ORA								
	Drug Interaction							
L								

	Potentiation					
	Drug Level Above Therapeutic					
	Malaise					
	Urinary Tract Infection					

Date:03/09/98ISR Number: 3051623-6Report Type:Expedited (15-DaCompany Report #9802883
Age:75 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Antidepressant Drug Level Above Therapeutic	Foreign Health	Zoloft	PS		ORAL	100.00 MG	TOTAL:DAILY:O
	Confusional State	Professional						
	Disturbance In Attention	Company	Lithium	SS		ORAL	84.00 MG	TOTAL:BID:ORA
	Drug Interaction	Representative						
	Potentiation							

Date:03/10/98ISR Number: 3049180-3Report Type:Direct Company Report #
Age:58 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dysarthria		Lithium	PS		ORAL	600MG BID PO	
	Feeling Jittery		Lithium	C				
	Overdose		Phenytoin	C				
	Tremor		Lorazepam	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/10/98ISR Number: 3054453-4Report Type:Expedited (15-DaCompany Report #8-98054-002D
Age:46 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Intentional Misuse	Foreign	Efexor	PS		ORAL	UNKNOWN	
Initial or Prolonged	Loss Of Consciousness	Health					AMOUNT ORAL	
		Professional	Diazepam	SS				
			Lithium	SS				
			Moclobemine	SS				
			Procyclidine	SS				
			N/A	C				

Date:03/12/98ISR Number: 3058532-7Report Type:Direct Company Report #
Age:42 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Abdominal Distension		Lithium	PS		ORAL	ORALLY	
Life-Threatening	Abdominal Pain		Metronidazole	C				
	Anorexia		Timentin	C				
	Antinuclear Antibody Positive		Methylprdenisolone	C				
	Aspiration		Diazepam	C				
	Bipolar Disorder		Phenytoin	C				
	Blood Creatinine Increased							
	Blood Culture Positive							
	Blood Pressure Decreased							
	Constipation							
	Convulsion							
	Dehydration							
	Depressed Level Of Consciousness							
	Dermatitis							
	Diabetes Mellitus							
	Eye Disorder							
	Haemorrhage							
	Hepatomegaly							
	Large Intestine Perforation							
	Lethargy							

Lupus Encephalitis
Metabolic Acidosis
Nausea
Nephrosclerosis
Oliguria
Pelvic Congestion
Peritoneal Haemorrhage
Petechiae
Pulmonary Oedema
Pyrexia
Renal Failure Acute
Sluggishness
Therapeutic Agent
Toxicity
Ventricular Hypertrophy
Vomiting

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/12/98ISR Number: 3135135-7Report Type:Periodic Company Report #JAUSA-27988
Age:23 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Confusional State	Health Professional	Risperdal (Risperidone), Janssen, Tablet	PS	Janssen	ORAL	2 MG DAILY	
			Lithium	SS		ORAL		

Date:03/12/98ISR Number: 3135137-0Report Type:Periodic Company Report #JAUSA-27989
Age:20 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Confusional State Extrapyramidal Disorder Sedation	Health Professional	Risperdal (Risperidone), Janssen, Tablet	PS	Janssen	ORAL	1.5 MG DAILY	
			Lithium (Lithium)	SS		ORAL		

Date:03/12/98ISR Number: 3139764-6Report Type:Periodic Company Report #JAUSA-28930
Age:12 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Albuminuria Haematuria Polyuria Thirst	Health Professional	Risperdal (Risperidone), Janssen, Tablet	PS	Janssen	ORAL	8 MG DAILY	
			Lithium (Lithium) Tablet	SS		ORAL	-,	ORAL,STOPPED

DUE TO

POLYURIA,

POLYDIPSIA

Depakote	C	
Ritalin	C	
Zoloft	C	

Date:03/19/98ISR Number: 3057674-XReport 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	Asthenia Visual Disturbance		Lithium	PS			600 MG Q AM; 900 MG Q HS;	

THERAPY: LONG

TERM

Salicylates Pru	C	
Risperidone	C	

Date:03/24/98ISR Number: 3059467-6Report Type:Expedited (15-DaCompany Report #96115
Age:36 YR Gender:Female I/FU:I

Outcome	PT
Death	Agitation
	Blood Thyroid Stimulating Hormone Increased
	Bundle Branch Block Right
	Drug Level Above

Therapeutic
Electrocardiogram Normal

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
		Foreign	Rivotril	PS		ORAL	8.000 MG	DAILY ORAL
		Other	Teralithe	SS		ORAL	800.0000 MG	DAILY ORAL
			Depakine Chrono	SS		ORAL	500.0000MG	DAILY ORAL
			Atarax	SS		ORAL	300.0000MG	DAILY ORAL
			Valium	C				
			Nozinan	C				

Date:03/24/98ISR Number: 3059577-3Report Type:Expedited (15-DaCompany Report #94721
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abnormal Behaviour	Health	Accutane	PS		ORAL	40.0000 MG	2.0 X PER DAY
	Hallucination	Professional						
	Mania							
	Psychotic Disorder		Lithium	SS		ORAL	1.0000 DOSE	FORM 1.0 X
	Self Mutilation							PER DAY ORAL

Date:03/25/98ISR Number: 3060427-XReport Type:Expedited (15-DaCompany Report #LITH002980004
Age:45 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Distension Blood Pressure Decreased Cardiac Failure Congestive Confusional State Delirium Diarrhoea Drug Level Above Therapeutic Dyspnoea Hallucination, Visual Oedema Peripheral Oxygen Saturation Decreased Pneumonia Vomiting Weight Increased	Consumer	Lithonate Morphine	PS C		ORAL ORAL	900 MG, PER	

Date:03/25/98ISR Number: 3060546-8Report Type:Direct Company Report #
Age:49 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	Diabetes Insipidus Hypernatraemia		Lithium Carbonate	PS		ORAL	300 MG BID PO	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/25/98ISR Number: 3132828-2Report Type:Periodic Company Report #8-98020-008N
Age:39 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Specific Antibody	Consumer	Lodine	PS		ORAL	400 MG BID;	
	Present							PRN
			Dayquil	SS				
			Depakote	SS				
			Imipramine	SS				
			Lithium	SS				
			Pseudophedrine Promethazine With Codeine	SS				
			E.E.S.	C				

Date:03/26/98ISR Number: 3059262-8Report Type:Expedited (15-DaCompany Report #1998007501-1
Age:59 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Cardiac Failure	Health Professional	Eskalith	PS	Smithkline Beecham		300 MILLIGRAMS	
	Drug Level Above Therapeutic							3.0 DAILY
	Dyspnoea		Hydrochlorothiazide	C				
	Pulmonary Oedema		Plendil (Felodipine Sr)	C				
			Atenolol	C				
			Zocor (Simvastatin)	C				
			Insulin	C				

Date:03/27/98ISR Number: 3062164-4Report Type:Direct Company Report #
Age:31 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Overdose		Lithium	PS		ORAL	300MG QID	

Initial or Prolonged
ORAL

			Risperidone	C		
			Vitamin B Complex Cap	C		

Date:03/31/98ISR Number: 3062158-9Report Type:Direct Company Report #
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Diabetes Insipidus		Lithium	PS				

Date:03/31/98ISR Number: 3063232-3Report Type:Direct Company Report #
Age:74 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Difficulty In Walking Disorientation Posture Abnormal	Health Professional	Lithium	PS				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/01/98ISR Number: 3071856-2Report Type:Direct Company Report #
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Ileus Paralytic		Clozapine	PS		ORAL	700 MG / DAY	PO BID
			Lithun Carbonate	SS			300MG TID	

Date:04/02/98ISR Number: 3071716-7Report Type:Direct Company Report #
Age:46 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Dysarthria		Lithium Carbonate	PS			300 MG III	
	Movement Disorder						QAM II QPM	
	Sedation							
	Tremor							

Date:04/03/98ISR Number: 3061334-9Report Type:Expedited (15-DaCompany Report #9806748
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Serotonin Syndrome	Health Professional	Lithane	PS		ORAL	ORAL	
			Trilafon	C				
			Klonopin	C				
			Trazodone	C				
			Nardil	C				

Date:04/06/98ISR Number: 3063010-5Report Type:Expedited (15-DaCompany Report #9905149
Age:36 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Death	Agitation	Foreign	Depakene	PS	Abbott	ORAL 500.00 MG PO
Hospitalization - Initial or Prolonged	Blood Thyroid Stimulating Hormone Increased	Health Professional	Lithium Carbonate	SS		ORAL 800 MG PO QD
	Bundle Branch Block		Diazepam	C		
	Electrocardiogram Normal		Clonazepam	C		
	Excitability					

Date:04/06/98ISR Number: 3152715-3Report Type:Periodic Company Report #9725041
Age:35 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Other	Drug Toxicity	Health	Zyrtec	PS		ORAL 10.00 MG TOTAL: DAILY: ORAL
	Hyperhidrosis	Professional				
	Nervousness					
	Tremor		Lithium	SS		ORAL ORAL
			Erythromycin Ointment	C		
			Restoril	C		
			Akineton	C		
			Haldol Deconoate	C		
			Elavil	C		
			Anaprox Ds	C		
			Beconase	C		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/07/98ISR Number: 3063332-8Report Type:Expedited (15-DaCompany Report #8-98086-028A
Age:25 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Electroencephalogram	Foreign	Stangyl	PS		ORAL	250 MD DAILY	
	Abnormal	Health				ORAL		
	Grand Mal Convulsion	Professional	Diazepam	SS		ORAL	40 MG DAILY UNTIL 1/16 THEN 5 MG DAILY	
			Lithium Carbonate	SS			1000 MG DAILY	
			Olanzapine	SS			20 MG DAILY THEN 30 MG DAILY SINCE 2/4	

Date:04/07/98ISR Number: 3153599-XReport Type:Periodic Company Report #1997005654-1
Age:52 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Alopecia	Consumer	Eskalith	PS	Smithkline Beecham	ORAL	ORAL	24 MON
			Risperidone	C				
			Premarin	C				
			Provera	C				
			Multiple Vitamins	C				

Date:04/07/98ISR Number: 3153600-3Report Type:Periodic Company Report #1997007414-1
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Level Below Therapeutic	Health Professional	Eskalith	PS	Smithkline Beecham	ORAL	450 MILLIGRAMS	2.0 DAILY

ORAL

Date:04/07/98ISR Number: 3153601-5Report Type:Periodic Company Report #1997007473-1
Age:58 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Diabetes Insipidus Diarrhoea	Health Professional	Eskalith	PS	Smithkline Beecham	ORAL	450 MILLIGRAMS	2.0 DAILY

ORAL

Date:04/07/98ISR Number: 3153602-7Report Type:Periodic Company Report #1997013298-1
Age:53 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Dizziness Malaise Pain In Extremity	Consumer	Eskalith	PS	Smithkline Beecham	ORAL	450 MILLIGRAMS	1.0 DAILY

ORAL

			Paxil	SS		ORAL	10 MILLIGRAMS	1.0 DAILY

ORAL

			Paxil	SS		ORAL	5 MILLIGRAMS	1.0 DAILY

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/07/98ISR Number: 3153603-9Report Type:Periodic Company Report #1997018471-1
Age:31 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Flushing	Health Professional	Eskalith	PS	Smithkline Beecham	ORAL	450 MILLIGRAMS	3.0 DAILY

ORAL

Date:04/07/98ISR Number: 3153604-0Report Type:Periodic Company Report #1997027460-1
Age:14 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Diarrhoea	Health Professional	Eskalith	PS	Smithkline Beecham	ORAL	2.0 DAILY	
	Hypomania					ORAL		
	Nausea		Eskalith	SS	Smithkline Beecham	ORAL	300 MILIGRAMS	2.0 DAILY

ORAL

Date:04/07/98ISR Number: 3153605-2Report Type:Periodic Company Report #1998003859-1
Age:57 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Dyspnoea	Consumer	Eskalith	PS	Smithkline Beecham	ORAL	900 MILLIGRAMS	1.0 DAILY
	Movement Disorder							
	Muscle Twitching							
	Tremor					ORAL		

			Zoloft	C		

Date:04/07/98ISR Number: 3153606-4Report Type:Periodic Company Report #1997000161-1
Age:40 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Diabetes Insipidus	Health	Eskalith	PS	Smithkline Beecham	ORAL	450	MILLIGRAMS
	Polyuria	Professional					2.0	DAILY
ORAL								
			Depakote	C				
			Tenex	C				
			Klonopin	C				
			Claritin	C				
			Theophylline	C				

Date:04/07/98ISR Number: 3153608-8Report Type:Periodic Company Report #1997009176-1
Age:53 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Interaction	Health	Eskalith	PS	Smithkline Beecham	ORAL	300	MILLIGRAMS
		Professional					2.0	DAILY
ORAL								

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/07/98ISR Number: 3153610-6Report Type:Periodic Company Report #1997009446-1
Age:48 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Alopecia	Consumer	Eskalith	PS	Smithkline Beecham	ORAL	450	
	Tremor						MILLIGRAMS	
							1.0	DAILY
							ORAL	
			Effexor	C				
			Xanax	C				
			Depakote	C				

Date:04/07/98ISR Number: 3153612-XReport Type:Periodic Company Report #1998000691-1
Age:23 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Menstruation Irregular	Consumer	Eskalith	PS	Smithkline Beecham	ORAL	450	
							MILLIGRAMS	
							2.0	DAILY
							ORAL	
			Wellbutrin	C				

Date:04/07/98ISR Number: 3153614-3Report Type:Periodic Company Report #1997002927-1
Age:55 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Polyuria	Health	Eskalith	PS	Smithkline Beecham	ORAL	300	
	Urinary Incontinence	Professional					MILLIGRAMS	
							2.0	DAILY

ORAL 3 YR

Date:04/07/98ISR Number: 3153615-5Report Type:Periodic Company Report #1997003303-1
Age:68 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Skin Odour Abnormal	Consumer	Eskalith	PS		ORAL	2.0	DAILY
ORAL								
			Zantac	C				
			Naprosyn	C				

Date:04/07/98ISR Number: 3153616-7Report Type:Periodic Company Report #1997003658-1
Age:52 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Constipation	Consumer	Eskalith	PS	Smithkline Beecham	ORAL		
ORAL								
	Dermatitis	Health	Prozac	C				
	Diarrhoea	Professional						
	Fatigue							

Date:04/07/98ISR Number: 3153617-9Report Type:Periodic Company Report #1997005636-1
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Hypercalcaemia	Health	Eskalith	PS	Smithkline Beecham	ORAL		
ORAL								
	Hyperparathyroidism	Professional						

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/07/98ISR Number: 3153618-0Report Type:Periodic Company Report #1997006020-1
Age:41 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Toxicity	Consumer	Eskalith	PS	Smithkline Beecham	ORAL		
	Migraine		Depakote	C				
			Lamotrigine	C				
			Risperidal	C				
			Synthroid	C				

Date:04/07/98ISR Number: 3153619-2Report Type:Periodic Company Report #1997010924-1
Age:54 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Blood Calcium Increased	Health	Eskalith	PS	Smithkline Beecham	ORAL	450	MILLIGRAMS
	Blood Parathyroid Hormone Increased	Professional					2.0	DAILY
	Gastrointestinal Disorder						ORAL	
	Nausea		Premarin	C				
			Moban	C				
			Ambien	C				
			Prozac	C				

Date:04/07/98ISR Number: 3153620-9Report Type:Periodic Company Report #1997011697-1
Age:30 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Muscle Spasms	Consumer	Eskalith	PS	Smithkline Beecham	ORAL	300	MILLIGRAMS
	Muscle Twitching						3.0	DAILY
							ORAL/300	

MILLIGRAM 2.0

	Dilantin	C
	Phenobarbital	C
	Tegretol	C

Date:04/07/98ISR Number: 3153621-0Report Type:Periodic Company Report #1997011729-1
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Hyperthyroidism	Consumer	Lithium	PS		ORAL	600	
		Health					MILLIGRAMS	
		Professional					2.0 DAILY	
							ORAL	
			Xanax	C				

Date:04/07/98ISR Number: 3153622-2Report Type:Periodic Company Report #1997011782-1
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Hyperkeratosis	Health	Lithium	PS				
		Professional						

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/07/98ISR Number: 3153843-9Report Type:Periodic Company Report #1997014796-1
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Renal Failure Acute	Health Professional	Eskalith	PS	Smithkline Beecham			

Date:04/07/98ISR Number: 3153846-4Report Type:Periodic Company Report #1997015517-1
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Leukocytosis	Consumer	Eskalith	PS	Smithkline Beecham			

Date:04/07/98ISR Number: 3153848-8Report Type:Periodic Company Report #1997015975-1
Age:45 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Acne	Consumer	Eskalith	PS	Smithkline Beecham	ORAL	300	
	Back Disorder						MILLIGRAMS	
	Capillary Disorder						4.0 DAILY	
	Muscle Disorder						300MG 2 DAILY	
	Skin Disorder		Depakote (Divalproex Sodium)	C				

Date:04/07/98ISR Number: 3153850-6Report Type:Periodic Company Report #1997017864-1
Age:80 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Bleeding Time Shortened	Consumer	Eskalith	PS	Smithkline Beecham		450	
	Drug Effect Decreased						MILLIGRAMS	

2.0 DAILY

			Coumadin	C		
			Lasix	C		

Date:04/07/98ISR Number: 3153852-XReport Type:Periodic Company Report #1997017935-1
Age:42 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Loss Of Consciousness	Health	Eskalith	PS	Smithkline Beecham	ORAL	3.0 DAILY	
Initial or Prolonged		Professional					2.0 DAILY	
							PO	
			Synthroid	C				

Date:04/07/98ISR Number: 3153854-3Report Type:Periodic Company Report #1997018032-1
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Psoriasis	Health	Eskalith	PS	Smithkline Beecham			
		Professional	Depakote	C				

Date:04/07/98ISR Number: 3153857-9Report Type:Periodic Company Report #1997019331-1
Age:30 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Raynaud'S Phenomenon	Health	Eskalith	PS	Smithkline Beecham	ORAL	750	
		Professional					MILLIGRAMS	

2.0 DAILY

			Risperdal	C		

Date:04/07/98ISR Number: 3153858-0Report Type:Periodic Company Report #1997019784-1
Age:50 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Weight Increased	Consumer	Eskalith	PS	Smithkline Beecham	ORAL	4	YR
			Zestril	C				
			Enduron	C				
			Potassium	C				

Date:04/07/98ISR Number: 3153860-9Report Type:Periodic Company Report #1997019914-1
Age:4 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Asthma	Health	Lithium	PS	Roxan Laboratories	ORAL	150	
		Professional					MILLIGRAMS	

3.0 DAILY

Date:04/07/98ISR Number: 3153862-2Report Type:Periodic Company Report #1997021397-1
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Alopecia	Consumer	Eskalith	PS	Smithkline Beecham	ORAL	300	
							MILLIGRAMS	

1.0 DAILY

Date:04/07/98ISR Number: 3153865-8Report Type:Periodic Company Report #1997021987-1
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Blood Alkaline Phosphatase Increased	Health Professional	Eskalith	PS	Smithkline Beecham	ORAL		
	Blood Creatinine Increased							
	Blood Urea Increased							
	Diabetes Insipidus							
	Hyponatraemia							

Date:04/07/98ISR Number: 3153866-XReport Type:Periodic Company Report #1997022826-1
Age:37 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Fat Tissue Increased	Consumer	Eskalith	PS	Smithkline Beecham	ORAL	450 MILLIGRAMS	3.0 DAILY
	Hair Disorder	Health Professional						
			Crixivan	C				
			3tc	C				
			Zovirax	C				
			Diflucan	C				
			Oxandrin	C				
			Zerit	C				
			D4t	C				
			Pentamidine	C				
			Ethambutol	C				
			Biaxin	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/07/98ISR Number: 3153869-5Report Type:Periodic Company Report #1997022839-1
Age:40 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Hypercalcaemia Hyperparathyroidism	Consumer	Eskalith	PS	Smithkline Beecham	ORAL		

Date:04/07/98ISR Number: 3153871-3Report Type:Periodic Company Report #197022844-1
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Diarrhoea	Health Professional	Eskalith	PS	Smithkline Beecham	ORAL		

Date:04/07/98ISR Number: 3153872-5Report Type:Periodic Company Report #1997023225-1
Age:45 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Cold Sweat	Consumer	Eskalith	PS	Smithkline Beecham	ORAL	1.0	DAILY
	Decreased Appetite		Prolixin	C				
	Hyperhidrosis		Risperdal	C				
	Nausea							

Date:04/09/98ISR Number: 3062812-9Report Type:Expedited (15-DaCompany Report #9803770
Age:51 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Confusional State	Foreign	Minipress	PS		ORAL	5.00	MG TOTAL:DAILY:ORAL
	Dysarthria	Health Professional						
	Hypothyroidism							
	Sinus Bradycardia		Lithium Carbonate	SS				
	Therapeutic Agent Toxicity		Haloperidol Clobazam	C C				

	Tremor		Citalopram	C		
			Carbamazepine	C		
			Disulfirame	C		

Date:04/09/98ISR Number: 3062813-0Report Type:Expedited (15-DaCompany Report #9803770
Age:51 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Confusional State		Minipress	PS		ORAL		
ORAL								
Initial or Prolonged	Dysarthria		Lithium Carbonate	SS		ORAL		
ORAL								
	Sinus Bradycardia		Haloperidol	C				
	Therapeutic Agent		Clobazam	C				
	Toxicity		Citalopram	C				
	Tremor		Carbamazepine	C				
			Disulfirame	C				

Date:04/13/98ISR Number: 3073098-3Report Type:Direct Company Report #
Age:37 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required	Polyuria		Eskalith Cr	PS			1T QD & 2HS	
Intervention to	Tremor		Relafen	SS			2QD	6 DAY
Prevent Permanent								
Impairment/Damage								

Date:04/16/98ISR Number: 3064399-3Report Type:Expedited (15-DaCompany Report #1998008534-1
Age:45 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Dehydration Diabetic Hyperosmolar Coma Nephrogenic Diabetes Insipidus Pancreatitis Polyuria	Literature	Lithium	PS				

Date:04/22/98ISR Number: 3071981-6Report Type:Direct Company Report #
Age:52 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hyperglycaemia		Lithium Carbonate	PS		ORAL	2G, 600MG BI, ORAL;	

THERAPY:

CHRONIC

Date:04/23/98ISR Number: 3073076-4Report Type:Direct Company Report #
Age:21 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Headache		Lithonate	PS		ORAL	300MG AD PO	

Date:04/24/98ISR Number: 3068508-1Report Type:Expedited (15-DaCompany Report #US_ 980401526
Age:51 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Hospitalization -	Condition Aggravated	Study	Lithium	PS
900 MG/DAY				
Initial or Prolonged	Delusional Disorder, Persecutory Type	Health Professional	Ativan	C
	Insomnia			

Date:04/24/98ISR Number: 3072192-0Report Type:Direct Company Report #
Age:21 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Headache		Lithonate	PS		ORAL
300MG A D PO						

Date:04/28/98ISR Number: 3071672-1Report Type:Expedited (15-DaCompany Report #B038068
Age:59 YR Gender:Male I/FU:I

Outcome	PT
Hospitalization -	Anxiety
Initial or Prolonged	Blood Creatine Phosphokinase Increased
	Blood Pressure Fluctuation
	Clonic Convulsion
	Coma
	Coordination Abnormal
	Delirium
	Depression
	Drug Interaction

	Dysarthria					
	Hyperhidrosis					
	Hyperreflexia	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
	Insomnia	Foreign	Trazodone	PS		ORAL
25-250 MG QD						
	Irritability	Literature				
ORAL						
	Medication Error	Health	Amitriptyline	SS		ORAL
75 MG QD ORAL 13 DAY						
	Muscle Rigidity	Professional	Lithium Carbonate	SS		
400-800MG QD						
	Pyrexia					
ORAL						
	Restlessness		Leveomepromazine	C		
	Serotonin Syndrome		Nitrazepam	C		
	Tremor					
	White Blood Cell Count Increased					

Date:04/30/98ISR Number: 3070686-5Report Type:Expedited (15-DaCompany Report #9800488
Age:19 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Abdominal Pain	Health	Zoloft	PS		ORAL
50.00 MG						
Hospitalization -	Bipolar Disorder	Professional				
TOTAL:DAILY:O						
Initial or Prolonged	Blood Lactate					
RAL						
	Dehydrogenase Decreased		Xanax	SS		
	Blood Sodium Decreased		Lithium	SS		ORAL
900.00 MG						
	Eye Movement Disorder					
TOTAL:TID:ORA						
	Haematuria					
L						
	Ketonuria		Risperidone	SS		ORAL
9.00 MG						
	Movement Disorder					
TOTAL:TID:ORA						
	Nervous System Disorder					
L						
	Urinary Tract Infection		Cogentin	C		

			Ativan	C			
			Restoril	C			
			Haldol Decanoate	C			
			Haldol	C			

Date:04/30/98ISR Number: 3070689-0Report Type:Expedited (15-DaCompany Report #9800488
Age:19 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Abdominal Pain	Health	Zoloft	PS		ORAL	50.00 MG	
Hospitalization -	Blood Lactate	Professional						TOTAL:DAILY:O
Initial or Prolonged	Dehydrogenase Decreased							RAL
	Blood Sodium Decreased		Xanax	SS				
	Eye Movement Disorder		Lithium	SS		ORAL	900.00 MG	
	Haematuria							TOTAL:TID:ORA
	Ketonuria							L
	Movement Disorder		Risperidone	SS		ORAL	9.00 MG	
	Nervous System Disorder							TOTAL:TID:ORA
	Overdose							L
	Urinary Tract Infection		Cogentin	C				
			Ativan	C				
			Restoril	C				
			Haldol Decanoate	C				
			Haldol	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/30/98ISR Number: 3070860-8Report Type:Expedited (15-DaCompany Report #9905149
Age:36 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Agitation	Foreign	Depakene	PS	Abbott	ORAL	500.00MG/PO/Q	
Hospitalization - D	Blood Thyroid Stimulating	Health						
Initial or Prolonged	Hormone Increased	Professional	Lithium Carbonate	SS		ORAL	PO	
	Bundle Branch Block		Diazepam	C				
	Electrocardiogram Normal		Clonazepam	C				
	Excitability							

Date:05/04/98ISR Number: 3074202-3Report Type:Expedited (15-DaCompany Report #WAES 98036106
Age:77 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Drug Interaction	Foreign	Vasotec	PS		ORAL	5 MG PO	15 DAY
Hospitalization -	Electrocardiogram	Other	Lithium	SS		ORAL	750 MG ORAL	
Initial or Prolonged	Abnormal							
	Ventricular Arrhythmia							

Date:05/06/98ISR Number: 3074082-6Report Type:Expedited (15-DaCompany Report #9810664
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Unevaluable Event	Consumer	Zoloft	PS		ORAL	TAB PO	
Initial or Prolonged			Lithium	SS				

Date:05/08/98ISR Number: 3074557-XReport Type:Direct Company Report #
Age:69 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Hospitalization - PO - DOSE	Bradycardia		Lithium	PS		ORAL
Initial or Prolonged UNKNOWN	Coma					
Required Intervention to Prevent Permanent Impairment/Damage	Heart Rate Decreased Hypotension Hypothermia Hypothyroidism Nephrogenic Diabetes Insipidus					

Date:05/08/98ISR Number: 3086666-XReport Type:Direct Company Report #
Age:34 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - PO;THERAPY:	Bradycardia		Lithium	PS		ORAL
Initial or Prolonged FOR SOME TIME	Depressed Level Of Consciousness		Tegretol	C		
	Hypotension		Risperdal	C		
	Hypothermia		Thorazine	C		
	Lethargy		Multivitamin	C		
			Klonopin	C		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/12/98ISR Number: 3163032-XReport Type:Periodic Company Report #9803056
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Intentional Misuse	Consumer	Lithane Tablets	PS		ORAL		
	Medication Error							
	Tremor							

Date:05/12/98ISR Number: 3163033-1Report Type:Periodic Company Report #9807323
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Constipation	Consumer	Lithane Tablets	PS		ORAL	1200.00 MG	TOTAL;BID;ORA
	Depression							
	Dermatitis							
	Pruritus		Atarax	SS		ORAL	100.00 MG	TOTAL;BID;ORA
	Sedation							
			Mellaril	SS		ORAL		
			Seroquel	C				
			Xanax	C				
			Klonopin	C				
			Neurontin	C				

Date:05/12/98ISR Number: 3163034-3Report Type:Periodic Company Report #9808181
Age:64 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Thyroid Disorder	Consumer	Lithane Tablets	PS		ORAL		
			Glucotrol Xl	C				
			Norvasc	C				

Date:05/12/98ISR Number: 3163035-5Report Type:Periodic Company Report #9808189
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Ineffective	Health	Lithane Tablets	PS		ORAL		
		Professional	Iron	C				

Date:05/12/98ISR Number: 3163037-9Report Type:Periodic Company Report #9809139
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Erectile Dysfunction	Consumer	Lithane Tablets	PS		ORAL	1800.00 MG	TOTAL;TID;ORAL
			Zoloft	SS		ORAL	50.00 MG	TOTAL;DAILY;ORAL

Date:05/13/98ISR Number: 3077134-XReport Type:Expedited (15-DaCompany Report #1998011902-1
Age:72 YR Gender:Female I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Blepharospasm
	Chorea
	Coordination Abnormal

	Dehydration					
	Depressed Level Of Consciousness	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
	Disorientation	Literature	Lithium	PS		
	Drug Level Above Therapeutic					
	Dysarthria					
	Dyskinesia					
	Reflexes Abnormal					
	Tardive Dyskinesia					
	Tremor					

Date:05/13/98ISR Number: 3078225-XReport Type:Expedited (15-DaCompany Report #1998011607-1
Age:42 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization -	Blood Sodium Increased	Literature	Lithium	PS	Smithkline Beecham	
10 YR						
Initial or Prolonged	Diabetic Hyperosmolar Coma					
Other	Nephrogenic Diabetes Insipidus					
	Nocturia					
	Pancreatitis Acute					
	Polyuria					

Date:05/18/98ISR Number: 3080058-5Report Type:Expedited (15-DaCompany Report #LITH002980010
Age:50 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization -	Clonic Convulsion	Foreign	Lithium	PS		ORAL
VARIED, PER						
Initial or Prolonged	Gait Disturbance	Literature				
ORAL	45 DAY					
	Hyperreflexia		Venlafaxine	SS		ORAL
37.5-225 MG,						
	Muscle Rigidity					
262.5MG,187.5						
	Restlessness					
MG,PER ORAL	45 DAY					

	Serotonin Syndrome					
	Tachycardia					

Date:05/18/98ISR Number: 3080652-1Report Type:Expedited (15-DaCompany Report #1998012322-1
Age:54 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Cardiomegaly	Health	Quilonorm	PS	Smithkline Beecham	
Initial or Prolonged	Pericardial Effusion	Professional				
	Respiratory Failure					
	Respiratory Gas Exchange Disorder					

Date:05/18/98ISR Number: 3081718-2Report Type:Expedited (15-DaCompany Report #1998001632-1
Age:59 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Asthenia	Health	Quilonum	PS	Smithkline Beecham	ORAL
675						
Initial or Prolonged	Hypergammaglobulinaemia	Professional				
MILLIGRAMS						
	Benign Monoclonal		Allopurinol	C		
	Paraesthesia					
	Plasmacytoma					
	Polyneuropathy					

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/19/98ISR Number: 3080074-3Report Type:Direct Company Report #
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Confusional State Nausea Tongue Oedema Vomiting		Lithium Carbonate	PS		ORAL	900 MG PO QHS	

Date:05/19/98ISR Number: 3081148-3Report Type:Expedited (15-DaCompany Report #1998012336-1
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Nephropathy Toxic	Health Professional	Lithium	PS				

Date:05/22/98ISR Number: 3081006-4Report Type:Direct Company Report #
Age:42 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	Dysphagia Hallucination Nausea Vomiting Weight Decreased		Lithium Carbamazepine Haloperidol Trihexyphenidyl	PS C C C		ORAL	1800 MG, 3T BID, ORAL	

Date:05/22/98ISR Number: 3081024-6Report Type:Direct Company Report #
Age:48 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Dysarthria		Lithium	PS			300 MG QID	

Initial or Prolonged	Renal Failure Acute					
	Therapeutic Agent					
	Toxicity					
	Tremor					

Date:05/26/98ISR Number: 3082977-2Report Type:Expedited (15-DaCompany Report #LBID002980014
Age:55 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Diarrhoea	Consumer	Lithobid	PS		ORAL	600 MG, PER	
Initial or Prolonged	Drug Level Above						DAY, PER ORAL	
	Therapeutic		Prozac	C				
	Hyperhidrosis		Xanax	C				
	Hypertension							
	Restlessness							
	Vomiting							

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

Outcome
Hospitalization -
Initial or Prolonged
Required

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

Date:05/27/98ISR Number: 3083411-9Report Type:Direct Company Report #
Age:74 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Amnesia		Lithium	PS			300MG BID	
	Asthenia		Humulin N	SS			30U BID	
	Confusional State		Hismopril	C				
	Drug Toxicity		Asa	C				
	Insomnia		Temazonym	C				
	Tremor		Thyrotime	C				
			Ntg	C				
			B1	C				

Date:05/27/98ISR Number: 3083438-7Report Type:Direct Company Report #
Age:40 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Diabetes Insipidus		Lithium	PS		ORAL	PO 900MG BID	
	Drug Toxicity							
	Mental Impairment						X YEARS	YR
	Sedation							

Date:05/28/98ISR Number: 3084591-1Report Type:Expedited (15-DaCompany Report #1998013117-1
Age: Gender:Not SpecifiI/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Condition Aggravated	Health	Lithium	PS			UNKNOWN	UNKNOWN
	Convulsion	Professional						

Date:05/28/98ISR Number: 3084856-3Report Type:Expedited (15-DaCompany Report #1998012855-1
Age:50 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Chills	Literature	Lithium	PS	Smithkline Beecham			
	Clonic Convulsion		Venlafaxine	C				
	Gait Disturbance							
	Hyperreflexia							
	Restlessness							
	Serotonin Syndrome							
	Tachycardia							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/29/98ISR Number: 3085347-6Report Type:Expedited (15-DaCompany Report #9813588
Age:75 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required	Confusional State	Consumer	Zoloft	PS		ORAL	250 MG	
Intervention to	Depression						TOTAL:DAILY:O	
Prevent Permanent	Fall						RAL	
Impairment/Damage	Infarction		Lithium	SS		ORAL	ORAL	
	Insomnia		Aricept	SS		ORAL	5 MG	
	Mood Altered						TOTAL:DAILY:O	
	Overdose						RAL	

Date:05/29/98ISR Number: 3085632-8Report Type:Expedited (15-DaCompany Report #9813535
Age: Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Convulsion	Foreign	Lithane	PS		ORAL	ORAL	
Hospitalization -	Coordination Abnormal	Health	Thiothixene	SS		ORAL	ORAL	
Initial or Prolonged	Drug Interaction	Professional						
Required								
Intervention to								
Prevent Permanent								
Impairment/Damage								

Date:06/01/98ISR Number: 3086984-5Report Type:Direct Company Report #
Age:86 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Renal Failure Acute		Lithium	PS		ORAL	300 MG PO BID	
Initial or Prolonged	Therapeutic Agent		Lasix	C				

	Toxicity		Digoxin	C		
			Zestoril	C		
			Zyprexa	C		
			K-Dur	C		
			Depakane	C		
			Verapamil	C		
			Metamicil	C		
			Amantadine	C		

Date:06/01/98ISR Number: 3087479-5Report Type:Expedited (15-DaCompany Report #B0056236
Age:60 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Cardiac Failure	Foreign	Ventolin	PS			INHALED
Initial or Prolonged	Lower Respiratory Tract Infection	Health Professional	Chlorpromazine	SS			
			Lithium	SS			
			Frusemide	SS		ORAL	40 MG /ORAL

Date:06/02/98ISR Number: 3088393-1Report Type:Expedited (15-DaCompany Report #LBIDOO2980015
Age:59 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Bladder Pain	Health	Lithobid Tablats 300				
Initial or Prolonged	Blood Creatine Increased	Professional	Mg (Lithium				
	Hepatotoxicity		Carbonate)	PS		ORAL	900 MG PER
	Jaundice						ORAL
	Mania		Pyridium				
	Nephropathy Toxic		(Phenazopyridine				

			Hydrochloride)	SS		ORAL
ORAL						

Date:06/02/98ISR Number: 3161082-0Report Type:Periodic Company Report #LITH002970016
Age:6 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Abdominal Distension Accidental Overdose Hallucination	Health Professional	Lithium Carbonate Capsules (Lithium Carbonate)	PS		ORAL
UNK, PER ORAL						

Date:06/02/98ISR Number: 3161086-8Report Type:Periodic Company Report #LITH002970028
Age:51 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Disability	Diabetes Insipidus Pollakiuria Thirst	Other	Lithium Carbonate Capsules 300 Mg (Lithium Carbonate)	PS		ORAL
600-900 MG/DAY, PER ORAL						
			Thorazine (Chlorpromazine Hydrochloride)	C		

Date:06/02/98ISR Number: 3161090-XReport Type:Periodic Company Report #LITH002970008
Age:60 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Skin Nodule	Health Professional	Lithium Capsules 300 Mg (Lithium Carbonate)	PS		ORAL
900 MG, PER DAY, PER ORAL						
			Benadryl			

			(Diphenhydramine Hydrochloride)	C		

Date:06/02/98ISR Number: 3161094-7Report Type:Periodic Company Report #LITH002970009
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Back Pain Hypertonia Insomnia	Consumer	Lithium Carbonate Capsules 300 Mg (Lithium Carbonate)	PS		ORAL	PER ORAL	

Date:06/02/98ISR Number: 3161096-0Report Type:Periodic Company Report #LITH002970019
Age:53 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hypothyroidism Pollakiuria Sedation Thirst Thyroid Disorder Urinary Tract Infection Weight Increased	Health Professional	Lithium Capsules 300 Mg (Lithium Carbonate) Acetic Acid Ear Drops Albuterol Sulfate Betopic Eye Drops Klonopin Navane	PS C C C C C		ORAL	900 MG, PER ORAL	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/02/98ISR Number: 3161099-6Report Type:Periodic Company Report #LITH002970022
Age:37 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Withdrawal Syndrome Migraine	Consumer	Lithium Carbonate Capsules 300 Mg (Lithium Carbonate)	PS		ORAL	1200 MG, PER	ORAL
			Copaxone	C				
			Diazepam	C				
			Tegretol	C				

Date:06/02/98ISR Number: 3161105-9Report Type:Periodic Company Report #LITH002970025
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Salivary Hypersecretion	Consumer	Lithonate Capsules 300 Mg (Lithium Carbonate)	PS		ORAL	UNKNOWN, PER	ORAL

Date:06/02/98ISR Number: 3161108-4Report Type:Periodic Company Report #LITH002970026
Age:45 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Ineffective Emotional Disorder Tremor	Consumer	Lithonate Capsules 300 Mg (Lithium Carbonate)	PS		ORAL	1200 MG; PER	ORAL
			Paxil	C				
			Synthroid	C				

Date:06/02/98ISR Number: 3161112-6Report Type:Periodic Company Report #LITH002970027
Age:15 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Galactorrhoea	Health Professional	Lithium Carbonate Capsules 300 Mg (Lithium Carbonate)	PS		ORAL	1500 MG, PER	DAY, PER ORAL
			Paroxetine (Paroxetine)	SS		ORAL	UNKNOWN, PER	ORAL

Date:06/02/98ISR Number: 3161115-1Report Type:Periodic Company Report #LITH002970033
Age:42 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Diarrhoea Tremor Visual Disturbance	Consumer	Lithium Capsules 300 Mg (Lithium Carbonate)	PS		ORAL	1200 MG PER	ORAL

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/02/98ISR Number: 3161117-5Report Type:Periodic Company Report #LITH002970036
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Face Oedema Hypersensitivity Pruritus Urticaria	Health Professional	Lithonate Capsules 300 Mg (Lithium Carbonate)	PS		ORAL	600 MG BID, PER ORAL	

Date:06/04/98ISR Number: 3090415-9Report Type:Expedited (15-DaCompany Report #1998013455-1
Age:42 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Creatinine Increased Blood Urea Increased Hyperkalaemia Metabolic Acidosis Nephropathy Renal Failure Acute Scan Abdomen Abnormal Therapeutic Agent Toxicity	Literature	Lithium	PS	Smithkline Beecham	ORAL		

Date:06/04/98ISR Number: 3091134-5Report Type:Expedited (15-DaCompany Report #1998013456-1
Age:54 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blood Creatinine Increased Blood Urea Increased Colon Cancer Stage Iv Renal Failure	Literature	Lithium	PS	Smithkline Beecham			

Date:06/04/98ISR Number: 3091139-4Report Type:Expedited (15-DaCompany Report #1998013457-1
Age:44 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Blood Creatinine Increased Blood Urea Increased Nephropathy Renal Atrophy Renal Impairment	Literature	Lithium	PS	Smithkline Beecham	

Date:06/04/98ISR Number: 3175328-6Report Type:Periodic Company Report #LITT002970001
Age:54 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Osteoporosis	Consumer	Lithotabs Tablets 300 Mg (Lithium Carbonate)	PS		ORAL
300 MG, PER ORAL						
			Anafranil (Clomipramine Hydrochloride)	C		
			Cardura (Doxazosin Mesilate)	C		

Darvocet-N-100 (Paracetamol, Dextropropoxyphene)	C
Luvox Tablets 100 Mg (Fluvoxamine Maleate)	C
Mysoline (Primidone)	C
Oxybutynin	C
Primex (Bumetanide)	C
Sinemet (Levodopa, Carbidopa)	C
Zoloft (Sertraline Hydrochloride)	C

Date:06/04/98ISR Number: 3175330-4Report Type:Periodic Company Report #LITT002980001
Age:41 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Alanine Aminotransferase Increased Gamma-Glutamyltransferase Increased	Consumer	Lithotabs Tablets 300 Mg (Lithium Carbonate)	PS		ORAL	1500 MG, PER ORAL	

Date:06/08/98ISR Number: 3090075-7Report Type:Direct Company Report #
Age:57 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Confusional State Drug Level Above Therapeutic Drug Toxicity Gait Disturbance		Lithium	PS		ORAL	900 MG PO. QD	2 YR

Date:06/08/98ISR Number: 3091448-9Report 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	Mental Disorder Therapeutic Agent Toxicity		Lithium	PS		ORAL	900 MG PO BID	

Date:06/08/98ISR Number: 3092027-XReport Type:Expedited (15-DaCompany Report #1998014020-1
Age:55 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Coma Depressed Level Of Consciousness Drug Level Above Therapeutic Pneumonia Subdural Haematoma	Health Professional	Lithium Hydrochlorothiazide Risperdal	PS C C			300 MILLIGRAMS 3.0 DAILY	10 DAY

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/08/98ISR Number: 3092033-5Report Type:Expedited (15-DaCompany Report #1998012769-1
Age:42 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Confusional State	Health	Eskalith	PS	Smithkline Beecham	ORAL	ORAL	
	Dehydration	Professional						
	Diabetes Mellitus							
	Hyperglycaemia							
	Hyperosmolar State							
	Hypotension							
	Loss Of Consciousness							

Date:06/09/98ISR Number: 3091805-0Report Type:Direct Company Report #
Age:43 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Asthenia		Lithium	PS			300MG TID	
	Blood Creatine Phosphokinase Increased						PRIOR TO ADMISSION	
	Cardiac Murmur Functional							
	Difficulty In Walking							
	Dizziness							
	Drug Toxicity							
	Hypertension							
	Nephrogenic Diabetes Insipidus							
	Neuroleptic Malignant Syndrome							
	Tremor							

Date:06/10/98ISR Number: 3179918-6Report Type:Periodic Company Report #LITH002970038
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Laboratory Test Abnormal	Health	Lithium Carbonate					

		Professional	(Lithium Carbonate)	PS		ORAL

1200 MG, PER

ORAL

Date:06/10/98ISR Number: 3179919-8Report Type:Periodic Company Report #LITH002980002
Age:28 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Other	Alopecia	Consumer	Lithonate Capsules	PS		ORAL
	Amblyopia					
	Dermatitis		Klonopin	C		
	Faecal Incontinence		Prozac	C		
	Hallucination					
	Hyperacusis					
	Hyperglycaemia					
	Paraesthesia					
	Skin Discolouration					
	Speech Disorder					
	Urinary Incontinence					
	Visual Field Defect					

Dose Duration

900 MG, PER

ORAL

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/10/98ISR Number: 3179920-4Report Type:Periodic Company Report #LITH002980003
Age:50 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Abdominal Pain	Health Professional	Lithium Carbonate Capsules	PS		ORAL	UNK, PER ORAL	
	Diarrhoea							
	Eosinophilia							
	Oesophageal Stenosis							

Date:06/11/98ISR Number: 3092824-0Report Type:Direct Company Report #
Age:37 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Nausea		Lithium	PS		ORAL	300 MG PO Q.I.D., LONG TERM	
	Tremor							
	Visual Disturbance							
	Vomiting		Sentraline	C				
			Trazadone	C				

Date:06/11/98ISR Number: 3095962-1Report Type:Periodic Company Report #17812-035
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Alopecia	Consumer	Lithium	PS	Roxane Laboratories, Inc.		4-5 MONTHS	

Date:06/11/98ISR Number: 3095972-4Report Type:Periodic Company Report #17812-036
Age:25 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dermatitis Exfoliative	Consumer	Lithium Carbonate	PS	Roxane		1 YR	

	Tooth Disorder					

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

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Interaction Dysphagia Gait Disturbance Speech Disorder Visual Disturbance	Consumer	Lithium Carbonate Capsules Usp, 300 Mg-Roxane Laboratories, Inc.	PS		ORAL	600 MG, BID, PO	
			Haloperidol (Manufacturer Unknown)	SS		ORAL	5 MG OHS PO	

Date:06/11/98ISR Number: 3095978-5Report Type:Periodic Company Report #17812-038
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Alopecia	Health Professional	Lithium	PS	Roxane Laboratories, Inc.			

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/11/98ISR Number: 3095980-3Report Type:Periodic Company Report #17812-039
Age:48 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Muscle Twitching	Health Professional	Lithium Carbonate	PS	Roxane	ORAL	300 MG TID, PO	
			Zoloft	C				
			Atenolol	C				
			Motrin	C				
			Trazodone	C				
			Premphase	C				

Date:06/11/98ISR Number: 3095983-9Report Type:Periodic Company Report #17812-041
Age:64 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Interaction Drug Level Above Therapeutic	Health Professional	Lithium	PS	Roxane Laboratories, Inc.	ORAL	300 MG TID, PO	
			Lisinopril	SS				
			Niacin	C				

Date:06/11/98ISR Number: 3095985-2Report Type:Periodic Company Report #17812-042
Age:53 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Interaction Drug Level Above Therapeutic	Health Professional	Lithium	PS	Roxane Laboratories, Inc.	ORAL	300 MG TID, PO	
			Lisinopril	SS		ORAL	10 MG BID, PO	
			Ibuprofen	C				
			Albuterol	C				
			Lorazepam	C				

Date:06/15/98ISR Number: 3093386-4Report Type:Direct Company Report #
Age:55 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Diabetes Insipidus		Lithium	PS		ORAL	600 MG QAM, Initial or Prolonged	900 MG QAM PO

Date:06/15/98ISR Number: 3094573-1Report Type:Expedited (15-DaCompany Report #1998014812-1
Age:59 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Alopecia	Health	Eskalith	PS	Smithkline Beecham	ORAL	1.0 DAILY	
	Asthenia	Professional				ORAL		
	Dental Caries		Buspar	C				
	Diabetes Mellitus		Inderal	C				
	Feeling Drunk		Cardura	C				
	Goitre							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/15/98ISR Number: 3094581-0Report Type:Expedited (15-DaCompany Report #1998012322-1
Age:54 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Cardiomegaly	Health	Quilonorm	PS	Smithkline Beecham		450 MILLIGRAMS	
	Pericardial Effusion	Professional						
	Respiratory Disorder		Antra	C				
	Respiratory Gas Exchange Disorder		Aspirin	C				
			Seresta	C				
			Valium	C				

Date:06/15/98ISR Number: 3095083-8Report Type:Expedited (15-DaCompany Report #1998007501-1
Age:59 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Cardiac Failure	Health	Eskalith	PS		ORAL	300 MILLIGRAMS	
	Dyspnoea	Professional						
	Pulmonary Oedema						3.0 DAILY	
	Therapeutic Agent						ORAL	
	Toxicity		Hydrochlorothiazide	C				
			Plendil	C				
			Atenolol	C				
			Zocor	C				
			Insulin	C				

Date:06/15/98ISR Number: 3095872-XReport Type:Periodic Company Report #LBID002970015
Age:47 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Muscle Spasms	Health	Lithobid	PS		ORAL	900 MG PER	
		Professional						
DAY, PER ORAL								

Date:06/15/98ISR Number: 3095877-9Report Type:Periodic Company Report #LBID002970017
Age:36 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	White Blood Cells Urine	Consumer	Lithobid	PS		ORAL	1200 MG, PER	
	Positive						DAY, PER ORAL	
			Claritin (Loratadine)	C				

Date:06/15/98ISR Number: 3095882-2Report Type:Periodic Company Report #LBID002970025
Age:11 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Aggression	Consumer	Lithobid	PS		ORAL	300,600,1200,	
	Coordination Abnormal						PER ORAL	
	Diarrhoea		Cylert	C				
	Muscular Weakness		Imipramine	C				
	Sedation		Trazodone	C				
	Thirst		Wellbutrin	C				
	Tremor							
	Vomiting							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/15/98ISR Number: 3095888-3Report Type:Periodic Company Report #LBID002970031
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Balance Disorder	Health	Lithobid	PS		ORAL	PER ORAL	
	Dizziness	Professional						

Date:06/15/98ISR Number: 3095891-3Report Type:Periodic Company Report #LBID002970032
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Balance Disorder	Health	Lithobid	PS		ORAL	PER ORAL	
	Dizziness	Professional	Depakote	SS		ORAL	PER ORAL	

Date:06/15/98ISR Number: 3095898-6Report Type:Periodic Company Report #LBID002970034
Age:16.5 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Galactorrhoea	Health	Lithobid	PS		ORAL	PER ORAL	
		Professional	Paxil	SS		ORAL	40 MG, PER	ORAL

Date:06/15/98ISR Number: 3095904-9Report Type:Periodic Company Report #LBID002970036
Age:75 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Aphasia	Health	Lithobid	PS		ORAL	600 MG, PER	ORAL
	Confusional State	Professional						

Date:06/15/98ISR Number: 3095906-2Report Type:Periodic Company Report #LBID002970038
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Abnormal Sleep-Related Event	Health Professional	Lithobid	PS		ORAL	PER ORAL	

Date:06/15/98ISR Number: 3095910-4Report Type:Periodic Company Report #LBID002980001
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Premature Ejaculation	Health Professional	Lithobid	PS		ORAL	900 MG, PER ORAL	

Date:06/15/98ISR Number: 3095913-XReport Type:Periodic Company Report #LBID002980002
Age:39 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Disturbance In Attention	Consumer	Lithobid	PS		ORAL	900-1200 MG PER DAY, PER ORAL	
	Haematuria							
	Memory Impairment							
	Pyrexia		Prozac	C				
	Tremor							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/15/98ISR Number: 3095917-7Report Type:Periodic Company Report #LBID002980005
Age:59 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Anxiety	Consumer	Lithobid	PS		ORAL	300 MG, PER	
	Asthenia						ORAL	
	Crying		Micronase	C				
	Decreased Appetite		Synthroid	C				
	Depression							
	Flatulence							
	Heart Rate Increased							
	Insomnia							
	Mania							
	Tachycardia							
	Thinking Abnormal							
	Tremor							

Date:06/15/98ISR Number: 3095920-7Report Type:Periodic Company Report #LBID002980011
Age:23 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Diarrhoea	Health	Lithobid	PS		ORAL	900 MG HS,	
	Faeces Discoloured	Professional					PER ORAL	
	Liver Function Test Abnormal		Zyprexa	C				

Date:06/15/98ISR Number: 3095924-4Report Type:Periodic Company Report #LBID002980012
Age:50 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Asthenia	Consumer	Lithobid	PS		ORAL	900 MG, 1200	
	Coordination Abnormal						MG, PER ORAL	
	Diarrhoea		Claritin	C				
	Fatigue		Klonopin	C				

	Gastrointestinal Disorder		Vancenase Aq	C	
	Genital Pruritus Male		Vicon	C	
	Palpitations				

Date:06/16/98ISR Number: 3094517-2Report Type:Direct Company Report #
Age:54 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Drug Toxicity		Lithium	PS			600MG QAM 300	
Initial or Prolonged	Mental Impairment						II QHS	
	Nausea		Indocin	C				
	Tremor		Lisinopril	C				
	Vomiting							

Date:06/18/98ISR Number: 3095298-9Report Type:Direct Company Report #
Age:71 YR Gender:Female I/FU:I

Outcome	PT
Hospitalization -	Decreased Appetite
Initial or Prolonged	Depression
	Drug Toxicity
	Hypercalcaemia
	Hypertension
	Insomnia

Lethargy
Myocardial Infarction

Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Lithium	PS			300 MG AT HS;	
					600MG AT HS	
	Nortriptyline	C				
	Enalapril	C				
	Hydralazine	C				
	Digoxin	C				

Date:06/22/98ISR Number: 3097185-9Report Type:Expedited (15-DaCompany Report #100632
Age:40 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blindness	Health Professional	Diazepam	PS		ORAL	30 MG DAILY ORAL	
		Other	Zyprexia	SS		ORAL	5 MG DAILY ORAL	
			Paxil	SS		ORAL	20 MG DAILY ORAL	
			Lithium	SS		ORAL	600 MG 2 X PER DAY ORAL	
			Vistaril	SS		ORAL	ORAL	
			Triazolam	SS		ORAL	ORAL	
			Tegretol	SS		ORAL	400 MG DAILY ORAL	
			Serzone	C		ORAL	250 MG DAILY	

ORAL

Date:06/24/98ISR Number: 3097891-6Report Type:Expedited (15-DaCompany Report #17812-048
Age:40 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blindness Diabetes Mellitus	Consumer	Lithium	PS	Roxanne Laboratories, Inc	ORAL	600 MG BID	
	Therapeutic Agent						PO	
	Toxicity		Zyprexa	C				
			Paxil	C				
			Ciazepam	C				
			Serzone	C				
			Trazodone	C				
			Vistaril	C				

Date:06/29/98ISR Number: 3099559-9Report Type:Expedited (15-DaCompany Report #LBID002980018
Age:77 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Drug Level Above	Health	Lithobid	PS		ORAL	PER ORAL	
Hospitalization - Initial or Prolonged	Therapeutic Hypovolaemia Lethargy Muscle Spasms Renal Failure Acute Therapeutic Agent Toxicity	Professional	Aspirin (Salicylic Acid) Cardura (Doxazosin Mesilate) Enoxaparin Vs Placebo (Heparin-Fraction, Sodium Salt) Norvasc (Amlodipine Besilate)	C C C C				

			Ticlid (Ticlopidine Hydrochloride)	C		

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

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

Date:06/30/98ISR Number: 3100123-3Report Type:Expedited (15-DaCompany Report #100632
Age:40 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Hospitalization -	Blindness	Health	Diazepam	PS		ORAL 30 MG DAILY
Initial or Prolonged	Blood Cholesterol	Professional				ORAL
	Increased	Other	Zyprexa	SS		ORAL 5 MG DAILY
	Diabetes Mellitus					ORAL
	Hyperlipidaemia		Paxil	SS		ORAL 20 MG DAILY

ORAL

		Lithium	SS	ORAL

600 MG 2 X

PER DAY ORAL

	Tegretol	SS	ORAL

400 MG DAILY

ORAL

	Serzone	SS	ORAL

250 MG DAILY

ORAL

	Triazolam	SS	ORAL

ORAL

	Vistaril	SS	ORAL

ORAL

Date:06/30/98ISR Number: 3100675-3Report Type:Expedited (15-DaCompany Report #1998016247-1
Age:71 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Calcium Increased	Health Professional	Lithium	PS		ORAL	600 MILLIGRAMS 1.0 DAILY	14 DAY
	Blood Urea Increased							
	Decreased Appetite							
	Depression							
	Drug Toxicity		Lithium	SS		ORAL	300 MILLIGRAMS 1.0 DAILY	14 DAY
	Fatigue							
	Hypercalcaemia							
	Hypertension							
	Insomnia		Lithium	SS			UNKNOWN	UNKNOWN
	Lethargy		Nortriptline	C				
	Myocardial Infarction		Enalapril	C				
			Hydralazine	C				
			Dicoxin	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/02/98ISR Number: 3108017-4Report Type:Expedited (15-DaCompany Report #9905149
Age:36 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Agitation	Foreign	Depakene	PS		ORAL	500.000 MG PO	
Hospitalization - Initial or Prolonged	Blood Thyroid Stimulating Hormone Increased	Health Professional	Lithium Carbonate	SS		ORAL	800.000 MG PO	QD
	Bundle Branch Block Right						UNK	
	Electrocardiogram Normal		Diazepam	C				
	Excitability		Clonazepam	C				
	Mania		Flunitrazepam	C				
			Hydroxyzine Hydrochlo	C				
			Levomepromazine	C				
			Tropatepine Hydrochlo	C				

Date:07/06/98ISR Number: 3103976-8Report Type:Direct Company Report #
Age:61 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Acute Prerenal Failure		Lithium	PS			300 MG PO BID	- CHRONIC
	Diarrhoea							
	Dizziness		Synthroid	C				
	Dysarthria							
	Mental Impairment							
	Pneumonia							
	Pyrexia							

Date:07/06/98ISR Number: 3103979-3Report Type:Direct Company Report #
Age:57 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Hospitalization -	Asthenia		Lithium Carbonate	PS		
300 MG AM,						
Initial or Prolonged	Diarrhoea					
600 MG PM 3 WK						
	Drug Level Above		Prozac	SS		ORAL
60 MG PO QD						
	Therapeutic		Lescol	C		
	Lethargy		Remeron	C		
	Parkinsonian Gait		Asa	C		

Date:07/08/98ISR Number: 3104088-XReport Type:Direct Company Report #
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
	Nausea		Allegra	PS		
60 MG QD						
			Lithium	SS		
300 MG AM,						
600 MG HS						
			St. John'S Wort	C		

Date:07/13/98ISR Number: 3104710-8Report Type:Expedited (15-DaCompany Report #8-98188-058A
Age:26 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Bundle Branch Block Right	Foreign	Efexor	PS		ORAL
2 GRAMS ORAL						
Initial or Prolonged	Convulsion	Health	Lithium	SS		
1.2 GRAM						
	Hypertension	Professional	Zolpidem	C		
60 MG						
	Overdose					
	Tachycardia					

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/14/98ISR Number: 3108656-0Report Type:Direct Company Report #
Age:71 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Diabetes Insipidus		Lithium 600MG, 300MG BI, ORAL	PS		ORAL		

Date:07/21/98ISR Number: 3108406-8Report 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	Confusional State		Lithium Carb BID	PS				
	Difficulty In Walking		Divalproex Na BID	SS				
	Dysarthria							
	Overdose							

Date:07/21/98ISR Number: 3109000-5Report Type:Direct Company Report #
Age:28 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Delirium		Droperidol	PS			INTRAVENOUS	0.625 MG Q 3HR IVP
Hospitalization - Initial or Prolonged	Hyperhidrosis							
	Hyperpyrexia		Lithium 600 MG PO BID:	SS		ORAL		
Required Intervention to Prevent Permanent Impairment/Damage	Muscle Rigidity							
			Ceftriaxone	C				
			Gentamicin	C				
			Phenazopyridine	C				

THERAPY:YEARS

Date:07/21/98ISR Number: 3109005-4Report Type:Direct Company Report #
Age:62 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Dehydration		Lithium Sa	PS		ORAL	450 MG PO HS	
Initial or Prolonged	Dizziness		Lasix	SS			80 MG QD	
	Fall		Acetominophen	C				
	Head Injury		Clonidine	C				
	Hypovolaemia		Benztropine	C				

Date:07/23/98ISR Number: 3109674-9Report Type:Direct Company Report #
Age:78 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Asthenia		Lithium Carbonate	PS		ORAL	300MG TID PO	
	Nausea		Buspar	C				
	Vomiting		Inderal	C				
			Maxzide	C				
			Lisinopril	C				
			Pepcid	C				
			Oxybutynin	C				
			Premarin	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/27/98ISR Number: 3109238-7Report Type:Expedited (15-DaCompany Report #1998018427-1
Age:81 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Akathisia	Foreign	Lithium Carbonate	PS	Smithkline Beecham		625	
	Anxiety	Literature					MILLIGRAMS	
	Delirium							
	Depression							
	Drug Toxicity							

Date:07/27/98ISR Number: 3109820-7Report Type:Direct Company Report #
Age:19 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Renal Failure Acute		Ultram	PS		ORAL	600MG PO BID	
			Lithium Carbonate	SS				

Date:07/28/98ISR Number: 3109766-4Report Type:Expedited (15-DaCompany Report #.58-98
Age:39 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Convulsion	Foreign	Remeron	PS		ORAL	30 MG/DAY PO	
Initial or Prolonged	Drug Interaction	Health Professional	Lithium	SS				
			Fluoxetine	C				

Date:07/28/98ISR Number: 3112921-0Report Type:Direct Company Report #
Age:48 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Thyroid Gland Cancer		Lithium Carbonate	PS			600 MG TWICE	
Hospitalization -							DAY	

Initial or Prolonged
Disability

Date:07/28/98ISR Number: 3113021-6Report Type:Direct Company Report #
Age:56 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required	Diabetes Insipidus		Lithium Carbonate	PS		ORAL	300 MG, T1	
Intervention to Prevent Permanent Impairment/Damage							QHS, ORAL	

Date:07/28/98ISR Number: 3113138-6Report Type:Direct Company Report #
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Agitation		Lithium	PS		ORAL	1T PO BID ;2	
	Delirium						PO BID ;2AM 3	
	Mania						HRS 2 BID; 2 AM 3 HS BAD	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/30/98ISR Number: 3111914-7Report Type:Expedited (15-DaCompany Report #9813535
Age:32 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Life-Threatening	Abdominal Distension	Foreign	Lithane	PS		ORAL	450.00 MG
Hospitalization -	Apathy	Health					TOTAL:BID:ORA
Initial or Prolonged	Aphasia	Professional					L
Disability	Confusional State		Thiothixene	SS		ORAL	10.00 MG
Required	Convulsion						TOTAL:DAILY:O
Intervention to	Diarrhoea						RAL
Prevent Permanent	Difficulty In Walking		Sertraline	SS		ORAL	50.00 MG
Impairment/Damage	Dysphonia						TOTAL:DAILY:O
	Hyperhidrosis						RAL
	Hyponatraemia		Clonazepam	C			
	Joint Stiffness		Lorazepam	C			
	Muscle Rigidity		Psyllium	C			
	Nausea		Fluoxetine	C			
	Psychotic Disorder		Flurazepam	C			
	Skin Discolouration		Procyclidine	C			
	Therapeutic Agent		Benzotropine	C			
	Toxicity						
	Tic						
	Tremor						
	Vomiting						

Date:08/03/98ISR Number: 3111547-2Report Type:Direct Company Report #
Age:42 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Coma		Lithium Carbonate	PS		ORAL	300MG PO TID
Initial or Prolonged	Drug Level Above		Alprazolam	SS		ORAL	0.5 MG PO BID
	Therapeutic						

Date:08/03/98ISR Number: 3226795-0Report Type:Periodic Company Report #97526.01
Age:55 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Personality Disorder	Consumer	Thiothixene Capsules	PS	Mylan	ORAL	15 MG HS,	
	Salivary Hypersecretion							
ORAL								20 YR
			Lithium	SS	Roxane	ORAL	600 MG AM AND 600 MG PM,	
ORAL								7 YR

Date:08/05/98ISR Number: 3113740-1Report Type:Direct Company Report #
Age:56 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Accidental Overdose		Lithium	PS		ORAL	300MG PO QD	
	Apnoea							
	Bradycardia							
	Drooling							
	Drug Toxicity							
	Nystagmus							
	Speech Disorder							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/07/98ISR Number: 3114289-2Report Type:Expedited (15-DaCompany Report #1998019810-1
Age:62 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Dehydration	Health	Lithium	PS		ORAL	450 MG	1.0
Initial or Prolonged	Dizziness	Professional					DAILY	ORAL
	Fall		Acetaminophen	C				
	Head Injury		Clonidine	C				
	Hypovolaemia		Warfarin	C				
			Benztropine	C				
			Lasix	C				
			..	C				
			Potassium Chloride	C				

Date:08/07/98ISR Number: 3114342-3Report Type:Expedited (15-DaCompany Report #9822838
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Hepatocellular Damage	Consumer	Lithane	PS		ORAL	ORAL	

Date:08/07/98ISR Number: 3114362-9Report Type:Expedited (15-DaCompany Report #9823435
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Anaemia	Foreign	Lithane	PS		ORAL	ORAL	
Initial or Prolonged		Health	Unspecified					
		Professional	Psychiatric Drugs	C				

Date:08/11/98ISR Number: 3115368-6Report Type:Expedited (15-DaCompany Report #D/98/02728/LEX
Age:28 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	Hepatomegaly Influenza Like Illness Pericardial Effusion Pleural Effusion Pyrexia Rash Erythematous	Health Professional	Leponex Lithium Recephin	PS SS C		ORAL ORAL	400 MG 1 G	

Date:08/12/98ISR Number: 3116034-3Report Type:Expedited (15-DaCompany Report #9823592
Age:40 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Congestive Cardiomyopathy Dyspnoea	Foreign Health Professional Other	Zoloft Lithium Zopiclone Chlorpromazine	PS SS C C		ORAL ORAL	50.00 MG 400.00 MG	TOTAL:DAILY:ORAL TOTAL:BID:ORAL

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/13/98ISR Number: 3116797-7Report Type:Expedited (15-DaCompany Report #D/98/02728/LEX
Age:28 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Hepatomegaly	Health	Leponex	PS		ORAL	600 MG ORAL	
Initial or Prolonged	Influenza Like Illness	Professional	Lithium	SS		ORAL	100 MG ORAL	
Required	Juvenile Arthritis		Recephin	C				
Intervention to	Leukocytosis							
Prevent Permanent	Pericardial Effusion							
Impairment/Damage	Pleural Effusion							
	Pyrexia							
	Rash Erythematous							

Date:08/14/98ISR Number: 3117160-5Report Type:Expedited (15-DaCompany Report #9726378
Age:57 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required	Anger	Health	Cardura	PS		ORAL	4.00MG	
Intervention to	Drug Ineffective	Professional					TOTAL:DAILY:O	
Prevent Permanent	Mania						RAL	
Impairment/Damage			Lithium	SS		ORAL	1350.00	
							MGTOTAL:TID:O	
							RAL	

Date:08/14/98ISR Number: 3117369-0Report Type:Expedited (15-DaCompany Report #9726378
Age:57 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required	Aggression	Health	Cardura	PS		ORAL	4.00 MG	
Intervention to	Drug Toxicity	Professional					TOTAL: DAILY:	

Prevent Permanent Impairment/Damage	Mania		Lithium	SS		ORAL 1350.00 MG

TOTAL: TID:

ORAL

Date:08/14/98ISR Number: 3117388-4Report Type:Expedited (15-DaCompany Report #980810-107055343
Age:15 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Hospitalization - Initial or Prolonged	Convulsion	Consumer	Topamax	PS		ORAL
	Jaundice		Lithium	SS		ORAL
	Tremor		Fluoxetine Hydrochloride	C		
			Loratadine	C		
			Coenzyme Q	C		

Date:08/20/98ISR Number: 3120098-0Report 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	Agitation		Benztropine	PS		2MG TID
	Delirium		Lithium	SS		ORAL 450MG BID PO
	Disorientation					LONG TERM
	Drug Toxicity		Halperidal	C		
	Hallucination, Visual					

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/20/98ISR Number: 3120100-6Report Type:Direct Company Report #
Age:50 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Confusional State Drug Toxicity Lethargy		Lithium	PS			450MG BID	LONG TERM

Date:08/20/98ISR Number: 3120711-8Report Type:Periodic Company Report #9726378
Age:57 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Anger	Health	Cardura	PS		ORAL	DAILY: ORAL	
	Drug Effect Decreased	Professional	Lithium	SS		ORAL	1350.00 MG	
	Drug Interaction						TOTAL:TID:	
	Mania						ORAL	

Date:08/24/98ISR Number: 3121188-9Report Type:Direct Company Report #
Age:54 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Confusional State Drug Toxicity Mental Disorder		Lithium	PS			300 MG BID	

Date:08/27/98ISR Number: 3122080-6Report Type:Direct Company Report #
Age:68 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Drug Toxicity		Lithium	PS				

Initial or Prolonged Metabolic Disorder

Date:08/28/98ISR Number: 3123312-0Report Type:Direct Company Report #
Age:71 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Mental Impairment Therapeutic Agent Toxicity		Lithium	PS			400/300 ALT	DAYS LONG TERM

Date:08/31/98ISR Number: 3124066-4Report Type:Expedited (15-DaCompany Report #9826047
Age:1 DY Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Congenital Anomaly	Complications Of Maternal Exposure To Therapeutic Drugs Multiple Congenital Abnormalities	Foreign Health Professional Company Representative	Zoloft Lithium	PS SS				

Date:09/01/98ISR Number: 3124535-7Report Type:Expedited (15-DaCompany Report #9201/18276
Age:56 YR Gender:Female I/FU:I

Outcome
Life-Threatening Hospitalization -

Initial or Prolonged
Other

	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Coma	Foreign	Xanax	PS		ORAL	.75 MG/DAY;	
	Hypochloraemia	Health					ORAL	
	Hyponatraemia	Professional	Lithium	SS			UNKNOWN	
		Company	Paroxetine	SS			20 MG /DAY	
		Representative						

Date:09/02/98ISR Number: 3125908-9Report Type:Direct Company Report #
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Catatonia	Health	Olanzapine	PS	Lilly	ORAL	10 MG Q AM PO	
Initial or Prolonged	Confusional State	Professional	Lithium Carbonate (600 Mg, Roxane)	SS	Roxane	ORAL	600 MG BID PO	
	Consciousness Depressed Level Of		Lorazepam	C				
	Disorientation							
	Disturbance In Attention							
	Dyskinesia							
	Dystonia							
	Leukocytosis							
	Masked Facies							
	Muscle Rigidity							
	Neuroleptic Malignant Syndrome							
	Psychotic Disorder							
	Pyrexia							
	Tachycardia							

Date:09/02/98ISR Number: 3126394-5Report Type:Direct Company Report #
Age:41 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Life-Threatening	Loss Of Consciousness		Lithium	PS		
300 MG TID						
Hospitalization -	Overdose		Librium	SS		
25 MG QID						
Initial or Prolonged			Elavil	SS		
100 MG QHS						
			Cocaine	C		
			Marijuana	C		
			Serax	C		

Date:09/03/98ISR Number: 3125581-XReport Type:Expedited (15-DaCompany Report #8-98243-055A
Age:41 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Life-Threatening	Drug Level Above	Health	Serax	PS		
Hospitalization -	Therapeutic	Professional	Cocaine	SS		
Initial or Prolonged	Electrocardiogram Qt		Lithium	SS		
	Prolonged		Marijuana	SS		
	Loss Of Consciousness		Elavil	SS		
	Overdose		Librium	SS		

Date:09/04/98ISR Number: 3126293-9Report Type:Direct Company Report #
Age:15 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Anxiety		Zoloft	PS		ORAL	100 MG PO QD	1 WK
Initial or Prolonged	Diarrhoea		Lithium	SS		ORAL	300 MG PO BID	1 WK
	Dyspnoea							
	Electrocardiogram Abnormal							
	Heart Rate Increased							
	Panic Disorder							
	Supraventricular Extrasystoles							
	Tremor							

Date:09/04/98ISR Number: 3126307-6Report Type:Expedited (15-DaCompany Report #9826538
Age:59 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required	Apathy	Foreign	Lithane	PS		ORAL	600.00 MG	
Intervention to	Diarrhoea	Literature						
TOTAL:ORAL							7	YR
Prevent Permanent	Drug Level Above	Health	Clopixol	SS			200.00 MG	
Impairment/Damage	Therapeutic	Professional						
TOTAL: EVERY								
	Dysarthria							
OTHER WEEK								
	Lethargy							
	Masked Facies							
	Muscle Twitching							
	Nephrotic Syndrome							
	Oedema							
	Oedema Peripheral							
	Proteinuria							
	Restlessness							
	Tremor							

Date:09/04/98ISR Number: 3126309-XReport Type:Expedited (15-DaCompany Report #9826539
Age:77 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Confusional State	Foreign	Lithane	PS		ORAL	625.00 MG	TOTAL;
	Coordination Abnormal	Literature						
	Drug Toxicity	Health	Diazepam	SS		ORAL	10.00 MG	TOTAL;
	Dysarthria	Professional						
	Hypertension		Nifedipine	SS		ORAL	30.00 MG	TOTAL;
			Losartan	SS		ORAL	50.00 MG	TOTAL;
			Tamoxifen	C				

Date:09/08/98ISR Number: 3127052-3Report Type:Expedited (15-DaCompany Report #9826537
Age:81 YR Gender:Female I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Atrial Fibrillation
Required Intervention to Prevent Permanent Impairment/Damage	Confusional State
	Decreased Activity
	Drug Toxicity
	Electrocardiogram T Wave Inversion
	Fall

	Hypotension						
	Memory Impairment						
	Mucosal Dryness	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Respiratory Rate	Literature	Lithane	PS		ORAL	300.00MG
	Increased	Health					TOTAL DAILY
	Sinus Bradycardia	Professional					ORAL
	Ventricular Extrasystoles						

Date:09/09/98ISR Number: 3126717-7Report Type:Expedited (15-DaCompany Report #LITH002980020
Age:48 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Agitation	Literature	Lithium Carbonate	PS		ORAL	1200 MG, PER
Initial or Prolonged	Anxiety						ORAL
	Blood Creatine		Trazodone	SS		ORAL	200 MG, PER
	Phosphokinase Increased						ORAL
	Blood Iron Decreased		Benztropine	C			
	Clonic Convulsion		Paroxetine	C			
	Coma		Perphenazine	C			
	Delirium						
	Depressed Mood						
	Disorientation						
	Dysarthria						
	Hypomania						
	Muscle Rigidity						
	Muscle Twitching						
	Neuroleptic Malignant Syndrome						
	Pyrexia						
	Serotonin Syndrome						
	White Blood Cell Count Increased						

Date:09/11/98ISR Number: 3127605-2Report Type:Expedited (15-DaCompany Report #9826907
Age:73 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	Condition Aggravated Confusional State Coordination Abnormal Drug Toxicity Dysarthria Extrapyramidal Disorder Mania Muscle Rigidity Pneumonia Posturing Tremor	Foreign Literature Health Professional	Lithane	PS		ORAL	ORAL	

Date:09/11/98ISR Number: 3128529-7Report Type:Expedited (15-DaCompany Report #9827177
Age:52 YR Gender:Female I/FU:I

Outcome
Death Hospitalization - Initial or Prolonged Required Intervention to

Prevent Permanent Impairment/Damage

	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Atherosclerosis	Literature	Lithane	PS		ORAL	600.00 MG	
	Bronchopneumonia	Health					TOTAL; BID;	
	Cardiomegaly	Professional					ORAL	5 YR
	Clonic Convulsion		Amitriptyline	SS		ORAL	50.00 MG	
	Clostridium Colitis						TOTAL; DAILY;	
	Coma						ORAL	
	Confusional State		Chlorpromazine	SS		ORAL	50 TOTAL;	
	Drug Toxicity						DAILY; ORAL	
	Haemodialysis							
	Hypertension							
	Lethargy							
	Metabolic Acidosis							
	Pancreatitis Chronic							
	Pyelonephritis Chronic							
	Pyrexia							
	Renal Impairment							

Date:09/11/98ISR Number: 3128676-XReport Type:Expedited (15-DaCompany Report #9827180
Age:29 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Goitre	Foreign	Lithane	PS		ORAL	600.00 MG	
Initial or Prolonged	Hyperthyroidism	Literature					TOTAL: ORAL	
Required	Irritability	Health						
Intervention to	Palpitations	Professional						
Prevent Permanent	Thyroid Function Test							
Impairment/Damage	Abnormal							
	Weight Decreased							

Date:09/13/98ISR Number: 3244846-4Report Type:Periodic Company Report #8-97329-003L
Age:20 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Interaction	Health	Minocycline Capsules	PS		ORAL	100 MG TWICE	
	Drug Level Changed	Professional					DAILY ORAL	
			Lithium	SS			900 MG -	
							1,050 MG	
							DAILY	

Date:09/15/98ISR Number: 3129164-7Report Type:Expedited (15-DaCompany Report #9827177
Age:52 YR Gender:Female I/FU:F

Outcome	PT
Death	Atherosclerosis
Hospitalization - Initial or Prolonged	Bronchopneumonia
Required Intervention to Prevent Permanent Impairment/Damage	Cardiomegaly
	Clonic Convulsion
	Clostridium Colitis
	Coma
	Confusional State
	Depressed Level Of Consciousness
	Drug Toxicity
	Haemodialysis
	Heart Rate Increased

	Hypertension Lethargy Metabolic Acidosis	Report Source	Product	Role	Manufacturer	Route Dose Duration
	Pancreatitis Chronic	Literature	Lithane	PS		ORAL 600.00 MG TOTAL:BID:ORA
	Pyelonephritis Chronic Pyrexia	Health Professional				L 5 YR
	Renal Impairment		Amitriptyline	SS		ORAL 50.00 MG TOTAL:DAILY:O RAL
			Chlorpromazine	SS		ORAL 50.00 TOTAL:DAILY:O RAL

Date:09/16/98ISR Number: 3130017-9Report Type:Expedited (15-DaCompany Report #8-98252-023A
Age:55 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Hospitalization -	Blood Creatinine	Literature	Verelan	PS		ORAL 240 MG DAILY
Initial or Prolonged	Increased					ORAL
	Confusional State		Aspirin	SS		ORAL 325 MG DAILY
	Drug Interaction					ORAL
	Drug Level Above		Lithium	SS		ORAL 900 MG DAILY
	Therapeutic					ORAL
	Dysarthria		Zestril (Lisinopril)	SS		ORAL 10 MG DAILY
	Haemodialysis					ORAL
	Mental Impairment					

Neurotoxicity

Date:09/16/98ISR Number: 3130054-4Report Type:Expedited (15-DaCompany Report #9827587
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required	Pollakiuria	Consumer	Lithane	PS		ORAL	ORAL	
Intervention to Prevent Permanent Impairment/Damage	Renal Impairment		Navane	SS		ORAL	ORAL	

Date:09/18/98ISR Number: 3131905-XReport Type:Direct Company Report #
Age:81 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required	Drug Effect Decreased	Health	Lithium Carbonate	PS			1 BID	
Intervention to Prevent Permanent Impairment/Damage		Professional						

Date:09/22/98ISR Number: 3133135-4Report Type:Direct Company Report #
Age: Gender:Female I/FU:I

Outcome	PT
Life-Threatening	Blood Pressure
Hospitalization - Initial or Prolonged	Fluctuation
	Bradycardia
Required	Deep Vein Thrombosis
Intervention to Prevent Permanent Impairment/Damage	Hypotension
	Pulse Abnormal
	Pulse Absent

Respiratory Arrest

		Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
			Lithium Carbonate	PS		ORAL
300MG TID PO						
			Atenolol	SS		ORAL
25MG						
ALTERNATING						
50MG QD PO						
			Xanax	C		
			Theragran	C		
			Pepcid	C		
			Colace	C		
			Tegretol	C		

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

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

Date:09/22/98ISR Number: 3232523-5Report Type:Periodic Company Report #9728953
Age:34 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Abdominal Pain	Consumer	Navane Capsules	PS		ORAL	2.00 MG	
	Albuminuria						TOTAL;	DAILY;
	Anorectal Disorder					ORAL		
	Blood Prolactin Increased		Prozac	SS		ORAL	DAILY;	ORAL
	Chills		Lithium	SS		ORAL	600.00 MG	
	Cough						TOTAL;	
	Depression						DAILY;	ORAL
	Diabetes Mellitus		Aleve	SS		ORAL	DAILY;	ORAL
	Eye Pain		Klonopin	C				
	Galactorrhoea		Lorazepam	C				
	Gastrointestinal Disorder							
	Libido Decreased							
	Libido Increased							
	Nausea							
	Palpitations							
	Sedation							
	Thyroid Disorder							
	Vaginal Infection							
	Visual Disturbance							
	Weight Increased							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/23/98ISR Number: 3133948-9Report Type:Direct Company Report #
Age:65 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Confusional State		Lithium	PS				
	Dehydration							
	Drug Level Above Therapeutic							
	Hypernatraemia							
	Nephrogenic Diabetes Insipidus							

Date:09/24/98ISR Number: 3134672-9Report Type:Expedited (15-DaCompany Report #9828720
Age:51 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Difficulty In Walking	Foreign	Zoloft	PS		ORAL	50.00 MG	
	Pain In Extremity	Consumer						
	Tachycardia		Lithium	SS		ORAL		
			Paroxetin	C				
			Unspecified Hormone	C				

Date:09/30/98ISR Number: 3136894-XReport 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	Abnormal Sleep-Related Event		Lithium	PS		ORAL	1 PO TID	
			Lisinopril	SS		ORAL	1 PO TID	
	Bradycardia							
	Dizziness							
	Drug Toxicity							
	Extrapyramidal Disorder							

Date:09/30/98ISR Number: 3232810-0Report Type:Periodic Company Report #18558-005
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Other	Abdominal Pain	Health Professional	Lithium Carbonate Tablets Usp, 300 Mg -Roxane Laboratories, Inc.	PS	Roxane Laboratories, Inc.	ORAL
300 MG BID PO						
			Ativan	C		
			Acetaminophen	C		
			Cogentin	C		
			Imodium	C		
			Haldol	C		
			Sinequan	C		
			Ambien	C		
			Compazine	C		

Date:09/30/98ISR Number: 3232813-6Report Type:Periodic Company Report #18558-006
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Other	Hypertonia Speech Disorder	Health Professional	Lithium Carbonate Tablets Usp, 300mg - Roxane Laboratories,			

			Inc.	PS	Roxane Laboratories, Inc.	ORAL
300 MG TID PO						
			Keflex	C		
			Phenobarbital	C		
			Percocet	C		
			Restoril	C		
			Catapres	C		
			Compazine	C		
			Mvi	C		
			Motrin	C		
			Monistat	C		

Date:09/30/98ISR Number: 3232817-3Report Type:Periodic Company Report #18558-007
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Hyperhidrosis	Health Professional	Lithium Carbonate Tablets Usp, 300 Mg -Roxane Laboratories, Inc.	PS	Roxane Laboratories, Inc.	ORAL
450 MG BID PO						
			Paxil	C		
			Nortriptyline	C		
			Antabuse	C		

Date:10/01/98ISR Number: 3260867-XReport Type:Periodic Company Report #001-0073-980091
Age:60 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	Coordination Abnormal Nystagmus	Health Professional	Dilantin (Phenytoin Sodium)	PS		
			Lithium	SS		
			Sertraline	C		
			Lisinopril	C		

Date:10/05/98ISR Number: 3138121-6Report Type:Expedited (15-DaCompany Report #9822838
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Ear Infection Hepatocellular Damage Hypersensitivity Weight Increased	Consumer	Lithane	PS		ORAL	ORAL	

Date:10/09/98ISR Number: 3140424-6Report Type:Direct Company Report #
Age:74 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Confusional State Disorientation		Lithium	PS		ORAL	300MG	ORAL BID
	Drug Toxicity		Lisinopril 10mg	SS		ORAL	10MG	ORAL QD
	Irritability		Ceftin	C				
	Nephrogenic Diabetes Insipidus		Asa Biaxin	C C		ORAL	500MG	QD
	Renal Failure Acute		Lorazepam Olanzepine Cozaar	C C C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/13/98ISR Number: 3142413-4Report Type:Direct Company Report #
Age:30 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Body Temperature		Trifluoperazine	PS	Zyprexa		TRIFLU 10 MG	
	Increased						BID	
	Circulatory Collapse		Lithium	SS			ZYPREXA 10 MG	
	Drug Toxicity						1 HS	
	Neuroleptic Malignant Syndrome							
	Petechiae							

Date:10/15/98ISR Number: 3142517-6Report Type:Expedited (15-DaCompany Report #98--10853
Age:50 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Toxic Skin Eruption	Foreign	Anafranil	PS		ORAL	DAILY, ORAL	
		Health	Teralithe	SS		ORAL	ORAL	
		Professional	Depamide	SS		ORAL	ORAL	
		Other						

Date:10/16/98ISR Number: 3143074-0Report Type:Expedited (15-DaCompany Report #USA/98/02387/LEX
Age:23 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Interaction	Health	Clozaril	PS		ORAL	25 MG ORAL	
	Renal Failure Acute	Professional	Lithium	SS				
			Zyprexa	C				

Date:10/16/98ISR Number: 3143084-3Report Type:Expedited (15-DaCompany Report #1046825A
Age:74 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Analgesic Drug Level	Literature	Acetaminophen	PS		ORAL	PO	
	Above Therapeutic	Health	Lithium	SS		ORAL	PO	
	Completed Suicide	Professional						
	Intentional Misuse							

Date:10/16/98ISR Number: 3143327-6Report Type:Direct Company Report #
Age:27 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Delirium Tremens		Perphenazine	PS			8 MG	
Disability	Hallucination		Lithotabs	SS			300 MG	
Required Intervention to Prevent Permanent Impairment/Damage	Muscular Weakness		Benztropine	C				
	Urticaria							

Date:10/19/98ISR Number: 3143367-7Report Type:Expedited (15-DaCompany Report #8-98280-099A
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required	Drug Interaction	Foreign	Effexor	PS		ORAL	ORAL	
Intervention to Prevent Permanent Impairment/Damage	Drug Toxicity	Health Professional	Lithium	SS		ORAL	ORAL	

Date:10/19/98ISR Number: 3143368-9Report Type:Expedited (15-DaCompany Report #8-98243-055A
Age:41 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Drug Level Above	Health	Serax	PS		ORAL	DOSE UNKNOWN	
Hospitalization -	Therapeutic	Professional					ORAL	
Initial or Prolonged	Electrocardiogram		Cocaine	SS				
Other	Abnormal		Elavil	SS			100 MG AT	
	Electrocardiogram Qt						BEDTIME,	
	Prolonged						OVERDOSE	
	Loss Of Consciousness						AMOUNT	
	Overdose		Librium	SS			25 MG FOUR	
	Toxicologic Test Abnormal						TIMES DAILY,	
							OVERDOSE	
							AMOUNT	
			Lithium	SS			300 MG THREE	
							TIMES DAILY,	
							OVERDOSE	
							AMOUNT	
			Marijuana	C				

Date:10/19/98ISR Number: 3143529-9Report Type:Direct Company Report #
Age:75 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Confusional State		Eskalith Cr	PS		ORAL	PO QD 450MG	
Initial or Prolonged	Drug Toxicity						M-F CHONIC	

	Fall		Ambiem	C		
	Thirst		Clonazepam	C		
	Tremor					

Date:10/19/98ISR Number: 3144247-3Report Type:Direct Company Report #
Age:76 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Abnormal Behaviour		Lithium Carbonate	PS		ORAL	300 MG PO	
Initial or Prolonged	Aggression						TID	
	Agitation		Folate	C				
	Drug Toxicity		Tylenol	C				
	Nephrogenic Diabetes		Levothyroxine	C				
	Insipidus		Thiamine	C				
	Oral Intake Reduced							
	Pseudomonas Infection							

Date:10/19/98ISR Number: 3144252-7Report Type:Direct Company Report #
Age:51 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Confusional State		Lithium Carbonate	PS		ORAL	900 MG PO	
Initial or Prolonged	Coordination Abnormal						BID	
	Drug Level Above		Ec Asa	C				
	Therapeutic		Dilantin	C				
	Dysarthria		Multivitamins	C				
	Lethargy		Propranolol Sr	C				
	Mental Impairment		Valproic Acid	C				
	Motor Dysfunction		Darvocet	C				
	Muscular Weakness		Milk Of Magnesia	C				
			Naproxen	C				
			Haldol	C				

			Hydroxyzine	C		
			Benztropine	C		
			Folate	C		
			Apap	C		
			Antabuse	C		
			Thiamine	C		
			Nitropatch	C		

Date:10/19/98ISR Number: 3144352-1Report Type:Direct Company Report #
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Medication Error		Lithium Citrate	PS	Rokane			

Date:10/19/98ISR Number: 3266340-7Report Type:Direct Company Report #
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Loss Of Consciousness	Health	Lithium 300 Mg Tid					
Hospitalization -	Overdose	Professional	Librium 25 Mg Qid	PS			300 MG TID	
Initial or Prolonged			Librium 25 Mg Qid	SS			25 MG QID	
			Elavil 100mg Qhs	SS				
			Cocaine	C				
			Marijuana	C				
			Serax	C				

Date:10/23/98ISR Number: 3146058-1Report Type:Expedited (15-DaCompany Report #1998024871-1
Age:52 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Atherosclerosis	Literature	Lithium	PS	Smithkline Beecham		600	
Hospitalization -	Blood Creatinine	Health					MILLIGRAMS	5 YR
Initial or Prolonged	Increased Bronchopneumonia	Professional						

Cardiomegaly
Cerebellar Atrophy
Clonic Convulsion
Clostridium Colitis
Coma
Depressed Level Of
Consciousness
Drug Level Above
Therapeutic
Electroencephalogram
Abnormal
Gliosis
Haemodialysis
Metabolic Acidosis
Metabolic Encephalopathy
Pancreatitis Chronic
Pyelonephritis
Pyrexia
Renal Impairment
Stupor
Therapeutic Agent
Toxicity

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/27/98ISR Number: 3244249-2Report Type:Periodic Company Report #9820966
Age:71 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Other	Asthenia	Consumer	Viagra Tablets	PS		ORAL	50.00 MG TOTAL; PRN;
	Tremor						
						ORAL	
			Eskalith	SS		ORAL	675.00 MG TOTAL; BID;
						ORAL	
			Cardura	C			
			Allegra	C			
			Flonase	C			
			Atrovent	C			

Date:10/28/98ISR Number: 3148754-9Report Type:Expedited (15-DaCompany Report #9905149
Age:36 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Death	Agitation	Foreign	Depakene	PS	Abbott	ORAL	500.000 MG PO
Hospitalization -	Blood Thyroid Stimulating	Health					QD
Initial or Prolonged	Hormone Increased	Professional	Lithium Carbonate	SS		ORAL	800.000MG PO
	Bundle Branch Block		Diazepam	C			
	Electrocardiogram Normal		Clonazepam	C			
	Excitability		Flunitrazepam	C			
			Dipotassium Clorazepa	C			
			Hydroxyzine Hl	C			
			Levomepromazine	C			
			Tropatepine Hydrochlo	C			

Date:10/28/98ISR Number: 3149112-3Report Type:Direct Company Report #
Age:13 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain		Depakote	PS		ORAL	1G BID PO	
	Laboratory Test Abnormal		Lithium	SS		ORAL	600AM 450PM	
	Pancreatitis						PO	
	Vomiting		Hepatitis B Vax #2 10/9/98	C				

Date:10/28/98ISR Number: 3149282-7Report Type:Expedited (15-DaCompany Report #1998025073-1
Age:25 YR Gender:Female I/FU:I

Outcome	PT
Other	Abortion Induced
	Angiopathy
	Cardiac Septal Defect
	Complications Of Maternal Exposure To Therapeutic Drugs
	Congenital Cystic Kidney Disease
	Ear Disorder
	Placental Disorder
	Pregnancy
	Renal Agenesis
	Talipes

	Transposition Of The Great Vessels Tricuspid Valve Incompetence	Report Source Literature	Product Lithium	Role PS	Manufacturer Smithkline Beecham	Route
Dose 900 MILLIGRAMS	Duration					
			Clozapine	C		

Date:10/28/98ISR Number: 3149432-2Report Type:Expedited (15-DaCompany Report #1998025220-1
Age:26 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Other	Duration Blood Sodium Decreased	Literature	Lithium	PS	Smithkline Beecham	
	Drug Toxicity	Health	Clonazepam	C		
	Feeling Drunk	Professional	Thiothixene	C		
	Hyperhidrosis					
	Malaise					
	Tremor					
	Weight Increased					

Date:10/29/98ISR Number: 3149778-8Report Type:Direct Company Report #
Age:73 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Hospitalization - 600AM, 300AM, Initial or Prolonged 300PM	Duration Polydipsia		Lithium	PS		
	Polyuria					
	Tremor					

Date:10/30/98ISR Number: 3149759-4Report Type:Direct Company Report #
Age:60 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Hospitalization - 600MG PO BID	Duration Agitation		Lithium	PS		ORAL

Initial or Prolonged	Bradycardia			
>6MONTHS 6 MON				
Required	Dialysis	Lisinopril	SS	ORAL
20MG PO BID				
Intervention to	Drug Toxicity			
< 1 MONTH				
Prevent Permanent	Electrocardiogram T Wave	Lopcessor	C	
Impairment/Damage	Inversion	Pepcid	C	
	Hypotension	Lasix	C	
	Mental Impairment	Ecasa	C	
	Renal Failure Acute	Atrovent	C	
	Speech Disorder	Ntg	C	
	Tremor	Tonazepam	C	
		Carbanafepine	C	
		Septra	C	

Date:10/30/98ISR Number: 3150119-0Report Type:Expedited (15-DaCompany Report #1998025218-1
Age:81 YR Gender:Female I/FU:I

Outcome	PT
Hospitalization -	Blood Disorder
Initial or Prolonged	Confusional State
	Drug Level Above
	Therapeutic
	Drug Toxicity
	Electrocardiogram
	Abnormal
	Memory Impairment

	Metabolic Disorder						
	Mucosal Dryness						
	Sinus Bradycardia	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Ventricular Extrasystoles	Literature	Lithium Carbonate	PS	Smithkline Beecham	ORAL	1200
		Health					MILLIGRAMS
		Professional					ORAL

Date:10/30/98ISR Number: 3150128-1Report Type:Expedited (15-DaCompany Report #B011992
Age:60 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Life-Threatening	Antinuclear Antibody	Foreign	Capoten	PS		ORAL	50 MG ORAL
Hospitalization -	Positive	Health	Lithium	SS		ORAL	ORAL
Initial or Prolonged	Ascites	Professional	Levomepromazine	C			
	Cardiac Failure	Other	Haloperidol	C			
	Drug Toxicity						
	Hypertensive Crisis						
	Oedema						
	Pericardial Effusion						
	Pleural Effusion						
	Renal Failure						
	Systemic Lupus Erythematosus						

Date:10/30/98ISR Number: 3150169-4Report Type:Expedited (15-DaCompany Report #9834295
Age:70 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Drug Level Above	Foreign	Zoloft	PS		ORAL	50.00 MG
Initial or Prolonged	Therapeutic	Health					TOTAL:DAILY:O
	Liver Function Test	Professional					RAL

		Abnormal	Company	Lithium	SS			
UNKNOWN	750.00 MG							
		Renal Failure	Representative					
TOTAL:DAILY								
		Serotonin Syndrome		Viloxazine	C			

Date:11/02/98ISR Number: 3150654-5Report Type:Direct Company Report #
Age:45 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - 25 YR	Confusional State	Health	Lithium	PS				
Initial or Prolonged	Diarrhoea	Professional	Benztropine	C				
	Drug Toxicity		Cyclobenzaprine	C				
	Dysphemia		Mg Ox	C				
	Tremor		Folate	C				
			Epivir	C				
			Retrovir	C				
			Crixtivan	C				
			Dapsone	C				
			Zyprexa	C				
			Apap	C				

Date:11/03/98ISR Number: 3151834-5Report Type:Expedited (15-DaCompany Report #1998025889-1
Age:77 YR Gender:Female I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Akinesia
	Atrophy

		Brain Scan Abnormal						
		Confusional State						
		Coordination Abnormal	Report Source	Product	Role	Manufacturer		Route
Dose	Duration							
		Dehydration	Literature	Lithium	PS	Smithkline Beecham		
		Depression		Parsoxetine	C			
		Drug Level Above Therapeutic						
		Hyperhidrosis						
		Hyperreflexia						
		Hypertension						
		Pyrexia						
		Sedation						

Date:11/03/98ISR Number: 3152506-3Report Type:Expedited (15-DaCompany Report #1998025999-1
Age:84 YR Gender:Female I/FU:I

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Disability		Fall	Literature	Lithium Carbonate	PS	Smithkline Beecham	
UNKNOWN	600						
		Gait Disturbance	Health				
MILLIGRAMS							
		Masked Facies	Professional				
UNKNOWN	4 YR						
		Muscle Rigidity					
		Parkinsonism					
		Tremor					

Date:11/04/98ISR Number: 3151753-4Report Type:Expedited (15-DaCompany Report #9834501
Age:85 YR Gender:Female I/FU:I

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Required		Blood Creatinine	Health	Trovafloxacin			
Intervention to		Increased	Professional	Tablets	PS		ORAL
200.00 MG							
Prevent Permanent		Nephritis					
TOTAL: DAILY:							
Impairment/Damage		Proteinuria					
ORAL							
		Renal Tubular Acidosis		Lithium	SS		ORAL
ORAL							

				Relafen	C		
				Prilosec	C		

Date:11/05/98ISR Number: 3152585-3Report Type:Expedited (15-DaCompany Report #LITH002980026
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Cerebrovascular Accident Therapeutic Agent Toxicity	Health Professional	Lithium Carbonate	PS		ORAL PER ORAL		

Date:11/10/98ISR Number: 3155599-2Report Type:Expedited (15-DaCompany Report #1998025887-1
Age:58 YR Gender:Female I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Agitation Blood Creatinine Increased Blood Pressure Increased Blood Urea Decreased Clonic Convulsion Confusional State Dehydration Depressed Level Of

	Consciousness						
	Drug Toxicity						
	Dysarthria						
	Electrocardiogram Qt	Report Source	Product	Role	Manufacturer	Route	
Dose	Duration						
	Prolonged	Literature	Lithium	PS	Smithkline Beecham		
	Electrocardiogram T Wave		Bisoprolol	C			
	Inversion		Dosulepin	C			
	Hypernatraemia		L-Thyroxine				
	Hypertension		(Levothyroxine				
	Hypertonia		Sodium)	C			
	Hypothyroidism		Viloxazine	C			
	Muscle Contractions						
	Involuntary						
	Nephrogenic Diabetes						
	Insipidus						
	Oral Intake Reduced						
	Polydipsia						
	Polyuria						
	Reflexes Abnormal						
	Renal Impairment						
	Skin Disorder						
	Tongue Disorder						
	Tremor						

Date:11/10/98ISR Number: 3155640-7Report Type:Expedited (15-DaCompany Report #1998026259-1
Age:65 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Death	Cardiac Arrest	Literature	Lithium	PS	Smithkline Beecham	
Hospitalization -	Condition Aggravated	Health	Frusemide	C		
Initial or Prolonged	Drug Toxicity	Professional				
	Parkinson'S Disease					

Date:11/10/98ISR Number: 3155651-1Report Type:Expedited (15-DaCompany Report #S98-FRA-00759-01 (-0)
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization -	Drug Level Above	Foreign	Seropram	PS		ORAL
20 MG DAILY,						
Initial or Prolonged	Therapeutic	Health				
PO						

Disability	Renal Impairment Serotonin Syndrome	Professional	Lithium	SS

Date:11/10/98ISR Number: 3155736-XReport Type:Expedited (15-DaCompany Report #1998025215-1
Age:70 YR Gender:Female I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Acute Respiratory Distress Syndrome Blood Antidiuretic Hormone Decreased Diabetes Insipidus Gastric Ulcer Haemorrhage Glycosuria Hyperglycaemic Hyperosmolar Nonketotic Syndrome Hypernatraemia Pancreatitis Polyuria

	Pulmonary Embolism Urine Osmolarity Increased	Report Source	Product	Role	Manufacturer	Route	Dose Duration
		Literature	Lithium Carbonate	PS	Smithkline Beecham		1200
		Health					MILLIGRAMS
		Professional	Amoxipine	C			

Date:11/10/98ISR Number: 3155737-1Report Type:Expedited (15-DaCompany Report #1998025922-1
Age:55 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Cardiac Failure	Literature	Lithium Carbonate	PS	Smithkline Beecham		1000
Initial or Prolonged	Cardiomegaly						MILLIGRAMS 40 YR
	Cardiomyopathy						
	Drug Toxicity						
	Ejection Fraction Abnormal						
	Electrocardiogram Abnormal						
	Pleural Effusion						

Date:11/10/98ISR Number: 3155822-4Report Type:Expedited (15-DaCompany Report #1998026425-1
Age:23 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Other	Renal Failure Acute	Health	Lithium	PS			
		Professional	Clozaril (Clozapine)	C			
			Clozaril (Clozapine)	C			
			Zyprexa (Olanzapine)	C			

Date:11/10/98ISR Number: 3155944-8Report Type:Expedited (15-DaCompany Report #1998025921-1
Age:42 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Atrioventricular Block Complete Bradycardia Cardiac Disorder Drug Toxicity Sinus Arrhythmia Syncope Tachycardia	Literature	Lithium Carbonate	PS		ORAL	750 MILLIGRAMS	ORAL

Date:11/12/98ISR Number: 3156881-5Report Type:Expedited (15-DaCompany Report #8-98309-134A
Age:74 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Interaction Drug Level Above Therapeutic	Foreign Health Professional	Efexor Lithium	PS SS		ORAL ORAL	ORAL SINGLE DOSE	ORAL

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/12/98ISR Number: 3157131-6Report Type:Expedited (15-DaCompany Report #WAES 98110032
Age:87 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Abdominal Pain	Health	Dolobid	PS		ORAL	500 MG/ BID /	
	Diarrhoea	Professional					PO	
	Drug Interaction		Lithiumco3	SS			150 MG / BID	
	Drug Level Above						/ UNK	
	Therapeutic		L-Thyroxine	C				
	Memory Impairment		Aspirin	C				
	Mental Disorder		Clonazepam	C				

Date:11/12/98ISR Number: 3158330-XReport Type:Expedited (15-DaCompany Report #1998027317-1
Age:48 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Biopsy Kidney Abnormal	Literature	Lithium	PS	Smithkline Beecham			
	Fibrosis	Health	Tricyclic					
	Nephritis Interstitial	Professional	Antidepressants	C				
	Renal Failure		Truxal	C				
	Renal Impairment							
	Renal Tubular Atrophy							
	White Blood Cell Disorder							

Date:11/13/98ISR Number: 3157030-XReport Type:Expedited (15-DaCompany Report #D/98/04349/LEX
Age:46 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Dystonia	Study	Leponex	PS		ORAL	500MG ORAL	
Initial or Prolonged	Posture Abnormal	Health	Hypnorex	SS			600MG	
Required		Professional	Bifiteral	C				
Intervention to			Sostril	C				
Prevent Permanent								
Impairment/Damage								

Date:11/13/98ISR Number: 3157119-5Report Type:Expedited (15-DaCompany Report #1046825A
Age:74 YR Gender:Female I/FU:F

Outcome	PT
Death	Abdominal Pain
	Acidosis
	Alanine Aminotransferase Increased
	Aspartate Aminotransferase Increased
	Blood Bicarbonate Decreased
	Blood Creatinine Increased
	Blood Glucose Increased
	Cardiovascular Disorder
	Coma
	Completed Suicide
	Confusional State
	Decreased Appetite
	Disorientation
	Dizziness
	Encephalopathy

	Haematochezia						
	Heart Rate Increased						
	Hepatorenal Syndrome	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Intentional Misuse	Literature	Unknown				
	International Normalised Ratio Increased	Health Professional	Acetaminophen Product	PS		ORAL	UNKNOWN DOSE, PO
	Pco2 Decreased						
	Respiratory Rate		Lithium	SS		ORAL	UNKNOWN DOSE, PO
	Increased						
			Tamoxifen	C			

Date:11/16/98ISR Number: 3158459-6Report Type:Expedited (15-DaCompany Report #1998027107-1
Age:21 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Death	Death	Health	Thorazine	PS	Smithkline Beecham	ORAL	ORAL
Hospitalization -		Professional	Lithium	SS		ORAL	2.0 DAILY Initial or Prolonged ORAL
			Ativan	C			
			Artane	C			
			Prolixin	C			
			Restoril	C			
			Loxitane	C			

Date:11/16/98ISR Number: 3281161-7Report Type:Periodic Company Report #9822120
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Other	Drug Ineffective	Consumer	Sinequan Capsules	PS		ORAL	ORAL
	Insomnia		Zoloft	SS		ORAL	50.00 MG

	Nervousness					
TOTAL:DAILY:O						
RAL						
			Lithium	SS		ORAL
ORAL						
			Macrobid	C		
			Urecholine	C		

Date:11/19/98ISR Number: 3159408-7Report Type:Expedited (15-DaCompany Report #LITH002980027
Age:51 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anorexia Blood Calcium Increased Blood Magnesium Decreased Blood Parathyroid Hormone Increased Calcium Metabolism Disorder Calculus Urinary Cholelithiasis Hyperparathyroidism Nausea Renal Colic Thyroid Adenoma Vomiting Weight Decreased	Foreign Literature	Lithium Carbonate	PS		ORAL	750 MG PER ORAL	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/19/98ISR Number: 3160266-5Report Type:Expedited (15-DaCompany Report #1998027185-1
Age:51 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Calcium Increased Blood Parathyroid Hormone Blood Parathyroid Hormone Increased Calculus Bladder Cholelithiasis Hyperparathyroidism Parathyroid Tumour Benign Renal Colic Thyroid Adenoma	Literature	Lithium	PS	Smithkline Beecham		750 MILLIGRAMS	10 YR

Date:11/19/98ISR Number: 3160944-8Report Type:Direct Company Report #
Age:19 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Toxicity Intentional Misuse Suicide Attempt		Lithobid Risperidal Cogentin Tylenol	PS C C C				

Date:11/19/98ISR Number: 3275971-XReport Type:Periodic Company Report #8-98212-048A
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Depression Hypertonia Myalgia	Health Professional	Effexor Xr Capsules Alcohol Eskalith Cr	PS SS		ORAL	112.5 DAILY REDUCED TO 37.5 MG TWICE DAILY ORAL	

			(Lithium) Extended Release Capsule	SS		ORAL
450 MG TWICE DAILY ORAL						
			Alcohol	C		
			Eskalith Cr	C		
			Estratest	C		
			Provera	C		
			Restoril	C		

Date:11/19/98ISR Number: 3280545-0Report Type:Periodic Company Report #0936843A
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Interaction Leukocytosis	Health Professional	Motrin (Ibuprofen) Product	PS		ORAL	UNKNOWN DOSE, PO	
			Lithium	SS		ORAL	UNKNOWN DOSE, PO	

Date:11/24/98ISR Number: 3162338-8Report Type:Expedited (15-DaCompany Report #1998027337-1
Age:76 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Amnesia Cerebral Atrophy	Foreign Literature	Lithium Carbonate Smithkline Beecham	PS	Smithkline Beecham		800	
Other	Clonic Convulsion	Health					MILLIGRAMS;	
	Dementia	Professional					600	
	Disorientation						MILLIGRAMS	9 YR
	Disturbance In Attention Drug Level Above Therapeutic Drug Toxicity Dysarthria Dysphagia Gait Disturbance Hypothyroidism Tremor		Haloperidol	C				

Date:11/24/98ISR Number: 3163509-7Report Type:Expedited (15-DaCompany Report #98HQ-10404
Age:68 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Serotonin Syndrome	Foreign Literature Health	Anafranil (Clomipramine Hydrochloride)	PS			DAILY	
		Professional	Lithium Carbonate (Lithium Carbonate)	SS		ORAL	ORAL	

Date:11/25/98ISR Number: 3163297-4Report Type:Expedited (15-DaCompany Report #WAES 98110032
Age:87 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Other	Abdominal Pain	Health	Dolobid	PS		ORAL
500 MG/BID/PO						
	Confusional State	Professional	Lithium	SS		
150						
	Delirium					
MG/BID/UNK						
	Diarrhoea		Lithium	SS		
150						
	Drug Interaction					
MG/BID/UNK						
	Drug Level Above		L-Thyroxine	C		
	Therapeutic		Aspirin	C		
	Mental Disorder		Clonazepam	C		

Date:11/25/98ISR Number: 3163903-4Report Type:Direct Company Report #
Age:42 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Lethargy		Lithium	PS		

Date:11/27/98ISR Number: 3163872-7Report Type:Expedited (15-DaCompany Report #JAKYO-41140
Age:71 YR Gender:Female I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Blood Creatine Decreased
	Blood Urea Decreased
	Dizziness
	Drug Ineffective
	Electrolyte Imbalance
	Face Oedema

		Ileus Paralytic					
		Liver Disorder					
		Oedema Peripheral	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
			Foreign	Risperidone	PS	Janssen	ORAL
3 MG DAILY							
			Health				
ORAL							
			Professional	Lithium Carbonate	SS		ORAL
300 MG DAILY							
ORAL							
				Haloperidol	C		
				Sulpiride	C		
				Amitriptyline Hydrochloride	C		
				Tiapride Hydrochloride	C		
				Promethazine Hydrochloride	C		
				Biperiden Hydrochloride	C		
				Flunitrazepam	C		
				Spironolactone	C		
				Vegetamin B	C		
				Levomepromzine Maleate	C		
				Alosenn	C		
				Sennoside	C		
				Sodium Picosulfate	C		

Date:11/30/98ISR Number: 3163987-3Report Type:Expedited (15-DaCompany Report #9838396
Age:72 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization -	Clonic Convulsion	Health	Lithane Tablets	PS		ORAL
ORAL						
Initial or Prolonged	Confusional State	Professional	Aricept	SS		ORAL
5.00 MG						
	Drug Toxicity					
TOTAL:BID:ORA						
	Tremor					
L						

			Sinemet	SS		ORAL
ORAL						
			Zestril	C		
			Tenormin	C		
			Timoptic Eye Drops	C		
			Zoloft	C		

Date:12/04/98ISR Number: 3174485-5Report Type:Periodic Company Report #18421-002
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Enamel Anomaly	Health Professional	Lithium Citrate Syrup	PS		

Date:12/09/98ISR Number: 3168801-8Report Type:Expedited (15-DaCompany Report #8-98336-037A
Age:30 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Drug Interaction	Foreign Health Professional	Trevilor Tablets (Venlafaxine Hydrochloride)	PS		ORAL
300MG ONCE DAILY ORAL, 225MG ONCE DAILY, 187.5MG ONCE 14 DAY	Drug Level Below Therapeutic					
	Libido Decreased					

			Quilonum Retard (Lithium Carbonate) 450mg Tablets	SS		ORAL

2.5 TABLETS

(1125MG)

BEFORE

02NOV98, 3

TABLETS

Date:12/09/98ISR Number: 3169169-3Report Type:Expedited (15-DaCompany Report #D/98/04732/LEX
Age:28 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	Complications Of Maternal Exposure To Therapeutic Drugs Congenital Anomaly Intra-Uterine Death	Health Professional	Leponex Lithium	PS SS		ORAL	100 MG ORAL	2 YR

Date:12/09/98ISR Number: 3169350-3Report Type:Expedited (15-DaCompany Report #M090416
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Drug Level Above Therapeutic	Health Professional	Prolixin Prolixin Inj	PS SS		ORAL	20 MG ORAL	
							INTRAMUSCULAR	10 MG PRN IM
			Ativan	SS		ORAL	2 MG TID ORAL	5 WK
			Artane	SS		ORAL	2 MG TID ORAL	
			Loxitane	SS		ORAL	150 MG QD	

ORAL

			Restoril	SS		ORAL
30 MG HS ORAL						
			Thorazine	SS		ORAL
50 MG QD ORAL						
			Lithium	SS		ORAL
900 MG OD						
ORAL						

Date:12/09/98ISR Number: 3169838-5Report Type:Direct Company Report #
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Agitation	Health	Lithium Carbonate	PS		ORAL
600 MG PO						
Initial or Prolonged	Blood Sodium Abnormal	Professional				
TID						
Other	Lethargy					

Date:12/09/98ISR Number: 3290530-0Report Type:Periodic Company Report #98119.01
Age:44 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Dysuria	Consumer	Lorazepam Tablets			
	Micturition Urgency		1mg Mylan	PS	Mylan	ORAL
1MG QID ORAL						
	Pollakiuria		Lithium	SS		
15 YR						

Date:12/10/98ISR Number: 3169135-8Report Type:Expedited (15-DaCompany Report #B042954
Age:68 YR Gender:Female I/FU:I

Outcome	PT
Hospitalization -	Apathy
Initial or Prolonged	Asthenia

	Coordination Abnormal Drug Interaction Faecal Incontinence	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Haemodialysis	Foreign	Capoten	PS		ORAL	100 MG QD
	Nervousness	Study					ORAL
	Therapeutic Agent	Health	Lithium Carbonate	SS		ORAL	1 GM QD ORAL
	Toxicity Urinary Incontinence	Professional	Fluoxetine Hydrochloride	SS		ORAL	20 MG ORAL
			Orfidal	C			
			Nortriptyline Hydrochloride	C			

Date:12/16/98ISR Number: 3170917-7Report Type:Expedited (15-DaCompany Report #8-98336-037A
Age:30 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged Other	Drug Interaction Drug Level Below Therapeutic Erectile Dysfunction	Foreign Health Professional	Trevilor (Venlafaxine Hydrochloride)	PS		ORAL	300 MG ONCE DAILY
			Quilonum Retard (Lithium Carbonate)	SS		ORAL	2.5 TABLETS (1125 MG)/187.5 MG ONCE DAILY 14 DAY
			Quilonum Retard	C			

Date:12/16/98ISR Number: 3171998-7Report Type:Direct Company Report #
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dizziness Drooling Hypernatraemia Syncope Tremor Urinary Incontinence		Lithium Carbonate	PS			300 MG X3 Q AM; 300 MG X2 Q PM	

Date:12/17/98ISR Number: 3170826-3Report Type:Direct Company Report #
Age:67 YR Gender:Female I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Amnesia Blood Creatine Phosphokinase Increased Blood Pressure Fluctuation Coma Confusional State Coordination Abnormal Dysarthria Dysphagia Hypotonia Lethargy Mental Disorder Muscle Rigidity

	Muscular Weakness						
	Myocardial Infarction						
	Posturing	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Speech Disorder		Eskalith	PS			300 MG AM/
	Urinary Incontinence						450 MG PM
			Haldol	SS			IM OR PO PRN

Date:12/17/98ISR Number: 3171466-2Report Type:Expedited (15-DaCompany Report #9834295
Age:77 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Depression	Foreign	Zoloft	PS		ORAL	TABLETS:
Initial or Prolonged	Drug Interaction	Health					50.00 MG
	Drug Level Above	Professional					TOTAL:DAILY:O
	Therapeutic						RAL
	Drug Toxicity		Lithium	SS		ORAL	750.00 MG
	Gamma-Glutamyltransferase						TOTAL:DAILY:O
	Increased						RAL
	Hepatic Enzyme Increased		Viloxazine	C			
	Renal Failure		Zolpidem	C			
	Serotonin Syndrome		Aspegic	C			
			Glibenclamide	C			

Date:12/21/98ISR Number: 3172199-9Report Type:Expedited (15-DaCompany Report #8-98344-046A
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Life-Threatening	Diarrhoea	Foreign	Trevilor Tablets				
Hospitalization -	Headache	Health	(Venlafaxine				

Initial or Prolonged	Joint Swelling	Professional	Hydrochloride)	PS		ORAL
75 MG ONCE						
	Leukocytoclastic					
DAILY ORAL						
	Vasculitis		Hypnorex (Lithium			
	Nausea		Carbonate) Tablets	SS		ORAL
600 MG DAILY						
	Oedema Peripheral					
ORAL						
	Purulent Discharge		Imodium (Loperamide)			
	Pyrexia		Capsules	SS		ORAL
4 MG GIVEN						
	Rash Erythematous					
ONLY ONCE						
	Rash Pustular					
ORAL						
	Toxic Epidermal		Zyprexa (Olanzapine)			
	Necrolysis		Tablets	SS		ORAL
20 MG / 15 MG						
SEE IMAGE						
ORAL						
			Zyprexa	C		
			Hypnorex	C		
			Ciatyl	C		
			Imodium	C		

Date:12/22/98ISR Number: 3173495-1Report Type:Direct Company Report #
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
	Cognitive Disorder		Lithium	PS		ORAL
600 BID ORAL						
	Drug Interaction		Clozaril	SS		ORAL
175 MG DAILY						
	Drug Toxicity					
PO						
	Leukocytosis		Ativan	SS		ORAL
1 MG PO TID						
	Polydipsia					

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/24/98ISR Number: 3173353-2Report Type:Direct Company Report #
Age:68 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Interaction		Lithium	PS				
	Drug Toxicity		Quinapril	C				
	Haemorrhagic Stroke		Valsartan	C				
	Hypertension							
	Syncope							

Date:12/24/98ISR Number: 3229447-6Report Type:Periodic Company Report #A001-002-002817
Age:72 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Clonic Convulsion	Health	Aricept (Donepezil)	PS		ORAL	5 MG (1 IN 1 D), PER ORAL	
	Confusional State	Professional						
	Tremor		Lithium (Lithium)	SS				
			Sinemet	C				
			Zoloft	C				
			Zestril	C				
			Tenormin	C				
			Timoptic	C				

Date:12/28/98ISR Number: 3175813-7Report Type:Expedited (15-DaCompany Report #9843242
Age:55 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Aphasia	Literature	Lithane	PS		ORAL	900.00 MG TOTAL:ORAL	
	Blood Creatinine Increased	Health Professional	Lisinopril	SS		ORAL	10.00 MG TOTAL:ORAL	
	Cerebrovascular Accident							
	Confusional State		Aspirin	SS		ORAL	325.00 MG	

	Drug Interaction					
TOTAL:ORAL						
	Drug Level Above		Verapamil	SS		ORAL
240.00 MG						
	Therapeutic					
TOTAL:ORAL						

Dysarthria
Haemodialysis
Hemiparesis
Hypertension
Mental Impairment

Date:12/30/98ISR Number: 3176937-0Report Type:Expedited (15-DaCompany Report #M090416
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Death	Health	Prolixin	PS		ORAL	20 MG ORAL	
		Professional	Prolixin Inj	SS			10 MG PRN IM	
			Ativan	SS		ORAL	2 MG TID ORAL	5 WK
			Artane	SS		ORAL	2 MG TID ORAL	
			Loxitane	SS		ORAL	150 MG QD	
							ORAL	
			Restoril	SS		ORAL	30 MG HS ORAL	
			Thorazine	SS		ORAL	50 MG QD ORAL	
			Lithium	SS		ORAL	900 MG QD	
							ORAL	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/31/98ISR Number: 3177510-0Report Type:Expedited (15-DaCompany Report #8-98355-088A
Age:27 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dysarthria	Foreign	Temesta (Lorazepam)	PS		ORAL	250 MG ONE	TIME ORAL
Other Required Intervention to Prevent Permanent Impairment/Damage	Overdose	Health						
	Suicide Attempt	Professional	Risperdal (Risperidone) Tablets	SS		ORAL	220 MG ONE	TIME ORAL
			Stablon (Tianeptine) Tablets	SS		ORAL	500 MG ONE	TIME ORAL
			Teralithe Lp (Lithium) Tablets	SS		ORAL	28 GRAMS ONE	TIME ORAL
			Stablon	C				
			Teralithe Lp	C				
			Risperdal	C				

Date:01/05/99ISR Number: 3177596-3Report Type:Expedited (15-DaCompany Report #JAFRA-42291
Age:27 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Toxicity	Foreign	Risperdal	PS	Janssen	ORAL	220 MG SINGLE	ORAL
	Dysarthria	Health						
	Overdose	Professional	Tianeptine	SS		ORAL	500 MG SINGLE	ORAL
			Lorazepam	SS		ORAL	250 MG SINGLE	

ORAL

FORM:TABLET

2.5 MG

		Lithium	SS		ORAL

2800 MG

SINGLE ORAL

FORM:TABLET

400 MG

Date:01/05/99ISR Number: 3178065-7Report Type:Expedited (15-DaCompany Report #9843254
Age:34 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Literature	Zoloft	PS				
Life-Threatening		Health Professional	Lithium	SS				
			Alprazolam	SS				

Date:01/06/99ISR Number: 3177991-2Report Type:Direct Company Report #
Age:57 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged (WAS TAKING THE WAY AT HOME,	Difficulty In Walking		Lithium	PS			300MG BID & 600MG AT HS	
	Drug Toxicity							
	Dysarthria							
	Haemodialysis							
	Sedation							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/11/99ISR Number: 3179347-5Report Type:Direct Company Report #
Age:65 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Asthenia		Lithium Carbonate	PS			300MG 1T BID	
	Blood Potassium Increased							
	Cough							
	Hyponatraemia							
	Oedema							
	Polydipsia							
	Pulmonary Congestion							

Date:01/11/99ISR Number: 3179532-2Report Type:Expedited (15-DaCompany Report #LBID002990002
Age:44 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agitation	Consumer	Lithobid	PS		ORAL	600 MG, PER DAY, PER ORAL	
	Drug Level Above Therapeutic		Zyprexa	SS		ORAL	PER ORAL	
	Feeling Drunk		Benzotropine	SS		ORAL	PER ORAL	
	Nausea		Wellbutrin	SS				
	Tremor		Neurontin	SS		ORAL	PER ORAL	
			Klonopin	SS		ORAL	PER ORAL	
			Ambien	SS		ORAL	PER ORAL	
			Zoloft	SS		ORAL	PER ORAL	
			Lithobid	SS		ORAL	600 MG, PER DAY, PER ORAL	

Date:01/13/99ISR Number: 3180149-4Report Type:Direct Company Report #
Age:73 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required	Confusional State		Lithium	PS			600MG Q AM;	
Intervention to	Faeces Discoloured						900MG Q PM	
Prevent Permanent	Lethargy		Ibuprofen	SS		ORAL	600MG PO TID	
Impairment/Damage	Sedation							
	Therapeutic Agent							
	Toxicity							

Date:01/13/99ISR Number: 3180319-5Report Type:Expedited (15-DaCompany Report #LBID002980038
Age:70 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Cerebrovascular Accident	Health	Lithobid	PS		ORAL	600 MG, PER	
Initial or Prolonged	Confusional State	Professional					DAY, PER ORAL	
	Dialysis		Haldol	C				
	Drug Level Above Therapeutic							
	Lethargy							
	Memory Impairment							

Date:01/13/99ISR Number: 3183647-2Report Type:Expedited (15-DaCompany Report #1998014020-1
Age:55 YR Gender:Male I/FU:F

Outcome	PT
Hospitalization -	Coma
Initial or Prolonged	Depressed Level Of Consciousness

	Drug Interaction					
	Drug Level Above Therapeutic	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
	Mental Impairment	Health	Lithium	PS		
300 MG , 3.0						
	Pneumonia Aspiration	Professional				
DAILY 10 DAY						
	Pyrexia		Hydrochlorothiazide	C		
	Subdural Haematoma		Risperdal	C		

Date:01/19/99ISR Number: 3182106-0Report Type:Expedited (15-DaCompany Report #8-99011-044A
Age:39 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Coordination Abnormal	Foreign	Efexor	PS		ORAL
1.5 G ONE						
Initial or Prolonged	Drug Level Above Therapeutic	Health				
TIME ORAL						
Other		Professional	Lithium	SS		ORAL
5.6 G ONE						
	Overdose					
TIME ORAL						
	Sedation		Thioridazine	SS		ORAL
750 MG ONE						
	Tremor					
TIME ORAL						
			Zopiclone	SS		ORAL
45 MG ONE						
TIME ORAL						

Date:01/19/99ISR Number: 3182794-9Report Type:Expedited (15-DaCompany Report #9806748
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Medication Error	Health	Lithane	PS		ORAL
ORAL						
Initial or Prolonged	Serotonin Syndrome	Professional	Trilafon	C		
			Klonopin	C		
			Trazodone	C		

			Nardil	C		

Date:01/21/99ISR Number: 3183993-2Report Type:Expedited (15-DaCompany Report #9821939
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Abdominal Pain	Health	Zoloft	PS		ORAL	25.00 MG	
Hospitalization -	Blood Amylase Increased	Professional					TOTAL:DAILY:O	
Initial or Prolonged	Drug Ineffective						RAL	
Required	Gastrooesophageal Reflux		Wellbutrin	SS		ORAL	75.00 MG	
Intervention to	Disease						TOTAL:DAILY:O	
Prevent Permanent	Obstruction						RAL	
Impairment/Damage	Pancreatitis Acute		Lithane	SS			900.00 MG	
							TOTAL:DAILY	
			Motrin	C				

Date:01/21/99ISR Number: 3184170-1Report Type:Expedited (15-DaCompany Report #99F--10026
Age:50 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Drug Level Above	Foreign	Tegretol	PS		ORAL	DAILY ORAL	
Initial or Prolonged	Therapeutic	Health	Teralithe	SS				
	Encephalopathy	Professional	Leponex	SS			ORAL	
		Other	Depamide	SS				
			Barnetil	SS		ORAL	ORAL	
			Deroxat	SS				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/25/99ISR Number: 3185404-XReport Type:Expedited (15-DaCompany Report #9901138
Age: Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required	Thyroiditis Chronic	Foreign	Lithane Tablets	PS		ORAL	ORAL	
Intervention to Prevent Permanent Impairment/Damage		Literature Health Professional						

Date:01/25/99ISR Number: 3185410-5Report Type:Expedited (15-DaCompany Report #9901139
Age: Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required	Thyroiditis Chronic	Foreign	Lithane Tablets	PS		ORAL	ORAL	
Intervention to Prevent Permanent Impairment/Damage		Literature Health Professional						

Date:01/25/99ISR Number: 3185413-0Report Type:Expedited (15-DaCompany Report #9901140
Age:48 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required	Hyperthyroidism	Foreign	Lithane Tablets	PS		ORAL	ORAL	
Intervention to Prevent Permanent Impairment/Damage		Literature Health Professional						

Date:01/25/99ISR Number: 3185419-1Report Type:Expedited (15-DaCompany Report #9901141
Age:59 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required	Hyperthyroidism	Foreign	Lithane Tablets	PS		ORAL	ORAL	
Intervention to		Literature						

Prevent Permanent Impairment/Damage | | Health Professional

Date:01/25/99ISR Number: 3185423-3Report Type:Expedited (15-DaCompany Report #9901142
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Goitre	Foreign Literature Health Professional	Lithane Tablets	PS		ORAL	ORAL	

Date:01/25/99ISR Number: 3185425-7Report Type:Expedited (15-DaCompany Report #9901143
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	Goitre	Foreign Literature Health Professional	Lithane Tablets	PS		ORAL	ORAL	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/25/99ISR Number: 3185637-2Report Type:Expedited (15-DaCompany Report #F/99/00037/LEX
Age:50 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Level Above		Leponex	PS		ORAL		
	Therapeutic		Tegretol	SS		ORAL		
Required Intervention to Prevent Permanent Impairment/Damage	Encephalopathy		Depamide	SS				
			Barnetil	SS				
			Teralithe	SS		ORAL		
			Deroxat	SS		ORAL	40 MG	ORAL

Date:01/27/99ISR Number: 3186879-2Report Type:Expedited (15-DaCompany Report #1999001675-1
Age:31 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Dysarthria	Health Professional	Lithium	PS	Smithkline Beecham	ORAL		
	Dysgraphia		Synthroid	C				
	Movement Disorder		Atenolol	C				
	Muscle Rigidity		Clozaril	C				
	Proctalgia							
	Tremor							

Date:01/27/99ISR Number: 3187837-4Report Type:Expedited (15-DaCompany Report #199910106RHF
Age:74 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Cholecystitis Acute	Foreign	Glibenclamide (Daonil 5 Mg) Tablets	PS		ORAL	PO	
			Simvastatin (Zocor) Tablets	SS		ORAL	20 MG	QD PO
			Venlafaxine					

			Hydrochloride	SS		ORAL
2 U/DAY PO						
			Triptorelin Acetate (Decapeptyl-Slow Release) Solution To Injection	SS		
INTRAMUSCULAR	1 U/DAY IM					
			Lithium Bromide (Lithium Microsol)	SS		ORAL
4 U/DAY PO						
			Buflomedil Hydrochloride	C		
			Acetylsalicylate Lysine	C		
			Diltiazem Hydrochloride	C		

Date:01/29/99ISR Number: 3188458-XReport Type:Expedited (15-DaCompany Report #LBID002980038
Age:70 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Cerebrovascular Accident	Health	Lithobid	PS		ORAL	600 MG PER	
Initial or Prolonged	Confusional State	Professional					ORAL	
	Dialysis		Depakote	C				
	Drug Level Above Therapeutic		Haldol	C				
	Lethargy							
	Memory Impairment							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/01/99ISR Number: 3189672-XReport Type:Expedited (15-DaCompany Report #9902754
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Bipolar Disorder	Foreign	Lithane	PS		ORAL	1200.00 MG	TOTAL DAILY
	Hydrocephalus	Health						
	Tremor	Professional						
						ORAL		
			Methotrimeprazine	C				

Date:02/01/99ISR Number: 3190235-0Report Type:Direct Company Report #
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Mental Impairment		Lithium	PS			?	

Date:02/01/99ISR Number: 3404643-3Report Type:Periodic Company Report #A0074390
Age:35 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Interaction	Health	Wellbutrin Tablet	PS		ORAL	150 MG/ THREE	TIMES PER DAY
	Primary Cerebellar Degeneration	Professional						
						ORAL		
	Tremor		Lithium Salt (Formulation Unknown)	SS				

Date:02/01/99ISR Number: 3410864-6Report Type:Periodic Company Report #A0068255
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Insomnia	Consumer Health Professional	Wellbutrin (Formulation Unknown)	PS		ORAL	ORAL	
		Other	Lithium Salt (Formulation Unknown)	SS				
			Nicotine (Formulation Unknown)	SS				

Date:02/02/99ISR Number: 3190266-0Report Type:Direct Company Report #
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Interaction	Health Professional	Lithium Carb	PS			2 Q AM + 3 QHS	20 YR
Required Intervention to Prevent Permanent Impairment/Damage	Drug Toxicity							
	Insomnia		Ibuprofen, 800 Mg Tab + Advil 200 Mg	SS			1 BID WM + 1 QID X 5D	
	Nausea							
	Polydipsia							
	Polyuria		Mesoridazine	C				
			Methocarbamol	C				
			Multivitamin	C				
			Advil	C			1 QID X5D	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/02/99ISR Number: 3190449-XReport Type:Direct Company Report #
Age:57 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Atrial Fibrillation		Depakote	PS			1500MG BID	
	Bowel Sounds Abnormal		Lithium Carbonate	SS			1200MG Q HS	
	Drug Level Above Therapeutic		Testostone	C				
	Mental Impairment		Asa	C				
	Sedation		Famotidine	C				
	Vomiting							

Date:02/02/99ISR Number: 3190455-5Report Type:Direct Company Report #
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Drug Toxicity		Lithium	PS		ORAL	1T PO AM 3 PO HS	
Life-Threatening								
Hospitalization - Initial or Prolonged			Diclofenac & Misoprostol	SS		ORAL	1T PO BID PC	
Other			Lisinopril	SS		ORAL	T PO QD	
Required Intervention to Prevent Permanent Impairment/Damage								

Date:02/04/99ISR Number: 3192283-3Report Type:Expedited (15-DaCompany Report #JAGER-42776
Age:54 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Blister	Foreign	Imodium (Loperamide)	PS	Janssen	ORAL	-, SINGLE	
Hospitalization -	Diarrhoea	Health					ORAL	

Initial or Prolonged	Leukocytoclastic Vasculitis Nausea Oedema Peripheral Pain Pyrexia Toxic Epidermal Necrolysis	Professional	Trevilor (Venlafaxine) Zyprexa (Olanzapine) Hypnorex (Lithium Carbonate) Ciatyl Praxiten	SS SS SS C C		ORAL ORAL ORAL

75 MG;
DAILY; ORAL 30 DAY
20MG DAILY;
15MG DAILY;
10MG DAILY;
ORAL; TABLET 38 DAY
600 MG DAILY;
ORAL; TABLET
400MG 17 DAY

Date:02/04/99ISR Number: 3298814-7Report Type:Periodic Company Report #M085770
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
	Malaise	Health Professional	Serzone Tabs Lithium	PS SS		ORAL

Dose Duration
ORAL

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/04/99ISR Number: 3298869-XReport Type:Periodic Company Report #M090676
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Weight Increased	Health	Serzone Tabs	PS		ORAL	300 MG QD	
		Professional				ORAL		
			Lithium	SS				

Date:02/04/99ISR Number: 3300574-8Report Type:Periodic Company Report #M075513
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Coordination Abnormal	Health	Serzone Tabs 250 Mg	PS		ORAL	250 MG BID	
	Drug Interaction	Professional				ORAL		
	Drug Level Below Therapeutic		Lithium	SS				
	Mania							
	Speech Disorder							
	Thinking Abnormal							

Date:02/04/99ISR Number: 3303832-6Report Type:Periodic Company Report #M085927
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Agitation	Health	Serzone Tabs	PS		ORAL	ORAL	
	Drug Interaction	Professional	Lithium	SS				
	Insomnia		Augmentin	C				
			Ssri	C				
			Wellbutrin	C				
			Effexor	C				
			Remeron	C				

Date:02/05/99ISR Number: 3198954-7Report Type:Periodic Company Report #FLUV002980256
Age:36 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Depression Hypertonia Leukocytosis	Health Professional	Luvox Tablets (Fluvoxamine Maleate)	PS		ORAL	PER ORAL	
	Neuroleptic Malignant Syndrome Pyrexia Urinary Incontinence		Lithium Carbonate Capsules (Lithium Carbonate)	SS		ORAL	300 MG , PER ORAL	
			Risperdal (Risperidone)	SS		ORAL	4.5 MG , PER ORAL	
			Thorazine (Chlorpromazine Hydrochloride)	SS		ORAL	PER ORAL	
			Effexor	C				

Date:02/05/99ISR Number: 3199672-1Report Type:Periodic Company Report #FLUV002980218
Age:53 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Confusional State Speech Disorder	Consumer	Luvox	PS		ORAL	300 MG, PER ORAL	
	Tongue Oedema		Lithium	SS		ORAL	1200 MG, PER	

ORAL

		Clozaril	C	
		Valium	C	

Date:02/05/99ISR Number: 4515995-5Report Type:Direct Company Report #USP 52040
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Medication Error		Lithium Carbonate	PS			CAPSULE	
			Lithium Carbonate	SS			TABLET	

Date:02/08/99ISR Number: 3193819-9Report Type:Direct Company Report #
Age:43 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Aphonia		Lithium	PS		ORAL	900MG PO BID	
Initial or Prolonged	Blood Creatinine Increased		Seventili	C				
			Hctz	C				
	Blood Urea Increased		Diltiazem Cd	C				
	Clonic Convulsion		Diphenhydiamine	C				
	Coma							
	Convulsion							
	Depressed Level Of Consciousness							
	Drug Level Above Therapeutic							
	Haemodialysis							
	Hyperreflexia							
	Hypokalaemia							
	Tremor							
	Vomiting							

Date:02/09/99ISR Number: 3193737-6Report Type:Direct Company Report #
Age:65 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Confusional State Difficulty In Walking Drug Toxicity		Lithium	PS			300MG PO BID	

Date:02/09/99ISR Number: 3194991-7Report Type:Direct Company Report #
Age:40 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Blood Creatinine Increased Blood Potassium Increased Blood Sodium Increased Confusional State Dialysis Drug Toxicity Gait Disturbance Lethargy Pco2 Decreased	Health Professional	Lithium Tegretal Haldol Congentin	PS C C C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/12/99ISR Number: 3198186-2Report Type:Expedited (15-DaCompany Report #1998-09-0774
Age:33 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Cold Sweat Dissociative Disorder Dizziness Dysphemia	Health Professional Other	Prometrium (Micronized Oral Progesterone) Capsules	PS		ORAL	80 MG DAILY	
	Flushing							ORAL
	Hyperhidrosis		Lithium Citrate	SS		ORAL	300 MG BID	
	Lethargy							ORAL
	Malaise Panic Attack Speech Disorder Syncope							

Date:02/12/99ISR Number: 3406117-2Report Type:Periodic Company Report #97USA12189
Age:8 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Aggression Food Intolerance	Consumer	Tegretol Chewable Tablet (Carbamazepine)	PS		ORAL	DAILY, ORAL	
			Lithium Citrate Syrup (Lithium Citrate)	SS		ORAL	300 MG,	
							DAILY, ORAL	

Date:02/16/99ISR Number: 3199128-6Report Type:Expedited (15-DaCompany Report #9903672
Age:66 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Hospitalization - Initial or Prolonged	Agitation	Foreign	Lithane Tablets	PS		ORAL 900.00 MG TOTAL:TID:ORA
	Drug Toxicity	Health				
	Nervous System Disorder	Professional				
			Pramipexole	C		
			Venlafaxine	C		

Date:02/16/99ISR Number: 3199705-2Report Type:Expedited (15-DaCompany Report #9904507
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Required Intervention to Prevent Permanent Impairment/Damage	Heart Rate Increased	Consumer	Lithane	PS		ORAL 900.00 MG TOTAL:TID:ORA
			Lithium	SS		

Date:02/17/99ISR Number: 3200770-4Report Type:Expedited (15-DaCompany Report #1999003648-1
Age:60 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Other	Diabetes Insipidus	Consumer	Lithium	PS		
	Nephrectomy		Thorazine	SS		
	Renal Failure					

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/18/99ISR Number: 3203018-XReport Type:Expedited (15-DaCompany Report #1998-09-0774
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Cold Sweat	Health	Prometrium	PS		ORAL	800MG DAILY	
	Depersonalisation	Professional				ORAL		
	Dissociation	Other	Lithium Citrate	SS		ORAL	300 MG BID	
	Dizziness					ORAL		
	Drug Interaction		Prozac Capsules	SS		ORAL	60 MG QD ORAL	
	Drug Level Above Therapeutic							
	Flushing							
	Hyperhidrosis							
	Lethargy							
	Malaise							
	Panic Attack							
	Speech Disorder							
	Syncope							

Date:02/24/99ISR Number: 3204839-XReport 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	Dysarthria	Health	Lithium Carbonate	PS				
	Mental Impairment	Professional	Divalproex Sodium	SS				
	Polydipsia							
	Polyuria							
	Tremor							
	Vomiting							

Date:02/24/99ISR Number: 3204859-5Report Type:Direct Company Report #
Age:45 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Drug Level Above	Health	Lithium	PS				

Initial or Prolonged	Therapeutic Dysarthria Medication Error Parkinsonian Gait Thirst	Professional	Carbamazepine	SS			

Date:02/24/99ISR Number: 3206755-6Report Type:Expedited (15-DaCompany Report #9834295
Age:77 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Confusional State Disorientation Gamma-Glutamyltransferase Increased Hepatic Enzyme Increased Loss Of Consciousness Renal Failure Serotonin Syndrome Therapeutic Agent Toxicity Tremor	Foreign Health Professional	Zoloft Lithium Viloxazine Zolpidem Aspegic Glibenclamide	PS SS C C C C		ORAL ORAL	TABLETS, 50.00 MG TOTAL:DAILY:ORAL 750.00 TOTAL:DAILY:ORAL

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/25/99ISR Number: 3208689-XReport Type:Periodic Company Report #9838140
Age:42 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Arthralgia	Health	Zoloft Tablets	PS		ORAL	200.00 MG	
	Drug Interaction	Professional						
TOTAL: DAILY:						ORAL		
			Lithium	SS		ORAL	1200.00 MG	
TOTAL: DAILY:						ORAL		

Date:02/25/99ISR Number: 3208778-XReport Type:Periodic Company Report #9836238
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Muscle Spasms	Health	Zoloft Tablets	PS		ORAL	ORAL	
	Muscle Twitching	Professional Company Representative	Lithane	SS				

Date:02/25/99ISR Number: 3209007-3Report Type:Periodic Company Report #9721690
Age:22 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Anorexia	Consumer	Zoloft Tablets	PS		ORAL	TABLET, ORAL	
	Depression	Health	Antibiotic	SS		ORAL	ORAL	
	Hostility	Professional	Redux	SS		ORAL	ORAL	
	Increased Appetite		Lithium	SS		ORAL	1200.00 MG	

Neurosis

TOTAL:BID:ORA

Weight Increased

L

			Ritalin	C		
			Tegretol	C		
			Klonopin	C		

Date:02/25/99ISR Number: 3210105-9Report Type:Periodic Company Report #9819344
Age:62 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Erectile Dysfunction	Health	Zoloft Tablets	PS		ORAL	150.00 MG	
		Professional						
TOTAL: DAILY:								
ORAL								
			Lithonate	SS		ORAL	300.00 MG	
TOTAL: DAILY:								
ORAL								
			Prilosec	C				
			Trinalin	C				
			Hydroxyzine	C				
			Synthroid	C				

Date:02/25/99ISR Number: 3210112-6Report Type:Periodic Company Report #9818616
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Tremor	Consumer	Zoloft Tablets	PS				
			Lithium	SS				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/25/99ISR Number: 3211927-0Report Type:Periodic Company Report #9804452
Age:45 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Arthralgia	Health	Zoloft Tablets	PS		ORAL	50.00 MG	
	Hypertonia	Professional						TOTAL:DAILY:O
	Osteoarthritis							RAL
			Lithium Carbonate	SS		ORAL	1200.00 MG	
								TOTAL:DAILY:O
								RAL

Date:02/25/99ISR Number: 3212168-3Report Type:Periodic Company Report #JAUSA-35342
Age:41 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dizziness	Consumer	Risperdal					
	Dyspnoea		(Risperidone),					
	Weight Increased		Janssen, Tablet 4 Mg	PS		ORAL	4 MG, 3	
								DAILY, ORAL
			Lithium Tablet	SS		ORAL		
								ORAL

Date:02/25/99ISR Number: 3213544-5Report Type:Periodic Company Report #JAUSA-35255
Age:34 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Thirst	Health	Risperdal					
	Weight Increased	Professional	(Risperidone)	PS	Janssen	ORAL	2 MG 2 DAILY	
								ORAL
			Eskalith (Lithium)					

			Tablet	SS		ORAL
450 MG 3 DAILY ORAL						
			Paxil (Paroxetine)	SS		ORAL
20 MG 2 DAILY ORAL						

Date:02/25/99ISR Number: 3217325-8Report Type:Periodic Company Report #9811456
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Interaction	Health	Zoloft Tablets	PS		ORAL	DAILY: ORAL	
	Drug Tolerance Decreased	Professional	Lithane	SS		ORAL	ORAL	
	Dysgeusia							
	Dyspepsia							
	Influenza Like Illness							

Date:02/26/99ISR Number: 3208903-0Report Type:Direct Company Report #
Age:65 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Gait Disturbance		Lithium	PS		ORAL	300MG DAILY ORAL	
	Lethargy							
Required Intervention to Prevent Permanent Impairment/Damage			Aspirin	C				
			Clonazepam	C				
			Buprion (Wellbutrin)	C				
			Risperidone	C				
			Furosemide	C				
			Lisinopril	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/26/99ISR Number: 3208985-6Report 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	Disorientation		Lithium	PS			450MG ,AT BEDTIME, ORAL	
	Lethargy							
			Oxazepam	C				
			Insulin Human 70/30	C				
			Cisapride	C				
			Divalproex	C				
			Bupropion (Wellbutrin)	C				
			Risperidone	C				
			Diphenhydramine	C				
			Furosemide	C				

Date:02/26/99ISR Number: 3217017-5Report Type:Periodic Company Report #8-98345-071A
Age:34 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Thirst	Health	Effexor	PS		ORAL	ORAL	
	Weight Increased	Professional	Eskalith (Lithium) Tablets	SS		ORAL	450 MG THREE TIMES DAILY	ORAL
			Paxil (Paroxetine)	SS		ORAL	20 MG TWICE DAILY	ORAL
			Risperdal (Risperidone) Tablets	SS		ORAL	2 MG TWICE DAILY	ORAL

Date:02/26/99ISR Number: 3416480-4Report Type:Periodic Company Report #1998011626-1
Age:37 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Interaction	Health	Relafen Smithkline					
	Pollakiuria	Professional	Beecham	PS	Smithkline Beecham	ORAL	1000	
	Tremor						MILLIGRAMS	
							1.0 DAILY	
ORAL								6 DAY
			Eskalith Cr (Lithium)	SS		ORAL	2.0 DAILY	
ORAL								

Date:03/01/99ISR Number: 3208245-3Report Type:Direct Company Report #
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Medication Error		Lithium Carbonate	PS			CAPSULE	
			Lithium Carbonate	SS			TABLET	

Date:03/01/99ISR Number: 3209574-XReport Type:Expedited (15-DaCompany Report #990222-008010775
Age:52 YR Gender:Male I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Condition Aggravated
	Idiopathic

	Thrombocytopenic Purpura Increased Tendency To Bruise Medication Error Platelet Count Decreased Psychotic Disorder	Report Source Health Professional	Product Haloperidol	Role PS	Manufacturer	Route ORAL	Dose Duration 5 MG, QD, ORAL
	Red Blood Cell Count Decreased		Lithium	SS		ORAL	300 MG, TID, ORAL
	White Blood Cell Count Increased		Depakote	SS		ORAL	1250 MG, QD, ORAL
			Risperidone	C		ORAL	1MG, BID, ORAL

Date:03/01/99ISR Number: 3210683-XReport Type:Direct Company Report #
Age:40 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Life-Threatening Hospitalization - Initial or Prolonged	Headache Hypertension Lethargy Movement Disorder Vomiting		Citalopram Lithium Dexatrim (Phenylpropanolamine) 	PS SS C			

Date:03/01/99ISR Number: 3217977-2Report Type:Periodic Company Report #M072945
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged Disability	Amnesia Drug Dependence Drug Withdrawal Syndrome	Other	Stadol Nasal Spray Xanax	PS SS		NASAL	10 MG/ML Q2H NASAL SP 5 YR 1 MG TID

	Skin Disorder		Prozac	SS		
20 MG BID						
			Lithobid	SS		
300 MG BID						

Date:03/01/99ISR Number: 3439088-3Report Type:Periodic Company Report #1998021859-1
Age:30 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
	Apathy	Consumer	Paxil Smithkline			
	Lethargy		Beecham	PS	Smithkline Beecham	ORAL
40 MILLIGRAMS						
	Suicidal Ideation					
ORAL						
			Eskalith (Lithium)			
			Smithkline Beecham	SS	Smithkline Beecham	ORAL
1350						
MILLIGRAMS						
ORAL						
			Paxil Smithkline			
			Beecham	SS	Smithkline Beecham	
			Paxil Smithkline			
			Beecham	SS	Smithkline Beecham	
			Paxil Smithkline			
			Beecham	SS	Smithkline Beecham	ORAL
20 MILLIGRAMS						
1.0 DAILY						
ORAL						
			Paxil Smithkline			
			Beecham	SS	Smithkline Beecham	
			Paxil Smithkline			
			Beecham	SS	Smithkline Beecham	
			Eskalith (Lithium)			
			Smithkline Beecham	SS	Smithkline Beecham	ORAL
900						
MILLIGRAMS						

ORAL						
			Klonopin Hs (Clonazepam) St Johns' Wart	C	St Johns' Wart	

Date:03/03/99ISR Number: 3211736-2Report Type:Expedited (15-DaCompany Report #9906597
Age:44 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Hospitalization -	Agitation	Health	Zoloft Tablets	PS		ORAL
ORAL						
Initial or Prolonged	Drug Level Above Therapeutic	Professional	Lithobid	SS		ORAL
600.00 MG						
TOTAL: DAILY:	Feeling Drunk					
ORAL						
	Nausea		Zyprexa	SS		ORAL
ORAL						
	Tremor		Benztropine	SS		ORAL
ORAL						
			Wellbutrin	C		
			Neurontin	C		
			Klonopin	C		
			Ambien	C		

Date:03/05/99ISR Number: 3214470-8Report Type:Expedited (15-DaCompany Report #A0082673
Age:44 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Hospitalization -	Agitation	Health	Wellbutrin Tablet	PS		ORAL
ORAL						
Initial or Prolonged	Drug Level Above Therapeutic	Professional Other	Lithium Carbonate Tablet	SS		ORAL
ORAL						
	Feeling Drunk		Olanzapine Tablet	SS		ORAL
ORAL						
	Nausea		Benzatropine Tablet	SS		ORAL
ORAL						
	Tremor		Gabapentin Tablet	SS		ORAL
ORAL						

			Clonazepam Tablet	SS		ORAL
ORAL						
			Zolpidem Tartrate Tablet	SS		ORAL
ORAL						
			Sertraline Hydrochloride Tablet	SS		ORAL
ORAL						

Date:03/08/99ISR Number: 3214965-7Report Type:Expedited (15-DaCompany Report #JAUSA-36247
Age:52 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Condition Aggravated Idiopathic Thrombocytopenic Purpura Increased Tendency To Bruise Medication Error Platelet Count Decreased Psychotic Disorder Red Blood Cell Count Decreased White Blood Cell Count Increased	Health Professional	Risperdal (Risperidone), Janssen, Tablet 1 Mg	PS	Janssen	ORAL	1 MG 2 DAILY ORAL 2 MG 2 DAILY ORAL 5 MG 1 DAILY ORAL 300 MG 3 DAILY ORAL ORAL 500 MG AT 8 AM AND 8 PM, 250 MG AT 12 N	8 DAY
			Haldol (Haloperidol), Janssen, Tablet	SS	Janssen	ORAL		
			Lithium (Lithium)	SS		ORAL		
			Depakote (Valproate Sodium)	SS		ORAL	1250 MG DAILY	
			Nifedipine	C				
			Klonopin	C				

			Prednisone	C			

Date:03/08/99ISR Number: 3216169-0Report Type:Direct Company Report #
Age:69 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Haemodialysis Therapeutic Agent Toxicity	Health Professional	Lithium	PS				

Date:03/08/99ISR Number: 3216240-3Report Type:Direct Company Report #
Age:68 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Asthenia Coma Dialysis Difficulty In Walking Eating Disorder Eye Discharge Hypernatraemia Hypovolaemia Insomnia Rash Erythematous Renal Failure Acute Sepsis Therapeutic Agent Toxicity	Health Professional	Lithium Theophiline Depakote Albuterol	PS C C C		ORAL	300 MG, BID, PO	

Date:03/10/99ISR Number: 3218232-7Report Type:Direct Company Report #
Age:42 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Asthenia Blood Pressure Decreased Confusional State		Lithium Gluburide Metoprolol	PS C C				

	Depressed Level Of Consciousness Diarrhoea Drug Toxicity Hallucination Heart Rate Decreased Irritability Lethargy Muscle Rigidity Tremor	Clonidine Benadryl	C C

Date:03/10/99ISR Number: 3218592-7Report Type:Direct Company Report #
Age:42 YR Gender:Male I/FU:I

Outcome Hospitalization - Initial or Prolonged	PT Asthenia Depressed Level Of Consciousness Diarrhoea Drug Level Above Therapeutic

	Drug Toxicity Hallucination Irritability	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Lethargy		Lithium	PS			DOSE WAS
	Medication Error						SUPPOSED TO
	Muscle Rigidity						BE 1 1/2 TAB
	Tremor						AM, 1/2 TAB NOON, 1 1/2

Date:03/16/99ISR Number: 3220487-XReport Type:Direct Company Report #
Age:36 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Drug Level Above Therapeutic	Health Professional	Lithium	PS			
			Haldol	C			
	Heart Rate Abnormal		Cogentin	C			
			Benadryl	C			
			Vitamins	C			

Date:03/19/99ISR Number: 3223450-8Report Type:Expedited (15-DaCompany Report #99USA10110
Age:68 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Accidental Overdose Atrioventricular Block	Health Professional	Diovan Capsule (Valsartan)	PS		ORAL	80 MG, DAILY,
	First Degree	Other					ORAL
	Blood Creatinine Increased Blood Urea Increased		Lithium Unnknown 300 Mg (Lithium Carbonate)	SS		ORAL	600MG, DAILY,
	Cerebrovascular Accident						ORAL
	Drug Interaction		Quinapril Tablet				

	Drug Toxicity		(Quinapril)	SS		ORAL
ORAL						
	Electrocardiogram		Warfarin Tablet	C		
	Abnormal					
	Hypertension					
	Hypotension					
	Sinus Bradycardia					
	Syncope					

Date:03/19/99ISR Number: 3223732-XReport Type:Expedited (15-DaCompany Report #1999001675-1
Age:31 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Required	Dysarthria	Consumer	Lithium	PS	Smithkline Beecham	ORAL
ORAL						
Intervention to	Movement Disorder	Health	Synthroid	C		
Prevent Permanent	Muscle Rigidity	Professional	Atenolol	C		
Impairment/Damage	Musculoskeletal Stiffness		Clozaril	C		
	Proctalgia					
	Tremor					

Date:03/22/99ISR Number: 3224105-6Report Type:Expedited (15-DaCompany Report #9910443
Age:16 YR Gender:Female I/FU:I

Outcome
Hospitalization -
Initial or Prolonged
Required

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Intervention to Prevent Permanent Impairment/Damage	Anorexia	Health	Zoloft Tablets	PS		ORAL	200.00 MG	TOTAL:DAILY:ORAL
	Bipolar Disorder	Professional						
	Drug Interaction							
	Hallucination		Lithium	SS				
	Heart Rate Increased		Depakote	SS				
	Intentional Misuse		Remeron	SS				
	Respiratory Rate Increased		Tylenol	C				
			Advil	C				
			Unspecified Prescription Medication	C				

Date:03/24/99 ISR Number: 3224433-4 Report Type:Direct Company Report #
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Drug Toxicity		Lisinopril 10mg Qd	PS		ORAL	10MG QD PO	
	Hyperkalaemia		Lithium ( )	SS				

Date:03/24/99 ISR Number: 3224446-2 Report Type:Direct Company Report #
Age:70 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Body Temperature Decreased		Lithium	PS			300MG Q AM 2PM +450MG QHS	LONG-TERM
	Confusional State		Risperidone 0.5mg Bid	SS				
	Drooling							
	Exophthalmos		Benztropine	C				
			Dipherhydramine	C				
			Lorazepam	C				

			Risperidone	C			

Date:03/25/99ISR Number: 3225616-XReport 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 Required Intervention to Prevent Permanent Impairment/Damage	Drug Toxicity	Health Professional	Lithium	PS				

Date:03/31/99ISR Number: 3418709-5Report Type:Periodic Company Report #981125-107058367
Age:39 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Asthenia Catatonia Erectile Dysfunction Hypertonia Malaise	Consumer	Haldol Decanoate, Unspecified (Haloperidol)	PS		IM (INTRAMUSCULAR)		
	Speech Disorder Urinary Incontinence		Lithium	SS		ORAL		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/01/99ISR Number: 3231240-5Report Type:Expedited (15-DaCompany Report #1999007024-1
Age:50 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Creatinine Increased	Literature Health Professional	Lithium Carbonate	PS			1200 MG	
Other	Coma		Haloperidol	C				
	Hypernatraemia		Lorazepam	C				
	Hyperosmolar State							
	Nephrogenic Diabetes Insipidus							
	Pollakiuria							
	Polydipsia							
	Polyuria							
	Sedation							
	Thirst							

Date:04/01/99ISR Number: 3231243-0Report Type:Expedited (15-DaCompany Report #1999007096-1
Age:52 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Creatinine Increased	Health Professional	Lithium Carbonate	PS				
	Blood Sodium Increased							
	Blood Urea Increased							
	Dehydration							
	Hypomania							
	Mania							
	Nephrogenic Diabetes Insipidus							
	Pollakiuria							
	Renal Failure Chronic							
	Thirst							

Date:04/01/99ISR Number: 3231962-6Report Type:Periodic Company Report #7397661
Age:35 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Other	Alopecia	Health	Abbott-Depakote	PS	Abbott	ORAL	500.000 MG PO
	Condition Aggravated	Professional					TID
	Thyroid Disorder	Other	Lithium	SS			300.000 MG QD
	Weight Increased		Zyprexa	C			

Date:04/06/99ISR Number: 3236474-1Report Type:Periodic Company Report #1998000342-1
Age:41 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Creatinine Increased	Health Professional	Eskalith Smithkline Beecham	PS	Smithline Beecham	ORAL	450MG 2	
	Blood Pressure Increased						DAILY; 150MG	
	Condition Aggravated						2 DAILY	19 DAY
	Hypothyroidism		Fluphenazine	C				
	Therapeutic Agent		Carbamazepine	C				
	Toxicity		Ativan	C				
	Tremor							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/06/99ISR Number: 3236477-7Report Type:Periodic Company Report #1998022961-1
Age:67 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Confusional State	Health Professional	Eskalith Smithkline Beecham	PS	Smithkline Beeecham	ORAL	1.0 DAILY	

ORAL

Date:04/06/99ISR Number: 3237294-4Report Type:Periodic Company Report #1998027577-1
Age:39 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Acne	Health Professional	Lithium Smithkline Beecham	PS			310 DAY	
	Benign Intracranial							
	Hypertension							
	Blood Thyroid Stimulating Hormone Increased							
	Fatigue							

Date:04/06/99ISR Number: 3237295-6Report Type:Periodic Company Report #1998011628-1
Age:81 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dehydration	Health Professional	Eskalith Smithkline Beecham	PS	Smithkline Beecham		300 MILLIGRAMS	
	Therapeutic Agent							
	Toxicity							
			Trilafon	C			3.0 DAILY	
			Ativan	C				
			Zoloft	C				

Date:04/06/99ISR Number: 3237296-8Report Type:Periodic Company Report #1998007471-1
Age:58 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Coronary Artery Disease	Health	Eskalith Smithkline					
	Heart Rate Decreased	Professional	Beecham	PS	Smithkline Beecham	ORAL		
ORAL							8	YR
			Lithobid	C				

Date:04/06/99ISR Number: 3237297-XReport Type:Periodic Company Report #1998005301-1
Age:58 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Drug Toxicity	Health	Lithium Smithkline					
Initial or Prolonged		Professional	Beecham	PS	Smithkline Beecham	ORAL		
300								
MILLIGRAMS								
4.0 DAILY								
ORAL								
			Guaifenesin / Dextromethorpham	C				
			Tobramycin	C				
			Accupril	C				
			Zocor	C				
			Toprol	C				
			Minipres	C				
			Cephalexin	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/07/99ISR Number: 3234309-4Report Type:Direct Company Report #
Age:52 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Confusional State		Lithium Carbonate	PS			T1C PO	T
	Coordination Abnormal		Famotidine	C				
	Drug Toxicity		Thiamine Hcl	C				
	Feeling Jittery		Thiamine Hcl	C				
			Albuterol	C				
			Vitamin B Complex/Vitamin C	C				
			Albuterol	C				
			Ipratropium Bromide	C				
			Levofloxacin Na (Synthroid)	C				
			Terazosin Hcl	C				
			Paroxetine Hcl	C				
			Nitroglycerin	C				
			Hydralazine Hcl	C				
			Doxepin Hcl	C				
			Buspirone Hcl	C				

Date:04/07/99ISR Number: 3234475-0Report Type:Direct Company Report #
Age:40 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Cough		Haloperidol	PS			5MG BID, 1-5	
Hospitalization - Initial or Prolonged	Dyspnoea						PRN	
	Movement Disorder						AGITATION; PRIOR TO ADMIT	
	Nervous System Disorder							
	Neuroleptic Malignant Syndrome		Lithium	SS			300MG BID PRIOR TO ADMIT	
	Pyrexia							

Date:04/07/99ISR Number: 3234909-1Report Type:Expedited (15-DaCompany Report #2553/12541
Age:20 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Aggression Balance Disorder Clonic Convulsion Condition Aggravated Convulsion Drug Interaction Psychotic Disorder	Health Professional	Depo-Provera Suspension Lithium Depakote (Divalproex) Haldol (Haloperidol) Ritalin (Methylphenidate Hcl)	PS SS SS SS C		ORAL	INTRAMUSCULAR 200-400 MG-1Q3WK, IM	

Date:04/08/99ISR Number: 3234973-XReport Type:Expedited (15-DaCompany Report #990329-008011259
Age:45 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Depressed Level Of Consciousness Syncope	Foreign Health Professional	Haloperidol Tablets Lithium Acetate	PS SS		ORAL ORAL	10 MG, QD, 900 MG, QD	

ORAL					
			Lorazepam	SS	ORAL
1.5 MG,					
QD,ORAL					
			Diclofenac Sodium	SS	ORAL
150 MG, QD,					
ORAL					
			Flunitrazepam	SS	ORAL
QD ORAL					
			Valproic Acid	C	
			Lorazepam	C	

Date:04/08/99ISR Number: 3235226-6Report Type:Expedited (15-DaCompany Report #1999007311-1
Age:46 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Abdominal Pain	Literature	Lithium Smithkline			
Hospitalization -	Blood Creatinine		Beecham	PS	Smithkline Beecham	
800						
Initial or Prolonged	Increased					
MILLIGRAMS 6 YR						
	Blood Urea Increased					
	Csf Glucose Abnormal					
	Csf Protein Increased					
	Depressed Level Of Consciousness					
	Diarrhoea					
	Hyperhidrosis					
	Nausea					
	Pyrexia					
	Tachycardia					
	Thyrotoxic Crisis					
	Thyroxine Increased					
	Vomiting					
	White Blood Cell Count Increased					

Date:04/08/99ISR Number: 3235239-4Report Type:Expedited (15-DaCompany Report #1999007308-1
Age:57 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Creatine Phosphokinase Increased	Literature	Lithium Smithkline Beecham	PS	Smithkline Beecham		1200 MILLIGRAMS	
	Blood Pressure Fluctuation						400 MILLIGRAMS	
	Dysarthria Dysphagia Mania Neuroleptic Malignant Syndrome Pyrexia Salivary Hypersecretion Sedation Tachycardia White Blood Cell Count Increased							

Date:04/08/99ISR Number: 3235247-3Report Type:Expedited (15-DaCompany Report #1999007306-1
Age:62 YR Gender:Female I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Akinesia Chills Delirium

	Disorientation						
	Drug Interaction						
	Dyskinesia	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Encephalopathy	Literature	Lithium Smithkline				
	Fear	Health	Beecham	PS	Smithkline Beecham		450
	Hallucination	Professional					MILLIGRAMS
	Muscle Rigidity						1125
	Restlessness						MILLIGRAMS
	Tardive Dyskinesia						675
			Biperiden	C			
			Haloperidol	C			
			Perazine	C			
			Valproate	C			

Date:04/12/99ISR Number: 3237930-2Report Type:Expedited (15-DaCompany Report #9904507
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Required	Heart Rate Increased	Consumer	Lithane Tablets	PS		ORAL	900 MG TOTAL
Intervention to							TID ORAL
Prevent Permanent			Lithium	SS			
Impairment/Damage							

Date:04/13/99ISR Number: 3239176-0Report Type:Expedited (15-DaCompany Report #001-0945-990134
Age:20 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Bipolar Disorder	Health	Neurontin Capsules				
Initial or Prolonged	Convulsion	Professional	300 Mg (Gabapentin)	PS		ORAL	2700 MG (900
	Dizziness						MG, TID), PER

	Drug Interaction			
ORAL				
	Drug Level Below		(Lithium)	SS
	Therapeutic		(Seroquel)	SS
	Headache		Ambien (Zolpidem	
	Lethargy		Tartrate	C
	Mania			
	Status Epilepticus			

Date:04/14/99ISR Number: 3239791-4Report Type:Direct Company Report #
Age:84 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Asthenia		Lithium	PS		
450MG QD; FOR						
Initial or Prolonged	Confusional State					
SOME TIME						
	Decreased Appetite		Synthroid	C		
			Compazine	C		

Date:04/19/99ISR Number: 3242354-8Report Type:Expedited (15-DaCompany Report #8-99098-011A
Age:32 YR Gender:Female I/FU:I

Outcome
Life-Threatening
Hospitalization -
Initial or Prolonged
Required
Intervention to
Prevent Permanent

Impairment/Damage

PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Atrioventricular Block First Degree Coma Heart Rate Increased Intentional Misuse Loss Of Consciousness Pneumonia Aspiration Sedation	Foreign Health Professional	Effexor (Ventlafaxine Hydrochloride)	PS		ORAL	TABLETS, 1.05 GRAMS ONCE ORAL	
		Chloral Hydrate	SS		ORAL	2.898 GRAMS (1) TIME ORAL	
		Lamotrigine	SS		ORAL	3.5 GRAMS (1) TIME ORAL	
		Lithium	SS		ORAL	5.6 GRAMS (1) TIME ORAL	
		Lorazepam	SS		ORAL	28 MG (1) TIME ORAL	
		Olanzepine	SS		ORAL	140 MG (1) TIME ORAL	

Date:04/19/99ISR Number: 3242383-4Report Type:Expedited (15-DaCompany Report #1999-04-0465
Age:47 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Apnoeic Attack Cerebellar Ataxia Coordination Abnormal Difficulty In Walking Dysarthria	Foreign Health Professional Other	Trilafon (Perphenazine) Tablets Litarex Panodil	PS SS C		ORAL ORAL	16 MG ORAL ORAL	

	Dyspnoea		Bricanyl Powder	C	
	Hyperventilation		Pulmicort Powder	C	
	Neurotoxicity				
	Pneumonia				
	Pyrexia				
	Sedation				
	Snoring				
	Visual Disturbance				

Date:04/20/99ISR Number: 3243298-8Report Type:Expedited (15-DaCompany Report #1999008279-1
Age:50 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Antibody Test Positive Blood Thyroid Stimulating Hormone Decreased Goitre Hyperthyroidism Iodine Uptake Increased Palpitations Thyroxine Increased Tri-Iodothyronine Increased Weight Decreased	Literature	Lithium Carbonate (Lithium)	PS	Smithkline Beecham		800 MILLIGRAMS	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/20/99ISR Number: 3243300-3Report Type:Expedited (15-DaCompany Report #1999008680-1
Age:65 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Chronic Lymphocytic Leukaemia	Health Professional	Eskalith	PS	Smithkline Beecham	ORAL	300 MILLIGRAMS, 2.0 DAILY	
Other	Pneumonia							

Date:04/22/99ISR Number: 3244618-0Report Type:Direct Company Report #
Age:55 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agitation	Health Professional	Lithium	PS				
	Confusional State		Paxil	C				
	Dizziness		Insulin	C				
	Electrocardiogram Abnormal		Lopid	C				
	Feeling Abnormal		Ativan	C				
	Nausea							

Date:04/23/99ISR Number: 3245877-0Report Type:Expedited (15-DaCompany Report #1999008544-2
Age:66 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Dyskinesia	Literature	Lithium	PS	Smithkline Beecham			
	Dystonia	Health	Antipsychotic Drugs					
	Movement Disorder	Professional	(Nos)	C				
	Muscle Hypertrophy		Benzhexol	C				
	Neck Pain		Botulinus Toxin	C				
	Paraproteinaemia		Clonazepam	C				
	Posturing		Co-Careldopa	C				
	Stereotypy		Diazepam	C				
	Torticollis		Methylprednisolone	C				
			Nitrazepam	C				
			Olanzapine	C				
			Sulipride	C				
			Tetrabenazine	C				

Thioridazine	C
Tricyclic Antidepressants (Nos)	C
Trifluoperazine	C

Date:04/26/99ISR Number: 3247053-4Report Type:Expedited (15-DaCompany Report #9915773
Age: Gender:Female I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Anxiety
	Bronchospasm
	Decreased Appetite
	Depression
	Diplopia
	Dysphemia
	Endometriosis
	Feeling Abnormal
	Headache
	Hyperhidrosis
	Hysterectomy
	Insomnia

	Liver Function Test Abnormal Migraine	Report Source	Product	Role	Manufacturer	Route Dose Duration
	Nausea		Zoloft Tablets	PS		ORAL 50.00 MG
	Nervous System Disorder					TOTAL: DAILY:
	Tremor					ORAL
	Vomiting		Lithium	SS		
	Weight Decreased		St. John'S Wort	SS		
			Milk Thistle	C		
			Premarin	C		

Date:04/29/99ISR Number: 3249988-5Report Type:Expedited (15-DaCompany Report #001-0945-990134
Age:20 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Hospitalization - Initial or Prolonged	Bipolar Disorder	Health Professional	Neurontin Capsules 300 Mg (Gabapentin)	PS		ORAL 2700 MG (900 MG, TID) PER
	Convulsion					
	Dizziness					ORAL
	Drug Interaction					
	Headache		Eskalith (Lithium Carbonate)	SS		
	Lethargy					
	Status Epilepticus		Seroquel	SS		
			Ambien	C		

Date:04/30/99ISR Number: 3251373-7Report Type:Direct Company Report #
Age:57 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Other	Tremor		Lithium	PS		

Date:04/30/99ISR Number: 3251475-5Report Type:Direct Company Report #
Age:65 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	Gait Disturbance Lethargy		Lithium Aspirin Clonazepam Bupropion (Wellbutrin)	PS C C C		ORAL	300MG , DAILY, ORAL	

Date:04/30/99ISR Number: 3251624-9Report 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	Disorientation Lethargy		Lithium Oxazepam Insulin, Human 70/30 (Nph/Reg) Cisapride	PS C C C		ORAL	450MG, AT BEDTI, ORAL	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/03/99ISR Number: 3255768-7Report Type:Periodic Company Report #LITH002990006
Age:60 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Tooth Disorder	Consumer	Lithonate Capsules 300 Mg (Lithium Carbonate)	PS		ORAL	1200 MG, PER	ORAL
			Carbidopa	C				
			Effexor	C				
			Klonopin	C				
			Levodopa	C				
			Pramipexole	C				
			Seroquel	C				
Other	Fall	Foreign	Fevarin	PS		ORAL	PO	
	Grand Mal Convulsion	Health Professional	Leponex	SS				
	Joint Dislocation		Hypnorex- Slow Release	SS				
			Gastrozepin	C				

Date:05/04/99ISR Number: 3253691-5Report Type:Expedited (15-DaCompany Report #FLUV00399000044
Age:37 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blood Creatinine Increased	Consumer	Lithium Carbonate Tablets	PS	Roxane Laboratories, Inc.	ORAL	600 MG BID PO	16 YR
	Dysuria							
			Depakote	C				

Date:05/04/99ISR Number: 3255885-1Report Type:Periodic Company Report #18558-010
Age:46 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Amnesia	Consumer	Lithium Carbonate Tablets	PS	Roxane Laboratories, Nc.	ORAL	600 MG BID PO	6 YR

Date:05/04/99ISR Number: 3255887-5Report Type:Periodic Company Report #18558-011
Age:45 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Headache	Consumer	Lithium Carbonate Tablets	PS	Roxane Laboratories Inc.	ORAL	300 MG AM, 900 MG PM PO	25 YR
			Aspirin	C				
			Antihistamine	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/04/99ISR Number: 3256590-8Report Type:Expedited (15-DaCompany Report #1999009592-1
Age:80 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain	Literature	Lithium Carbonate (Lithium)	PS	Smithkline Beecham		400 MILLIGRAMS	YR
	Coordination Abnormal	Health						
	Decreased Appetite	Professional						
	Diarrhoea		Carbamazepine	C				
	Dizziness		Digoxin	C				
	Drug Interaction		Hydrochlorothiazide/ Amiloride	C				
	Faecal Incontinence							
	Irritable Bowel Syndrome		Local Anaesthetic Skin Infiltrations (Nos)	C				
	Movement Disorder							
	Nausea		Mebeverine	C				
	Oral Candidiasis							
	Sedation							
	Therapeutic Agent							
	Toxicity							
	Vomiting							

Date:05/06/99ISR Number: 3255251-9Report Type:Direct Company Report #
Age:52 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Frequent Bowel Movements	Health	Lithium	PS		ORAL	300MG TID	
	Heart Rate Increased	Professional					ORAL	
	Hypercalcaemia							
	Hyperthyroidism							
	Palpitations							
	Tremor							
	Vision Blurred							

Date:05/07/99ISR Number: 3256378-8Report Type:Direct Company Report #
Age:44 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Hospitalization - Initial or Prolonged	Asthenia Bradycardia Disorientation Dizziness Lethargy Tremor		Lithium	PS		

900MG BID

Date:05/07/99ISR Number: 3256582-9Report Type:Expedited (15-DaCompany Report #1999008680-1
Age:65 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - Initial or Prolonged	Chronic Lymphocytic Leukaemia Pneumonia Viral White Blood Cell Count Increased	Health Professional	Eskalith Smithkline Beecham	PS	Smithkline Beecham	ORAL

Dose Duration
300 MILLIGRAMS
2.0 DAILY
ORAL

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/11/99ISR Number: 3259258-7Report Type:Expedited (15-DaCompany Report #8-99117-162A
Age:36 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Interaction Gait Disturbance	Foreign Health	Bi-Profenid (Ketoprofen)	PS		INTRAVENOUS	100 MG TWICE DAILY IV	
Other	Hyporeflexia Hypotonia Intervertebral Disc Protrusion Multiple Sclerosis Muscle Contractions Involuntary Myalgia Spinal Cord Compression Therapeutic Agent Toxicity	Professional	Lithium Carbonate Propranolol Dihydroergotamine Mesilate	SS C C			250 MG THREE TIMES DAILY	

Date:05/13/99ISR Number: 3260879-6Report Type:Direct Company Report #
Age:35 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hypercalcaemia Renal Failure Acute	Health Professional	Lithium Carbonate 300 Mg Capsules (Roxanne) Ativan Trilafon	PS C C	Roxanne	ORAL	600MG PO BID	

Date:05/13/99ISR Number: 3261186-8Report Type:Expedited (15-DaCompany Report #1999010080-1
Age:43 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Optic Neuritis		Lithium Smithkline Beecham	PS	Smithkline Beecham	ORAL	1 GRAMS	

Date:05/14/99ISR Number: 3262826-XReport Type:Expedited (15-DaCompany Report #1999007838-1
Age:28 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Abortion Spontaneous	Consumer	Eskalith Smithkline					
	Alopecia	Health	Beecham	PS	Smithkline Beecham	ORAL		
ORAL								
	Depression	Professional	Eskalith Smithkline					
	Disorientation		Beecham	SS		ORAL		
900								
	Dizziness							
MILLIGRAMS								
	Drug Level Above							
ORAL								
	Therapeutic		Serzone	C				
	Drug Level Below		Wellbutrin	C				
	Therapeutic							
	Fear							

Date:05/19/99ISR Number: 3265573-3Report Type:Expedited (15-DaCompany Report #9806748
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Serotonin Syndrome	Health	Lithane Tablets	PS		ORAL		
ORAL								
Initial or Prolonged		Professional	Trilafon	C				
			Klonopin	C				
			Trazodone	C				

			Nardil	C			

Date:05/20/99ISR Number: 3266123-8Report Type:Expedited (15-DaCompany Report #1999010856-1
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Toxicity Nervous System Disorder	Consumer	Eskalith Smithkline Beecham	PS	Smithkline Beecham	ORAL		
			Zestril	C				

Date:05/21/99ISR Number: 3267975-8Report Type:Expedited (15-DaCompany Report #9712480
Age:41 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Distension Alopecia Anger Blood Lactate Dehydrogenase Increased Dizziness Drug Ineffective Dry Mouth Face Oedema Headache Hyperhidrosis Hypoaesthesia Insomnia Periorbital Oedema Pollakiuria Salivary Hypersecretion Skin Odour Abnormal Tinnitus Tongue Oedema Urinary Incontinence	Health Professional	Zoloft Tablets	PS		ORAL	100.00 MG	TOTAL:DAILY:ORAL
			Lithium Carbonate	SS		ORAL	900.00MG	TOTAL:TID:ORAL
			Famotidine	C				

	Vision Blurred						

Date:05/25/99ISR Number: 3270013-4Report Type:Direct Company Report #
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Anxiety		Lithium Citrate Syrup Usp (8m Eq Of Lithium Per 5ml)	PS	Roxanne Lab			

Date:05/25/99ISR Number: 3275374-8Report Type:Expedited (15-DaCompany Report #1999010626-1
Age:53 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Bipolar Disorder		Lithium Smithkline Beecham	PS	Smithkline Beecham	ORAL	ORAL	5 MON
	Oesophageal Carcinoma							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/26/99ISR Number: 3270180-2Report Type:Expedited (15-DaCompany Report #9921021
Age:33 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Anoxia	Literature	Zoloft Tablets	PS				
	Bronchospasm	Health	Lithium	SS				
	Coma	Professional	Nortriptyline	C				
	Dyspnoea		Buspirone	C				
	Haemoglobin Decreased		Clonazepam	C				
	Haemorrhage		Trazodone	C				
	Hypoxia		Carisoprodol	C				
	Oedema Peripheral		Analgesic	C				
	Pain		Lidocaine	C				
	Post Procedural Complication							
	Pulmonary Oedema							
	Syncope							
	Ventricular Fibrillation							

Date:05/28/99ISR Number: 3273385-XReport Type:Periodic Company Report #LITH002980016
Age:66 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Confusional State	Health	Lithium Carbonate Capsules 300 Mg (Lithium Carbonate)	PS		ORAL	600 MG, PER ORAL	
	Drug Level Above Therapeutic	Professional						
	Tremor							
			Amitriptyline	C				
			Prilosec	C				
			Zestril	C				

Date:05/28/99ISR Number: 3273387-3Report Type:Periodic Company Report #LITH002980018
Age:32 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Mania	Health Professional	Lithium Carbonate Capsules 300 Mg					

			(Lithium Carbonate)	PS		ORAL	600 MG, PER ORAL
			Prozac (Fluoxetine Hydrochloride)	SS		ORAL	PER ORAL

Date:05/28/99ISR Number: 3273389-7Report Type:Periodic Company Report #LITH002980028
Age:36 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Depression Hypertonia Leukocytosis Neuroleptic Malignant Syndrome Pyrexia Urinary Incontinence	Health Professional	Lithium Carbonate Capsules 300 Mg (Lithium)	PS		ORAL	300 MG , PER ORAL
			Luvox Tablets 50 Mg (Fluvoxamine Maleate)	SS		ORAL	PER ORAL
			Risperdal (Risperidone)	SS		ORAL	4.5 MG , PER ORAL
			Thorazine (Chlorpromazine Hydrochloride)	SS		ORAL	PER ORAL

			Effexor	C		

Date:05/28/99ISR Number: 3273394-0Report Type:Periodic Company Report #LITH002990001
Age:72 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Amnesia	Health	Lithium Carbonate			
	Diarrhoea	Professional	Capsules 300 Mg			
	Drug Interaction		(Lithium Carbonate)	PS		ORAL
SEE IMAGE						
	Drug Level Above		Lisinopril			
	Therapeutic		(Lisinopril)	SS		ORAL
20 MG , PER						
ORAL						
			Deltasone	C		
			Fosamax	C		
			Synthroid	C		

Date:05/28/99ISR Number: 3273396-4Report Type:Periodic Company Report #LITH002980006
Age:44 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Cystitis	Consumer	Lithonate Capsules			
	Insomnia		300 Mg (Lithium			
	Pain		Carbonate)	PS		ORAL
900 MG , PER						
	Pollakiuria					
ORAL						
			Ativan	C		

Date:05/28/99ISR Number: 3273400-3Report Type:Periodic Company Report #LITH002980008
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Cardiomyopathy	Health	Lithium Carbonate			
		Professional	Capsules 300 Mg			

			(Lithium Carbonate)	PS		ORAL

300 MG, PER

ORAL

Date:05/28/99ISR Number: 3273402-7Report Type:Periodic Company Report #LITH002980012
Age:44 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Other	Asthenia	Consumer	Lithium Carbonate Capsules 300 Mg (Lithium Carbonate)	PS		ORAL
	Skin Disorder					
	Skin Hypertrophy					
			Klonopin	C		
			Posicor	C		

Dose Duration

1200 MG, PER

DAY, PER ORAL

Date:05/28/99ISR Number: 3273406-4Report Type:Periodic Company Report #LITH002980015
Age:36 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Other	Bradycardia	Health	Lithium (Lithium)	PS		ORAL
	Electrocardiogram Abnormal	Professional				
	Ventricular Extrasystoles					

Dose Duration

ORAL

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/28/99ISR Number: 3273410-6Report Type:Periodic Company Report #LITH002980022
Age:50 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hormone Level Abnormal Oedema Peripheral	Consumer	Lithonate Capsules 300 Mg (Lithium Carbonate)	PS		ORAL	600 MG, PER DAY, PER ORAL	
			Nardil	C				

Date:05/28/99ISR Number: 3273414-3Report Type:Periodic Company Report #LITH002980030
Age:77 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Pain Weight Increased	Consumer	Lithonate Capsules 300 Mg (Lithium Carbonate)	PS		ORAL	600 MG, PER ORAL	

Date:05/28/99ISR Number: 3273417-9Report Type:Periodic Company Report #LITH002980031
Age:41 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dizziness	Health	Lithium (Lithium)	PS		ORAL	ORAL	
	Dyspnoea Weight Increased	Professional	Risperdal (Risperidone)	SS		ORAL	4 MG, PER ORAL	
			Loestrin (Norethisterone Acetate, Ethinylestradiol)	SS		ORAL	ONE TABLET	

PER DAY, PER

ORAL

Date:05/28/99ISR Number: 3273422-2Report Type:Periodic Company Report #LITH002990002
Age:28 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dermatitis	Health	Lithonate Capsules					
	Vasodilatation	Professional	300 Mg (Lithium Carbonate)	PS		ORAL	600 MG, PER	
							ORAL	
			Alprazolam	C				
			Neurontin	C				

Date:06/01/99ISR Number: 3274621-6Report Type:Direct Company Report #
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Coordination Abnormal		Lithium	PS		ORAL	600 MG PO BID	
	Malaise		Amlodipine	C				
	Tremor		Diphenhydramine	C				
			Fluphenazine Decanoate	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/01/99ISR Number: 3275094-XReport Type:Expedited (15-DaCompany Report #1999007838-1
Age:28 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Abortion Spontaneous	Consumer	Eskalith Smithkline					
	Affective Disorder	Health	Beecham	PS	Smithkline Beecham	ORAL	ORAL	
	Alopecia	Professional	Eskalith Smithkline					
	Depression		Beecham	SS	Smithkline Beecham	ORAL	900 MG ORAL	
	Disorientation		Serzone	C				
	Dizziness		Wellbutrin	C				
	Headache							
	Nausea							
	Stress							

Date:06/01/99ISR Number: 3275097-5Report Type:Direct Company Report #
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Blood Creatinine	Health	Lithium Carbonate	PS				
Initial or Prolonged	Increased	Professional	Divalproex Sodium	SS		ORAL	500 MG PO TID	
	Blood Urea Increased		Fluphenazine	C				
	Coordination Abnormal		Diphenhydramine	C				
	Drug Level Above Therapeutic							
	Sedation							
	Tremor							

Date:06/03/99ISR Number: 3275147-6Report Type:Direct Company Report #
Age:69 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Drug Toxicity		Lithium	PS				
LONGTERM USE								
Initial or Prolonged	Hypotension							
BEFORE ADMIT								
	Mental Disorder							

Date:06/03/99ISR Number: 3281437-3Report Type:Periodic Company Report #9827209
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dermatitis	Consumer	Lithane Tablets	PS		ORAL	ORAL	
	Rash Maculo-Papular		Zoloft	SS		ORAL	50.00 MG	
	Urticaria						TOTAL; DAILY;	
							ORAL	
			Psyllium	SS		ORAL	ORAL	
			Aspirin	SS		ORAL	ORAL	
			Ecotrin	C				
			Stool Disorders	C				

Date:06/03/99ISR Number: 3281438-5Report Type:Periodic Company Report #9837369
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Constipation	Health	Lithane Tablets	PS		ORAL	ORAL	
	Hypercholesterolaemia	Professional	Azmacort	C				
	Upper Respiratory Tract Infection		Klonopin	C				
			Folic Acid	C				
			Zyprexa	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/03/99ISR Number: 3281439-7Report Type:Periodic Company Report #9911960
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hypothyroidism	Health Professional	Lithane Tablets	PS				
			Synthroid	C				
			Midrin	C				
			Potassium Chloride	C				
			Risperidol	C				
			Carbidopa/Levodopa	C				
			Permax	C				
			Captopril	C				

Date:06/03/99ISR Number: 3281440-3Report Type:Periodic Company Report #9808189
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Ineffective	Health	Lithane Tablets	PS		ORAL	ORAL	
		Professional	Iron	C				

Date:06/04/99ISR Number: 3276168-XReport Type:Expedited (15-DaCompany Report #1999012249-1
Age:28 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Aggression Bipolar Disorder Brief Psychotic Disorder, With Postpartum Onset Caesarean Section Paranoia Restlessness Sleep Disorder	Literature	Lithium Carbonate (Lithium)	PS	Smithkline Beecham		1800 MILLIGRAMS	

Date:06/04/99ISR Number: 3276169-1Report Type:Expedited (15-DaCompany Report #1999012134-1
Age:27 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Aggression Brief Psychotic Disorder, With Postpartum Onset Disinhibition Euphoric Mood Fluid Retention Hallucination Hypomania Intensive Care Mania Oedema Peripheral Pregnancy On Oral Contraceptive Weight Increased	Literature Health Professional	Lithium Diazepam Oxazepam Risperidone Terazepam	PS C C C C	Smithkline Beecham			

Date:06/07/99ISR Number: 3277480-0Report Type:Direct Company Report #
Age:69 YR Gender:Male I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Accidental Overdose Asthenia

	Confusional State Drug Level Above Therapeutic	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
			Lithium	PS		
300 MG T.I.D.; THERAPY: LONG TERM						

Date:06/07/99ISR Number: 3277713-0Report Type:Expedited (15-DaCompany Report #9906597
Age:44 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Agitation	Health	Zoloft Tablets	PS		ORAL
600.00 MG TOTAL:DAILY:ORAL	Drug Level Above Therapeutic	Professional	Lithobid	SS		ORAL
	Feeling Drunk					
	Nausea		Zyprexa	SS		ORAL
	Tremor		Benztropine	SS		ORAL
			Wellbutrin	C		
			Neurontin	C		
			Klonopin	C		
			Ambien	C		

Date:06/10/99ISR Number: 3280563-2Report Type:Expedited (15-DaCompany Report #9822838
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Required Intervention to	Cardiac Disorder	Consumer	Lithane Tablets	PS		ORAL
	Depression					

Prevent Permanent Impairment/Damage	Ear Infection
	Hepatocellular Damage
	Medication Error
	Multiple Allergies

Date:06/15/99ISR Number: 3285161-2Report Type:Expedited (15-DaCompany Report #1999CBX0001
Age:51 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Drug Level Above Therapeutic	Literature Health	Carbex (Selegiline Hcl)	PS		ORAL	PO	
	Drug Toxicity	Professional	(Lithium)	SS		ORAL	PO	

Date:06/16/99ISR Number: 3284095-7Report Type:Direct Company Report #
Age:48 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Demyelination		Lithium	PS				

Date:06/17/99ISR Number: 3286241-8Report Type:Expedited (15-DaCompany Report #LBID002990002
Age:44 YR Gender:Female I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Agitation
	Drug Level Above Therapeutic
	Drug Toxicity

	Feeling Drunk Nausea Tremor	Report Source	Product	Role	Manufacturer	Route	Dose Duration
		Consumer	Lithobid Tablets 300 Mg (Lithium Carbonate)	PS		ORAL	1200 MG, PER ORAL
			Benzotropine (Benzatropine Mesilate)	SS		ORAL	PER ORAL
			Neurontin (Gabapentin)	SS		ORAL	PER ORAL
			Ambien (Zolpidem Tartrate)	SS		ORAL	PER ORAL
			Buspar	C			
			Lamictal	C			
			Wellbutrin	C			
			Zoloft	C			
			Zyprexa	C			

Date:06/18/99ISR Number: 3288485-8Report Type:Periodic Company Report #LITT002980004
Age:65 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Other	Depression Insomnia Nervousness Pollakiuria	Consumer	Lithotabs Tablets 300 Mg (Lithium Carbonate)	PS		ORAL	1050 MG , PER ORAL
			Lithobid Tablets 300 Mg (Lithium Carbonate)	SS		ORAL	300 MG , PER ORAL
			Lithotabs Tablets 300 Mg (Lithium				

			Carvbonate)	SS		
300 MG						
			Transene (Clorazepate Dipotassium)	C		

Date:06/18/99ISR Number: 3288487-1Report Type:Periodic Company Report #LITT002980005
Age:76 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Diplopia Myasthenic Syndrome Neuropathy Peripheral	Health Professional	Lithotabs Tablets 300 Mg (Lithium Carbonate)	PS		ORAL	900 MG , PER	ORAL

Date:06/18/99ISR Number: 3288491-3Report Type:Periodic Company Report #LITT002990001
Age:40 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Abdominal Pain Pain	Consumer	Lithotabs Tablets 300 Mg (Lithium Carbonate)	PS		ORAL	600 MG , PER	ORAL
			Lithotabs Tablets 300 Mg (Lithium					

			Carbonate)	SS		ORAL	300 MG, PER ORAL
Date:06/23/99ISR Number: 3289556-2Report Type:Direct Company Report # Age:66 YR Gender:Female I/FU:I							
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Life-Threatening	Sedation	Consumer	Mirapex / 0.5mg / Upjohn	PS	Upjohn	ORAL	0.5MG / 5XD /PO 3 MON
			Eskalith Sr / 450 Mg / Po	SS		ORAL	450 MG / BID / PO
Date:06/25/99ISR Number: 3293302-6Report Type:Expedited (15-DaCompany Report #PRIUSA1999002546 Age:30 YR Gender:Unknown I/FU:I							
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Death	Overdose	Literature	Haldol (Unspecified)				
		Health	(Haloperidol)	PS		ORAL	ORAL
		Professional	Fluoxetine (Fluoxetine)	SS		ORAL	ORAL
			Lithium (Lithium)	SS		ORAL	ORAL
Date:06/25/99ISR Number: 3295538-7Report Type:Periodic Company Report #LBID002990010 Age: Gender: I/FU:I							
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Drug Level Above Therapeutic	Health Professional	Lithobid Tablets 300 Mg (Lithium				

			Carbonate)	PS		ORAL
1200 MG, PER ORAL						
			Naprosyn	C		

Date:06/25/99ISR Number: 3295540-5Report Type:Periodic Company Report #LBID002980017
Age:37 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Abdominal Distension	Consumer	Lithobid Tablets 300			
	Acne		Mg (Lithium			
	Alopecia		Carbonate)	PS		ORAL
600 MG, PER						
	Chills					
ORAL						
	Confusional State		Inderal La	C		
	Dehydration		Pravacol	C		
	Dry Mouth		Synthroid	C		
	Pollakiuria					

Date:06/25/99ISR Number: 3295542-9Report Type:Periodic Company Report #LBID002980026
Age:43 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Tooth Discolouration	Health	Lithobid Tablets 300			
		Professional	Mg (Lithium			
			Carbonate)	PS		ORAL
900 MG, PER						
ORAL						
			Azmacort	C		
			Glucotrol	C		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/25/99ISR Number: 3295543-0Report Type:Periodic Company Report #LBID002980029
Age:37 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dyspepsia Hypersensitivity Urticaria	Consumer	Lithobid Tablets 300 Mg (Lithium Carbonate)	PS		ORAL	900 MG, PER DAY, PER ORAL / 900 MG, PER ORAL	

Date:06/25/99ISR Number: 3295545-4Report Type:Periodic Company Report #LBID002980031
Age:17 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Anxiety Headache Nausea Thinking Abnormal	Health Professional	Lithobid Tablets 300 Mg (Lithium Carbonate)	PS		ORAL	1200 MG, 2 IN 1 D, PER ORAL	
	Tremor		Zyprexa (Olanzapine)	SS		ORAL	5 MG, PER ORAL	

Date:06/25/99ISR Number: 3295546-6Report Type:Periodic Company Report #LBID002980032
Age:45 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hostility Insomnia Vasodilatation	Consumer	Lithobid Tablets 300 Mg (Lithium Carbonate)	PS		ORAL	600 MG, PER ORAL	

			Buspar	C		
			Inderal	C		
			Premarin	C		
			Sinquan	C		
			Zoloft	C		

Date:06/25/99ISR Number: 3295549-1Report Type:Periodic Company Report #LBID002980036
Age:63 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Glossitis Headache	Consumer	Lithobid Tablets 300 Mg (Lithium Carbonate)	PS		ORAL	300 MG, PER	
ORAL								14 YR
			Avapro	C				
			Calcium	C				
			Premarin	C				
			Vitamin B Compex	C				
			Vitamin E	C				
			Ziac	C				

Date:06/25/99ISR Number: 3295550-8Report Type:Periodic Company Report #LBID002980037
Age:42 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Interaction	Health Professional	Lithobid Tablets 300 Mg (Lithium Carbonate)	PS		ORAL	300 MG, PER	

ORAL

			Nicoderm Cq (Nicotine)	SS		
TOPICAL	21 MG,					
TOPICAL /						
14 MG,						
TOPICAL						

Date:06/25/99ISR Number: 3295552-1Report Type:Periodic Company Report #LBID002990009
Age:50 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Glossitis	Health Professional	Lithobid Tablets 300 Mg (Lithium Carbonate)	PS		ORAL	1200 MG, PER DAY, PER ORAL	

Date:06/25/99ISR Number: 3295554-5Report Type:Periodic Company Report #LBID002990011
Age:8 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Accident Accidental Overdose Drug Level Above Therapeutic Dysarthria Sedation	Health Professional	Lithobid Tablets 300 Mg (Lithium Carbonate	PS		ORAL	300 MG, PER ORAL	

Date:06/25/99ISR Number: 3295557-0Report Type:Periodic Company Report #LBID002990012
Age:54 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Constipation Fungal Skin Infection Pain	Consumer	Lithobid Tablets 300 Mg (Lithium Carbonate)	PS		ORAL	600MG Q AM AND 900MG Q PM, PER ORAL	
			Trilafon	C				
			Valium	C				

Date:06/25/99ISR Number: 3295559-4Report Type:Periodic Company Report #LBID002990013
Age:46 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Accident Diarrhoea Mydriasis	Consumer	Lithobid Tablets 300 Mg (Lithium Carbonate)	PS		ORAL	PER ORAL	
			Clonazepam	C				

Date:06/25/99ISR Number: 3295560-0Report Type:Periodic Company Report #LBID002990014
Age:35 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Pruritus Rhinitis Weight Increased	Consumer	Lithobid Tablets 300 Mg (Lithium Carbonate)	PS			STARTED ON 900 MG/D THEN DECREASED TO	

600

			Zoloft	C		

Date:06/25/99ISR Number: 3295561-2Report Type:Periodic Company Report #LBID002990016
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Paraesthesia	Health Professional	Lithobid Tablets 300 Mg (Lithium Carbonate)	PS		ORAL	1500 MG, PER ORAL	

Date:06/25/99ISR Number: 3295563-6Report Type:Periodic Company Report #LBID002990017
Age:81 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dementia Overdose	Other	Lithobid Tablets 300 Mg (Lithium Carbonate)	PS		ORAL	PER ORAL	

Date:06/25/99ISR Number: 3295565-XReport Type:Periodic Company Report #LBID00299000052
Age:40 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Cyst	Consumer	Lithobid	PS		ORAL	300 MG QD PO	
	Dyspepsia		Prozac	C				
			Klonopin	C				

Date:06/28/99ISR Number: 3292484-XReport Type:Direct Company Report #
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Chronic Obstructive		Lithium	PS			600MG QHS	
	Airways Disease							
	Exacerbated							
	Drug Level Above							
	Therapeutic							
	Pneumonia							

Date:06/28/99ISR Number: 3292494-2Report Type:Direct Company Report #
Age:78 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Asthenia		Lithium 600mg Po Bid	PS		ORAL	600MG PO BID	
Initial or Prolonged	Confusional State							
	Decreased Appetite							
	Dehydration							
	Drooling							
	Drug Toxicity							
	Lethargy							
	Parkinsonian Gait							
	Pyrexia							
	Sinus Bradycardia							
	Tremor							

Date:06/28/99ISR Number: 3292768-5Report Type:Expedited (15-DaCompany Report #9468/18276
Age:62 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Cardiac Ventriculogram Left	Foreign Consumer	Xanax Tablets (.25mg)	PS		ORAL	.25 MG-1Q1DY;	
	Cardiomyopathy	Company				ORAL		
	Echography Abnormal	Representative	Lormetazepam (1 Mg)	SS		ORAL	2 MG / DAY;	
	Ejection Fraction					ORAL		
	Abnormal		Fluvoxamine (50 Mg)	SS		ORAL	50 MG/DAY;	
						ORAL		
			Lithium (250 Mg)	SS		ORAL	1625 MG/DAY;	
						ORAL		
			Ramipril	C				

Date:06/28/99ISR Number: 3292847-2Report Type:Expedited (15-DaCompany Report #WAES 99061391
Age:26 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anticholinergic Syndrome	Literature	Tab Cogentin 1 Mg	PS		ORAL	1 MG/TID/PO	1 DAY
	Bowel Sounds Abnormal	Health	Tab Cogentin Unk	SS		ORAL	UNK / UNK /	
	Bradykinesia	Professional				PO		3 DAY
	Confusional State		Sertraline 200 Mg	SS		UNK / UNK /		
	Coordination Abnormal					UNK		
	Delirium		Haloperidol 0.5 Mg	SS		0.5 MG / BID		
	Disorientation					/ UNK		2 WK
	Drug Interaction		Haloperidol 9 Mg	SS		UNK / UNK /		

Dry Mouth
UNK
Dry Skin Lithiumco3 600 Mg SS
UNK / UNK /
Gastrointestinal Motility
UNK 2 DAY
Disorder Lithiumco3 900 Mg SS
UNK / UNK /
Hallucination, Visual
UNK 3 DAY
Masked Facies
Muscle Rigidity
Mydriasis
Neurotoxicity
Parkinsonism
Skin Warm
Speech Disorder
Tremor

Date:06/28/99ISR Number: 3292864-2Report Type:Expedited (15-DaCompany Report #WAES 99061391
Age:26 YR Gender:Female I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Anticholinergic Syndrome
	Bowel Sounds Abnormal
	Bradykinesia
	Coordination Abnormal
	Delirium
	Disorientation
	Drug Interaction
	Dry Mouth
	Dry Skin
	Gastrointestinal Motility
	Disorder
	Hallucination
	Masked Facies
	Muscle Rigidity
	Mydriasis

	Parkinsonism					
	Skin Warm					
	Speech Disorder	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
	Tremor	Literature	Cogentin	PS		ORAL
1 MG TID						
		Health				
PO 3 DAY						
		Professional	Sertraline	SS		
			Haloperidol	SS		
0.5 MG BID						
			Lithium	SS		
3 DAY						

Date:06/28/99ISR Number: 3293113-1Report Type:Expedited (15-DaCompany Report #10022424
Age:36 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Confusional State	Foreign	Buspar Tabs			
Initial or Prolonged	Drug Effect Increased	Health	(Buspirone Hci)	PS		ORAL
10 MILLIGRAM,						
Other	Drug Interaction	Professional				
4/1 DAY ORAL						
	Medication Error		Lithium (Lithium			
	Tremor		Salts)	SS		
1 YR						
	Vomiting		Temazepam	C		
			Luvox	C		
			Disulfiram	C		
			Vitamin B6	C		

Date:06/29/99ISR Number: 3293692-4Report Type:Direct Company Report #
Age:72 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Difficulty In Walking		Lithium 300mg	PS		ORAL
300,G PO BID						
Initial or Prolonged	Lethargy					
	Mental Impairment					

Date:06/30/99ISR Number: 3295088-8Report Type:Expedited (15-DaCompany Report #99D--10493
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Agitation	Foreign	Ludiomil Film-Coated Tablet (Maprotiline Hydrochloride)	PS		ORAL	UNK, DAILY,	
	Anxiety	Health						
	Delirium	Professional						
	Disorientation	Other						
	Restlessness		Hypnorex Retard Slow Release Tablet (Lithium Carbonate)	SS		ORAL	UNK, UNK,	
	Tremor							
			Seroxat Unknown (Paroxetine Hydrochloride)	SS		ORAL	40 MG, DAILY,	

ORAL 10 MON

ORAL 10 DAY

ORAL

Date:06/30/99ISR Number: 3295092-XReport Type:Expedited (15-DaCompany Report #1195977A
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Interaction	Consumer	Motrin Ib Product	PS		ORAL	UNKNOWN DOSE, PO	
	Drug Level Above Therapeutic		Lithium	SS		ORAL	UNKNOWN DOSE, PO	
	Paralysis							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/01/99ISR Number: 3294896-7Report Type:Direct Company Report #
Age:39 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cold Sweat		Haloperidol	PS			5MG BID, 10MG	
	Coma						HS	
	Condition Aggravated		Lithium	SS		ORAL	900MG PO BID	
	Cyanosis							
	Delusion							
	Dermatitis							
	Respiratory Distress							
	Stridor							
	Tremor							

Date:07/02/99ISR Number: 3296199-3Report Type:Direct Company Report #
Age:76 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Dermatitis	Health	Lithium Carbonate	PS			1 BID / TID	
Initial or Prolonged	Pruritus	Professional						
ALT							15	MON
	Psoriasis							

Date:07/06/99ISR Number: 3303064-1Report Type:Periodic Company Report #201181
Age:44 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Agitation	Health	Klonopin Tablets					
Initial or Prolonged	Feeling Drunk	Professional	(Clonazepam)	PS		ORAL	ORAL	
	Nausea	Other	Lithobid (Lithium					
	Tremor		Carbonate) 300 Mg	SS		ORAL	300 MG DAILY	
							ORAL	
			Zyprexa					

			(Olanzapine)	SS		ORAL
ORAL						
			Benzotropine	C		
			Wellbutrin	C		
			Neurontin	C		
			Ambien	C		
			Zoloft	C		

Date:07/15/99ISR Number: 3354302-0Report Type:Periodic Company Report #990421-SK285
Age:50 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Depression	Health	Celebrex	PS		ORAL	PO	
	Drug Interaction	Professional	Zoloft	SS		ORAL	PO	
			Lithium	SS		ORAL	PO	
			Digoxin	C				

Date:07/16/99ISR Number: 3305766-XReport Type:Expedited (15-DaCompany Report #9929900
Age: Gender:Female I/FU:I

Outcome	PT
Required	Accident At Work
Intervention to	Aggression
Prevent Permanent	Drug Ineffective
Impairment/Damage	Drug Interaction
	Fall
	Headache

	Irritability Laceration Medication Error	Report Source	Product	Role	Manufacturer	Route Dose Duration
		Consumer	Zoloft Tablets	PS		ORAL 50.00MG TOTAL DAILY ORAL
			Lithium	SS		ORAL 100.00MG TOTAL DAILY ORAL
			Baby Aspirin	C		

Date:07/19/99ISR Number: 3306512-6Report Type:Expedited (15-DaCompany Report #9930980
Age:35 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Required Intervention to Prevent Permanent Impairment/Damage	Flushing Malaise Road Traffic Accident Vomiting	Consumer	Sinequan Capsules Lithium Cogentin Trilafon Prozac	PS SS SS SS C		ORAL 50.00 MG TOTAL: DAILY: ORAL

Date:07/19/99ISR Number: 3306860-XReport Type:Expedited (15-DaCompany Report #8-99193-014A
Age:54 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Hospitalization - Initial or Prolonged Other	Acute Respiratory Distress Syndrome Oedema Peripheral	Health Professional	Effexor	PS		ORAL 300 MG DAILY DISCONTINUED IN JAN. 1999;

	Pulmonary Oedema			
REINITIATED				
	Sedation			
(DATE AND				
	Sleep Apnoea Syndrome	Lithium	SS	ORAL
ORAL				
	Weight Increased	Temazepam	SS	ORAL
5 TO 7 DOSES				
DAILY ORAL				
		Zyprexa (Olanzapine) Tablets	SS	ORAL
"AS MUCH AS				
25 MG PER				
DAY" ORAL				
		Temazepam	C	
		Zyprexa	C	
		Lithium	C	
		Depakote	C	
		Lorazepam	C	

Date:07/19/99ISR Number: 3306931-8Report Type:Expedited (15-DaCompany Report #99HQ-10291
Age:49 YR Gender:Male I/FU:I

Outcome	PT
Disability	C-Reactive Protein Increased
	Cerebellar Syndrome
	Chest Pain
	Coordination Abnormal
	Difficulty In Walking
	Dizziness
	Drug Level Above Therapeutic
	Drug Toxicity

		Dysarthria						
		Dyspnoea						
		Lobar Pneumonia	Report Source	Product	Role	Manufacturer	Route	
Dose	Duration							
		Pneumonia Pneumococcal	Foreign	Carbamazepine				
		Pyrexia	Literature	Unknown				
		Red Blood Cell	Health	(Carbamazepine)	PS			
1200 MG,								
		Sedimentation Rate	Professional					
DAILY								
		Increased	Other	Lithium Unknown				
		Tremor		(Lithium Carbinate)	SS			
		White Blood Cell Count		Trifluperidol				
		Increased		Unknown	SS			
1.5 MG, DAILY								

Date:07/19/99ISR Number: 3307341-XReport Type:Expedited (15-DaCompany Report #1191259A
Age:68 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Completed Suicide	Literature	Unknown			
	Drug Level Above	Health	Acetaminophen			
	Therapeutic	Professional	Product	PS		ORAL
PO 1 DAY						
			Glyburide	SS		ORAL
PO 1 DAY						
			Amitriptyline	SS		
			Metformin	SS		
			Lithium	SS		
			Paroxetine	SS		
			Trazodone	SS		

Date:07/20/99ISR Number: 3307542-0Report Type:Expedited (15-DaCompany Report #PRIUSA1999002546
Age:30 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Anticholinergic Syndrome	Literature	Haldol	PS		ORAL
ORAL						
Hospitalization -	Coma	Health	Fluoxetine			
Initial or Prolonged	Convulsion	Professional	(Fluoxetine)	SS		ORAL
ORAL						

	Disseminated	Lithium (Lithium)	SS	ORAL
ORAL				
	Intravascular Coagulation	Cogentin		
	Drug Level Above	(Benzatropine		
	Therapeutic	Mesilate)	SS	
	Electrocardiogram Qrs	Amoxicillin		
	Complex Prolonged	(Amoxicillin)	SS	
	Epistaxis			
	Heart Rate Increased			
	Hypotension			
	Neuroleptic Malignant			
	Syndrome			
	Paralysis Flaccid			
	Pulmonary Oedema			
	Pupil Fixed			
	Pyrexia			
	Respiratory Rate			
	Decreased			
	Serotonin Syndrome			

Date:07/22/99ISR Number: 3309009-2Report Type:Expedited (15-DaCompany Report #1999017012-1
Age:72 YR Gender:Female I/FU:I

Outcome	PT
Hospitalization -	Apraxia
Initial or Prolonged	Blepharospasm

	Clonic Convulsion Confusional State Drug Level Above	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
	Therapeutic	Foreign	Lithium	PS	Smithkline Beecham	
800						
	Eyelid Disorder	Literature				
MILLIGRAMS;						
	Fall	Health				
1200						
	Gait Disturbance	Professional				
MILLIGRAMS						
	Muscle Rigidity		Amlodipine	C		
	Tremor		Enalapril	C		
	Vomiting		Levodopa-Benserazide	C		

Date:07/29/99ISR Number: 3313829-8Report Type:Expedited (15-DaCompany Report #8-99201-212A
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Drug Withdrawal Syndrome	Foreign	Effexor Tablets			
Initial or Prolonged	Mania	Study	(Venlafaxine			
	Stress		Hydrochloride)	PS		ORAL
SLOWLY						
	Suicide Attempt					
TITRATED TO						
75 MG DAILY,						
THEN SLOWLY						
TAPERED OFF						
			Clonazepam Oral	SS		ORAL
2 MG DAILY,						
TWENY 0.5 MG						
TABLETS TAKEN						
IN OVERDOSE						
ORAL						
			Flunitrazepam			

			Tablets	SS		ORAL
TWENTY 2MG TABLETS (OVERDOSE AMOUNT)						
			Lithium	SS		ORAL
900MG DAILY ORAL						
			Levothyroxine	C		
			Ethinyl Estradiol	C		
			Gestodene	C		

Date:07/30/99ISR Number: 3315076-2Report Type:Expedited (15-DaCompany Report #LBID00299000666
Age:38 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Other	Abortion Spontaneous	Health	Lithobid	PS		ORAL	300 MG BID PO
	Amyotrophic Lateral Sclerosis	Professional	Effexor Xr	SS		ORAL	150 MG BID PO
	Extensor Plantar Response		Alprazolam	C			
	Hyperreflexia		Trazodone	C			
	Insomnia						
	Restlessness						
	Vaginal Haemorrhage						

Date:07/30/99ISR Number: 3315299-2Report Type:Expedited (15-DaCompany Report #210600
Age:59 YR Gender:Male I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Abdominal Pain
	Balance Disorder
	Bipolar Disorder

	Chest Discomfort Chest Pain Circulatory Collapse	Report Source	Product	Role	Manufacturer	Route Dose Duration
	Coordination Abnormal Diarrhoea Disorientation Flatulence	Consumer Health Professional	Lariam Tablets (Mefloquine Hydrochloride) 250 Mg	PS		ORAL 250 MG 1 PER
	Hypersensitivity					WEEK ORAL
	Insomnia Palpitations		Lithium (Lithium Nos)	SS		ORAL 300 MG DAILY
	Psychotic Disorder					ORAL
	Pyrexia Syncope Tremor Vomiting		Lorazepam Atenolol	C C		

Date:08/02/99ISR Number: 3321138-6Report Type:Periodic Company Report #8-97273-045L
Age:42 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Hospitalization -	Alopecia	Consumer	Pondimin	PS		ORAL 3 TIMES DAILY
Initial or Prolonged	Amnesia					
ORAL 5 YR						
	Chest Pain		Prozac	SS		3 DAILY
	Dyspnoea		Lithium	SS		
	Migraine		Xanax	C		
	Oedema					
	Tachycardia					

Date:08/03/99ISR Number: 3316753-XReport Type:Expedited (15-DaCompany Report #210600
Age:59 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Hospitalization -	Abdominal Pain	Consumer	Lariam Tablets			

Initial or Prolonged	Bipolar Disorder	Health	(Mefloquine		
	Chest Discomfort	Professional	Hydrochloride) 250		
	Chest Pain		Mg	PS	ORAL
250 MG 1 PER					
	Circulatory Collapse				
WEEK ORAL					
	Coordination Abnormal		Lithium (Lithium		
	Diarrhoea		Nos)	SS	ORAL
300 MG DAILY					
	Drug Hypersensitivity				
ORAL					
	Flatulence		Lorazepam	C	
	Insomnia		Atenolol	C	
	Mania				
	Medication Error				
	Nausea				
	Palpitations				
	Pruritus				
	Pyrexia				
	Tremor				
	Urticaria				
	Vomiting Projectile				
	White Blood Cell Count Increased				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/05/99ISR Number: 3317528-8Report Type:Periodic Company Report #8-97301-004L
Age:58 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hallucination Increased Appetite Insomnia	Consumer	Pondimin	PS		ORAL	20 MG THREE TIMES DAILY ORAL	
			Buspar	SS			225MG IN THE A.M. AND 450MG H.S.	
			Eskalith Cr	SS				
			Paxil	SS			30 MG ONCE DAILY	
			Phentermine	SS				
			Albuterol Sulfate	C				
			Flovent Inhaler	C				
			Klonopin	C				
			Lasix	C				
			Premarin	C				
			Synthroid	C				
			Zaroxolyn	C				

Date:08/05/99ISR Number: 3320199-8Report Type:Expedited (15-DaCompany Report #9933436
Age:52 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Amnesia Ecchymosis Polytraumatism Sleep Walking Spinal Fracture	Foreign Literature Health Professional	Lithane Tablets	PS		ORAL	ORAL	
			Diazepam	C				

Date:08/06/99ISR Number: 3320670-9Report Type:Expedited (15-DaCompany Report #781/20667
Age:66 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Abdominal Pain	Consumer	Mirapex Tablets (.5					
Other	Decreased Appetite	Other	Mg)	PS		ORAL	.5	
	Drug Effect Decreased						MG-5Q1DY;ORAL	
	Sedation		Eskalith	SS		ORAL	450 MG -	
							2Q1DY;ORAL	
			Sinemet Cr	C				

Date:08/12/99ISR Number: 3326106-6Report Type:Periodic Company Report #17812-043
Age:52 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Acne	Consumer	Lithium Carbonate					
	Weight Increased		Capsules- Roxane					
			Laboratories, Inc.	PS	Roxane Laboratories, Inc.		A) 450 MG BID	
							B) 300 MG BID	2 DAY
			Elavil	C				
			Zoloft	C				
			Ativan	C				
			Lipitor	C				
			Klonopin	C				
			Depakote	C				
			Pamate	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/12/99ISR Number: 3326113-3Report Type:Periodic Company Report #17812-045
Age:47 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hypersensitivity	Consumer	Lithium Carbonate Capsules, 300 Mg - Roxane Laboratories, Inc.	PS	Roxane Laboratories, Inc.	ORAL	300 MG/DAY, PO	
			Antibiotic (Unknown Name, Strength, Manufacturer)	SS				1 MON

Date:08/12/99ISR Number: 3326125-XReport Type:Periodic Company Report #17812-047
Age:50 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Constipation Dysgeusia Flatulence Malaise Tongue Disorder	Consumer	Lithium Carbonate Capsules Usp, 300 Mg - Roxane Laboratories, Inc.	PS	Roxane Laboratories, Inc.	ORAL	600 - 900 MG DAILY PO	

Date:08/12/99ISR Number: 3326129-7Report Type:Periodic Company Report #17812-049
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Thrombocytopenia	Health Professional	Lithium Carbonate Capsules Usp, 300mg - Roxane Laboratories, Inc.	PS	Roxane Laboratories, Inc.		300 MG TID	

			Inderal	C		
			Ativan	C		

Date:08/12/99ISR Number: 3326134-0Report Type:Periodic Company Report #17812-050
Age:80 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Other	Overdose	Consumer	Lithium Carbonate Capsules Usp, 150 Mg - Roxane Laboratories, Inc.	PS	Roxane Laboratories, Inc.	
			Dyazide (Long Time)	C		
			Tamoxifen	C		
			Niacin	C		
			Ecotrin	C		
			Mellaril	C		
			Antioxidants	C		

Dose: 150 MG 1-2X DAILY
Duration:

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/12/99ISR Number: 3326139-XReport Type:Periodic Company Report #17812-051
Age:73 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Amnesia Confusional State Nervousness	Consumer	Lithium Carbonate Capsules Usp 300 Mg Roxane Laboratories, Inc.	PS	Roxane Laboratories, Inc.		600 MG AM, 300 MG PM	
			Flomax	C				
			Synthroid	C				

Date:08/12/99ISR Number: 3326145-5Report Type:Periodic Company Report #17812-052
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Asthenia Paraesthesia Thirst Visual Disturbance	Consumer	Lithium Carbonate Capsules Usp 300 Mg Roxane Laboratories, Inc.	PS	Roxane Laboratories, Inc.	ORAL	600 MG QHS PO	
			Synthroid	C				

Date:08/12/99ISR Number: 3326156-XReport Type:Periodic Company Report #17812-053
Age:95 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hypersensitivity	Consumer	Lithium Capsules Usp 150 Mg Roxane Laboratories, Inc.	PS	Roxane Laboratories, Inc.	ORAL	300 MG QHS PO; SEVERAL YEARS	

			Zoloft	C		
			Docusate	C		
			Psyllium	C		
			Aspirin	C		

Date:08/12/99ISR Number: 3326163-7Report Type:Periodic Company Report #17812-054
Age:45 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Confusional State Headache	Consumer	Lithium Carbonate Capsules Usp, 300 Mg - Roxane Laboratories, Inc.	PS	Roxane Laboratories, Inc.	ORAL	600 MG/ DAY	ORAL
			Neurontin	C				
			Synthroid	C				
			Wellbutrin	C				
			Zyrtec	C				
			Zovirax	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/13/99ISR Number: 3325595-0Report Type:Expedited (15-DaCompany Report #8-99193-014A
Age:54 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Acute Respiratory Distress Syndrome	Health Professional	Effexor	PS		ORAL	300 MG DAILY; DISCONTINUED
Other	Asthma						IN, JAN. 1999, REINITIATED
	Cardiac Failure						
	Congestive Dyspnoea		Lithium	SS		ORAL	UNKNOWN ORAL
	Ejection Fraction Abnormal		Temazepam	SS		ORAL	5 T0 7 DOSES DAILY ORAL
	Gout		Zyprexa (Olanzapine)				
	Hypertensive Heart Disease		Tablets	SS		ORAL	" AS MUCH AS 25 MG PER DAY" ORAL
	Hypoxia						
	Oedema		Temazepam	C			
	Oedema Peripheral		Zyprexa	C			
	Pulmonary Oedema		Lithium	C			
	Respiratory Failure		Depakote	C			
	Sedation		Lorazepam	C			
	Sleep Apnoea Syndrome						
	Weight Increased						

Date:08/13/99ISR Number: 3325605-0Report Type:Expedited (15-DaCompany Report #LIT/99/00316/LEX
Age:59 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Bipolar Disorder Clonic Convulsion	Foreign Literature	Clozapine (Clozapine)	PS		ORAL	150 MG; ORAL
Required	Coordination Abnormal	Health	Lithium Carbonate				

Intervention to	Drug Interaction	Professional	(Lithium Carbonate)	SS	
600 MG					
Prevent Permanent	Dyskinesia				
Impairment/Damage	Gait Disturbance				
	Hyperreflexia				
	Mania				
	Muscle Contractions				
	Involuntary				
	Neuropathy Peripheral				
	Neurotoxicity				
	Tremor				

Date:08/13/99ISR Number: 3326020-6Report Type:Expedited (15-DaCompany Report #1999016226-1
Age:21 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Required	Chest Pain	Health	Eskalith	PS	Smithkline Beecham	ORAL	450
Intervention to	Pleuritic Pain	Professional					MILLIGRAMS
Prevent Permanent	Sinus Arrhythmia						ORAL
Impairment/Damage			Eskalith	SS	Smithkline Beecham	ORAL	900
							MILLIGRAMS
							ORAL
			Pepcid Ac	C			

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/17/99ISR Number: 3327663-6Report Type:Expedited (15-DaCompany Report #ZA/99/00374/MELR
Age:29 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death Hospitalization - Initial or Prolonged	Agitation Bipolar Disorder Extrapyramidal Disorder Mania Sudden Death	Foreign Health Professional	Melleril Retard (Thioridazine Hydrochloride)	PS		ORAL	100 MG, ORAL;, 300 MG, TWICE A DAY, ORAL;,	
			Lithium (Lithium)	SS			300 MG, ORAL; 800 MG, ONCE A DAY	
			Akineton (Biperiden Hydrochloride)	SS				
			Rivotril (Clonazepam)	C				
			Bactrim (Bactrim)	C				
			Modecate Depot (Fluphenazine Decanoate)	C				

Date:08/17/99ISR Number: 3329308-8Report Type:Direct Company Report #
Age:39 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Disability Required Intervention to Prevent Permanent Impairment/Damage	Difficulty In Walking Dysphagia Heart Rate Increased Hypertension Muscle Twitching Muscular Weakness Paralysis		Lithium 300mg	PS		ORAL	300MG BID ORAL	
			Seroquel 300mg	SS		ORAL	300MG HS ORAL	
			Ambien	C				
			Depakote	C				
			Paxil	C				
			Synthroid	C				

	Tremor		Tenormin	C		
			Zestril	C		

Date:08/18/99ISR Number: 3328470-0Report Type:Expedited (15-DaCompany Report #10072981
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Pancreatitis	Foreign Health Professional	Modecate Inj 25 Mg/Ml (Fluphenazine Decanoate)	PS		INTRAMUSCULAR	25 MILLIGRAM,	1/1 MONTH
			Lithium (Lithium Salts)	SS		ORAL	800 MILLIGRAM,	1/1 DAY ORAL
			Vitamin B	C				
			Vitamin C	C				
			Cod Liver Oil	C				
			Atenolol	C				

Date:08/19/99ISR Number: 3329645-7Report Type:Expedited (15-DaCompany Report #8-99201-212A
Age: Gender:Female I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Drug Withdrawal Syndrome
	Mania

Stress
Suicide Attempt

Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Foreign Study	Effexor Tablets (Venlafaxine Hydrochloride)	PS		ORAL	SLOWLY TITRATED TO 75 MG DAILY, THEN SLOWLY TAPERED TO	
	Clonazepam Oral	SS		ORAL	2 MG DAILY, TWENTY 0.5 MG TABLETS TAKEN IN OVERDOSE	ORAL
	Flunitrazepam Tablets	SS		ORAL	TWENTY 2MG TABLETS (OVERDOSE AMOUNT)	ORAL
	Lithium Oral	SS		ORAL	900 MG DAILY	ORAL
	Clonazepam	C				
	Lithium	C				
	Flunitrazepam	C				
	Levothyroxine	C				
	Ethinyl Estradiol	C				
	Gestodene	C				

Date:08/19/99ISR Number: 3331776-2Report Type:Periodic Company Report #8-99148-040A
Age:38 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Abortion	Health	Effexor Xr Capsules	PS		ORAL	150 MG TWICE	
	Hyperreflexia	Professional					DAILY THEN	
	Insomnia						TAPERED AND	
	Nervousness						DISCONTINUED	
							, ORAL	
			Lithobid (Lithium Carbonate) Tablets, Slow Release	SS		ORAL	600 MG DAILY	
							ORAL	
			Lithobid Tablets, Slow Release	C				
			Alprazolam Tablets	C				
			Trazodone Tablets	C				

Date:08/20/99ISR Number: 3331207-2Report Type:Expedited (15-DaCompany Report #781/20667
Age:66 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Sedation	Health	Mirapex Tablets (.5					
Other		Professional	Mg)	PS		ORAL	.5 MG - 5	
		Other					Q1DY; ORAL	
			Eskalith	SS		ORAL	450 MG	
							2QD1DY; ORAL	
			Sinemet Cr 25/100	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/24/99ISR Number: 3333038-6Report Type:Direct Company Report #
Age:66 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Coordination Abnormal Drug Level Above Therapeutic		Lithium Carbonate Aspirin Clonazepam Nph Insulin Verapamil Glipizide-Xl	PS C C C C C		ORAL	500 MG Q AM ; 600MG PO QPM	

Date:08/26/99ISR Number: 3335613-1Report Type:Expedited (15-DaCompany Report #ZA/99/00374/MELR
Age:29 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Sudden Death	Foreign Health Professional	Melleril Retard (Thioridazine Hydrochloride) Lithium (Lithium) Akineton (Biperiden Hydrochloride) Rivotril Bactrim Modecate Depot Decanoate	PS SS SS C C C C		ORAL	100 MG, ORAL;, 300 MG, TWICE A DAY, ORAL;, 300 MG, 800 MG, ONCE A DAY	

Date:08/30/99ISR Number: 3336243-8Report Type:Direct Company Report #
Age:38 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Grand Mal Convulsion		Clozaril	PS		ORAL	400MG AM/ 500MG HS	
Hospitalization - Initial or Prolonged			Lithium	SS		ORAL	450MG BID	

Date:08/30/99ISR Number: 3337816-9Report Type:Expedited (15-DaCompany Report #10086304
Age:17 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Cardiovascular Disorder	Literature	Prolixin(Fluphenazine Hcl)	PS				
Hospitalization - Initial or Prolonged	Confusional State	Health Professional						
Other	Disorientation		Cogentin(Benztropine Mesylate)	SS				
	Dystonia		Lithium Carbonate	SS				
	Hypertonia							
	Lethargy							
	Mental Impairment							
	Muscle Rigidity							
	Neuroleptic Malignant Syndrome							
	Overdose							
	Suicide Attempt							
	Tachycardia							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/30/99ISR Number: 3339371-6Report Type:Expedited (15-DaCompany Report #99J--10260
Age:33 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Blood Gases Abnormal Blood Pressure Diastolic Increased Cardiac Arrest Coma Electrocardiogram Abnormal Heart Rate Increased Hypotension Mydriasis Oliguria Ventricular Fibrillation	Foreign Health Professional	Anafranil Tablet (Clomipramine Hydrochloride) Limas Tablet (Lithium Carbonate)	PS SS		ORAL ORAL	242 DF, DAILY, ORAL 206 DG, DAILY, ORAL	

Date:08/31/99ISR Number: 3337231-8Report Type:Direct Company Report #
Age:49 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Hospitalization - Initial or Prolonged	Akinesia Aphasia Catatonia Coma Confusional State Dysphagia Extrapyramidal Disorder Joint Stiffness Labile Blood Pressure Laryngospasm Leukocytosis Liver Function Test Abnormal Muscle Rigidity Neuroleptic Malignant		Risperidone Lithium Levothyroxine	PS SS C		ORAL ORAL ORAL	6MG HS ORAL 300MG BID	

	Syndrome
	Parkinsonism
	Proteinuria
	Pulmonary Congestion
	Pyrexia
	Speech Disorder
	White Blood Cell Count
	Increased

Date:09/02/99ISR Number: 3339917-8Report Type:Expedited (15-DaCompany Report #210600
Age:59 YR Gender:Male I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Abdominal Pain
	Bipolar Disorder
	Chest Discomfort
	Chest Pain
	Circulatory Collapse
	Coordination Abnormal
	Diarrhoea
	Drug Hypersensitivity
	Flatulence
	Insomnia
	Mania

	Palpitations						
	Pruritus						
	Pyrexia	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Tremor	Consumer	Lariam Tablets				
	Urticaria	Health	(Mefloquine				
	Vomiting Projectile	Professional	Hydrochloride) 250				
	White Blood Cell Count		Mg	PS		ORAL	250 MG 1 PER
	Increased						WEEK ORAL
			Lithium (Lithium				
			Nos)	SS		ORAL	300 MG DAILY
							ORAL
			Lorazepam	C			
			Atenolol	C			

Date:09/07/99ISR Number: 3342051-4Report Type:Expedited (15-DaCompany Report #9937194
Age:72 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Apraxia	Foreign	Lithane Tablets	PS		ORAL	800.00 MG
Initial or Prolonged	Bipolar Disorder	Literature					ORAL
	Blepharospasm	Health	Amlodipine	SS		ORAL	ORAL
	Clonic Convulsion	Professional	Haloperidol	SS		ORAL	ORAL 6 YR
	Confusional State		Enalapril	C			
	Difficulty In Walking		Levothyroxine	C			
	Disorientation		Levodopa/Benserazide	C			
	Drug Toxicity		Pergolide	C			
	Eyelid Function Disorder						
	Fall						
	Gait Disturbance						
	Hyperreflexia						
	Memory Impairment						
	Muscle Rigidity						
	Poverty Of Speech						
	Tremor						
	Vomiting						

Date:09/09/99ISR Number: 3343608-7Report Type:Direct Company Report #
Age:52 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Confusional State Coordination Abnormal Hallucination Renal Failure Chronic Tremor		Lithium Hctz	PS SS				

Date:09/10/99ISR Number: 3345188-9Report Type:Direct Company Report #
Age:60 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Confusional State Diabetes Insipidus Hypothyroidism Sedation		Lithium	PS				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/10/99ISR Number: 3345241-XReport Type:Direct Company Report #
Age:51 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	Confusional State Convulsion Lethargy		Lithium	PS				

Date:09/10/99ISR Number: 3345270-6Report Type:Direct Company Report #
Age:72 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	Neurotoxicity Renal Failure Acute	Health Professional	Lithium	PS				

Date:09/11/99ISR Number: 3345550-4Report Type:Direct Company Report #
Age:76 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Hospitalization - Initial or Prolonged	Diabetes Insipidus		Lithium	PS				

Date:09/16/99ISR Number: 3347862-7Report 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	Cholecystectomy		Eskalith 450mg -Oral	PS		ORAL	450MG BID	

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

Date:09/20/99ISR Number: 3351752-3Report Type:Expedited (15-DaCompany Report #9938803
Age:65 YR Gender:Female I/FU:I

Outcome	PT
Hospitalization -	Ammonia Increased
Initial or Prolonged	Blood Creatine
Required	Phosphokinase Increased
Intervention to	Clonic Convulsion
Prevent Permanent	Coma
Impairment/Damage	Convulsion
	Decreased Appetite
	Depressed Level Of
	Consciousness
	Diarrhoea
	Drug Level Above

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Therapeutic Drug Toxicity Electrocardiogram T Wave Inversion	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Electroencephalogram	Foreign	Lithane Tablets	PS		ORAL	200.00 MG	
	Abnormal	Literature						TOTAL: ORAL
	Gait Disturbance		Chlorpromazine	SS		ORAL	25.00	TOTAL: ORAL
	Hyporeflexia							
	Hypotonia		Levomepromazine	SS		ORAL	10.00 MG	TOTAL: ORAL
	Liver Function Test Abnormal		Phenobarbiton	SS		INTRAMUSCULAR	200.00 MG	
	Medication Error							TOTAL:
	Memory Impairment					INTRAMUSCULAR	3	DAY
	Visual Disturbance							

Date:09/20/99ISR Number: 3352509-XReport Type:Expedited (15-DaCompany Report #1997023054-1
Age:59 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Alpha 2 Globulin Increased	Literature Health Professional	Lithium Carbonate (Lithium)	PS	Smithkline Beecham		600	MILLIGRAMS 7 YR
	Blood Albumin Decreased							
	Diarrhoea		Clopixol (Clopenthixol Decanoate)	C				
	Drug Level Above Therapeutic							
	Drug Toxicity							
	Dysarthria							
	Glomerulonephritis							
	Minimal Lesion							
	Lethargy							
	Muscle Twitching							
	Nephrotic Syndrome							
	Oedema							

	Oedema Peripheral					
	Proteinuria					
	Restlessness					
	Tremor					

Date:09/21/99ISR Number: 3352831-7Report Type:Direct Company Report #
Age:68 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Confusional State	Health Professional	Lithium Cn750	PS				
	Mental Impairment							

Date:09/21/99ISR Number: 3352948-7Report 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	Drug Toxicity		Lithium	PS				
	Fall		Thiazide	C				
	Sedation		Duriter	C				
	Thirst							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/21/99ISR Number: 3353037-8Report Type:Direct Company Report #
Age:49 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Confusional State Drug Level Above Therapeutic Feeling Jittery		Lithium Carbonate	PS		ORAL	600MG PO BID	

Date:09/21/99ISR Number: 3353511-4Report Type:Expedited (15-DaCompany Report #1999023291-1
Age:65 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Clonic Convulsion Convulsion Decreased Appetite Dementia Depressed Level Of Consciousness Diarrhoea Electrocardiogram T Wave Inversion Electroencephalogram Abnormal Gait Disturbance Hyporeflexia Hypotonia Memory Impairment Visual Disturbance	Literature	Lithium Carbonate (Lithium) Smithkline Beecham Chlorpromazine Levomepromazine	PS C C	Smithkline Beecham	ORAL	200 MILLIGRAMS	8 YR

Date:09/21/99ISR Number: 3353538-2Report Type:Expedited (15-DaCompany Report #PRIUSA1999005952
Age:20 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Blood Creatinine	Literature	Haldol (Unspecified)					

	Increased	Health	(Haloperidol)	PS			ORAL
10 MG, 4 IN 1							
	Blood Potassium Increased	Professional					
DAILY, ORAL							
	Blood Pressure Systolic		Lithium	SS			ORAL
600 MG, 3 IN							
	Decreased						
1 DAILY, ORAL							
	Cardiac Arrest						
	Circulatory Collapse						
	Coma						
	Dehydration						
	Drug Level Above						
	Therapeutic						
	Haemodialysis						
	Heart Rate Increased						
	Hypernatraemia						
	Medication Error						

Date:09/22/99ISR Number: 3355340-4Report Type:Expedited (15-DaCompany Report #99D--10840
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Arrhythmia	Foreign	Tegretal Tablet					
	Atrioventricular Block	Health	(Carbamazepine)	PS		ORAL		
ORAL								
	Bundle Branch Block Left	Professional	Lithium Unknown					
			(Lithium Carbonate)	SS				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/22/99ISR Number: 3359275-2Report Type:Periodic Company Report #9828185
Age:43 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Endocrine Disorder	Consumer	Navane Capsules	PS		ORAL	DAILY: ORAL	
	Neoplasm		Lithium	SS		ORAL	ORAL	
	Tremor							

Date:09/22/99ISR Number: 3359285-5Report Type:Periodic Company Report #9844382
Age:57 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Libido Decreased	Health	Navane Capsules	PS		ORAL	5.00 MG	
		Professional					TOTAL:DAILY:O	
							RAL	
			Lithium	SS			900.00 MG	
							TOTAL:DAILY	

Date:09/23/99ISR Number: 3356751-3Report Type:Expedited (15-DaCompany Report #8-99257-129A
Age:50 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agitation	Foreign	Efexor Tablets					
	Clonic Convulsion	Literature	(Venlafaxine					
Other	Condition Aggravated		Hydrochloride)	PS			SEE IMAGE	
	Confusional State		Lithicarb (Lithium					
	Depressed Mood		Carbonate)	SS		ORAL	SEE IMAGE	
	Depression		Lithicarb	C				
	Drug Interaction							
	Emotional Distress							
	Expressive Language							

Disorder
Hyperhidrosis
Hyperreflexia
Hypertonia
Insomnia
Obsessive-Compulsive
Disorder
Palpitations
Restlessness
Serotonin Syndrome
Tachycardia
Tremor
Trismus

Date:09/27/99ISR Number: 3359315-0Report Type:Expedited (15-DaCompany Report #8323/17892
Age:51 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dermatitis	Foreign Health Professional Company Representative	Halcion Tablets (.25 Mg)	PS		ORAL	ORAL	
Other			Carbamazepine (600 Mg)	SS		ORAL	ORAL	
			Levomepromazine (600 Mg)	SS		ORAL	ORAL	
			Lithium Carbonate (600 Mg)	SS		ORAL	ORAL	
			Nitrazepam (600 Mg)	SS		ORAL	ORAL	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/28/99ISR Number: 3360064-3Report Type:Expedited (15-DaCompany Report #210600
Age:59 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain Bipolar Disorder Chest Discomfort Chest Pain Circulatory Collapse Coordination Abnormal Diarrhoea Disorientation Drug Hypersensitivity Insomnia Mania Palpitations Pruritus Psychotic Disorder Pyrexia Tremor Urticaria Vomiting Vomiting Projectile White Blood Cell Count Increased	Consumer Health Professional	Lariam Tablets (Mefloquine Hydrochloride) 250 Mg Lithium (Lithium Nos) Lorazepam (Lorazepam) Atenolol (Atenolol)	PS SS C C		ORAL ORAL	250 MG 1 PER WEEK 300 MG DAILY	

Date:09/29/99ISR Number: 3360219-8Report Type:Direct Company Report #
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Nephrogenic Diabetes Insipidus	Health Professional	Lithium 800mg	PS		ORAL	PO BID	1 YR

Date:09/30/99ISR Number: 3362043-9Report Type:Expedited (15-DaCompany Report #WAES 99069204
Age:72 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Amnesia	Foreign	Tab Vasotec (Enalapril Maleate)	PS		ORAL	PO	
	Apraxia	Literature						
	Blepharospasm	Health Professional	Tab Benserazide/Levodopa	SS		ORAL	300/75 MG PO	
	Clonic Convulsion							
	Confusional State		Tab Lithium Carbonate Tablets	SS		ORAL	1200 MG PO	121 DAY
	Disorientation							
	Drug Effect Decreased		Amlodipine	C				
	Drug Toxicity		Levothyroxine Na	C				
	Eyelid Disorder		Pergolide	C				
	Fall							
	Gait Disturbance							
	Hyperreflexia							
	Muscle Rigidity							
	Speech Disorder							
	Tremor							
	Vomiting							

Date:10/01/99ISR Number: 3362900-3Report Type:Expedited (15-DaCompany Report #210600
Age:59 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain Bipolar Disorder Chest Discomfort Circulatory Collapse Condition Aggravated Coordination Abnormal Diarrhoea Dry Skin Flatulence Hypersensitivity Insomnia Palpitations Pruritus Pyrexia Tremor Urticaria Vomiting Vomiting Projectile White Blood Cell Count Increased	Consumer Health Professional	Lariam Tablets (Mefloquine Hydrochloride) 250 Mg Lithium (Lithium Nos) Lorazepam (Lorazepam) Atenolol (Atenolol)	PS SS C C		ORAL ORAL ORAL ORAL	250 MG 1 PER WEEK 300 MG DAILY	

Date:10/04/99ISR Number: 3363292-6Report Type:Expedited (15-DaCompany Report #JRFBEL1999001314
Age:68 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Intervention to Prevent Permanent Impairment/Damage	Cerebral Infarction Crying Delirium Dialysis Drug Level Above Therapeutic	Foreign Health Professional	Risperidone (Tablet) (Risperidone) Lithium Carbonate (Lithium Carbonate)	PS SS		ORAL ORAL	MG, DAILY, MG, DAILY,	Required

	Dysarthria	Trihexyphenidyl	
	Faecal Incontinence	Hydrochloride	C
	Gait Disturbance	Brotizolam	C
	Inadequate Diet	Zopiclone	C
	Insomnia	Aniracetam	C
	Iron Deficiency Anaemia	Furosemide	C
	Logorrhoea	Allopurinol	C
	Medication Error	Probucol	C
	Renal Impairment	Flunitrazepam	C
	Restlessness	Temocapril	
	Therapeutic Agent	Hydrochloride	C
	Toxicity		
	Thirst		
	Tremor		

Date:10/04/99ISR Number: 3364380-0Report Type:Expedited (15-DaCompany Report #HQ0514128SEP1999
Age:38 YR Gender:Male I/FU:I

Outcome	PT
Hospitalization -	Agitation
Initial or Prolonged	Autonomic Nervous System
Other	Imbalance
	Confusional State
	Delirium
	Disorientation

	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Interaction Drug Toxicity Drug Withdrawal Syndrome	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Nausea Nocturia	Health Professional	Effexor (Venlafaxine Hydrochloride)	PS		ORAL	ORAL	
	Polydipsia Polyuria		Effexor (Venlafaxine Hydrochloride)	SS			75 MG	58 DAY
	Psychomotor Hyperactivity		Lithium (Lithium)	SS		ORAL	1750 MG 1 X	
	Serotonin Syndrome						PER 1 DAY	
	Tremor						ORAL	
			Lithium (Lithium)	SS			750 MG 2X PER	
							1 DAY	
			Panadeine Forte	C				
			Rohypnol	C				

Date:10/05/99ISR Number: 3368016-4Report Type:Periodic Company Report #8-99230-153A
Age:45 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Interaction	Health	Premarin Tablets	PS		ORAL	3	DAY
		Professional	Lithobid (Lithium)	SS				

Date:10/06/99ISR Number: 3365433-3Report Type:Direct Company Report #
Age:52 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Accidental Overdose Blood Magnesium Decreased	Health Professional	Lithium Carb. 300mg, Roxane 0054-8527-25	PS	Roxanne	ORAL	300MG PO QID	9 DAY
	Blood Pressure Decreased Dehydration		Thioridazine 200mg 51079-580-20	SS			3-4PRN DOSES	

	Depressed Level Of Consciousness Drug Level Above Therapeutic Sedation Urinary Retention		Chlorpromazine 100mg 51079-130-20	SS			EACH

Date:10/06/99ISR Number: 3366057-4Report Type:Expedited (15-DaCompany Report #1999023009-1
Age:59 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Lipase Increased Pancreatitis	Health Professional	Quilonum Retard (Lithium) Smithkline Beecham	PS	Smithkline Beecham	ORAL	18.3	MILLIMOLES
			Antihistamine, Nos	C		ORAL		
			Cholspasmin (Hymecromone)	C				

Date:10/06/99ISR Number: 3366059-8Report Type:Expedited (15-DaCompany Report #1999019384-1
Age:40 YR Gender:Male I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Bradycardia Circulatory Collapse Hypoglycaemia

Hypotension

Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Health Professional	Quilonum Retard (Lithium) Smithkline Beecham	PS	Smithkline Beecham	ORAL	675 MILLIGRAMS	ORAL
	Dominal Forte (Prothipendyl)	C				
	Eunerpan (Melperon)	C				
	Euthyrox (Levothyroxin-Sodium)	C				

Date:10/07/99ISR Number: 3365595-8Report Type:Direct Company Report #
Age:69 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Decreased Appetite		Lithium Carbonate	PS		ORAL	150MG PO	
	Drug Level Above Therapeutic		Pse	C				
			Apap	C				
	Drug Toxicity		Terazodin	C				
	Gait Disturbance		Oxybutynin	C				
	Lethargy		Risperidone	C				
	Pneumonia		Levothyroxine	C				
			Lithium	C				

Date:10/07/99ISR Number: 3366418-3Report Type:Direct Company Report #
Age:47 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Potassium Decreased	Health Professional	Lithium Carbonate 300mg	PS			600MG IN AM	
	Drug Level Above							

	Therapeutic					
900 MG IN PM						

Date:10/07/99ISR Number: 3367613-XReport Type:Expedited (15-DaCompany Report #PRIUSA1999006543
Age:31 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Literature	Haldol (Unspecified)					
	Drug Level Above Therapeutic	Health	(Haloperidol)	PS		ORAL	ORAL	
		Professional	Lithium (Lithium)	SS		ORAL	ORAL	
	Intentional Self-Injury		Fluoxetine (Fluoxetine)	SS		ORAL	ORAL	

Date:10/08/99ISR Number: 3368321-1Report Type:Direct Company Report #
Age:69 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agitation	Health	Lithium Carbonate	PS				PTA-LONG TERM
	Decreased Activity	Professional						
	Oral Intake Reduced							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/08/99ISR Number: 3368977-3Report Type:Expedited (15-DaCompany Report #1999008680-1
Age:65 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Arthropathy Chronic Lymphocytic Leukaemia Leukocytosis Pneumonia Viral Surgery	Health Professional	Eskalith Smithkline Beecham	PS	Smithkline Beecham	ORAL	300 MILLIGRAMS 2.0 DAILY	Other ORAL

Date:10/08/99ISR Number: 3369023-8Report Type:Expedited (15-DaCompany Report #PRIUSA1999006689
Age:70 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide Intentional Self-Injury	Literature Health Professional	Haldol (Unspecified) (Haloperidol)	PS		ORAL		ORAL
			Hydrochlorothiazide / Troamterence (Dyazide)	SS		ORAL		ORAL
			Lithium (Lithium)	SS		ORAL		ORAL

Date:10/12/99ISR Number: 3370755-6Report Type:Expedited (15-DaCompany Report #9912255
Age:57 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hyponatraemia Pituitary Tumour Polydipsia Polyuria	Foreign Health Professional	Abbott-Depakote Lithium	PS SS	Abbott	ORAL	500.000 MG PO BID	

Date:10/14/99ISR Number: 3372131-9Report Type:Direct Company Report #
Age:69 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Coordination Abnormal		Lithium	PS		ORAL	PO	
	Mental Impairment		Eskalith	C				

Date:10/14/99ISR Number: 3372976-5Report Type:Expedited (15-DaCompany Report #1999026279-1
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hepatic Neoplasm Malignant	Consumer	Eskalith Smithkline Beecham	PS	Smithkline Beecham	ORAL	1.0 DAILY	
ORAL								31 YR

Date:10/15/99ISR Number: 3374053-6Report Type:Expedited (15-DaCompany Report #HQ1758108OCT1999
Age:75 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Drug Interaction	Health Professional	Effexor (Venlafaxine Hydrochloride)	PS		ORAL	ORAL	
	Haemorrhage							
	Hypertensive Crisis		Aurorix (Moclobemide)	SS		ORAL	ORAL	
	Medication Error							
	Peripheral Ischaemia		Lithium (Lithium)	SS		ORAL	ORAL	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/18/99ISR Number: 3375657-7Report Type:Periodic Company Report #990713-SK942
Age:59 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Drug Interaction	Health Professional	Celebrex	PS		ORAL	100.000 MG	BID PO
			Eskalith	SS		ORAL	450.000 MG QD	PO
			Carbamazepine	C				
			Olanzapine	C				
			Levothyroxine	C				

Date:10/18/99ISR Number: 3376898-5Report Type:Periodic Company Report #990913-SK052
Age:53 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Interaction	Consumer	Celebrex	PS		ORAL	PO	
			Lithium	SS		ORAL	675.000 MG	BID PO
			Calcium	C				
			Alendronate	C				
			Propoxyphene	C				
			Acetaminophen	C				
			Omeprazole	C				
			Levothyroxine	C				

Date:10/20/99ISR Number: 3376225-3Report Type:Direct Company Report #
Age:47 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Diarrhoea	Health	Eskalith Cr	PS		ORAL	450 PO BID	

Initial or Prolonged	Disorientation	Professional			
CHRONIC BUT					
	Drug Level Above				
ADJUSTED 3					
	Therapeutic				
WKS AGO 3 WK					
	Lethargy		Depakote	C	
	Lung Infiltration		Clonazepam	C	
	Mania		Risperdal	C	
	Mental Impairment				
	Pneumonia Aspiration				
	Vomiting				

Date:10/20/99ISR Number: 3377208-XReport Type:Expedited (15-DaCompany Report #9944064
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Required	Sideroblastic Anaemia	Foreign	Lithane Tablets	PS		ORAL	ORAL
Intervention to		Health	Fluoxetine	SS		ORAL	ORAL
Prevent Permanent		Professional					
Impairment/Damage							

Date:10/22/99ISR Number: 3379439-1Report Type:Expedited (15-DaCompany Report #9943368
Age:55 YR Gender:Male I/FU:I

Outcome	PT
Hospitalization -	Alcoholism
Initial or Prolonged	Back Pain
	Circadian Rhythm Sleep
	Disorder

Condition Aggravated Delusion Depression	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Emotional Disorder	Foreign	Procardia Capsules	PS		ORAL	30.00 MG TOTAL; TID;
Grandiosity	Literature					
Hypomania	Health					ORAL
Impulsive Behaviour	Professional	Lithium	SS		ORAL	900.00 MG TOTAL; ORAL
Mood Altered						
Pain In Extremity		Ibuprofen	SS		ORAL	1200.00 MG TOTAL; TID;
						ORAL
		Naproxen	SS		ORAL	750.00 MG TOTAL; TID;
						ORAL
		Hydrochlorothiazide	C			
		Atenolol	C			
		Ranitidine	C			
		Nitroglycerine	C			
		Moperone	C			
		Alprazolam	C			
		Lorazepam	C			

Date:10/26/99ISR Number: 3381302-7Report Type:Direct Company Report #
Age:80 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Cough	Health	Lithium 300mg	PS		ORAL	300 MG PO 1 DAY
	Depressed Level Of Consciousness	Professional	Klopopin 0.5mg	SS		ORAL	0.5MG PO 1 DAY
			Olanzepine 5mg	SS		ORAL	5 MG PO 1 DAY

	Lethargy		Mvi	SS		ORAL
TAB 1 DAY	Medication Error					
	Speech Disorder					

Date:10/26/99ISR Number: 3381322-2Report Type:Direct Company Report #
Age:49 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Abnormal Behaviour		Lithium 300mg Caps (Roxane)	PS	Roxane	
2 C QAM AND HS AND 1C AT NOON	Agitation					
	Blood Creatinine Increased					
	Blood Thyroid Stimulating Hormone Increased		Albuterol	C		
	Confusional State		Amlodipine	C		
	Delusion		Carbamazepine	C		
	Depression		Haloperidol	C		
	Drug Level Above Therapeutic		Imipramine	C		
	Mental Impairment		Ipratropium	C		
	Nocturia					
	Pneumonia					
	Polyuria					
	Tremor					
	Water Intoxication					

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/26/99ISR Number: 3381358-1Report Type:Direct Company Report #
Age:57 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Creatine Phosphokinase Increased		Lithium 300mg	PS		ORAL	300MG,600 AM,PM	
	Depressed Level Of Consciousness		Thioridazine 100mg	SS		ORAL	100MG BID	
	Hyponatraemia		Lorazepam	C				
	Muscle Rigidity		Potassium	C				
	Neuroleptic Malignant Syndrome		Atenolol	C				
	Pyrexia							
	Schizophrenia							

Date:11/01/99ISR Number: 3387512-7Report Type:Expedited (15-DaCompany Report #JRFBEL1999001735
Age:50 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Anxiety	Literature	Risperidone					
Hospitalization - Initial or Prolonged	Blood Ph Increased	Health	(Unspecified)					
	Cardiac Arrest	Professional	(Risperidone)	PS		ORAL	28, 1 IN 1	
Required	Completed Suicide						TIME (S),	
Intervention to	Confusional State						ORAL	
Prevent Permanent	Disorientation		Aspirin	SS		ORAL	ORAL	
Impairment/Damage	Drug Level Above		Lithium (Lithium)	SS		ORAL	ORAL	
	Therapeutic							
	Dyspnoea							
	Hyperhidrosis							
	Intentional Misuse							
	Nausea							
	Pco2 Decreased							
	Respiratory Rate Increased							

Vomiting

Date:11/02/99ISR Number: 3388562-7Report Type:Expedited (15-DaCompany Report #HQ3358225OCT1999
Age:55 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Level Above Therapeutic	Health Professional	Effexor (Venlafaxine Hydrochloride)	PS		ORAL	1350 MG (AS OVERDOSE)	ORAL ONCE
	Nephrogenic Diabetes Insipidus	Other						
	Overdose Polyuria		Amlodipine (Amlodipine)	SS		ORAL	60MG (AS OVERDOSE)	ORAL ONCE
			Cerivastatin (Ceriastatin)	SS			600MG (AS OVERDOSE)	ORAL ONCE
			Lithium (Lithium)	SS		ORAL	3600MG (AS OVERDOSE)	ORAL ONCE
			Quinine (Quinine()	SS		ORAL	1.8MG (AS OVERSODE)	ORAL ONCE
			Temazepam	SS			120MG (AS OVERDOSE)	

ORAL ONCE

Date:11/02/99ISR Number: 3388671-2Report Type:Expedited (15-DaCompany Report #LBID002980017
Age:33 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Distension	Consumer	Lithobid Tablets 300 Mg	PS		ORAL	SEE IMAGE	
	Alopecia							
	Amnesia		Inderal	C				
	Anxiety		Synthroid	C				
	Blood Cholesterol Increased		Levoxyl	C				
			Calan	C				
	Condition Aggravated		Hctz	C				
	Confusional State		Lipitor	C				
	Dehydration		Neurontin	C				
	Dry Mouth		Tegretol	C				
	Headache		Depakote	C				
	Hypertension		Prozac	C				
	Hypoaesthesia							
	Insomnia							
	Mania							
	Neurotoxicity							
	Paraesthesia							
	Pollakiuria							
	Sedation							
	Temperature Intolerance							

Date:11/04/99ISR Number: 3389210-2Report Type:Expedited (15-DaCompany Report #1999028110-1
Age:59 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Coordination Abnormal	Health Professional	Eskalith Smithkline Beecham	PS	Smithkline Beecham	ORAL	ORAL	
	Drug Level Above Therapeutic		Eskalith	SS	Smithkline Beecham	ORAL	ORAL	
	Drug Toxicity		Celebrex	C				
	Dysarthria		Carbamazepine	C				
	Tremor		Olanzapine	C				
			Levothyroxine	C				

Date:11/04/99ISR Number: 3389304-1Report Type:Direct Company Report #
Age:73 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Confusional State	Health	Lithium	PS		ORAL	300MG, TID,	
Hospitalization - Initial or Prolonged	Tremor	Professional				ORAL		
Required Intervention to Prevent Permanent Impairment/Damage			Captopril	C				
			Warfarin (Coumadin)	C				
			Vitamin E	C				
			Docusate Sodium	C				

Date:11/05/99ISR Number: 3389358-2Report Type:Direct Company Report #
Age:67 YR Gender:Female I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Drug Level Above Therapeutic
	Mental Impairment

Renal Failure Acute

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
			Lithium 300mg	PS		ORAL	300MG PO BID	
			Dyazide	C				
			Accupril	C				
			Lipitor	C				
			Kcl	C				
			Coumadin	C				
			Levoxyl	C				
			Lithium	C				
			Ritalin	C				
			Risperidal	C				
			Xanax	C				
			Darvocet	C				
			Naprosyn	C				

Date:11/09/99ISR Number: 3391332-7Report Type:Direct Company Report #
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Abnormal Behaviour		Elavil	PS			100MG DAILY	
Hospitalization -	Decreased Activity		Lithium	SS			300MG 3XDAILY	
Initial or Prolonged	Loss Of Consciousness							
Disability	Psychotic Disorder							

Date:11/09/99ISR Number: 3391857-4Report Type:Expedited (15-DaCompany Report #1999010856-1
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Asthenia	Consumer	Eskalith Smithkline					
Initial or Prolonged	Cognitive Disorder		Beecham	PS	Smithkline Beecham	ORAL	ORAL	
	Dizziness		Zestril (Lisinopril)	C				
	Dyspnoea							
	Nervous System Disorder							
	Personality Change							

	Vomiting					

Date:11/10/99ISR Number: 3392793-XReport Type:Direct Company Report #
Age:48 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Blood Pressure Diastolic		Lithium 300mg	PS		ORAL	300MG PO TID	
Initial or Prolonged	Increased		Valproic Acid	SS			1500 TID	
	Drug Toxicity							
	Hostility							
	Lethargy							
	Mental Impairment							
	Sedation							
	Urinary Incontinence							

Date:11/10/99ISR Number: 3392813-2Report Type:Direct Company Report #
Age:47 YR Gender:Male I/FU:I

Outcome
Life-Threatening
Hospitalization -

Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Cyanosis	Health	Lithium Carbonate	PS		ORAL	600MG BID PO	
	Drug Level Above Therapeutic	Professional						
	Drug Toxicity							
	Dyspnoea							
	Hypotension							
	Lethargy							
	Pallor							
	Pyrexia							
	Tachycardia							
	Tremor							

Date:11/10/99ISR Number: 3394249-7Report Type:Expedited (15-DaCompany Report #HQ1758108OCT1999
Age:75 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Drug Interaction	Health	Effexor (Venlafaxine Hydrochloride)	PS		ORAL	ORAL	
	Hypertensive Crisis	Professional						
	Medication Error		Aurorix (Moclobemide)	SS		ORAL	ORAL	
	Peripheral Ischaemia							
			Lithium (Lithium)	SS		ORAL	ORAL	

Date:11/16/99ISR Number: 3399066-XReport Type:Expedited (15-DaCompany Report #7399440
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Neuroleptic Malignant	Health	Abbott- Depakote	PS	Abbott	ORAL	4.000 GM PO	
Initial or Prolonged	Syndrome	Professional					QD	
	Pyrexia		Lithium	SS		ORAL	PO	

Date:11/16/99ISR Number: 3399112-3Report Type:Expedited (15-DaCompany Report #9947310
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Congenital Anomaly	Benign Congenital Hypotonia Cerebral Palsy Complications Of Maternal Exposure To Therapeutic Drugs	Foreign Consumer	Lithane Tablets	PS		ORAL		

Date:11/17/99ISR Number: 3399514-5Report Type:Expedited (15-DaCompany Report #LBID00299001671
Age:45 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Cataract Retinal Detachment	Consumer	Lithobid	PS		ORAL	300 MG BID PO	

Date:11/22/99ISR Number: 3404807-9Report Type:Expedited (15-DaCompany Report #PRIUSA1999006543
Age:31 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Death	Anuria	Literature	Haldol (Unspecified)				
Hospitalization - Initial or Prolonged	Blood Creatine Increased	Health	(Haloperidol)	PS		ORAL	ORAL
Required Intervention to Prevent Permanent Impairment/Damage	Blood Urea Increased	Professional	Lithium (Lithium)	SS		ORAL	ORAL
	Body Temperature Increased		Prozac (Fluoxetine Hydrochloride)	SS		ORAL	ORAL
	Coma		Cogentin (Benzatropine Mesilate)	SS		ORAL	ORAL
	Completed Suicide						
	Convulsion						
	Drug Level Above Therapeutic						
	Electroencephalogram Abnormal						
	Haemodialysis						
	Hypotension						
	Nervous System Disorder						

Date:11/22/99ISR Number: 3404822-5Report Type:Expedited (15-DaCompany Report #LITH00299001702
Age:58 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Blood Thyroid Stimulating Hormone Increased	Foreign	Lithium Carbonate	PS		ORAL	600/400 MG DAILY
		Literature					
	Bradycardia	Health					PO 2 YR
	Cardiac Pacemaker Insertion	Professional					
		Other					
	Hypothyroidism						
	Sick Sinus Syndrome						
	Sinus Arrest						
	Sinus Bradycardia						
	Syncope						
	Thyroxine Decreased						
	Ventricular Extrasystoles						

Date:11/23/99ISR Number: 3405373-4Report Type:Direct Company Report #
Age:51 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Level Above		Lithium 300mg Roxane	PS	Roxane	ORAL	600MG BID PO	
	Therapeutic Lethargy		Celebrex 200mg Searle	SS	Searle	ORAL	200MG BID PO	

Date:11/23/99ISR Number: 3406203-7Report Type:Expedited (15-DaCompany Report #1999026279-1
Age:55 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Metastasis Oesophageal	Consumer Health	Eskalith Smithkline Beecham	PS	Smithkline Beecham	ORAL	1.0 DAILY	
ORAL	Adenocarcinoma Stage Iv	Professional					30	YR

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/23/99ISR Number: 3406707-7Report Type:Periodic Company Report #USA/98/02927/LEX
Age:54 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Delirium	Health	Clozaril (Clozapine)	PS		ORAL	275 MG, ORAL	
Required Intervention to Prevent Permanent Impairment/Damage	Drug Interaction Hyperglycaemia Muscular Weakness Pyrexia Salivary Hypersecretion Urinary Tract Infection	Professional	Depakote (Valproate Semisodium) Lithium	SS SS		ORAL ORAL	1 G, ORAL 300 MG, THREE TIMES A DAY, ORAL	

Date:11/23/99ISR Number: 3406946-5Report Type:Periodic Company Report #USA/99/02002/LEX
Age:26 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Convulsion	Health	Clozaril (Clozapine)	PS		ORAL	450 MG, ORAL	
Required Intervention to Prevent Permanent Impairment/Damage	Fall Leukocytosis Sedation Tachycardia Tremor	Professional	Lithium Risperdal (Risperidone) Effexor (Venlafaxine Hydrochloride) Lithobid (Lithium Carbonate) Depakene (Valproate Sodium)	SS C C C C			900 MG	

Date:11/24/99ISR Number: 3410004-3Report Type:Expedited (15-DaCompany Report #LBID00299001810
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Mycosis Fungoides	Health	Lithobid	PS		ORAL	1200 MG DAILY	

		Professional				
PO						
			Adderal	C		
			Ativan	C		
			Effexor	C		

Date:11/29/99ISR Number: 3409396-0Report Type:Direct Company Report #
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Blood Amylase Increased		Clozaril	PS			200MG BID	
	Lactose Intolerance		Lithium	SS			300MG QD	1 YR
	Lipase Increased							
	Pancreatitis							

Date:11/29/99ISR Number: 3409498-9Report Type:Direct Company Report #
Age:63 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Diarrhoea	Health Professional	Lisinopril 5mg Unknown	PS		ORAL	5MG PO QD	
	Disorientation							
	Drug Interaction		Lithium 300mg Unknown	SS		ORAL	600MG PO BID	
	Gait Disturbance							
	Speech Disorder							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/29/99ISR Number: 3409542-9Report Type:Direct Company Report #
Age:75 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agitation		Lithium	PS			300MG BID	
	Akathisia		Depakote	C				
	Confusional State							
	Speech Disorder							
	Tremor							

Date:11/29/99ISR Number: 3409862-8Report Type:Expedited (15-DaCompany Report #9912255
Age:57 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hyponatraemia	Foreign	Abbott- Depakote	PS	Abbott	ORAL	500.000 MG PO	BID
	Nephrogenic Diabetes Insipidus	Health Professional	Lithium	SS				
	Pollakiuria							
	Polydipsia							
	Polyuria							

Date:11/30/99ISR Number: 3409619-8Report Type:Direct Company Report #
Age:57 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Nephritis		Lithium	PS		ORAL	300MG PO TID	
Hospitalization - Initial or Prolonged	Nephrogenic Diabetes Insipidus							

Date:12/03/99ISR Number: 3413543-4Report Type:Expedited (15-DaCompany Report #210600
Age:59 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Hospitalization - Initial or Prolonged	Abdominal Pain Bipolar Disorder Chest Discomfort Circulatory Collapse Coordination Abnormal Diarrhoea Disorientation Drug Hypersensitivity Dry Skin Flatulence Hypertension Insomnia Leukocytosis Mania Palpitations Pruritus Pyrexia Tremor Urticaria Vomiting Projectile	Consumer Health Professional	Lariam Tablets (Mefloquine Hydrochloride) 250 Mg Lithium (Lithium Nos) Lorazepam (Lorazepam) Atenolol (Atenolol)	PS SS C C	ORAL ORAL

250 MG 1 PER WEEK ORAL

300 MG DAILY ORAL

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/09/99ISR Number: 3417763-4Report Type:Expedited (15-DaCompany Report #9912255
Age:57 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Toxicity Hyponatraemia	Foreign Health	Abbott - Depakote	PS		ORAL	500.000 MG PO BID	
	Nephrogenic Diabetes Insipidus Pollakiuria Polydipsia Polyuria	Professional	Lithium	SS				

Date:12/09/99ISR Number: 3418170-0Report Type:Expedited (15-DaCompany Report #1999004849NL
Age:72 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dizziness Electrocardiogram Abnormal Electrocardiogram T Wave Amplitude Decreased Nausea Syncope Ventricular Tachycardia	Health Professional Other	Detrusitol (Tolterodine) Tablet	PS		ORAL	2 MG, QD, ORAL	
			Theolin-Slow Release (Theophylline)	SS			300 MG, BID	8 DAY
			Zestril (Lisinopril)	SS			10 MG, QD	8 DAY
			Clomipramine (Clomipramine)	SS			25 MG, TID	8 DAY
			Aspirine (Acetylsalicylic Acid)	SS			80 MG, QD	8 DAY
			Priadel (Lithium Carbonate)	SS			400 MG, BID	8 DAY
			Acetylcysteine (Acetylcysteine)	SS			600, QD	8 DAY
			Ventoline					

				(Salbutamol)	SS		
8 DAY							

Date:12/10/99ISR Number: 3417871-8Report Type:Direct Company Report #
Age:9 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Diabetes Insipidus	Health	Lithium 300mg	PS		ORAL	450MG AM	
Hospitalization -		Professional					300MG HS ORAL	
Initial or Prolonged			Valproic Acid	C				
			Olanzapine	C				

Date:12/10/99ISR Number: 3418557-6Report Type:Expedited (15-DaCompany Report #PRIUSA1999006655
Age:57 YR Gender:Female I/FU:F

Outcome	PT
Death	Abdominal Distension
Hospitalization -	Blood Pressure Increased
Initial or Prolonged	Cardiac Arrest
Required	Coma
Intervention to	Completed Suicide
Prevent Permanent	Convulsion
Impairment/Damage	Dialysis
	Drug Level Above
	Therapeutic
	Electrocardiogram St
	Segment Elevation
	Electrocardiogram T Wave

		Peaked Extrapyramidal Disorder Hypoventilation Ileus Paralytic	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
		Injury Overdose	Literature Health	Haldol (Unspecified) (Haloperidol)	PS		ORAL
ORAL							
		Sinus Tachycardia Tachypnoea	Professional	Eskalith (Lithium Carbonate)	SS		ORAL
300 MG, ORAL							
		Therapeutic Agent Toxicity Tremor		Lopressor (Metoprolol Tartrate)	SS		ORAL
ORAL							
		Ventricular Tachycardia		Kaolin (Kaolin)	SS		ORAL
ORAL							
				Klonopin (Clonazepam)	SS		ORAL
ORAL							
				Theochron (Theophylline)	SS		ORAL
ORAL							
				Synthroid (Levothyroxine Sodium)	SS		ORAL
ORAL							
				Sodium Fluoride (Sodium Fluoride)	SS		ORAL
ORAL							
				Aspirin (Acetylsalicylic Acid)	SS		ORAL
ORAL							
				Tylenol (Paracetamol)	SS		ORAL
ORAL							
				Naprosyn (Naproxen)	SS		ORAL
ORAL							
				Cogentin (Benzatropine Mesilate)	SS		ORAL
ORAL							
				Nitroglycerin (Glyceril Trinitrate)	SS		ORAL
ORAL							
				Vitamin B Complex			

			(B-Komplex "Leciva")	SS		ORAL
ORAL						

Date:12/10/99ISR Number: 3418591-6Report Type:Expedited (15-DaCompany Report #PRIUSA1999006689
Age:70 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Blood Creatinine	Literature	Haldol(Unspecified)			
Hospitalization -	Increased	Health	(Haloperidol)	PS		ORAL
ORAL						
Initial or Prolonged	Blood Glucose Increased	Professional	Synthroid(Levothyrox			
Required	Blood Potassium Decreased		ine Sodium)	SS		ORAL
ORAL						
Intervention to	Bradycardia		Prinivil(Lisinopril)	SS		ORAL
ORAL						
Prevent Permanent	Cardiac Arrest		Eskalith(Lithium			
Impairment/Damage	Cardio-Respiratory Arrest		Carbonate)	SS		ORAL
ORAL						
	Completed Suicide		Dyazide(Dyazide)	SS		ORAL
ORAL						
	Depressed Level Of Consciousness					
	Hypotension					
	Intentional Misuse					
	Lethargy					
	Medication Residue					
	White Blood Cell Count Increased					

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/10/99ISR Number: 3424965-XReport Type:Direct Company Report #
Age:59.5 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Blood Pressure Increased	Consumer	Lithium	PS				DAILY
Initial or Prolonged	Breast Pain		Trazodone	SS				
	Cognitive Disorder		Effexor	SS				
	Confusional State		Klonopin	SS				
	Diarrhoea							
	Headache							
	Hearing Impaired							
	Hostility							
	Hypertonia							
	Memory Impairment							
	Personality Change							
	Sedation							
	Suicidal Ideation							

Date:12/14/99ISR Number: 3426113-9Report Type:Expedited (15-DaCompany Report #1999032202-2
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Aggression	Consumer	Lithium	PS		ORAL	ORAL	9 YR
Initial or Prolonged	Cardiomegaly		Thorazine	C				
Required	Hypertension							
Intervention to	Liver Function Test							
Prevent Permanent	Abnormal							
Impairment/Damage	Renal Disorder							

Date:12/15/99ISR Number: 3422723-3Report Type:Expedited (15-DaCompany Report #JACGER1999000854
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Bradycardia Foetal	Foreign	Haldol (2 Mg/Ml					
	Caesarean Section	Health	Drops) (Haloperidol)	PS		ORAL	DROPS, DAILY,	
	Complications Of Maternal	Professional						
ORAL/ UTERINE								

	Exposure To Therapeutic Drugs		Litium (Lithium Carbonate)	SS		ORAL
ORAL/UTERINE						

Date:12/16/99ISR Number: 3423548-5Report Type:Expedited (15-DaCompany Report #1999004849NL
Age:72 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Cardiomyopathy	Health Professional	Detrusitol(Tolterodine) Tablet	PS		ORAL	2 MG, QD,	
	Circulatory Collapse							
	Dizziness						ORAL	
	Electrocardiogram T Wave Amplitude Decreased		Theolin - Slow Release	SS		ORAL	300 MG, QD,	
	Hypokalaemia						ORAL	8 DAY
	Malaise		Clomipramine (Clomipramine)	SS			25 MG, TID	8 DAY
	Nausea							
	Pulse Pressure Decreased		Priadel(Lithium Carbonate)	SS			400 MG, BID	8 DAY
	Syncope							
	Tremor		Ventoline (Salbutamol)	SS			8 DAY	
	Ventricular Fibrillation							
	Ventricular Tachycardia		Zestril	C				
			Aspirine	C				
			Acetylcysteine	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/16/99ISR Number: 3426827-0Report Type:Expedited (15-DaCompany Report #1999031983-1
Age:49 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Haematemesis		Lithium Smithkline Beecham	PS	Smithkline Beecham			
			Cloazaril (Clozapine)	C				

Date:12/17/99ISR Number: 3424972-7Report Type:Expedited (15-DaCompany Report #9951716
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Congenital Anomaly	Cardiac Septal Defect	Foreign	Lithane Tablets	PS		ORAL	UNKNOWN; ORAL	
	Coarctation Of The Aorta	Health Professional						
	Complications Of Maternal Exposure To Therapeutic Drugs							
	Heart Disease Congenital							

Date:12/17/99ISR Number: 3425533-6Report Type:Periodic Company Report #9903582
Age:11 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Interaction	Health Professional	Zithromax Pediatric Oral Suspension	PS		ORAL	ORAL	
	Sedation		Lithobid	SS		ORAL	900.00 MG	TOTAL; TID; ORAL
			Wellbutrin	C				

Date:12/20/99ISR Number: 3426057-2Report Type:Direct Company Report #
Age:36 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Aggression		Lithium	PS				
	Convulsion		Anafranil	C				
	Drug Level Above Therapeutic		Depakote	C				
			Chromagen	C				
	Restlessness		Kava	C				

Date:12/20/99ISR Number: 3426583-6Report Type:Expedited (15-DaCompany Report #10184109
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Amnesia	Foreign	Avapro(Irbesartan)	PS		ORAL	300 MILLIGRAM,	
	Drug Toxicity	Study						
		Health						
		Professional	Enalapril(Enalapril Maleate)	SS			40 MILLIGRAM	
			Lithium(Lithium Salts)	SS				
			Diabeta(Glyburide)	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/23/99ISR Number: 3430073-4Report Type:Expedited (15-DaCompany Report #990809-LX254
Age:57 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Dysphonia	Health	Ambien	PS		ORAL	QHS PO	
	Stereotypy	Professional	Lithium Carbonate	SS		ORAL	900.000 MG QD	
		Company					PO	
		Representative	Wellbutrin	SS		ORAL	150.000 MG	
							TID PO	
			Other Cns Drugs	C				
			Celecoxib	C				

Date:12/28/99ISR Number: 3431432-6Report Type:Direct Company Report #
Age:59.5 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Pressure Increased		Lithium	PS			DAILY	
	Breast Pain		Trazodone	SS			DAILY	
	Cognitive Disorder		Effexor	SS			DAILY	
	Confusional State		Klonopin	SS			DAILY	
	Diarrhoea							
	Headache							
	Hearing Impaired							
	Hostility							
	Hypertonia							
	Memory Impairment							
	Personality Change							
	Sedation							
	Suicidal Ideation							

Date:12/28/99ISR Number: 3432380-8Report Type:Direct Company Report #
Age:51 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dyspnoea	Health	Lithium 300mg	PS			300MG TID	
	Nephrotic Syndrome	Professional	Ptu	SS			25MG/D	
	Oedema		Furosemide	C				
	Oedema Peripheral		Kcl	C				
	Oliguria		Metalazone	C				
	Proteinuria		Ipatropium	C				
			Lisinopril	C				
			Cetrizine	C				

Date:12/29/99ISR Number: 3433484-6Report Type:Direct Company Report #
Age:68 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Toxicity		Lithium Carbonate Interaction?	PS		ORAL	300MG PO TID	
	Lethargy		Lisinopril 10mg	SS			10MG QD	
			Aspirin	C				
			Atenocol	C				
			Benztropine	C				
			Furosemide	C				
			Lisinopril	C				
			Lithium	C				
			Nifedipine	C				
			Thiothixine	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/30/99ISR Number: 3435343-1Report Type:Expedited (15-DaCompany Report #JRFBEL1999002168
Age:70 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blepharospasm	Foreign	Haldol (Unspecified)					
	Parkinsonism	Literature	(Haloperidol)	PS			3MG 3 IN 1	
	Tardive Dyskinesia	Health						DAY (S)
	Tremor	Professional	Lithium (Lithium)	SS				

Date:01/03/00ISR Number: 3435492-8Report Type:Direct Company Report #
Age:23 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Intentional Misuse		Lithium	PS				TAKEN PRIOR TO ADMISSION
			Clonidine	C				
			Seroqual	C				
			Trimethobenzamide	C				
			Lorazepam	C				
			Trazodone	C				
			Clonidine	C				
			Provera	C				
			Valtrex	C				

Date:01/05/00ISR Number: 3437688-8Report Type:Direct Company Report #
Age:54 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Neurotoxicity	Health	Seroquel	PS				SEE IMAGE
		Professional	Lithobid	SS				SEE IMAGE
			Depakote	C				
			Ativan	C				
			Hytrin	C				
			Maxzide	C				

Vioxx	C	
Prozac	C	
Prilosec	C	
Ogen	C	
Albuterol Inh	C	

Date:01/07/00ISR Number: 3440011-6Report Type:Direct Company Report #
Age:51 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Blood Creatinine	Health	Furosemide	PS			20MG BID	
Initial or Prolonged	Increased	Professional	Lithium	SS			600MG BID	
	Blood Urea Increased							
	Confusional State							
	Metabolic Acidosis							
	Renal Failure Acute							
	Tremor							

Date:01/10/00ISR Number: 3441688-1Report Type:Expedited (15-DaCompany Report #10222974
Age:59 YR Gender:Female I/FU:I

Outcome
Life-Threatening
Hospitalization -

Initial or Prolonged

PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Atrioventricular Block First Degree	Foreign Health	Captopril	PS		ORAL	50 MILLIGRAM,	1 DAY, ORAL
Blood Creatine Increased Bradycardia Cyanosis Drug Level Above Therapeutic Electrocardiogram T Wave Inversion Hypotension Pulse Absent Shock Tremor	Professional	Meloxicam Lithium (Lithium Salts) Lorazepam (Lorazepam) Mirtazapine (Mirtazapine) Temazepam (Temazepam) Xipamide (Xipamide)	SS SS C C C C		ORAL ORAL	7.5 MILLIGRAM, 1 DAY, ORAL 900 MILLIGRAM, 1 DAY, ORAL	

Date:01/11/00ISR Number: 3442675-XReport Type:Direct Company Report #
Age:60 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abnormal Behaviour Confusional State Diarrhoea Drug Toxicity Oral Intake Reduced Tremor		Lithium Metgmolol Valproic Acid Terazosin Ecasa Lipitor Plavix	PS C C C C C C			300MG Q AM & 600 Q HS	

Date:01/11/00ISR Number: 3442870-XReport Type:Expedited (15-DaCompany Report #9953096
Age:59 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Required	Drug Level Above	Foreign	Norvasc Tablets	PS		ORAL	5.00 MG
Intervention to	Therapeutic	Health					TOTAL:DAILY:O
Prevent Permanent		Professional					RAL
Impairment/Damage		Other	Lithium	SS		ORAL	600.00 MG

TOTAL:DAILY:O

RAL

Date:01/12/00ISR Number: 3446105-3Report Type:Expedited (15-DaCompany Report #2000000633-1
Age:57 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Required	Abnormal Behaviour	Health	Lithium Carbonate	PS		ORAL	900
Intervention to		Professional					MILLIGRAMS
Prevent Permanent							1.0 DAILY
Impairment/Damage							ORAL
			Ambien (Zolpidem Tartrate)	C			
			Wellbutrin	C			
			Celebrex (Celecoxib)	C			
			Other Psychotropic Medications (Nos)	C			

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/13/00ISR Number: 3444273-0Report Type:Periodic Company Report #990913-SK052
Age:53 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Drug Interaction	Consumer	Celebrex	PS		ORAL	PO	
Initial or Prolonged			Lithium	SS		ORAL	675.000 MG	
							BID PO	
			Calcium	C				
			Alendronate	C				
			Propoxyphene	C				
			Acetaminophen	C				
			Omeprazole	C				
			Levothyroxine	C				

Date:01/13/00ISR Number: 3528672-4Report Type:Periodic Company Report #991118-SK311
Age:38 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Interaction	Consumer	Celebrex	PS	Gd Searle And Co	ORAL	200.000 MG QD	
	Drug Level Above	Health					PO	
	Therapeutic	Professional	Lithobid	SS		ORAL	900.000 MG QD	
							PO	
			Bupropion	C				
			Clonazepam	C				
			Risperidone	C				
			Lamotrigine	C				

Date:01/18/00ISR Number: 3445091-XReport Type:Expedited (15-DaCompany Report #10230852
Age:53 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Agitation	Foreign	Cefzil Tabs					

Initial or Prolonged	Confusional State	Health	(Cefprozil)	PS	ORAL
ORAL					
	Drug Toxicity	Professional	Lithium Carbonate	SS	ORAL
600					
		Other			
MILLIGRAM,					
2/1 DAY, ORAL					
			Haldol (Halopridol)	C	
			Cogentin (Benztropine Mesylate)	C	
			Ventolin (Albuterol)	C	
			Becloforte Inhaler (Beclomethasone Dipropionate)	C	

Date:01/24/00ISR Number: 3446084-9Report Type:Direct Company Report #
Age: Gender:Male I/FU:I

Outcome	PT
Life-Threatening	Abdominal Distension
Hospitalization - Initial or Prolonged	Aortic Occlusion
	Coagulopathy
Disability	Coma
Required Intervention to Prevent Permanent Impairment/Damage	Decreased Activity
	Diabetes Mellitus
	Drug Interaction
	Dry Mouth
	Embolism
	Foot Amputation

	Gallbladder Disorder					
	Gangrene					
	Hyperglycaemia	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
	Hyperpyrexia		Zyprexa	PS		
2 MG ONCE						
	Renal Impairment					
DAILY						
	Skin Discolouration		Lithium	SS		
300 MG 5X/DAY						
	Stupor		Vasotec	C		
	Surgery		Niapsan	C		
	Vision Blurred		Clonazepam	C		
	Vomiting		Paxil	C		
	Weight Increased					

Date:01/24/00ISR Number: 3446426-4Report Type:Expedited (15-DaCompany Report #10184109
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization -	Amnesia	Foreign	Avapro (Irbesartan)	PS		ORAL
300						
Initial or Prolonged	Memory Impairment	Study				
MILLIGRAM,						
	Neurotoxicity	Health				
ORAL						
	Therapeutic Agent	Professional	Enalapril (Enalapril			
	Toxicity	Other	Maleate)	SS		
40 MILLIGRAM						
			Lithium (Lithium			
			Salts)	SS		
			Diabeta	C		

Date:01/24/00ISR Number: 3447243-1Report Type:Expedited (15-DaCompany Report #JRFUSA2000000200
Age:13 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
	Autonomic Nervous System	Health	Risperdal (Tablet)			
	Imbalance	Professional	(Risperidone)	PS		ORAL
1 MG, 2 IN 1						

	Blood Creatine			
DAY(S) ORAL				
	Phosphokinase Increased	Seroquel (Seroquel)	SS	ORAL
600 MG, DAILY				
	Conjunctivitis			
ORAL				
	Dehydration	Loxitane (Loxapine		
	Drug Level Above	Succinate)	SS	ORAL
ORAL				
	Therapeutic	Lithium (Lithium)	SS	ORAL
ORAL				
	Drug Toxicity	Synthroid		
	Hypertension	(Levothyroxine		
	Leukopenia	Sodium)	C	
	Mental Impairment	Depakote (Valproate		
	Muscle Rigidity	Semisodium)	C	
	Neuroleptic Malignant			
	Syndrome			
	Pyrexia			

Date:01/27/00ISR Number: 3447251-0Report Type:Expedited (15-DaCompany Report #A001108
Age:76 YR Gender:Male I/FU:I

Outcome	PT
Hospitalization -	Barium Swallow Abnormal
Initial or Prolonged	Cough
	Dysphagia
	Dysphonia
	Hyporeflexia
	Neuroleptic Malignant
	Syndrome
	Parkinsonism

Weight Decreased

Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Foreign	Zoloft Tablets	PS		ORAL	200.00 MG	TOTAL:ORAL 6 WK
Literature						
Health Professional	Haloperidol	SS		ORAL	6.00 MG	TOTAL:ORAL 6 WK
	Lithium	SS		ORAL	ORAL	6 WK
	Temazepam	SS				

Date:01/27/00ISR Number: 3447896-8Report Type:Expedited (15-DaCompany Report #LITH00200000388
Age:41 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Convulsion	Health Professional	Lithium	PS		ORAL	DAILY PO 500 MG DAILY,	
	Drug Level Above Therapeutic		Clozaril	SS			DAILY, DAILY	
	Muscle Twitching		Luvox	SS			150 MG BID,	
							50 MG BID	
			Depakote	C				
			Zyprexa	C				
			Loxapine	C				

Date:01/28/00ISR Number: 3446958-9Report Type:Direct Company Report #
Age:51 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Chest Pain		Propulsid	PS			1T 2 XD	

Required	Coordination Abnormal		Lithium	SS	
600 BID					
Intervention to	Dyspnoea		Prozac	SS	
1T Q AM					
Prevent Permanent	Fall				
Impairment/Damage	Heart Rate Irregular				
	Palpitations				
	Tremor				

Date:01/28/00ISR Number: 3449161-1Report Type:Expedited (15-DaCompany Report #2000001172-1
Age:40 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Biopsy Kidney Abnormal	Literature	Lithium Smithkline			
	Blood Creatinine Increased	Health Professional	Beecham	PS	Smithkline Beecham	
	Blood Urea Increased					
	Glomerulonephritis					
	Hypertension					
	Hypomania					
	Proteinuria					
	Renal Failure					
	Renal Impairment					
	Renal Interstitial Fibrosis					
	Renal Tubular Atrophy					

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/31/00ISR Number: 3447860-9Report Type:Direct Company Report #
Age:59 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Condition Aggravated		Lithium	PS			300 MG BID	
	Decreased Appetite							
	Drug Toxicity							
	Dysarthria							
	Muscle Spasms							
	Tremor							

Date:01/31/00ISR Number: 3452129-2Report Type:Expedited (15-DaCompany Report #2000001826-1
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Interaction		Lithium Smithkline Beecham	PS	Smithkline Beecham		1200 MILLIGRAMS DAILY	
	Mania							
			Erythromycin	C				
			Prednisolone	C				

Date:01/31/00ISR Number: 3452140-1Report Type:Expedited (15-DaCompany Report #2000001713-1
Age:53 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Asthenia	Health Professional	Lithium Smithkline Beecham	PS	Smithkline Beecham	ORAL	675 MILLIGRAMS 2.0 DAILY ORAL	
	Drug Interaction							
	Drug Level Above Therapeutic							
	Drug Toxicity							
	Nausea		Lithium Smithkline					

	Tremor		Beecham	SS	Smithkline Beecham	ORAL
675 MG 2.0						
	Vomiting					
DAILY ORAL						
			Calcium	C		
			Alendronate	C		
			Propoxyphene	C		
			Omeprazole	C		
			Levothyroxine	C		
			Celebrex (Celecoxib)	C		

Date:02/01/00ISR Number: 3449652-3Report Type:Expedited (15-DaCompany Report #JACGER2000000104
Age:30 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Cardiomegaly	Foreign	Haldol (Tablet)			
		Health	(Haloperidol)	PS		ORAL
MG, DAILY,						
		Professional				
ORAL						
			Neurocil (Levomepromazine Maleate)	SS		ORAL
MG, DAILY,						
ORAL (SEE						
IMAGE)						
			Hypnorex (Lithium Carbonate)	SS		ORAL
MG, DAILY,						
ORAL						
			Diazepam (Diazepam)	SS		ORAL
MG, DAILY,						
ORAL						

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/01/00ISR Number: 3449658-4Report Type:Expedited (15-DaCompany Report #JACGBR2000000028
Age:43 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Depressed Level Of Consciousness	Foreign Health Professional	Haldol (Unspecified) (Haloperidol)	PS		ORAL	MG, DAILY,	ORAL
	Faecal Incontinence							
	Hypotonia		Lithium Carbonate (Lithium Carbonate)	SS		ORAL	MG, DAILY,	ORAL
	Neurotoxicity							
	Tremor							
			Carbamazepine (Carbamazepine)	C				
			Propantheline (Propantheline)	C				
			Procyclidine (Procyclidine)	C				
			Entera (Other Combinations Of Nutrients)	C				

Date:02/02/00ISR Number: 3449879-0Report Type:Direct Company Report #
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Bradycardia		Lithium	PS		ORAL	1000 MG PO QD	

Date:02/02/00ISR Number: 3450098-2Report Type:Direct Company Report #
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Bradycardia		Lithium Carbonate	PS		ORAL	300MG PO BID	
Other	Lethargy							
	Mental Impairment							

Date:02/02/00ISR Number: 3450163-XReport Type:Direct Company Report #
Age:67 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Level Above		Lithium	PS		ORAL	600MG PO TID	
	Therapeutic		Levothyroxine	C				
	Mental Impairment		Benztropin	C				
			Atenolol	C				
			Haloperidol	C				
			Acetaminophen	C				

Date:02/02/00ISR Number: 3450201-4Report Type:Direct Company Report #
Age: Gender:Male I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Blood Creatinine Increased
	Blood Pressure Diastolic Decreased
	Blood Urea Increased
	Bradycardia
	Drug Level Above Therapeutic

		Drug Toxicity Tremor					
			Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
			Health	Lithium 600mg	PS		
BID							
			Professional	Diclofenac	SS		
				Etoh	SS		

Date:02/02/00ISR Number: 3450259-2Report Type:Direct Company Report #
Age:72 YR Gender:Male I/FU:I

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Hospitalization -		Abdominal Pain		Lithium Carbonate	PS		ORAL
600 MG BID PO							
Initial or Prolonged		Diarrhoea					
6 YR.	6 YR						
		Dysarthria					
		Headache					
		Lethargy					
		Vision Blurred					

Date:02/02/00ISR Number: 3450537-7Report Type:Expedited (15-DaCompany Report #18588-021
Age:32 YR Gender:Female I/FU:I

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Hospitalization -		Communication Disorder	Health	Lithium Carbonate			
Initial or Prolonged		Distractibility	Professional	Tablets Usp, 300mg			
Other		Drug Interaction		Roxane Laboratories,			
		Mental Status Changes		Inc.	PS	Roxane Laboratories,	
						Inc.	ORAL
450MG QAM &							
600MG QPM, PO							
				Seroquel (Quetiapine Fumarate) 200mg			
				Zeneca Pharmaceuticals,			
				Inc.	SS	Zeneca Pharmaceuticals,	

					Inc.	ORAL
400MG QHS, PO						
			Gabitril	C		
			Ambien (Zolpidem Tartrate)	C		
			Mysoline (Primidone)	C		
			Prometrium(Progesterone)	C		
			Vitamin B6	C		
			Calcium Supplements	C		

Date:02/02/00ISR Number: 3450553-5Report Type:Expedited (15-DaCompany Report #FLUV00300000423
Age:68 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Agitation	Foreign	Fluvoxamine	PS		ORAL	50 MG DAILY
	Akathisia	Literature					PO
	Drug Level Above Therapeutic	Other	Flupenthixol Decanoate	SS			DAILY
	Poisoning Deliberate		Haloperidol	SS		ORAL	5 MG DAILY PO
	Restless Legs Syndrome		Lithium	SS		ORAL	400 MG BID
	Restlessness						PO; 400 MG
	Suicidal Ideation						DAILY
	Suicide Attempt		Trihexyphenidyl	SS		ORAL	2 MG PO

Date:02/02/00ISR Number: 3451030-8Report Type:Expedited (15-DaCompany Report #WAES 99128377
Age:62 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Drug Level Above	Foreign	Tab Singulair					
Hospitalization -	Therapeutic	Health	(Montelukast Sodium)	PS		ORAL	10 MG PO	48 DAY
Initial or Prolonged	Drug Toxicity	Professional	Tab Lithiumco3	SS		ORAL	750 MG PO	67 DAY
	Renal Impairment		Albuterol	C				
			Fluticasone Propionate	C				
			Furosemide	C				
			Potassium Chloride	C				
			Sulfasalazine	C				
			Trimipramine	C				

Date:02/04/00ISR Number: 3452449-1Report Type:Expedited (15-DaCompany Report #10230852
Age:53 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Agitation	Foreign	Cefzil Tabs					
Initial or Prolonged	Confusional State	Health	(Cefprozil)	PS		ORAL	ORAL	
	Drug Level Above	Professional	Lithium Carbonate	SS		ORAL	600 MILLIGRAM, 2/1 DAY ORAL	
	Therapeutic							
	Drug Toxicity							
			Haldol (Haloperidol)	C				
			Cogentin (Benztropine Mesylate)	C				
			Ventolin (Albuterol)	C				
			Becloforte Inhaler (Beclomethasone Dipropionate)	C				

Date:02/07/00ISR Number: 3453259-1Report Type:Direct Company Report #
Age:49 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Diarrhoea Drug Level Above Therapeutic Dysarthria Vomiting	Health Professional	Lithium 300mg Q 8hrs	PS				

Date:02/07/00ISR Number: 3453469-3Report Type:Expedited (15-DaCompany Report #USA/00/00235/SIM03
Age:58 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Confusional State Drug Interaction Drug Level Above Therapeutic Drug Toxicity Hypertension	Health Professional	Sandimmune Neoral (Cyclosporine, Usp) Lithium	PS SS		ORAL	200 MG TWICE A DAY	ORAL

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/07/00ISR Number: 3454161-1Report Type:Expedited (15-DaCompany Report #LITH00200000551
Age:68 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agitation	Foreign	Lithium	PS		ORAL	400 MG BID	
	Akathisia	Literature					PO, 400 MG	
	Condition Aggravated	Other					DAILY UNK	
	Depressed Mood		Fluvoxamine	SS		ORAL	50 MG DAILY	
	Drug Interaction						PO	
	Drug Level Above		Navane	SS			DAILY	
	Therapeutic		Haloperidol	SS		ORAL	5 MG DAILY PO	
	Poisoning Deliberate		Trihexyphenidyl	SS		ORAL	2 MG PO	
	Restlessness							
	Suicidal Ideation							
	Tremor							

Date:02/08/00ISR Number: 3454366-XReport Type:Direct Company Report #
Age:50 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Lethargy		Lithium Cap, Oral	PS		ORAL	300 MG, QNOON, PO	
	Nausea							
	Vomiting		Lithium Cap, Oral	SS		ORAL	600 MG, BID, PO	

Date:02/10/00ISR Number: 3456304-2Report Type:Expedited (15-DaCompany Report #00F--10078
Age:77 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Coma Dehydration Drug Interaction Pyrexia Rhabdomyolysis Shock	Foreign Health Professional Other	Anafranil Tablet (Clomipramine Hydrochloride)	PS		ORAL	DAILY, ORAL	
			Modopar Capsule (Madopar)	SS		ORAL	3 DF, DAILY,	
			Teralithe Slow Release Tablet (Lithium Carbonate)	SS		ORAL	800 MG, DAILY, ORAL	9 MON
			Deprenyl Tablet (Selegiline)	SS		ORAL	10 MG, DAILY, ORAL	
			Lysanxia Tablet	C				

Date:02/11/00ISR Number: 3457131-2Report Type:Expedited (15-DaCompany Report #A003235
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Interaction Lower Respiratory Tract Infection Mania	Foreign Health Professional Other	Sterane Tablets	PS		ORAL	30.00 MG TOTAL:DAILY:ORAL	
			Lithium	SS			600.00 MG TOTAL:BID	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/11/00ISR Number: 3457289-5Report Type:Expedited (15-DaCompany Report #A003576
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Drug Interaction Electrocardiogram Qt Prolonged	Health Professional	Procardia Xl Extended Release Tablets	PS		ORAL		
			Lithium	SS				
			Nardil	SS				
			Mellaril	SS				
			Yohimbine	C				

Date:02/14/00ISR Number: 3457311-6Report Type:Direct Company Report #
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Confusional State		Lithium 900mg	PS		ORAL	900MG BID PO	2 MON
	Diarrhoea		Vasotec	C				
	Drug Toxicity		Valium	C				
	Dysarthria		Prilosec	C				
	Lethargy		Prozac	C				
	Tremor		Norvasc	C				

Date:02/14/00ISR Number: 3457402-XReport Type:Direct Company Report #
Age:53 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Coma	Health	Zyprexa 15 Mg/Day	PS			15MG/DAY	
	Muscle Rigidity	Professional	Lithobid 600 Mg Bid	SS			600 MG BID	
	Pyrexia		Neurontil 600mg Tid	SS			600MG TID	
	Tremor		Symmetrel 900mg/Day	SS			900MG/DAY	

Date:02/14/00ISR Number: 3457548-6Report Type:Expedited (15-DaCompany Report #A003284
Age:68 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Agitation	Foreign	Lithane Tablets	PS		ORAL	ORAL
	Akathisia	Literature	Fluvoxamine	SS		ORAL	50.00 MG TOTAL: ORAL
	Condition Aggravated	Health					
	Depressed Mood	Professional	Haloperidol	SS		ORAL	ORAL
	Difficulty In Walking		Chlorpromazine	C			
	Emotional Distress		Thioridazine	C			
	Movement Disorder		Mianscrin	C			
	Poisoning Deliberate		Amitriptyline	C			
	Restlessness						
	Suicidal Ideation						
	Tremor						

Date:02/14/00ISR Number: 3459611-2Report Type:Periodic Company Report #001-0945-990106
Age:44 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Agitation	Consumer	Neurontin (Gabapentin)	PS		ORAL	PER ORAL
	Drug Level Above Therapeutic		Lithobid (Lithium Carbonate)	SS		ORAL	600 MG (DAILY), PER ORAL
	Feeling Drunk						
	Nausea						

			Zyprexa (Olanzapine)	SS		ORAL	PER ORAL
			Wellbutrin (Amfebutamone Hydrochloride)	SS		ORAL	PER ORAL
			Ambien (Zolpidem Tartrate)	SS		ORAL	PER ORAL
			Zoloft (Sertraline Hydrochloride)	SS		ORAL	PER ORAL
			Klonopin (Clonazepam)	SS		ORAL	PER ORAL
			Benzotropine (Benzatropine Mesilate)	SS		ORAL	PER ORAL
			Inderal (Propranolol Hydrochloride)	C			

Date:02/15/00ISR Number: 3458200-3Report Type:Expedited (15-DaCompany Report #1999026279-1
Age:55 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Lymphadenopathy Metastases To Liver Oesophageal Adenocarcinoma	Consumer Health Professional	Eskalith Smithkline Beecham	PS	Smithkline Beecham	ORAL	1.0 DAILY ORAL	30 YR

Date:02/16/00ISR Number: 3458750-XReport Type:Expedited (15-DaCompany Report #JRFBEL2000000274
Age:68 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agitation Akathisia Chemical Poisoning Condition Aggravated	Foreign Literature Health Professional	Haldol (Unspecified) (Haloperidol) Chlorpromazine (Cloropromazine)	PS SS				

	Depressed Mood Drug Interaction Restlessness Suicidal Ideation Suicide Attempt Tremor		Thioridazine (Thioridazine) Amitriptyline (Amitriptyline) Mianserin (Mianserin) Lithium (Lithium) Flupenthixol Decanoate (Flupentixol Decanoate)	SS SS SS SS SS			
MG, 1 IN 1 MONTH(S)							
			Trihexyphenidyl (Trihexyphenidyl)	SS			ORAL
2 MG, 2 IN 1 DAY(S), ORAL							
			Fluvoxamine (Fluvoxamine)	SS			
MG, DAILY							

Date:02/17/00ISR Number: 3459422-8Report Type:Expedited (15-DaCompany Report #2000UW00488
Age:32 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Drug Interaction	Health	Seroquel	PS	Zeneca	ORAL	400 MG HS PO	
Initial or Prolonged	Mental Impairment	Professional	Lithium Carbonate Tablets	SS		ORAL	450 MG QD PO	

			Lithium Carbonate Tablets	SS		ORAL 600 MG HS PO
			Gabitril	C		
			Ambien	C		
			Mysoline	C		
			Prometrium	C		
			Multiple Vitamins	C		
			Vitamin B6	C		
			Calcium	C		

Date:02/18/00ISR Number: 3460384-8Report Type:Expedited (15-DaCompany Report #HQ0890403FEB2000
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Cellulitis	Health	Effexor	PS		ORAL	ORAL	1 WK
	Dermatitis	Professional	Lithium	SS				
	Oedema		Seroquel "Zeneca"	SS	Zeneca	ORAL	ORAL	
	Pyrexia							
	Weight Increased							

Date:02/22/00ISR Number: 3461233-4Report Type:Expedited (15-DaCompany Report #USA/00/00358/LEX
Age:31 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain	Health	Clozaril (Clozapine)	PS		ORAL	200 MG, ORAL	
	Back Pain	Professional	Lithobid	SS			600 MG	
	Bronchitis		Depakote	C				
	Dehydration		Ativan	C				
	Drug Level Above Therapeutic		Prolixin	C				
	Gait Disturbance							
	Leukocytosis							
	Myalgia							
	Pyrexia							
	Renal Failure Acute							
	Vomiting							

Date:02/22/00ISR Number: 3462027-6Report Type:Expedited (15-DaCompany Report #JACFRA2000000125
Age:35 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Leukocytosis Pyrexia	Foreign Health Professional	Haldol (20 Mg Tablet) (Haloperidol)	PS		ORAL	20 MG, 3 IN 1	DAY (S), ORAL
			Tercian (Cyamemazine0	SS		ORAL	ORAL	
			Teralithe Sodium (Lithium Carbonate)	SS		ORAL	MG, DAILY,	ORAL
			Clopixol (Zuclopenthixol Decanoate)	SS		INTRAMUSCULAR	IM	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/23/00ISR Number: 3461294-2Report Type:Direct Company Report #
Age:68 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Confusional State Delirium		Lithium Carbonate 300mg Cap	PS		ORAL	300MG TID/	
	Renal Failure Acute						ORAL	
	Urinary Retention		Alprazolam	C				
			Furosemide	C				
			Glyburide	C				
			Potassium Chloride	C				
			Lisinopril	C				

Date:02/23/00ISR Number: 3461386-8Report Type:Direct Company Report #
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Drug Level Above Therapeutic	Health Professional	Fosinopril 10 Mg Licos 300mg Lithium Carbonate	PS SS			1 BID 2 BID	

Date:02/23/00ISR Number: 3463280-5Report Type:Periodic Company Report #9925224
Age:50 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Depression	Consumer	Zoloft Tablets	PS		ORAL	150.00 MG	
	Drug Ineffective						TOTAL:DAILY:O	
							RAL	
			Lithium	SS				
			Remeron	SS				
			Buspar	SS		ORAL	10.00 MG	

TOTAL:DAILY:O

RAL

			Prempro	C		

Date:02/23/00ISR Number: 3463370-7Report Type:Periodic Company Report #9925631
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Depression	Consumer	Zoloft Tablets	PS		ORAL	150.00 MG	

TOTAL; DAILY;

ORAL

			Lithium	SS		
			Remeron	SS		
			Synthroid	SS		
			Hormone Replacement	C		
			Perphenazine	C		

Date:02/23/00ISR Number: 3466903-XReport Type:Periodic Company Report #JAUSA36133
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Coma	Health Professional	Risperdal (Risperidone)	PS		ORAL	ORAL	
	Condition Aggravated							
	Suicide Attempt		Zyprexa (Olanzapine)	SS		ORAL	ORAL	
			Lithium (Lithium)	SS		ORAL	ORAL	
			Prozac (Fluoxetine)	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/23/00ISR Number: 3466916-8Report Type:Periodic Company Report #JAUSA36236
Age:17 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Creatine Phosphokinase Increased	Health Professional	Risperdal (Risperidone)	PS			(1 MG 2 DAILY	30-JUN-97):(2 MG DAILY 16-JAN-99)
	Condition Aggravated		Lithium (Lithium)	SS			(16-JAN-99):DOSE INCREASED (NOS)600 MG 2 DAILY	

Date:02/24/00ISR Number: 3463237-4Report Type:Expedited (15-DaCompany Report #00P-163-0087101-00 (0)
Age:32 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abnormal Behaviour Akathisia	Health Professional	Gabitril (Gabitril) (Tiagabine Hcl)	PS		ORAL	24 MG 1 IN 1 D PER ORAL	
	Communication Disorder Crying Drug Interaction		Lithium Carbonate (Lithium Carbonate)	SS		ORAL	1050 MG 1 IN 1 D PER ORAL	
	Dyskinesia Dyspnoea		Seroquel (Seroquel)	SS		ORAL	PER ORAL	
	Fear Mental Impairment Muscle Contractions Involuntary Muscle Twitching		Mtv(Vitamins Nos) Calcium (Calcium) Pyridoxine Hydrochloride (Pyridoxine	C C				

			Hydrochloride)	C		
			Progesterone (Progesterone)	C		
			Primidone (Primidone)	C		

Date:02/28/00ISR Number: 3464828-7Report Type:Expedited (15-DaCompany Report #USA/00/00235/SIM03
Age:58 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Asthenia Confusional State Coordination Abnormal Drug Interaction Drug Level Above Therapeutic Drug Toxicity Hypertension Liver Function Test Abnormal	Health Professional	Sandimmune Neoral (Cyclosporine, Usp) Lithium	PS SS		ORAL	200 MG, TWICE A DAY, ORAL UNSPECIFIED	

Date:02/28/00ISR Number: 3466039-8Report Type:Direct Company Report #
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Delirium Drug Toxicity		Lithium 300mg	PS		ORAL	1200MG QD ORAL	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/28/00ISR Number: 3466292-0Report Type:Periodic Company Report #WAES 99060264
Age:72 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Other	Diarrhoea	Health	Tab Prinivil Unk	PS		ORAL	20 MG/DAILY/PO
	Drug Interaction	Professional					
	Drug Level Above Therapeutic		Cap Lithiumco3 300 Mg	SS		ORAL	600; 900; 600 MG/2XW/PO; 900; 600; 300 MG/DAILY/PO
	Memory Impairment						
			Deltasone	C			
			Fosamax	C			
			Synthroid	C			

Date:03/01/00ISR Number: 3466978-8Report Type:Expedited (15-DaCompany Report #A003576
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Required Intervention to Prevent Permanent Impairment/Damage	Drug Interaction	Health Professional	Procardia Xl Extended Release Tablets	PS		ORAL	ORAL
	Electrocardiogram Abnormal						
			Lithium	SS			
			Nardil	SS			
			Mellaril	SS			
			Yohimbine	C			

Date:03/01/00ISR Number: 3467064-3Report Type:Expedited (15-DaCompany Report #FLUV00399000044
Age:37 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Other	Bite	Foreign	Fevarin	PS		ORAL	50 MG DAILY

	Depressed Level Of Consciousness Fall Grand Mal Convulsion Joint Dislocation	Health Professional Other	Leponex	SS			PO 700 MG DAILY UNK, 725 MG DAILY UNK, 800 MG DAILY UNK, 600 MG
			Hypnorex - Slow Release	SS			800 MG DAILY UNK, 1000 MG DAILY UNK, 1200 MG DAILY UNK
			Gastrozepin	C			

Date:03/02/00ISR Number: 3468284-4Report Type:Expedited (15-DaCompany Report #JACGER2000000226
Age:42 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Angina Pectoris Dyspnoea Hypokalaemia	Foreign Health Professional	Haldol Glianimon (Benperidol)	PS SS		INTRAVENOUS	DAILY, IV DAILY
			Hypnorex (Lithium Carbonate)	SS			DAILY, ORAL
			Ciatyl-Z Akuphase (Zuclopenthixol Acetate)	SS		INTRAMUSCULAR	DAILY, IM
			Ciatyl (Clopenthixol				

			Hydrochloride)	C			
INTRAVENOUS	DAILY, IV						
			Diazepam	C			
			Tavor	C			
			Clexane	C			

Date:03/02/00ISR Number: 3473364-3Report Type:Expedited (15-DaCompany Report #LBID00200000843
Age:31 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Bronchitis	Health	Lithobid	PS		ORAL	600 MG DAILY	
Initial or Prolonged	Dehydration	Professional					PO	
	Drug Toxicity		Clozaril	SS		ORAL	200 MG DAILY	
	Gait Disturbance						PO	
	Leukocytosis		Depakote	C				
	Myalgia		Ativan	C				
	Pyrexia		Prolixin	C				
	Renal Failure Acute							
	Vomiting							

Date:03/06/00ISR Number: 3470428-5Report Type:Expedited (15-DaCompany Report #HQ1275828FEB2000
Age:45 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Blood Pressure Increased	Health	Effexor (Venlafaxine					
	Headache	Professional	Hydrochloride)	PS		ORAL	SEE IMAGE	
	Photophobia		Lithium (Lithium)	SS				
	Ruptured Cerebral							
	Aneurysm							

Date:03/06/00ISR Number: 3470633-8Report Type:Expedited (15-DaCompany Report #JRFBEL2000000398
Age:49 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

	Blood Pressure Decreased	Foreign	Risperidone (Tablet)		
	Bradycardia	Health	(Risperidone)	PS	ORAL
MG DAILY ORAL					
	Drug Interaction	Professional	Lithium Carbonate		
	Sick Sinus Syndrome		(Lithium Carbonate)	SS	ORAL
MG DAILY ORAL					
			Fluvoxamine Maleate (Fluvoxamine Maleate)	SS	ORAL
MG DAILY ORAL					
			Magnesium Oxide (Magnesium Oxide)	C	

Date:03/08/00ISR Number: 3470848-9Report Type:Direct Company Report #
Age:48 YR Gender:Male I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Condition Aggravated
	Confusional State
	Drug Level Above Therapeutic
	Drug Toxicity
	Dysarthria
	Gait Disturbance
	Lethargy
	Polydipsia
	Tremor
	Urinary Incontinence

Vomiting

		Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
		Health	Lithium 300mg Roxane	PS	Roxane	ORAL
300MG TID PO						
		Professional	Chlorpromazine	C		
			Valproate	C		
			Triamcinolone	C		
			Serosol	C		
			Olanzapine	C		
			Furosemide	C		
			Oxybutin	C		
			Ipratropium	C		
			Albuterol	C		
			Kcl	C		
			Theophylline	C		
			Lansoprazole	C		
			Digoxin	C		

Date:03/10/00ISR Number: 3474118-4Report Type:Periodic Company Report #8-99137-155A
Age:46 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Other	Alopecia	Consumer	Lo/Ovral Tablet	PS		ORAL
1 TABLET 1X						
PER DAY, ORAL						
			Lithium	SS		ORAL
ORAL						
			Wellbutrin	SS		ORAL
ORAL						
			Lithium	C		
			Ritalin (Methylphenidate)	C		
			Wellbutrin (Bupropion)	C		

Date:03/13/00ISR Number: 3474403-6Report Type:Direct Company Report #
Age:68 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Confusional State Coordination Abnormal	Health Professional	Lithium	PS				

Date:03/13/00ISR Number: 3475326-9Report Type:Periodic Company Report #6100640
Age:46 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Interaction	Consumer	Aleve Caplets - 150s	PS		ORAL	2TAB ORAL	01X/D
			Lithobid (Lithium Carbonate)	SS				
			Lithobid (Lithium Carbonate)	C				

Date:03/14/00ISR Number: 3475234-3Report Type:Expedited (15-DaCompany Report #2000-DE-G0035
Age:62 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Coma Drug Level Above Therapeutic	Foreign Health Professional	Micardis (Telmisartan) Lithium Salt	PS SS		ORAL	80/1/PO 900 MG/NR	

Glimepiride	C
Glucophage	C
Isosorbide Mononitrate	C

Date:03/14/00ISR Number: 3475460-3Report Type:Expedited (15-DaCompany Report #2000014049JP
Age:54 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abnormal Behaviour Apathy	Foreign Health	Halcion (Triazolam) Tablet	PS			0.5 MG,	
	Delirium Dementia Alzheimer'S Type	Professional Other	Lithium Carbonate (Lithium Carbonate)	SS			200 MG	
	Depression Drug Withdrawal Syndrome		Maprotiline (Maprotiline)	SS			70 MG	
	Electroencephalogram Abnormal		Sultopride (Sultopride)	SS			150 MG	
	Elevated Mood		Etaxolam	SS			4 MG	
	Mania Mental Impairment		Nitrazepam (Nitrazepam)	SS			10 MG	
	Restlessness		Flunitrazepam (Flunitrazepam)	SS			4 MG	
			Pentobarbital (Pentobarbital)	SS			100 MG	
			Chlorpromazine (Chlorpromazine)	SS			25 MG	
			Promethazine (Promethazine)	SS			12.5 MG	
			Phenobarbital (Phenobarbital)	SS			40 MG	

Date:03/16/00ISR Number: 3476325-3Report Type:Direct Company Report #
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dehydration	Health Professional	Lithium	PS				

Date:03/20/00ISR Number: 3477328-5Report Type:Expedited (15-DaCompany Report #A008797
Age:64 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Gamma-Glutamyltransferase Increased	Foreign Health Professional Company Representative	Unasyn For Injection	PS		ORAL	6.00 GRAM TOTAL:BID:ORA	L
			Lithium Carbonate	SS		ORAL	400.00 MG TOTAL:BID:ORA	L
			Amoxapine	C				
			Alprazolam	C				
			Levomepromazine Maaleate	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/20/00ISR Number: 3477833-1Report Type:Expedited (15-DaCompany Report #WAES 00030893
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Confusional State Dialysis Disorientation Drug Level Above Therapeutic	Health Professional Company Representative	Tab Vioxx 25 Mg Lithium 450 Mg	PS SS		ORAL ORAL	25 MG/DAILY/PO 450 MG/BID/UNK	

Date:03/21/00ISR Number: 3478586-3Report Type:Expedited (15-DaCompany Report #230941
Age:38 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Delirium Depressed Level Of Consciousness Sedation	Foreign Other	Rivotril (Clonazepam) Anafranil (Clomipramine Hydrochloride) Atrium (Difebarbamate/Febarbamate/Phenobarbital) Teralithe (Lithium Carbonate) Tercian (Cyamemazine) Theralene (Trimeprazine Tartrate)	PS SS SS SS SS SS		ORAL ORAL ORAL ORAL ORAL ORAL	ORAL ORAL ORAL ORAL ORAL ORAL	

Date:03/22/00ISR Number: 3482420-5Report Type:Expedited (15-DaCompany Report #WAES 00031459
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Disorientation	Consumer	Tab Vioxx Unk	PS		ORAL PO		
	Drug Interaction		Lithium Co3 Unknown	SS		ORAL PO		

Date:03/23/00ISR Number: 3479106-XReport Type:Direct Company Report #USP 52934
Age:29 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Medication Error		Imodium	PS	Novopharm Limited			
			Eskalith	SS	Roxane			

Date:03/23/00ISR Number: 3479188-5Report Type:Expedited (15-DaCompany Report #A0111218A
Age:50 YR Gender:Male I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Coordination Abnormal
	Dermatitis
Disability	Drug Interaction
	Dysarthria
	Fatigue
	Malaise
	Mutism
	Nausea
	Nervous System Disorder

	Petechiae Pharyngolaryngeal Pain Pyrexia	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Rash Maculo-Papular	Health Professional	Ziagen Tablet (Abacavir Sulfate)	PS		ORAL	300 MG, TWICE PER DAY, ORAL
			Lithium Carbonate Tablet (Lithium Carbonate)	SS		ORAL	300 MG, VARIABLE DOSE, ORAL
			Combivir	C			
			Thyroxine Sodium	C			
			Trazodone	C			
			Enalapril Maleate	C			

Date:03/23/00ISR Number: 3479336-7Report Type:Direct Company Report #
Age:42 YR Gender:Female 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	Alanine Aminotransferase Increased Aspartate Aminotransferase Increased Blood Creatine Phosphokinase Increased Blood Lactate Dehydrogenase Increased Convulsion Encephalopathy Extrapyramidal Disorder Muscle Rigidity Pyrexia Rhabdomyolysis		Lithium 300 Mg	PS			

Date:03/24/00ISR Number: 3479752-3Report Type:Expedited (15-DaCompany Report #A008820
Age:51 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abnormal Behaviour	Literature	Lithane Tablets	PS		ORAL		
	Depression	Health	Haloperidol	SS		ORAL		
	Feeling Abnormal	Professional	St. John'S Wort	SS		ORAL	900.00 MG	TOTAL:TID:ORAL
	Hallucination							
	Inappropriate Affect							
	Libido Increased							
	Mania							
	Psychomotor Hyperactivity							
	Speech Disorder							
	Stress							

Date:03/24/00ISR Number: 3480106-4Report Type:Expedited (15-DaCompany Report #2000UW00926
Age:13 YR Gender:Female I/FU:I

Outcome	PT
	Blood Creatine Phosphokinase Increased
	Conjunctivitis

Dehydration Drug Toxicity Leukopenia	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Mental Impairment	Health	Seroquel "Zeneca"	PS	Zeneca	ORAL	600 MG QD PO
Muscle Rigidity	Professional	Seroquel "Zeneca"	SS	Zeneca	ORAL	400 MG BID PO
Neuroleptic Malignant		Risperdal	SS		ORAL	1 MG BID PO
Syndrome		Risperdal	SS		ORAL	3 MG QD PO
Pyrexia		Risperdal	SS		ORAL	4 MG QD PO
		Loxitane	SS			
		Lithium	SS			
		Synthroid	C			
		Depakote	C			

Date:03/24/00ISR Number: 3480312-9Report Type:Expedited (15-DaCompany Report #JRFBEL2000000398
Age:49 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Bradycardia	Foreign	Risperidone (Tablet)				
	Cardiac Output Decreased	Health	(Risperidone)	PS		ORAL	MG, DAILY,
	Condition Aggravated	Professional					ORAL
	Dizziness		Lithium Carbonate				
	Drug Interaction		(Lithium Carbonate)	SS		ORAL	MG, DAILY,
	Hypotension						ORAL
	Kleptomania		Fluvoxamine Maleate				
	Nausea		(Fluvoxamine				
	Sick Sinus Syndrome		Maleate)	SS		ORAL	MG, DAILY,
							ORAL
			Magnesium Oxide				
			(Magnesium Oxide)	C			

Date:03/24/00ISR Number: 3481078-9Report Type:Expedited (15-DaCompany Report #2000007354-1
Age:30 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Osmolarity Increased	Literature	Lithium Smithkline Beecham	PS	Smithkline Beecham			
	Confusional State	Health Professional	Oral Contraceptive (Nos)	C				
	Dehydration		Risperidone	C				
	Headache							
	Hemiparesis							
	Hypernatraemia							
	Nephrogenic Diabetes Insipidus							
	Papilloedema							
	Platelet Count Decreased							
	Polyuria							
	Renal Tubular Disorder							
	Superior Sagittal Sinus Thrombosis							
	Urine Osmolarity Decreased							
	Vision Blurred							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/24/00ISR Number: 3544612-6Report Type:Periodic Company Report #USA012229
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Confusional State	Other	Meridia	PS	Knoll Pharmaceutical Co Sub Basf Corp			
	Paranoia							
	Thinking Abnormal		Lithium	SS				

Date:03/27/00ISR Number: 3480014-9Report Type:Direct Company Report #
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Coordination Abnormal		Lithium Carbonate					
Hospitalization - Initial or Prolonged	Dialysis		300 Mg	PS		ORAL	300 MG TID	
	Difficulty In Walking						ORAL	
	Drug Toxicity		Rofecoxib 25 Mg	SS		ORAL	25MG QD ORAL	
	Nystagmus		Stelazine	C				
	Oral Intake Reduced		Ditropan	C				
	Tremor							
	Visual Disturbance							

Date:03/28/00ISR Number: 3480287-2Report Type:Direct Company Report #
Age:41 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Hepatitis C	Consumer	Lithium Carbonate					
Hospitalization - Initial or Prolonged	Hepatocellular Damage		Tab Cr 900 M	PS		ORAL	900M, PO BID, TAB	
Disability			Clozapine Tab 300m	SS		ORAL	300 M PO BID	
Other							TAB	
Required Intervention to Prevent Permanent								

Impairment/Damage

Date:03/28/00ISR Number: 3481351-4Report Type:Expedited (15-DaCompany Report #00P-163-0087101-00 (1)
Age:32 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abnormal Behaviour Akathisia Amnesia Anxiety Crying Drug Interaction Fear Mental Impairment Movement Disorder Muscle Twitching Psychomotor Hyperactivity	Health Professional	Gabitril (Gabitril) (Tiagabine Hcl) Lithium Carbonate (Lithium Carbonate) Seroquel (Seroquel) Mtv (Vitamins Nos) Calcium (Calcium) Pyridoxine Hydrochloride (Pyridoxine Hydrochloride) Progesterone (Progesterone) Primidone (Primidone)	PS SS SS C C C C C		ORAL ORAL ORAL	24 MG, 1 IN 1 D, PER ORAL 1050 MG 1 IN 1 D PER ORAL PER ORAL	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/28/00ISR Number: 3481502-1Report Type:Periodic Company Report #9909532
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Depression	Consumer	Diflucan Tablets	PS				
			Lithium	SS				
			Unknown					
			Antidepressant	SS				

Date:03/29/00ISR Number: 3481293-4Report Type:Direct Company Report #
Age:69 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Drug Level Above		Lithium 600 Mg	PS		ORAL	PO BID	
Initial or Prolonged	Therapeutic		Lorazepam 2 Mg	SS				
INTRAMUSCULAR	IM Q6H, PRN							
	Lethargy							

Date:03/29/00ISR Number: 3481824-4Report Type:Periodic Company Report #1999UW02015
Age:72 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Diarrhoea	Health	Lisinopril	PS		ORAL	20 MG QD PO	
	Drug Interaction	Professional	Lithium	SS		ORAL	600 MG DAILY	
	Drug Level Above						PO	
	Therapeutic		Lithium	SS		ORAL	SEE IMAGE	9 DAY
	Memory Impairment		Deltasone	C				
			Fosamax	C				
			Synthroid	C				

Date:03/31/00ISR Number: 3482771-4Report Type:Expedited (15-DaCompany Report #A008797
Age:64 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required	Gamma-Glutamyltransferase	Foreign	Unasyn For Injection	PS		INTRAVENOUS	6.00 GRAM	
Intervention to	Increased	Health				TOTAL;BID;INT		
Prevent Permanent		Professional				RAVENOUS		
Impairment/Damage		Company	Lithium Carbonate	SS		ORAL	400.00 MG	
		Representative				TOTAL;BID;ORA		
L								
			Amoxapine	C				
			Alprazolam	C				
			Levomepromazine Maleate	C				

Date:04/03/00ISR Number: 3483006-9Report Type:Direct Company Report #
Age:33 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anxiety		Lithium	PS				
	Drug Toxicity							
	Feeling Jittery							
	Hypothyroidism							
	Tremor							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/05/00ISR Number: 3484454-3Report Type:Expedited (15-DaCompany Report #JRFUSA2000000200
Age:13 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Creatine Phosphokinase Increased	Health Professional	Risperdal (1 Mg Tablet) (Risperidone)	PS		ORAL	SEE IMAGE	
	Conjunctivitis		Seroquel (Seroquel)	SS		ORAL	SEE IMAGE	
	Dehydration		Loxitane (Loxitane Succinate)	SS		ORAL	SEE IMAGE	
	Diabetes Mellitus		Lithium (Lithium)	SS		ORAL	SEE IMAGE	
	Drug Level Above Therapeutic		Depakote (Valproate Semisodium)	SS		ORAL	SEE IMAGE	
	Drug Toxicity		Fiber Lax (Polycarbophl Calcium)	C				
	Hypertension		Synthroid (Levothyroxine Sodium)	C				
	Lethargy		Trazodone (Trazodone)	C				
	Leukopenia		Cogentin (Benzatropine Mesilate)	C				
	Mental Impairment		Colace (Docusate Sodium)	C				
	Muscle Rigidity		Ddavrp (Desmopressin)	C				
	Neuroleptic Malignant Syndrome		Zoloft (Sertraline Hydrochloride)	C				
	Neutropenia		Lactaid (Tilactase)	C				
	Polyuria		Erythromycin (Erythromycin)	C				
	Pyrexia		Lac-Hydrin (Ammonium Lactate)	C				
	Tachycardia							
	Tremor							

Date:04/06/00ISR Number: 3484838-3Report Type:Expedited (15-DaCompany Report #JRFBEL2000000398
Age:49 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Bradycardia	Foreign	Risperidone (Tablet)					
	Cardiac Disorder	Health	(Risperidone)	PS		ORAL	MG, DAILY,	
	Condition Aggravated	Professional					ORAL	
	Dizziness		Lithium Carbonate					
	Drug Interaction		(Lithium Carbonate)	SS		ORAL	MG,	
	Hypotension						DAILY,ORAL	
	Kleptomania		Fluvoxamine Maleate					
	Nausea		(Fluvoxamine					
	Sick Sinus Syndrome		Maleate)	SS		ORAL	MG,	
							DAILY,ORAL	
			Magnesium Oxide					
			(Magnesium Oxide)	C				

Date:04/07/00ISR Number: 3485234-5Report Type:Direct Company Report #
Age:69 YR Gender:Male I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Coordination Abnormal
	Drug Toxicity
	Dysarthria

	Fall Tremor						
		Report Source	Product	Role	Manufacturer	Route	Dose Duration
			Lithium Carbonate 300mg Cap	PS			600MG BID

Date:04/07/00ISR Number: 3485273-4Report Type:Expedited (15-DaCompany Report #00P-163-0087101-00 (2)
Age:32 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Abnormal Behaviour Akathisia	Health Professional	Gabitril (Gabitril) (Tiagabine Hcl)	PS		ORAL	24 MG, 1 IN 1 D, PER ORAL
	Amnesia Anxiety Communication Disorder		Lithium Carbonate (Lithium Carbonate)	SS		ORAL	1050 MG, 1 IN 1 D, PER ORAL
	Drug Interaction Dyspnoea		Seroquel (Seroquel)	SS		ORAL	PER ORAL
	Electroencephalogram Abnormal Fear Mental Disorder Movement Disorder Muscle Twitching Serotonin Syndrome Upper Respiratory Tract Infection		Mtv (Vitamins Nos) Calcium (Calcium) Pyridoxine Hydrochloride (Pyridoxine Hydrochloride) Progesterone (Progesterone) Primidone (Primidone)	C C C C			

Date:04/07/00ISR Number: 3485764-6Report Type:Expedited (15-DaCompany Report #00F--10078
Age:77 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Coma Dehydration	Foreign Health	Anafranil Tablet (Clomipramine				

	Drug Interaction	Professional	Hydrochloride)	PS			ORAL
DAILY, ORAL							
	Dysphagia	Other	Modopar Capsule				
	Life Support		(Madopar)	SS			ORAL
3 DF, DAILY,							
	Motor Dysfunction						
ORAL	9 MON						
	Neuropathy Peripheral		Teralithe Slow				
	Pyrexia		Release Tablet				
	Quadriplegia		(Lithium Carbonate)	SS			ORAL
800 MG,							
	Rhabdomyolysis						
DAILY, ORAL							
	Shock		Deprenyl Tablet				
			(Selegiline)	SS			ORAL
10 MG, DAILY,							
ORAL							
			Lysanxia Tablet	C			

Date:04/10/00ISR Number: 3485335-1Report Type:Direct Company Report #
Age:74 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Bradyphrenia		Lithium Carbonate			
Initial or Prolonged	Coordination Abnormal		300mg	PS		
300 MG BID;						
	Drug Interaction					
YEARS						
	Drug Level Above		Lotrel (Ciba-Geigy)	SS	Ciba-Geigy	
1 WK						
	Therapeutic					
	Speech Disorder					

Date:04/11/00ISR Number: 3488128-4Report Type:Expedited (15-DaCompany Report #2000009165-1
Age:61 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Creatine Phosphokinase Increased	Health Professional	Lithium Smithkline Beecham	PS	Smithkline Beecham		900 MILLIGRAM	
	Blood Creatine Phosphokinase Mb Increased							
	Chromaturia							
	Coma							
	Diarrhoea							
	Drooling							
	Drug Level Above Therapeutic							
	Drug Toxicity							
	Dysarthria							
	Dysphagia							
	Gait Disturbance							
	Hyperphosphataemia							
	Hypocalcaemia							
	Hyporeflexia							
	Hypotonia							
	Liver Function Test Abnormal							
	Malaise							
	Motor Dysfunction							
	Muscle Necrosis							
	Myoglobinuria							
	Nephrogenic Diabetes Insipidus							
	Neuropathy Peripheral							
	Pyrexia							
	Renal Impairment							
	Rhabdomyolysis							
	Sensory Loss							
	Tremor							
	Vomiting							

Date:04/11/00ISR Number: 3488131-4Report Type:Expedited (15-DaCompany Report #2000009214-1
Age:76 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Aspiration Cough Dysphagia Dysphonia Dyspnoea Hyporeflexia Nasopharyngeal Disorder Oesophageal Stenosis Parkinsonism Productive Cough Weight Decreased	Health Professional	Lithium Smithkline Beecham Haloperidol Sertraline Temazepam	PS C C C	Smithkline Beecham			

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/14/00ISR Number: 3488273-3Report Type:Direct Company Report #
Age:66 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Arrhythmia Coma Dialysis Therapeutic Agent Toxicity	Health Professional	Lithium Carbonate	PS		ORAL	600 MG PO BID	

Date:04/18/00ISR Number: 3489429-6Report Type:Expedited (15-DaCompany Report #S00-FRA-00500-01
Age:51 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hypercalcaemia Hyperparathyroidism	Foreign Health Professional Other	Seropram (Citalopram Hydrobromide) Hygroton (Chlortalidone) Tenormine (Atenolol) Teralithe (Lithium Carbonate) Tercian (Cyamemazine)	PS SS SS SS C		ORAL	40 MG QD PO 50 MG QD 1200 MG QD 25 MG QD	

Date:04/18/00ISR Number: 3489558-7Report Type:Expedited (15-DaCompany Report #2000010163-1
Age:66 YR Gender:Male I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Aggression Agitation Blood Creatinine Increased Blood Urea Increased Coma Confusional State Drug Level Above

Therapeutic
Dysphagia
Haematocrit Decreased
Haemoglobin Decreased
Hyperglycaemia
Hypoglycaemia
Hyponatraemia
Hypotension
Jaundice
Movement Disorder
Oliguria
Oxygen Saturation Decreased
Pco2 Decreased
Pneumonia
Productive Cough
Pyrexia
Respiratory Rate Increased
Restlessness
Retching
Skin Discolouration
Speech Disorder
Sputum Abnormal

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Therapeutic Agent Toxicity Tremor	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Urinary Incontinence	Consumer	Eskalith	PS	Smithkline Beecham	ORAL	ORAL
	Health Professional					

Date:04/19/00ISR Number: 3489680-5Report 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	Dermatitis		Lithium Co3 300 Mg	PS		ORAL	300 MG TID ORAL
			Penicillin Vk 500 Mg	SS		ORAL	500 MG QID ORAL
			Lisinopril	C			
			Fluoxetine	C			
			Insulin	C			

Date:04/19/00ISR Number: 3490211-4Report Type:Expedited (15-DaCompany Report #00P-163-0087101-00 (3)
Age:32 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Abnormal Behaviour Akathisia Amnesia Anxiety Communication Disorder Crying Drug Interaction	Health Professional	Gabitril (Gabitril) (Tiagabine Hcl)	PS		ORAL	24 MG, 1 IN 1 D, PER ORAL
			Lithium Carbonate (Lithium Carbonate)	SS		ORAL	1050 MG, 1 IN 1 D, PER ORAL
			Seroquel (Seroquel)	SS		ORAL	PER ORAL

	Dyspnoea	Mtv (Vitamins Nos)	C
	Electroencephalogram	Calcium (Calcium)	C
	Abnormal	Pyridoxine Hydrochloride (Pyridoxine)	C
	Fear	Progesterone (Progesterone)	C
	Mental Impairment	Primidone (Primidone)	C
	Movement Disorder		
	Muscle Twitching		
	Restlessness		
	Tremor		
	Upper Respiratory Tract Infection		

Date:04/21/00ISR Number: 3490998-0Report Type:Expedited (15-DaCompany Report #USA/00/00358/LEX
Age:31 YR Gender:Male I/FU:F

Outcome	PT
Life-Threatening	Blood Iron Decreased
Hospitalization - Initial or Prolonged	Bronchitis
	Dehydration
	Drug Toxicity
	Eosinophil Count Increased
	Eosinophilia
	Gait Disturbance
	Hypersensitivity
	Iron Metabolism Disorder
	Leukocytosis
	Myalgia

	Nausea					
	Nephritis Interstitial					
	Neuroleptic Malignant	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
	Syndrome	Health	Clozaril (Clozapine)	PS		ORAL
200 MG,						
	Pyrexia	Professional				
UNKNOWN; ORAL						
	Renal Failure Acute		Lithobid (Lithium			
	Vomiting		Carbonate)	SS		
600 MG,						
UNKNOWN						
			Depakote	C		
			Ativan	C		
			Prolixin	C		

Date:05/01/00ISR Number: 3494762-8Report Type:Expedited (15-DaCompany Report #A013620
Age:30 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Blood Osmolarity	Literature	Lithane Tablets	PS		ORAL
ORAL						
Initial or Prolonged	Increased	Health	Oral Contraceptive	SS		ORAL
ORAL						
Required	Blood Sodium Increased	Professional	Risperidone	C		
Intervention to	Brain Scan Abnormal					
Prevent Permanent	Confusional State					
Impairment/Damage	Dehydration					
	Headache					
	Hemiparesis					
	Nephrogenic Diabetes					
	Insipidus					
	Papilloedema					
	Platelet Count Decreased					
	Polyuria					
	Superior Sagittal Sinus					
	Thrombosis					
	Thrombosis					
	Urine Osmolarity					
	Decreased					
	Urine Sodium Decreased					
	Vision Blurred					

Date:05/01/00ISR Number: 3495052-XReport Type:Expedited (15-DaCompany Report #JRFBEL2000001142
Age:27 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Disability Required Intervention to Prevent Permanent Impairment/Damage	Cerebellar Atrophy Computerised Tomogram Abnormal Convulsion Coordination Abnormal Depressed Level Of Consciousness Drug Interaction Electroencephalogram Abnormal Extensor Plantar Response Gait Disturbance Muscle Rigidity Nystagmus Speech Disorder	Literature Health Professional	Haldol (Unspecified) (Haloperidol) Lithium Carbonate (Lithium Carbonate) Diazepam (Diazepam)	PS SS SS				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/02/00ISR Number: 3495005-1Report Type:Direct Company Report #
Age:44 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Delirium Feeling Jittery Mental Impairment Speech Disorder	Health Professional	Lithium	PS			600 MG TID	

Date:05/03/00ISR Number: 3496475-5Report Type:Expedited (15-DaCompany Report #JRFBEL2000001143
Age:32 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Aggression Apathy	Foreign Literature	Haloperidol (Tablet) (Haloperidol)	PS			MG, DAILY	
	Brain Neoplasm Cerebellar Syndrome	Health Professional	Lithium Carbonate (Lithium Carbonate)	SS			MG, DAILY	3 YR
	Coordination Abnormal Cough Diarrhoea Difficulty In Walking Drug Toxicity Dysarthria Intention Tremor Irritability Memory Impairment Osteosarcoma Localised Pyrexia Q Fever Speech Disorder Stupor		Levomepromazin (Levomepromazine)	C				

Date:05/05/00ISR Number: 3497218-1Report Type:Expedited (15-DaCompany Report #00P-163-0089497-00 (0)
Age:13 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required	Autonomic Nervous System	Health	Depakote (Depakote)					

Intervention to Prevent Permanent Impairment/Damage (SEE IMAGE)	Imbalance Blood Creatine Phosphokinase Increased Conjunctivitis Dehydration Diabetes Mellitus Drug Level Above Therapeutic Drug Toxicity Enuresis Feeling Abnormal Hypertension Lethargy Leukopenia Mental Impairment Muscle Rigidity Neuroleptic Malignant Syndrome Neutropenia Pyrexia Tachycardia Tremor	Professional Other	(Divalproex Sodium) Risperidone (Risperidone) Seroquel (Seroquel) Loxapine Succinate (Loxapine Succinate) Lithium (Lithium) Polycarbophil Calcium (Polycarbophil Calcium) Levothyroxine Sodium (Levothyroxine	PS SS SS SS C	ORAL ORAL ORAL ORAL
1500 MG, 1 IN 1 D, PER ORAL (SEE IMAGE) 1 MG, 2 IN 1 D, PER ORAL (SEE IMAGE) 600 MG, 1 IN 1 D, PER ORAL (SEE IMAGE) 10 MG, 1 IN 1 D, PER ORAL (SEE IMAGE) 300 MG, 2 IN 1 D, PER ORAL (SEE IMAGE)					

Sodium)	C
Trazodone (Trazodone)	C
Benzatropine Mesilate (Benzatropine Mesilate)	C
Docusate Sodium (Docusate Sodium)	C
Desmopressin (Desmopressin)	C
Sertraline Hydrochloride (Sertraline Hydrochloride)	C
Tilactase (Tilactase)	C
Erythromycin (Erythromycin) (Erythromycin)	C
Ammonium Lactate (Ammonium Lactate)	C

Date:05/08/00ISR Number: 3497807-4Report Type:Expedited (15-DaCompany Report #JRFBEL2000001143
Age:32 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abnormal Behaviour Aggression Apathy Cerebellar Syndrome	Foreign Literature Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute Div Ortho Pharm		MG, DAILY	
	Coordination Abnormal Cough		Lithium Carbonate (Lithium Carbonate)	SS			MG, DAILY	3 YR
	Depression Diarrhoea Difficulty In Walking Drug Level Above Therapeutic Drug Toxicity Dysarthria Intention Tremor Irritability Mental Disorder Due To A		Levomepromazin (Levomepromazine)	C				

General Medical Condition
Pyrexia
Q Fever
Stupor

Date:05/10/00ISR Number: 3500120-XReport Type:Periodic Company Report #17812-058
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Insomnia	Consumer	Lithium Carbonate	PS	Roxane Laboratories, Inc.	ORAL	1500MG/DAY PO	
			Clonazepam	C				
			Synthroid	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/10/00ISR Number: 3500122-3Report Type:Periodic Company Report #17812-059
Age:35 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Alopecia Weight Increased	Health Professional	Lithium Carbonate	PS	Roxane Laboratories, Inc.	ORAL	600 MG BID PO	
			Depakote (Divalproex Sodium)-Abbott	SS	Abbott	ORAL	500 MG TID PO	
			Synthroid	C				

Date:05/10/00ISR Number: 3500123-5Report Type:Periodic Company Report #18912-060
Age:58 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hyperglycaemia	Health Professional	Lithium Carbonate	PS	Roxane Laboratories, Inc.	ORAL	1200MG TO 1350MG QHS PO	
			Clorazepate	C				
			Cytomel	C				
			Seroquel	C				

Date:05/10/00ISR Number: 3500125-9Report Type:Periodic Company Report #17812-061
Age:40 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Diabetes Mellitus	Health Professional	Lithium Carbonate	PS	Roxane Laboratories, Inc.	ORAL	600MG AM, 900 MG PM PO	
			Doxepin	C				
			Valproic Acid	C				
			Levotyroxine	C				
			Fluazepam	C				
			Diazepam	C				
			Risperidal	C				

Date:05/10/00ISR Number: 3500128-4Report Type:Periodic Company Report #17812-062
Age:41 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Diabetes Mellitus	Health Professional	Lithium Carbonate	PS	Roxane Laboratories, Inc.	ORAL	900MG HS PO	

Date:05/10/00ISR Number: 3500135-1Report Type:Periodic Company Report #17812-063
Age:26 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Ineffective	Consumer	Lithium Carbonate	PS	Roxane Laboratories, Inc.	ORAL	300MG TID PO	3 YR

Date:05/10/00ISR Number: 3500138-7Report Type:Periodic Company Report #17812-064
Age:23 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Ineffective	Consumer	Lithium Carbonate	PS	Roxane Laboratories, Inc.	ORAL	900MG QAM,	
							600MG QHS PO	
			Seroquel Tablets	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/10/00ISR Number: 3500140-5Report Type:Periodic Company Report #17812-065
Age:23 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Ineffective	Consumer	Lithium Carbonate	PS	Roxane Laboratories Inc	ORAL	600MG BID PO	
			Zoloft	C				
			Seroquel	C				

Date:05/10/00ISR Number: 3500142-9Report Type:Periodic Company Report #17812-066
Age:59 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Pain	Consumer	Lithium Carbonate	PS	Roxane Laboratories Inc	ORAL	300MG BID PO	2 YR
	Psoriasis	Other						

Date:05/10/00ISR Number: 3500151-XReport Type:Periodic Company Report #17812-067
Age:63 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Psoriasis	Consumer	Lithium Carbonate	PS	Roxane Laboratories Inc	ORAL	300MG BID PO	
			Albuterol	C				
			Serevent	C				
			Pulmicort Turbuhaler Inhalation Powder	C				

Date:05/10/00ISR Number: 3500154-5Report Type:Periodic Company Report #17812-068
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Renal Impairment	Consumer	Lithium Carbonate	PS	Roxane Laboratories Inc	ORAL	300MG HS PO	

Other			Prazosin	C		
			Lisinopril	C		
			Butabital	C		
			Beconase Inhaler	C		

Date:05/10/00ISR Number: 3500157-0Report Type:Periodic Company Report #17812-069
Age:40 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dermatitis	Consumer	Lithium Carbonate	PS	Roxane Laboratories Inc	ORAL	700MG HS PO ALTERNATING WITH 350MG HS PO	11 YR
			Prozac	C				

Date:05/10/00ISR Number: 3500160-0Report Type:Periodic Company Report #17812-070
Age:19 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Convulsion	Consumer	Lithium Carbonate	PS	Roxane Laboratories Inc	ORAL	900 MG/DAY; 1200 MG/DAY (ALTERNATING	

DAYS) PO

Date:05/10/00ISR Number: 3500162-4Report Type:Periodic Company Report #17812-071
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Abdominal Pain	Consumer	Lithium Carbonate	PS	Roxane Laboratories Inc	ORAL	900MG PO HS	2 YR
			Buspar	C				
			Cytomel	C				

Date:05/10/00ISR Number: 3500165-XReport Type:Periodic Company Report #17812-072
Age:43 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Flatulence Oedema	Consumer	Lithium Carbonate	PS	Roxane Laboratories Inc	ORAL	600MG BID PO	20 YR
			Synthroid	C				

Date:05/10/00ISR Number: 3500167-3Report Type:Periodic Company Report #17812-074
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Headache	Consumer	Lithium Carbonate	PS	Roxane Laboratories Inc	ORAL	600 MG BID PO	
			Lithium Carbonate Tablets Usp, 300 Mg Roxane Laboratories, Inc.	SS	Roxane Laboratories	ORAL	600 MG BID PO	
			Trilafon	C				
			Benadryl	C				

Date:05/10/00ISR Number: 3500168-5Report Type:Periodic Company Report #17812-075
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Insomnia	Consumer	Lithium Carbonate	PS	Roxane Laboratories Inc	ORAL	INITIAL: 300 MG BID PO / CURRENT: 600 MG HS PO	
			Ambien (Zolpidem Tartrate)	C				
			Klonopin (Clonazepam)	C				

Date:05/10/00ISR Number: 3500171-5Report Type:Periodic Company Report #17812-076
Age:57 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Vasodilatation	Consumer	Lithium Carbonate	PS	Roxane Laboratories Inc	ORAL	300MG TID, PO	
			Xanax	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/10/00ISR Number: 3500176-4Report Type:Periodic Company Report #17812-077
Age:51 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Pathological Fracture	Consumer	Lithium Carbonate	PS	Roxane Laboratories Inc	ORAL	300 MG QID PO	
			Tylenol Extra Strength	C				
			Tylenol With Codeine #3	C				
			Voltaren Or Oruvail	C				
			Furosemide	C				
			Univasc	C				
			Zoloft	C				
			Trazodone	C				

Date:05/10/00ISR Number: 3500179-XReport Type:Periodic Company Report #17812-079
Age:57 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Amblyopia	Consumer	Lithium Carbonate	PS	Roxane Laboratories Inc	ORAL	300MG TID PO	
			1/2 Aspirin	C				
			Accupril	C				
			Tums	C				

Date:05/10/00ISR Number: 3500181-8Report Type:Periodic Company Report #17812-080
Age:35 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dizziness	Consumer	Lithium Carbonate	PS	Roxane Laboratories Inc	ORAL	300 MG SIX TIMES/DAY PO	2 MON

Date:05/10/00ISR Number: 3500185-5Report Type:Periodic Company Report #17812-081
Age:49 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Overdose	Health Professional	Lithium Carbonate	PS	Roxane Laboratories Inc	ORAL	2 CAPS, BID & 1 CAP QD, PO	
			Albuterol	C				
			Amlodipine	C				
			Carbamazepine	C				
			Imipramine	C				
			Ipatrophium	C				

Date:05/10/00ISR Number: 3500192-2Report Type:Periodic Company Report #17812-082
Age:69 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Asthenia Dyspepsia	Consumer	Lithium Carbonate	PS	Roxane Laboratories Inc	ORAL	150MG TID PO	
			Diazepam	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/11/00ISR Number: 3499604-2Report Type:Expedited (15-DaCompany Report #2000007399-1
Age:71 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Constipation	Consumer	Paxil	PS	Smithkline Beecham			
Hospitalization -	Drug Ineffective				Pharmaceuticals	ORAL		
Initial or Prolonged	Dry Mouth		Eskalith (Lithium					
	Hyperglycaemia		Carbonate)					
	Insomnia		Smithkline Beecham	SS	Smithkline Beecham			
	Intentional Misuse		Imipramine	C				
	Suicidal Ideation		Amoxapine	C				
	Suicide Attempt		Elavil					
	Tremor		(Amitriptyline Hcl)	C				
			Desipramine	C				

Date:05/12/00ISR Number: 3500077-1Report Type:Expedited (15-DaCompany Report #00P-167-0089617-00 (0)
Age:30 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required	Drug Level Changed	Foreign	Depakene	PS	Abbott Laboratories			
Intervention to		Health			Pharmaceutical			
Prevent Permanent		Professional			Products Div	ORAL	500 MG, 1 IN	
Impairment/Damage							1 D, PER ORAL	
			Lithium Carbonate					
			(Lithium Carbonate)	SS		ORAL	750 MG, 1 IN	
							1 D, PER	
							ORAL; 650 MG,	
							I IN I D, PER	
							ORAL	
			Doxazosin	C				
			Atenolol	C				
			Lisniopril	C				

Date:05/12/00ISR Number: 3500084-9Report Type:Expedited (15-DaCompany Report #2000011924-1
Age:41 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Affect Lability	Literature Health	Eskalith	PS	Smithkline Beecham Pharmaceuticals		1.0 DAILY	
Other	Agitation	Professional	Perphenazine	C				
	Anxiety		Temazepam	C				
	Excitability		Lorazepam	C				
	Grandiosity		Nifedipine	C				
	Mania							
	Nephritis Interstitial							
	Pressure Of Speech							
	Renal Impairment							
	Sleep Disorder							
	Suspiciousness							
	Tension							
	Thinking Abnormal							

Date:05/15/00ISR Number: 3499835-1Report Type:Direct Company Report #
Age: Gender:Male I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Coordination Abnormal
	Decreased Appetite
	Dysarthria

	Polydipsia Polyuria Tremor	Report Source	Product	Role	Manufacturer	Route Dose Duration
			Lithium	PS		ORAL 600MG PO BID; PRIOR TO ADMISSION
			Acebutolol	C		
			Aciphex	C		
			Ditropan Xl	C		

Date:05/15/00ISR Number: 3500695-0Report Type:Expedited (15-DaCompany Report #NL/00/01008/LEX
Age:36 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Death Hospitalization - Initial or Prolonged	Complications Of Maternal Exposure To Therapeutic Drugs	Foreign Health Professional	Clozaril	PS	Novartis Pharmaceuticals Corp	ORAL 25 MG, ONCE A DAY, ORAL; 8 WK
	Foetal Disorder Hepatic Haemorrhage	Other	Lithii Carbonas (Lithium Carbonate)	SS		400 MG, ONCE A DAY,
	Hepatic Steatosis Intra-Uterine Death					

Date:05/15/00ISR Number: 3501276-5Report Type:Expedited (15-DaCompany Report #10379097
Age:57 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Hospitalization - Initial or Prolonged	Confusional State Disorientation	Foreign Health	Fluphenazine Hcl	PS	Apothecon Inc Div Bristol Myers Squibb	INTRAMUSCULAR 50 MILLIGRAM, 1/3 WEEK IM
	Drug Level Above Therapeutic	Professional Other	Teralithe (Lithium			

	Fall	Carbonate)	SS	ORAL

500

MILLIGRAM,

1/1 DAY ORAL

	Tegretol (Carbamazepine)	SS	ORAL

400

MILLIGRAM,

1/1 DAY ORAL

	Akineton (Biperiden Lactate)	SS	ORAL

8 MILLIGRAM,

1/1 DAY ORAL

	Diosmil (Diosmin)	SS	ORAL

600

MILLIGRAM,

1/1 DAY ORAL

Date:05/16/00ISR Number: 3500817-1Report Type:Direct Company Report #
Age:66 YR Gender:Female I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Blood Ph Decreased
Required Intervention to Prevent Permanent Impairment/Damage	Chest Pain
	Dialysis
	Drug Level Above Therapeutic
	Dyspnoea
	Encephalopathy
	Feeling Jittery
	Malaise
	Mental Impairment

Pco2 Increased
Urinary Incontinence

Dose	Duration	Report Source	Product	Role	Manufacturer	Route
40 MG BID PO		Health Professional	Eskalith	PS		ORAL

Date:05/16/00ISR Number: 3504279-XReport Type:Periodic Company Report #18421-004
Age:39 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Other	Dermatitis	Health Professional	Lithium Citrate	PS	Roxane Laboratories Inc	
300MG TID						
			Benadryl-Prn	C		

Date:05/16/00ISR Number: 3504280-6Report Type:Periodic Company Report #18421-005
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Other	Drug Ineffective	Consumer	Lithium Citrate	PS	Roxane Laboratories Inc	ORAL
3/4 TSP TID PO ALTERNATING WITH 1/2 TSP						
TID PO	1 YR					
			Buspar	C		
			Benedryl	C		

Date:05/16/00ISR Number: 3504281-8Report Type:Periodic Company Report #18421-007
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Malaise Medication Error	Health Professional	Lithium Citrate	PS	Roxane Laboratories Inc	ORAL	TWO DOSES, PO	Other

Date:05/18/00ISR Number: 3501465-XReport Type:Expedited (15-DaCompany Report #A015018
Age:43 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Interaction Mania	Foreign Health Professional	Viagra Lithium	PS SS	Pfizer Agricultural Div	ORAL ORAL	ORAL	

Date:05/18/00ISR Number: 3502207-4Report Type:Expedited (15-DaCompany Report #00P-056-0089833-00(0)
Age:58 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anorexia Apathy Blood Thyroid Stimulating Hormone Increased Depressed Mood	Foreign Health Professional	Tranxene (Tranxene) (Clorazepate Dipotassium)	PS	Abbott Laboratories Pharmaceutical Products Div	ORAL	PER ORAL	
	Thyroid Neoplasm Thyroiditis Chronic Thyroxine Decreased		Amitriptyline Hydrochloride (Amitriptyline Hydrochloride)	SS		ORAL	PER ORAL	

			Zolpidem (Zolpidem)	SS		ORAL	PER ORAL
			Lithium Carbonate (Lithium Carbonate)	SS		ORAL	500 MG, 1 IN 1 D, PER ORAL

Date:05/19/00ISR Number: 3503630-4Report Type:Expedited (15-DaCompany Report #2000013810-1
Age:43 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Drug Interaction Mania		Eskalith Cr	PS	Smithkline Beecham Pharmaceuticals	ORAL	ORAL
Other			Viagra (Sildenafil)	C			

Date:05/22/00ISR Number: 3503090-3Report Type:Expedited (15-DaCompany Report #2000014038-1
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Drug Toxicity Metabolic Encephalopathy Renal Impairment	Consumer	Eskalith	PS	Smithkline Beecham Pharmaceuticals		

Date:05/22/00ISR Number: 3503149-0Report Type:Expedited (15-DaCompany Report #00P-163-0087101-00 (4)
Age:32 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Abnormal Behaviour Akathisia Amnesia Anxiety Communication Disorder Crying	Health Professional	Gabitril	PS	Abbott Laboratories Pharmaceutical Products Div	ORAL	24MG, 1 IN 1 D, PER ORAL
			Lithium Carbonate (Lithium Carbonate)	SS		ORAL	1050 MG, 1 IN

	Drug Interaction					
1 D, PER ORAL						
	Dyskinesia		Seroquel (Seroquel)	SS		ORAL
PER ORAL						
	Fear		Mtv	C		
	Mental Impairment		Calcium	C		
	Movement Disorder		Pyridoxine			
	Muscle Twitching		Hydrochloride	C		
	Tremor		Progesterone	C		
	Upper Respiratory Tract		Primidone	C		
	Infection					

Date:05/23/00ISR Number: 3503976-XReport Type:Periodic Company Report #9917108
Age:50 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Depression	Health	Lithium Carbonate	PS	Pfizer Inc	ORAL
ORAL						
	Drug Interaction	Professional	Zoloft	SS		ORAL
ORAL						
			Digoxin	C		
			Diltiazem			
			Hydrochloride	C		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/23/00ISR Number: 3503979-5Report Type:Periodic Company Report #9911960
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hypothyroidism	Health	Lithium Carbonate	PS	Pfizer Inc	UNKNOWN		
		Professional	Synthroid	C				
			Midrin	C				
			Amantadine	C				
			Potassium Chloride	C				
			Risperidol	C				
			Carbidopa/Levodopa	C				
			Permax	C				
			Captopril	C				

Date:05/25/00ISR Number: 3505013-XReport Type:Expedited (15-DaCompany Report #B0081779A
Age:29 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Abortion	Foreign	Lamictal	PS	Glaxo Wellcome Inc			
			Lithium Salt (Formulation Unknown) (Lithium Salt)	SS				

Date:05/25/00ISR Number: 3506305-0Report Type:Expedited (15-DaCompany Report #2000008954-1
Age:23 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Suicide Attempt	Foreign	Eskalith	PS	Smithkline Beecham Pharmaceuticals		1350	MILLIGRAMS
		Health					DAILY	
		Professional						
		Other						
			Efexor Xr (Venlafaxine)	C				
			Staphylex (Flucloxacillin)	C				

Date:05/26/00ISR Number: 3505335-2Report Type:Expedited (15-DaCompany Report #FLUV00300002750
Age:26 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Interaction Fatigue Myalgia Pyrexia	Foreign Health Professional Other	Luvox	PS	Solvay Pharmaceuticals	ORAL	DAILY PO, 150 MG DAILY PO	
			Hirnamin (Levomepromazine)	SS		ORAL	50 MG DAILY PO	
			Lexotan (Bromazepam)	SS		ORAL	4 MG DAILY PO	
			Solanax (Alprazolam)	SS		ORAL	1.2 MG DAILY PO	
			Lendormin (Brotizolam)	SS		ORAL	0.25 MG DAILY PO	
			Rohypnol (Flunitrazepam)	SS		ORAL	2 MG DAILY PO	
			Pyrethia (Promethazine Hydrochloride)	SS		ORAL	50 MG DAILY PO	

			Lithium Carbonate (Lithium Carbonate)	SS		ORAL

200 MG DAILY

PO

Date:05/26/00ISR Number: 3505613-7Report Type:Periodic Company Report #18558-012
Age:62 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Sedation	Consumer	Lithium Carbonate	PS	Roxane Laboratories Inc	ORAL

300MG BID PO/

MORE THAN 2

YEARS

Date:05/26/00ISR Number: 3505616-2Report Type:Periodic Company Report #18558-013
Age:40 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Dystonia Myasthenic Syndrome	Consumer	Lithium Carbonate	PS	Roxane Laboratories Inc	ORAL

300 MG TID

PO/

APPROXIMATELY

6 TO 7 YEARS

Date:05/26/00ISR Number: 3505620-4Report Type:Periodic Company Report #18558-014
Age:45 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Keratoconjunctivitis	Consumer	Lithium Carbonate	PS	Roxane Laboratories	

	Sicca					Inc
300MG Q 4 HRS						
			Moban	C		
			Prozac	C		
			Ambien	C		

Date:05/26/00ISR Number: 3505632-0Report Type:Periodic Company Report #18558-015
Age:51 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Weight Increased	Consumer	Lithium Carbonate	PS	Roxane Laboratories Inc	
1 MON						
			Seroquel Tablets	SS	Zeneca Laboratories	
			Diazepam Tablets	C		

Date:05/26/00ISR Number: 3505633-2Report Type:Periodic Company Report #18558-016
Age:46 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Drug Interaction	Consumer	Lithium Carbonate	PS	Roxane Laboratories Inc	ORAL
	Oedema					
300MG PO ONCE						
A DAY 17 YR						
			Ceclor (Cefaclor) Eli Lilly & Co.	SS	Eli Lilly & Co.	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/26/00ISR Number: 3505634-4Report Type:Periodic Company Report #18558-017
Age:22 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Accidental Overdose Agitation	Consumer	Lithium Carbonate	PS	Roxane Laboratories Inc		300 MG TID OR 900 MG ONCE A DAY;***MAY HAVE HAD 1800MG ONCE	

Date:05/26/00ISR Number: 3505635-6Report Type:Periodic Company Report #18558-019
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Asthenia Diarrhoea Nausea Vomiting	Consumer	Lithium Carbonate Biaxin	PS C	Roxane Laboratories Inc	ORAL	300 TO 900MG DAILY, PO	

Date:05/26/00ISR Number: 3505642-3Report Type:Periodic Company Report #18558-020
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Alopecia Nausea	Consumer	Lithium Carbonate	PS	Roxane Laboratories Inc	ORAL	450MG DAILY PO X 1 WEEK THEN 45MG BID PO	

Sertraline Hcl	C
Alprazolam (Xanax)	C
Spironolactone	C
Oxycodone 5mg/Acetaminophen (Roxicet)	C
Ibuprofen Otc	C

Date:05/30/00ISR Number: 3505753-2Report Type:Direct Company Report #
Age:49 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Toxicity Vomiting		Lithium 450mg	PS		ORAL	450MG Q8H	ORAL

Date:05/30/00ISR Number: 3506850-8Report Type:Periodic Company Report #1999-08-0894
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Renal Impairment Skin Discolouration	Consumer	Trilafon	PS	Schering Corp Sub Schering Plough Corp	ORAL	UNKNOWN ORAL	10 YR
	Weight Increased		Lithium	SS		ORAL	UNKNWN ORAL	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/02/00ISR Number: 3507437-3Report Type:Direct Company Report #
Age:56 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Acidosis		Lithium	PS				
Hospitalization - Initial or Prolonged	Blood Bicarbonate Increased							
Required Intervention to Prevent Permanent Impairment/Damage	Clonic Convulsion							
	Confusional State							
	Convulsion							
	Drug Level Above Therapeutic							
	Dyspnoea							
	Oxygen Saturation Decreased							
	Respiratory Failure							

Date:06/02/00ISR Number: 3507608-6Report Type:Expedited (15-DaCompany Report #A015018
Age:43 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Condition Aggravated	Foreign	Viagra	PS	Pfizer Agricultural Div	ORAL	ORAL	
	Depression	Health						
	Drug Interaction	Professional	Lithium	SS		ORAL	ORAL	
	Mania		Dothiepin	C				
			Flupentixol	C				

Date:06/02/00ISR Number: 3507842-5Report Type:Expedited (15-DaCompany Report #JRFBEL2000001423
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agitation	Literature	Risperdal	PS	Janssen Research Fdn Div Johnson And Johnson	ORAL	MG, DAILY,	
	Akathisia	Health						
	Anxiety	Professional						
	Bradykinesia						ORAL	
	Catatonia		Lithium Carbonate					

	Cognitive Disorder	(Lithium Carbonate)	SS
MG, DIALY			
	Constipation	Paroxetine	
	Depression	(Paroxetine)	SS
MG, DAILY			
	Drug Interaction	Olanzapine	
	Dry Mouth	(Olanzapine)	SS
MG, DAILY			
	Fatigue	Benztropine	
	Insomnia	(Benztropine)	SS
MG, DAILY			
	Irritability	Nortriptyline	SS
MG, DAILY			
	Mania		
	Muscle Rigidity		
	Parkinsonism		
	Pressure Of Speech		
	Pyrexia		
	Thinking Abnormal		
	Tremor		
	Vision Blurred		

Date:06/02/00ISR Number: 3508206-0Report Type:Expedited (15-DaCompany Report #2000015366-1
Age:52 YR Gender:Female I/FU:I

Outcome
Hospitalization -
Initial or Prolonged

Other Required Intervention to	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Prevent Permanent Impairment/Damage	Arthralgia	Consumer	Eskalith Cr	PS	Smithkline Beecham Pharmaceuticals	ORAL	ORAL	10 YR
	Balance Disorder							
	Bipolar Disorder		Depakote (Valproate Semisodium)	C				
	Cerebellar Syndrome							
	Choking							
	Coma							
	Communication Disorder							
	Coordination Abnormal							
	Decreased Activity							
	Depressed Level Of Consciousness							
	Depression							
	Dialysis							
	Difficulty In Walking							
	Drug Level Above Therapeutic							
	Drug Toxicity							
	Dysarthria							
	Dysphagia							
	Encephalopathy							
	Faecal Incontinence							
	Fall							
	Hyporeflexia							
	Movement Disorder							
	Muscular Weakness							
	Nervous System Disorder							
	Paranoia							
	Renal Failure Acute							
	Renal Impairment							
	Rhinorrhoea							
	Speech Disorder							
	Suicide Attempt							
	Urinary Incontinence							
	Vitamin B12 Deficiency							

Date:06/02/00ISR Number: 3566197-0Report Type:Periodic Company Report #10291482
Age: Gender:Not SpecifiI/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

	Drug Interaction Drug Toxicity	Health Professional	Avapro	PS	Sanofi Synthelabo Inc

150

MILLIGRAM,

1/1 DAY

		Lithium (Lithium Salts)	SS

600

MILLIGRAM, 1

DAY

Date:06/05/00ISR Number: 3508445-9Report Type:Expedited (15-DaCompany Report #WAES 00031459
Age: Gender:Female I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Disorientation Drug Interaction Drug Level Above Therapeutic

Dysarthria Therapeutic Agent Toxicity	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Urinary Incontinence	Consumer Health Professional	Vioxx	PS	Merck Research Laboratories Div Merck Co Inc	ORAL	25 MG/DAILY/PO
		Lithiumco3	SS		ORAL	PO
		Oxybutynin Chloride	C			

Date:06/05/00ISR Number: 3508772-5Report Type:Expedited (15-DaCompany Report #AUS/00/00230/LEX
Age:47 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Hospitalization - Initial or Prolonged	Cardiomyopathy Laboratory Test Abnormal	Foreign Health Professional	Clozaril	PS	Novartis Pharmaceuticals Corp	ORAL 950 MG, ORAL
			Clonazepam	SS		2 MG, TWICE A DAY
			Lithium	SS		500 MG, ONCE A DAY, 750 MG, ONCE A DAY
			Sodium Valproate	C		
			Benztropine	C		
			Amlodipine	C		

Date:06/06/00ISR Number: 3508774-9Report Type:Direct Company Report #
Age:51 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration

Life-Threatening	Amnesia		Neurotin	PS		
SEE IMAGE						
	Cognitive Disorder		Klonapin	SS		
SEE IMAGE						
	Road Traffic Accident		Lamictal	SS		
SEE IMAGE						
	Speech Disorder		Lithium	SS		
SEE IMAGE						
	Visual Acuity Reduced					

Date:06/06/00ISR Number: 3566307-5Report Type:Periodic Company Report #HQ5466305MAY2000
Age: Gender:Not SpecifiI/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Interaction	Health Professional	Sonata	PS	Wyeth Ayerst Laboratories Inc	ORAL	ORAL	
	Hallucination							
		Company Representative	Lithium	SS				

Date:06/08/00ISR Number: 3509814-3Report Type:Direct Company Report #
Age:41 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Blood Creatine		Clozaril 500mg Qhs					
Hospitalization -	Phosphokinase Increased		Po	PS		ORAL		
500MG QHS PO								
Initial or Prolonged	Circulatory Collapse		Lithium 600mg Bid Po	SS		ORAL		
600MG BID PO								
Required	Coma		Neurontin	C				
Intervention to	Pyrexia		Bowel Regimen	C				
Prevent Permanent	Tachycardia							
Impairment/Damage								

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/08/00ISR Number: 3564782-3Report Type:Periodic Company Report #2000UW00926
Age:13 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Conjunctivitis	Health	Seroquel	PS	Astrazeneca Uk Ltd	ORAL	600 MG QD PO	
	Dehydration	Professional	Seroquel	SS		ORAL	600 MG QD PO	
	Drug Toxicity		Risperdal	SS		ORAL	1 MG BID PO	
	Neuroleptic Malignant		Risperdal	SS		ORAL	3 MG PO	
	Syndrome		Risperdal	SS		ORAL	4 MG QD PO	
	White Blood Cell Count Decreased		Loxitane	SS				
			Lithium	SS				
			Synthroid	C				
			Depakote	C				

Date:06/09/00ISR Number: 3510697-6Report Type:Direct Company Report #
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Asthenia		Lithium Carbonate					
Hospitalization -	Blood Creatine Increased		300mg	PS		ORAL	1500MG DAILY	
Initial or Prolonged	Drug Level Above						ORAL	
Required	Therapeutic		Lisinopril	SS		ORAL	5MG QD ORAL	
Intervention to	Dysarthria		Asa	C				
Prevent Permanent	Mental Impairment		Chlorpromazine	C				
Impairment/Damage	Renal Impairment		Glyburide	C				
	Tremor		Lisinopril	C				
			Lithium	C				

Date:06/09/00ISR Number: 3510934-8Report Type:Expedited (15-DaCompany Report #WAES 00060222
Age:68 YR 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
Hospitalization - Initial or Prolonged	Cerebrovascular Accident Confusional State Drug Interaction Speech Disorder	Health Professional	Vioxx	PS	Merck Research Laboratories Div Merck Co Inc	ORAL	12.5 MG/DAILY/PO	
			Lithiumco3	SS			600 MG/DAILY/UNK	
			Fosamax	C				
			Klonopin	C				
			Calcium Supplement	C				
			Nortriptyline	C				
			Thyroid	C				

Date:06/12/00ISR Number: 3511767-9Report Type:Expedited (15-DaCompany Report #WAES 00060222
Age:67 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Confusional State Coordination Abnormal Drug Interaction Drug Toxicity	Health Professional	Vioxx	PS	Merck Research Laboratories Div Merck Co Inc	ORAL	12.5 MG/DAILY/PO	5 DAY
	Dysarthria		Lithiumco 3	SS			600 MG, DAILY	
	Speech Disorder Tremor		Allegra	C				
			Fosamax	C				
			Klonopin	C				
			Levoxyl	C				
			Calcium Supplement	C				
			Nortriptyline	C				

			Thyroid	C		

Date:06/12/00ISR Number: 3512169-1Report Type:Expedited (15-DaCompany Report #2000-DE-G0035
Age:62 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Coma	Foreign	Micardis	PS	Boehringer Ingelheim	ORAL	80/1/PO
	Drug Level Above Therapeutic	Health Professional	Lithium Salt	SS			900 MG
			Glimepiride	C			
			Glucophage	C			
			Isosorbide Mononitrate	C			

Date:06/12/00ISR Number: 3512475-0Report Type:Expedited (15-DaCompany Report #EWC000506839
Age:33 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Depression	Foreign	Lithium	PS			3600 MG/DAY
	Suicide Attempt	Study	Olanzapine	SS			7.5 MG/DAY
		Health Professional Other	Lorazepam	C			

Date:06/15/00ISR Number: 3514186-4Report Type:Expedited (15-DaCompany Report #A019091
Age:56 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Alcohol Withdrawal	Foreign	Lithium Carbonate	PS	Pfizer Inc	ORAL	ORAL
	Syndrome	Health Professional	Risperidone	C			
	Chronic Obstructive Airways Disease Exacerbated		Oxazepam	C			
			Flurazepam	C			
			Citalopram	C			
	Drug Level Above						

	Therapeutic					
	Malaise					
	Metabolic Acidosis					

Date:06/15/00ISR Number: 3514417-0Report Type:Expedited (15-DaCompany Report #2000016923-1
Age:20 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Aggression Blister	Consumer	Eskalith	PS	Smithkline Beecham Pharmaceuticals	ORAL	450 MILLIGRAMS 2.0 DAILY	
	Colitis Ulcerative Condition Aggravated Dehydration							
	Diarrhoea Large Intestinal Ulcer Mental Disorder Psychotic Disorder Vomiting		Risperdal (Risperidone)	C			ORAL	2 YR

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/15/00ISR Number: 3514533-3Report Type:Expedited (15-DaCompany Report #A018216
Age:49 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Confusional State	Foreign	Zoloft	PS	Pfizer			
	Disturbance In Attention	Health			Pharmaceuticals Inc	ORAL	25.00 MG	
	Memory Impairment	Professional						TOTAL:
	Reading Disorder							DAILY:ORAL
	Thinking Abnormal		Lithium	SS		ORAL		DAILY:ORAL
			Clonazepam	C				

Date:06/19/00ISR Number: 3515827-8Report Type:Expedited (15-DaCompany Report #2000017081-1
Age:51 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Interaction		Eskalith	PS	Smithkline Beecham Pharmaceuticals			
	Drug Level Above Therapeutic		Ciprofloxacin	C				
			Oxybutynin	C				
			Senna	C				
			Thioridazine	C				
			Venlafaxine	C				

Date:06/21/00ISR Number: 3521931-0Report Type:Expedited (15-DaCompany Report #2000-06-0664
Age:56 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dehydration	Foreign	Intron A (Interferon Alfa-2b Recombinant)					
	Diarrhoea	Other						
	Drug Toxicity		Soluble Powder	PS				
SUBCUTANEOUS							15 MU QD	
SUBCUTANEOUS								
			Camcolit	SS		ORAL		
1000 MG QD								

ORAL

Furosemide	SS	ORAL

40 MG QD ORAL

Cardura	C
Metformin	C
Zocor	C

Date:06/22/00ISR Number: 3518280-3Report Type:Expedited (15-DaCompany Report #2000015366-1
Age:52 YR Gender:Female I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Arthralgia
Other	Asthenia
Required Intervention to Prevent Permanent Impairment/Damage	Blood Creatinine Increased
	Blood Urea Increased
	Cerebellar Syndrome
	Cerebral Ischaemia
	Cerebrovascular Accident
	Choking
	Coordination Abnormal
	Decreased Activity
	Dehydration
	Delirium
	Depressed Level Of Consciousness
	Depression
	Dialysis

Difficulty In Walking Drug Level Above Therapeutic	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Drug Toxicity Dysarthria	Consumer	Eskalith Cr	PS	Smithkline Beecham Pharmaceuticals	ORAL	ORAL 10 YR
Dysphagia Encephalopathy		Eskalith Smithkline Beecham	SS		ORAL	675 MILLIGRAMS 2.0 DAILY ORAL
Faecal Incontinence						
Fall						
Gait Disturbance						
Hyporeflexia		Depakote (Valproate Semisodium)	C			
Hypovolaemia		Synthroid (Levothroxine)	C			
Motor Dysfunction		Effexor (Venlafaxine Hydrochloride)	C			
Muscular Weakness		Restoril	C			
Nephrogenic Diabetes Insipidus						
Nervous System Disorder						
Nuclear Magnetic Resonance Imaging Abnormal						
Overdose						
Pernicious Anaemia						
Pneumonia Aspiration						
Renal Failure						
Renal Failure Acute						
Renal Impairment						
Rhinorrhoea						
Speech Disorder						
Suicide Attempt						
Urinary Incontinence						
Urinary Retention						
Urinary Tract Infection						
Vitamin B12 Absorption Test Abnormal						
Vitamin B12 Deficiency						

Date:06/22/00ISR Number: 3567922-5Report Type:Periodic Company Report #WAES 00030770
Age:40 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Interaction Drug Level Above Therapeutic	Health Professional	Vioxx	PS	Merck Research Laboratories Div Merck Co Inc	ORAL	SEE IMAGE	
			Lithiumco 3 300mg;Lithiumco3	SS			600 MG/TID;300 MG/BID	
			...	C			300 MG/BID	

Date:06/23/00ISR Number: 3518631-XReport Type:Expedited (15-DaCompany Report #HQ7402515JUN2000
Age:63 YR Gender:Male I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Body Temperature Decreased Bradycardia Hypotension Overdose Sedation

		Tremor Vomiting					
Dose	Duration		Report Source	Product	Role	Manufacturer	Route
			Health Professional	Effexor	PS	Wyeth Ayerst Laboratories Inc	ORAL
1350 MG							
			Other				
OVERDOSE							
AMOUNT ORAL	1 DAY						
				Atenolol (Atenolol)	SS		ORAL
350 MG							
OVERDOSE							
AMOUNT ORAL	1 DAY						
				Lithium (Lithium)	SS		ORAL
2800 MG							
OVERDOSE							
AMOUNT ORAL	1 DAY						
				Thioridazine (Thioridazine)	SS		ORAL
525 MG							
OVERDOSE							
AMOUNT ORAL	1 DAY						

Date:06/29/00ISR Number: 3522625-8Report Type:Expedited (15-DaCompany Report #2000018625-1
Age:59 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization - Initial or Prolonged	Alpha 2 Globulin Increased	Literature Health	Eskalith	PS	Smithkline Beecham Pharmaceuticals	
800						
	Anaemia	Professional				
MILLIGRAMS						
	Blood Albumin Decreased					
DAILY						
	Blood Urea Increased		Biperiden	C		
	Cerebellar Ataxia		Doxepin	C		

	Diarrhoea	Haloperidol	C
	Drug Level Above Therapeutic		
	Dysarthria		
	Glomerulonephritis Proliferative		
	Haemoglobin Decreased		
	Hypercholesterolaemia		
	Lethargy		
	Leukopenia		
	Nephrotic Syndrome		
	Oedema		
	Pleural Effusion		
	Polyuria		
	Proteinuria		

Date:06/30/00ISR Number: 3523153-6Report Type:Expedited (15-DaCompany Report #NL/00/01265/TER
Age:39 YR Gender:Female I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Clonic Convulsion
	Convulsion
	Drug Interaction
	Drug Level Above Therapeutic
	Dysarthria
	Muscle Contractions Involuntary
	Overdose
	Sedation
	Speech Disorder

	Stupor Tremor Vomiting	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
		Foreign Health	Sanorex	PS	Novartis Pharmaceuticals Corp	ORAL
1 MG, ONCE A DAY, ORAL						
		Professional				
		Other	Lithli Carbonas (Lithium Carbonate)	SS		
800 MG, ONCE A DAY						
			Efexor (Venlafaxine Hydrochloride)	C		
			Cisordinol Depot (Clopenthixol Hydrochloride)	C		
			Minrin (Desmopressin)	C		

Date:07/03/00ISR Number: 3523586-8Report Type:Expedited (15-DaCompany Report #WAES 00064287
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged Disability	Pain Tremor	Consumer	Vioxx	PS	Merck Research Laboratories Div Merck Co Inc	ORAL
PO 4 WK						
			Lithiumco3	SS		

Date:07/03/00ISR Number: 3523624-2Report Type:Expedited (15-DaCompany Report #2000018942-1
Age:51 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Blood Urea Increased Condition Aggravated	Health Professional	Eskalith	PS	Smithkline Beecham Pharmaceuticals	ORAL
750 MILLIGRAMS	Confusional State					

		Coordination Abnormal						
ORAL	5 YR							
		Delirium		Ciproflaxacin	C			
		Drug Interaction		Conjugated Estrogens	C			
		Grandiosity		Glyburide	C			
		Mania		L-Tryptophan	C			
		Medication Error		Lorazepam	C			
				Quetiapine	C			
				Valsartan	C			

Date:07/03/00ISR Number: 3523891-5Report Type:Expedited (15-DaCompany Report #2000018615-1
Age:60 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Apnoea	Health	Eskalith	PS	Smithkline Beecham			
	Cardio-Respiratory Arrest	Professional			Pharmaceuticals	ORAL	1125	
	Depression						MILLIGRAMS	
	Diabetes Mellitus							
ORAL	3 DAY							
	Drug Level Above		Amaryl (Glimepirid)	C				
	Therapeutic		Heparin	C				
	Mania		Orfiril (Valproat)	C				
	Pulse Absent		Pirenzepin					
	Sedation		(Pirenzepin)	C				
			Risperdal					
			(Risperidon)	C				
			Truxal					

(Chlorprothixen)	C		
Eskalith	C	Smithkline Beecham Pharmaceuticals	

Date:07/03/00ISR Number: 3524076-9Report Type:Expedited (15-DaCompany Report #2000015366-1
Age:52 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Asthenia	Consumer	Eskalith Cr	PS	Smithkline Beecham Pharmaceuticals	ORAL	SEE IMAGE	10 YR
Other	Blood Creatinine Increased	Professional	Depakote (Valproate Semisodium)	C				
Required Intervention to Prevent Permanent Impairment/Damage	Blood Potassium Abnormal		Synthroid (Levothyroxine)	C				
	Carpal Tunnel Syndrome		Effexor (Venlafaxine Hydrochloride)	C				
	Choking		Restoril (Famotidine)	C				
	Confusional State							
	Convulsion							
	Coordination Abnormal							
	Dehydration							
	Depressed Level Of Consciousness							
	Depression							
	Diabetes Insipidus							
	Dialysis							
	Difficulty In Walking							
	Disorientation							
	Disturbance In Attention							
	Drug Toxicity							
	Dysarthria							
	Dyskinesia							
	Dysphagia							
	Encephalopathy							
	Eye Injury							
	Faecal Incontinence							
	Fall							
	Fatigue							
	Feeding Disorder							
	Hypernatraemia							
	Hyperreflexia							
	Ischaemic Stroke							
	Memory Impairment							
	Meningitis							
	Mental Impairment							
	Neck Pain							

Neurological Symptom
Pain In Extremity
Paraesthesia
Paranoid Personality Disorder
Pneumonia Aspiration
Psychotic Disorder
Pyrexia
Reflexes Abnormal
Renal Failure Acute
Rhinorrhoea
Sepsis
Speech Disorder
Tremor
Urinary Incontinence
Vitamin B12 Deficiency

Date:07/03/00ISR Number: 3524777-2Report Type:Expedited (15-DaCompany Report #00HQ-10279
Age:51 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Other	Confusional State	Foreign	Diovan	PS	Novartis Pharmaceuticals Corp		80 MG, DAILY,
	Coordination Abnormal	Literature					
	Delirium	Health					UNKNOWN
	Drug Interaction	Professional	Lithium Carbonate				
	Drug Level Above Therapeutic	Other	Unknown (Lithium Carbonate)	SS			
			Glyburide	C			
			Lorazepam	C			
			L-Tryptophan	C			
			Estrogens	C			
			Ciprofloxacin	C			

Date:07/03/00ISR Number: 3524842-XReport Type:Expedited (15-DaCompany Report #A020604
Age:35 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Life-Threatening	Arthralgia	Foreign	Feldene	PS	Pfizer Laboratories Div Pfizer Inc	ORAL	20.00 MG
Hospitalization - Initial or Prolonged	Back Pain	Health					TOTAL DAILY
	Coma	Professional					ORAL
	Depressed Level Of Consciousness	Company Representative	Lithium	SS		ORAL	TID, ORAL
	Drug Interaction		Carbamazepine	C			
	Drug Level Above Therapeutic		Amitriptylin	C			
			Levotiroxine	C			
	Drug Toxicity		Levopromacine	C			
	Proteus Infection		Lormetazepam	C			
	Pyrexia						
	Sepsis						

Date:07/05/00ISR Number: 3524271-9Report Type:Direct Company Report #
Age:43 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Life-Threatening	Drug Toxicity		Lithium	PS		
Hospitalization - Initial or Prolonged	Hypernatraemia Psychotic Disorder Renal Failure					

Date:07/05/00ISR Number: 3524320-8Report Type:Expedited (15-DaCompany Report #239346
Age:60 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Drug Level Above Therapeutic	Foreign Study	Valium	PS	Hoffmann La Roche Inc	
INTRAVENOUS 30 MG DAILY ;						
	Mania	Health				
10 MG DAILY						
	Pulse Absent	Professional				
INTRAVENOUS						
	Respiratory Arrest		Quilonium Retard (Lithium Carbonate)	SS		
	Stupor					
1350 MG DAILY						
			Orfiril (Valproate Sodium)	SS		
600 MG DAILY						
			Truxal (Chlorprothixene)	SS		
INTRAVENOUS 150 MG DAILY;						
100 MG						
INTRAVENOUS ;						
100 MG DAILY						

ORAL						
			Risperdal (Risperidone)	SS		
6 MG DAILY						
			Amaryl (Glimepiride)	C		
			Pirenzepine (Pirenzepine Hydrochloride)	C		
			Heparin (Heparin Sodium)	C		

Date:07/06/00ISR Number: 3525322-8Report Type:Direct Company Report #
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Bradycardia		Lithium Cr	PS		ORAL	PO 300MG Q AM	
	Cardiac Arrest						& 900GM HS	
	Syncope		Carbamazepine	SS			100MG Q	
							AM/200 Q PM	

Date:07/06/00ISR Number: 3525788-3Report Type:Periodic Company Report #LBID00200000012
Age:50 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hypersensitivity	Consumer	Lithobid	PS	Solvay Pharmaceuticals	ORAL	QD PO	
	Tremor							
			Tegretol	C				
			Klonopin	C				
			Synthroid	C				
			Estrace	C				
			Claritin	C				

Date:07/06/00ISR Number: 3525790-1Report Type:Periodic Company Report #LBID00200000084
Age:55 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dysgeusia Insomnia	Consumer	Lithobid	PS	Solvay Pharmaceuticals	ORAL	300 MG QD PO;	
			Serzone	C			QD PO	
			Xanax	C				

Date:07/06/00ISR Number: 3525792-5Report Type:Periodic Company Report #LBID00200000239
Age:52 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Psoriasis	Health Professional	Lithobid	PS	Solvay Pharmaceuticals	ORAL	900 MG QD PO	
			Premarin	C				
			Klonopin	C				
			Maxzide	C				
			Zoloft	C				
			Methotrexate	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/06/00ISR Number: 3525796-2Report Type:Periodic Company Report #LBID00200000337
Age:55 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Abnormal Dreams	Consumer	Lithobid	PS	Solvay Pharmaceuticals	ORAL	1200 MG DAILY	
	Amnesia						PO	
	Weight Increased							
			Nardil	C				

Date:07/06/00ISR Number: 3525801-3Report Type:Periodic Company Report #LBID00200000387
Age:38 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Interaction	Health Professional	Lithobid	PS	Solvay Pharmaceuticals	ORAL	900 MG DAILY,	
	Drug Level Above Therapeutic						PO, 300 MG	
	Dyspepsia						BID PO	
	Influenza Like Illness		Celebrex (Celecoxib)	SS		ORAL	200 MG DAILY	
	Tremor						PO	
			Bupropion	C				
			Clonazepam	C				
			Risperidone	C				
			Lamotrigine	C				

Date:07/06/00ISR Number: 3525803-7Report Type:Periodic Company Report #LBID00200000431
Age:8 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hormone Level Abnormal	Health Professional	Lithobid	PS	Solvay Pharmaceuticals	ORAL	600 MG DAILY	
							PO	

			Depakote	C		
			Wellbutrin	C		
			Ritalin	C		

Date:07/06/00ISR Number: 3525811-6Report Type:Periodic Company Report #LBID00200000447
Age:39 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Interaction Sedation	Foreign Literature Other	Lithobid	PS	Solvay Pharmaceuticals	ORAL	400 MG DAILY, PO, 800 MG DAILY PO	
			Luvox (Fluvoxamine Maleate)	SS		ORAL	DAILY, PO	

Date:07/06/00ISR Number: 3525813-XReport Type:Periodic Company Report #LBID00200000506
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Depersonalisation	Health Professional Company Representative	Lithobid	PS	Solvay Pharmaceuticals	ORAL	1200 MG DAILY PO	
			Desipramine	C				
			Prozac	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/06/00ISR Number: 3525815-3Report Type:Periodic Company Report #LBID00200000616
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hypernatraemia	Health Professional	Lithobid	PS	Solvay Pharmaceuticals	ORAL	DAILY PO	
		Company Representative	Neurontin	C				

Date:07/06/00ISR Number: 3525817-7Report Type:Periodic Company Report #LBID00200000651
Age:47 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dermatitis	Consumer	Lithobid	PS	Solvay Pharmaceuticals	ORAL	600 MG DAILY	
							PO, 900 MG	DAILY PO
			Effexor	C				
			Buspar	C				

Date:07/06/00ISR Number: 3525854-2Report Type:Periodic Company Report #LBID00200000697
Age:47 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Nausea	Consumer	Lithobid	PS	Solvay Pharmaceuticals	ORAL	DAILY, PO,	
							900 MG DAILY	
							PO	

Date:07/06/00ISR Number: 3525867-0Report Type:Periodic Company Report #LBID00200000793
Age:68 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Face Oedema Paraesthesia	Consumer	Lithobid	PS	Solvay Pharmaceuticals	ORAL	600 MG DAILY	PO
			Premarin	C				
			Levoxyl	C				
			Ambien	C				
			Hyzaar	C				

Date:07/06/00ISR Number: 3525868-2Report Type:Periodic Company Report #LBID00200000809
Age:46 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Tremor	Consumer	Lithobid	PS	Solvay Pharmaceuticals	ORAL	900 MG DAILY	PO
			Zoloft	C				
			Paxil	C				
			Clonazepam	C				
			Zyrtec	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/06/00ISR Number: 3525870-0Report Type:Periodic Company Report #LBID00200000816
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blood Creatinine Increased	Consumer	Lithobid	PS	Solvay Pharmaceuticals	ORAL	DAILY PO	
	Renal Impairment							

Date:07/06/00ISR Number: 3525871-2Report Type:Periodic Company Report #LBID00200000818
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Erectile Dysfunction	Consumer	Lithobid	PS	Solvay Pharmaceuticals	ORAL	900 MG DAILY PO, 600 MG DAILY PO, 900 MG DAILY PO	

Date:07/06/00ISR Number: 3525872-4Report Type:Periodic Company Report #LBID00200000967
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dermatitis Pruritus	Health Professional	Lithobid	PS	Solvay Pharmaceuticals	ORAL	600 MG BID PO	
			Zyprexa	C				
			Wellbutrin	C				

Date:07/06/00ISR Number: 3525874-8Report Type:Periodic Company Report #LBID00200001089
Age:58 YR 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	Arthralgia Oedema Peripheral Tremor Vomiting	Consumer	Lithobid	PS	Solvay Pharmaceuticals	ORAL	300 MG QD PO	

Date:07/06/00ISR Number: 3525875-XReport Type:Periodic Company Report #LBID00200001646
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hormone Level Abnormal	Health Professional	Lithobid	PS	Solvay Pharmaceuticals	ORAL	1200 MG DAILY PO	

Date:07/06/00ISR Number: 3525876-1Report Type:Periodic Company Report #LBID00200001647
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Diarrhoea	Consumer	Lithobid	PS	Solvay Pharmaceuticals	ORAL	300 MG BID PO	

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Freedom Of Information (FOI) Report

Date:07/06/00ISR Number: 3525877-3Report Type:Periodic Company Report #LBID00200002115
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Headache	Consumer	Lithobid	PS	Solvay Pharmaceuticals	ORAL	300 MG DAILY	PO

Date:07/06/00ISR Number: 3525878-5Report Type:Periodic Company Report #LBID00200002129
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Diarrhoea	Health Professional	Lithobid	PS	Solvay Pharmaceuticals	ORAL	DAILY PO	
	Intentional Misuse							
	Nausea							

Date:07/06/00ISR Number: 3525882-7Report Type:Periodic Company Report #LBID00200002369
Age:42 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Acne	Consumer	Lithobid	PS	Solvay Pharmaceuticals	ORAL	PO, 450 MG	BID PO
	Salivary Hypersecretion							
	Weight Increased							
			Lithonate (Lithium Carbonate)	SS		ORAL	300 MG QD PO	
			Depakote	C				
			Zoloft	C				

Date:07/06/00ISR Number: 3525885-2Report Type:Periodic Company Report #LBID00200002457
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dermatitis Oedema	Health Professional	Lithobid	PS	Solvay Pharmaceuticals	ORAL	300 MG BID PO	

Date:07/06/00ISR Number: 3525886-4Report Type:Periodic Company Report #LBID00200002464
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Psoriasis	Health Professional	Lithobid	PS	Solvay Pharmaceuticals	ORAL	300 MG BID PO, 300 MG BID PO	

Date:07/06/00ISR Number: 3525891-8Report Type:Periodic Company Report #LBID00299000155
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Ineffective	Consumer	Lithobid	PS	Solvay Pharmaceuticals	ORAL	MG QD PO	
			Lithobid (Lithium Carbonate) Eskalith	SS C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/06/00ISR Number: 3525893-1Report Type:Periodic Company Report #LBID00299000171
Age:7 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Flatulence	Consumer	Lithobid	PS	Solvay Pharmaceuticals	ORAL	600 MG QD PO	10 DAY
	Pallor							
	Sedation							

Date:07/06/00ISR Number: 3525895-5Report Type:Periodic Company Report #LBID00299000249
Age:35 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Depression		Lithobid	PS	Solvay Pharmaceuticals	ORAL	600 MG BID PO	
			Acidophilus "Zyma" (Lactobacillus Acidophilus)	SS			DAILY	
			Serzone	C				
			Levoxyl	C				

Date:07/06/00ISR Number: 3525898-0Report Type:Periodic Company Report #LBID00299000256
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hallucination	Consumer	Lithobid	PS	Solvay Pharmaceuticals	ORAL	1500 MG QD PO	
			Zyprexa	C				
			Excedrin	C				

Date:07/06/00ISR Number: 3525900-6Report Type:Periodic Company Report #LBID00299000257
Age:14 YR 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	Laboratory Test Abnormal Tremor	Consumer	Lithobid	PS	Solvay Pharmaceuticals	ORAL
300 MG TID PO						
			Wellbutrin	C		

Date:07/06/00ISR Number: 3525902-XReport Type:Periodic Company Report #LBID00299000358
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Other	Hypoglycaemia	Consumer	Lithobid	PS	Solvay Pharmaceuticals	
DAILY						
			Wellbutrin	C		

Date:07/06/00ISR Number: 3525904-3Report Type:Periodic Company Report #LBID00299000450
Age:54 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Other	Amblyopia Asthenia	Consumer	Lithobid	PS	Solvay Pharmaceuticals	ORAL
300 MG BID PO						
			Celexa	C		

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Freedom Of Information (FOI) Report

Date:07/06/00ISR Number: 3525905-5Report Type:Periodic Company Report #LBID00299000486
Age:40 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Level Above Therapeutic	Health Professional	Lithobid	PS	Solvay Pharmaceuticals		DAILY	
	Hypercalcaemia Mania		Cortisone Injection (Cortisone)	SS		INTRAMUSCULAR	DAILY IM	

Date:07/06/00ISR Number: 3525907-9Report Type:Periodic Company Report #LBID00299000529
Age:61 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Convulsion Tremor	Consumer	Lithobid	PS	Solvay Pharmaceuticals	ORAL	300 MG QD PO	
			Desipramine	C				
			Diazepam	C				
			Prempro	C				

Date:07/06/00ISR Number: 3525921-3Report Type:Periodic Company Report #LBID00299000538
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Weight Increased	Consumer	Lithobid	PS	Solvay Pharmaceuticals	ORAL	900 MG DAILY	
			Zoloft	C			PO	
			Premarin	C				

Date:07/06/00ISR Number: 3525923-7Report Type:Periodic Company Report #LBID00299000555
Age:50 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Aggression	Health Professional	Lithobid	PS	Solvay Pharmaceuticals		300 MG TID PO	IN

Date:07/06/00ISR Number: 3525925-0Report Type:Periodic Company Report #LBID00299000625
Age:45 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hyperkalaemia	Health Professional	Lithobid	PS	Solvay Pharmaceuticals	ORAL	600 MG BID PO	

Date:07/06/00ISR Number: 3525926-2Report Type:Periodic Company Report #LBID00299000633
Age:50 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Pollakiuria Tremor	Consumer	Lithobid	PS	Solvay Pharmaceuticals	ORAL	900 MG DAILY	PO, 600 MG BID PO, 900 MG DAILY PO, 600 MG BID PO
			Propranolol	C				
			Klonopin	C				
			Saw Palmetto					

			Enzymatic Therapy	C		

Date:07/06/00ISR Number: 3525927-4Report Type:Periodic Company Report #LBID00299000674
Age:38 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Abdominal Pain	Consumer	Lithobid	PS	Solvay Pharmaceuticals	ORAL	300 MG TID PO	
			Librax	C				
			Mellaril	C				
			Melatonin	C				

Date:07/06/00ISR Number: 3525929-8Report Type:Periodic Company Report #LBID00299000828
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Electroencephalogram Abnormal	Consumer	Lithobid	PS	Solvay Pharmaceuticals	ORAL	900 MG BID PO	
	Sleep Disorder							

Date:07/06/00ISR Number: 3525931-6Report Type:Periodic Company Report #LBID00299001021
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Oedema	Health Professional	Lithobid	PS	Solvay Pharmaceuticals	ORAL	DAILY PO	
		Company Representative						

Date:07/06/00ISR Number: 3525944-4Report Type:Periodic Company Report #LBID00299001086
Age:47 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Other	Convulsion	Health Professional	Lithobid	PS	Solvay Pharmaceuticals	ORAL DAILY PO
			Buspar (Buspirone Hydrochloride)	C		
			Zoloft (Sertraline Hydrochloride)	C		

Date:07/06/00ISR Number: 3525947-XReport Type:Periodic Company Report #LBID00299001087
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hostility	Consumer	Lithobid	PS	Solvay Pharmaceuticals	ORAL	900 MG DAILY PO	

Date:07/06/00ISR Number: 3525951-1Report Type:Periodic Company Report #LBID00299001129
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Anorgasmia	Health Professional	Lithobid	PS	Solvay Pharmaceuticals	ORAL	DAILY PO	
		Company Representative						

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/06/00ISR Number: 3525962-6Report Type:Periodic Company Report #LBID00299001131
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Abdominal Pain Diarrhoea Dry Mouth	Consumer	Lithobid	PS	Solvay Pharmaceuticals	ORAL	DAILY PO	

Date:07/06/00ISR Number: 3525964-XReport Type:Periodic Company Report #LBID00299001175
Age:35 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Pruritus	Health Professional	Lithobid	PS	Solvay Pharmaceuticals	ORAL	PO	

Date:07/06/00ISR Number: 3525966-3Report Type:Periodic Company Report #LBID00299001184
Age:37 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Vomiting	Health Professional	Lithobid	PS	Solvay Pharmaceuticals	ORAL	DAILY PO	
			Luvox (Fluvoxamine Maleate)	SS		ORAL	PO	
			Ativan (Lorazepam)	C				
			Ambien (Zolpidem Tartrate)	C				
			Navane (Tiotixene)	C				
			Cogentin (Benzatropine Mesilate)	C				

Date:07/06/00ISR Number: 3525969-9Report Type:Periodic Company Report #LBID00299001193
Age:46 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Pain	Consumer	Lithobid	PS	Solvay Pharmaceuticals	ORAL	600 MG BID PO	
			Elavil (Amitriptuline Hydrochloride)	C				
			Tegretol (Carbamazepine)	C				
			Prozac (Fluoxetine Hydrochloride)	C				
			Synthroid (Levothyroxine Sodium)	C				
			Klonopin (Clonazepam)	C				

Date:07/06/00ISR Number: 3525973-0Report Type:Periodic Company Report #LBID00299001320
Age:30 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Tremor	Consumer	Lithobid	PS	Solvay Pharmaceuticals	ORAL	900 MG DAILY	
							PO	
			Anafranil					

			(Clomipramine Hydrochloride)	C
			Synthroid (Levothyroxine Sodium)	C

Date:07/06/00ISR Number: 3525974-2Report Type:Periodic Company Report #LBID00299001327
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Level Above Therapeutic	Health Professional	Lithobid	PS	Solvay Pharmaceuticals	ORAL	DAILY PO	
		Company Representative	Lamictal (Lamotrigine)	C				

Date:07/06/00ISR Number: 3525976-6Report Type:Periodic Company Report #LBID00299001353
Age:13 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Paraesthesia	Consumer	Lithobid	PS	Solvay Pharmaceuticals	ORAL	300 MG BID PO	
			Adderall (Dexamphetamine Sulphate; Deamphetamine Saccharate;	C				
			Tenex (Guanfacine Hydrochloride)	C				
			Zoloft (Sertraline Hydrochloride)	C				
			Claritin (Loratadine)	C				

Date:07/06/00ISR Number: 3525978-XReport Type:Periodic Company Report #LBID00299001477
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	Laryngospasm	Health Professional	Lithobid	PS	Solvay Pharmaceuticals	ORAL	DAILY PO	

Date:07/06/00ISR Number: 3525980-8Report Type:Periodic Company Report #LBID00299001635
Age:57 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Pollakiuria Weight Increased	Consumer	Lithobid	PS	Solvay Pharmaceuticals	ORAL	900 MG DAILY PO	
			Ditropan (Oxybutrin)	C				
			Risperdal (Risperidone)	C				
			Meridia ()	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/06/00ISR Number: 3525982-1Report Type:Periodic Company Report #LBID00299001669
Age:14 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Headache Nausea Vomiting	Consumer	Lithobid	PS	Solvay Pharmaceuticals	ORAL	1500 MG DAILY	PO
			Risperdal (Riperidone)	C				

Date:07/06/00ISR Number: 3525983-3Report Type:Periodic Company Report #LBID00299001822
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Interaction Drug Level Above Therapeutic	Health Professional Company Representative	Lithobid	PS	Solvay Pharmaceuticals	ORAL	1800 MG DAILY	PO
			Vioxx (Vioxx)	C				

Date:07/06/00ISR Number: 3525985-7Report Type:Periodic Company Report #LBID00299001970
Age:35 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Diarrhoea Headache Mania	Consumer	Lithobid	PS	Solvay Pharmaceuticals	ORAL	300 MG BID PO	

Date:07/06/00ISR Number: 3525988-2Report Type:Periodic Company Report #LBID00299002038
Age:10 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Agitation	Consumer	Lithobid	PS	Solvay			

	Insomnia				Pharmaceuticals	ORAL
300 MG BID PO						
			Tenex (Guanfacine Hydrochloride)	C		
			Benadryl (Diphenhydramine Hydrochloride)	C		

Date:07/06/00ISR Number: 3525989-4Report Type:Periodic Company Report #LBID00299002141
Age:60 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Hyperkalaemia	Health Professional	Lithobid	PS	Solvay Pharmaceuticals	
DAILY						
		Company Representative	Ativan (Lorazepam)	C		

Date:07/06/00ISR Number: 3525990-0Report Type:Periodic Company Report #LBID00299002190
Age:35 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Visual Disturbance	Health Professional	Lithobid	PS	Solvay Pharmaceuticals	ORAL
600 MG DAILY						
PO						

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/06/00ISR Number: 3525994-8Report Type:Periodic Company Report #LBID00299002192
Age:51 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dry Mouth Thirst	Health Professional	Lithobid	PS	Solvay Pharmaceuticals	ORAL	300 MG BID PO	

Date:07/07/00ISR Number: 3526587-9Report Type:Expedited (15-DaCompany Report #HQ8154405JUL2000
Age:1 DY Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Benign Congenital Hypotonia	Health Professional	Effexor	PS	Wyeth Ayerst Laboratories Inc	TRANSPLACENTAL	25 MG, TRANSPLACENTA	
	Complications Of Maternal Exposure To Therapeutic Drugs Drug Withdrawal Syndrome Neonatal	Other	Anafranil (Clomipramine Hydrochloride)	SS		TRANSPLACENTAL	TRANSPLACENTA	L 9 MON
	Feeding Problem In Newborn Hyperreflexia Opisthotonus Tachypnoea		Lithium (Lithium) Ludiomil (Maprotiline Hydrochloride)	SS C		TRANSPLACENTAL	TRANSPLACENTA	L
	Thrombocytopenia Neonatal							L

Date:07/10/00ISR Number: 3526775-1Report Type:Expedited (15-DaCompany Report #00CH-10028
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Benign Congenital Hypotonia	Foreign Health	Anafranil	PS	Novartis Pharmaceuticals Corp	TRANSPLACENTAL	DAILY,	

		Complications Of Maternal	Professional		
TRANSPLACENTA					
		Exposure To Therapeutic	Other		
L					
		Drugs		Lithium Carbonate	SS
TRANSPLACENTAL	TRANSPLACENTA				
		Feeding Problem In			
L					
		Newborn		Ludiomil	
		Hyperreflexia		(Maprotiline	
		Neonatal Disorder		Hydrochloride)	SS
TRANSPLACENTAL	TRANSPLACENTA				
		Opisthotonus			
L					
		Psychomotor Hyperactivity		Effexor	
		Tachypnoea		(Venlafaxine)	SS
TRANSPLACENTAL	TRANSPLACENTA				
		Thrombocytopenia			
L					

Date:07/10/00ISR Number: 3527274-3Report Type:Expedited (15-DaCompany Report #00HQ-10282
Age:42 YR Gender:Female I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Coordination Abnormal
	Diarrhoea
	Dizziness
	Drug Interaction
	Drug Level Above Therapeutic
	Electrocardiogram Normal
	Electrocardiogram T Wave Inversion
	Fall
	Grand Mal Convulsion
	Haemodialysis

		Hypokalaemia					
		Leukocytosis					
		Loss Of Consciousness	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
		Sedation	Foreign	Tegretol	PS	Novartis	
		Sinus Arrhythmia	Literature			Pharmaceuticals Corp	
400 MG DAILY							
		Sinus Bradycardia	Health	Lithium (Lithium			
		Therapeutic Agent	Professional	Carbonate)	SS		
900 MG DAILY							
		Toxicity	Other	Trihexyphenidyl	C		
		Tremor		Trazodone	C		
				Bethanechol Chloride	C		
				Clonazepam	C		
				Moperone Hydrochlori	C		

Date:07/10/00ISR Number: 3578116-1Report Type:Periodic Company Report #USA013191
Age:53 YR Gender:Female I/FU:I

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
		Anxiety	Consumer	Meridia	PS	Knoll Pharmaceutical	
		Confusional State	Other			Co Sub Basf Corp	ORAL
10 MG OD PO							
		Depression		Lithium	SS		ORAL
450 MG NOCTE							
		Dry Mouth					
PO							
		High Density Lipoprotein		Lithium	SS		ORAL
225 MG MANE							
		Decreased					
PO							
		Hypercholesterolaemia		Neurontin	C		
		Insomnia		Ambien	C		
		Low Density Lipoprotein		Calcium	C		
		Increased		Vitamin E	C		
		Nervousness		Rose Hips	C		
		Restlessness		Evista	C		
		Tremor					

Date:07/11/00ISR Number: 3527488-2Report Type:Expedited (15-DaCompany Report #239099
Age:59 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Infection Lymphoedema	Foreign Health Professional	Xenical	PS	Hoffmann La Roche Inc	ORAL	120 MG 3 PER DAY	ORAL
			Priadel (Lithium Carbonate Or Lithium Citrate) 600 Mg	SS		ORAL	600 MG 1 PER DAY	ORAL

Date:07/13/00ISR Number: 3528924-8Report Type:Expedited (15-DaCompany Report #2000018615-1
Age:60 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Nervous System Disorder Pulse Absent	Health Professional	Eskalith	PS	Smithkline Beecham Pharmaceuticals	ORAL	1125 MG, ORAL	3 DAY
	Respiratory Arrest Sedation		Amaryl (Glimepirid) Heparin Orfiril (Valproat) Pirenzepin (Pirenzepin) Risperdal (Risperidon) Truxal (Chlorprothixen)	C C C C C C				

			Valium (Diazepam)	C			

Date:07/13/00ISR Number: 3528928-5Report Type:Expedited (15-DaCompany Report #2000019161-1
Age:32 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Other	Bradycardia Foetal	Health	Eskalith	PS	Smithkline Beecham		
	Complications Of Maternal	Professional			Pharmaceuticals	ORAL	1350 MG, ORAL
	Exposure To Therapeutic		Gladem (Sertraline				
	Drugs		Hydrochloride)	C			
	Intra-Uterine Death		Saroten				
	Multiple Congenital		(Amitriptyline				
	Abnormalities		Hydrochloride)	C			
	Unwanted Pregnancy						

Date:07/13/00ISR Number: 3528959-5Report Type:Expedited (15-DaCompany Report #HQ8422112JUL2000
Age:53 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Other	Asthenia	Consumer	Effexor	PS	Wyeth Ayerst		
	Dizziness				Laboratories Inc	ORAL	150 MG DAILY
	Drug Interaction		Alcohol (Ethanol)	SS		ORAL	
	Hypotension		Lithium (Lithium)	SS		ORAL	4 DAY
	Malaise						
	Nervous System Disorder						
	Serotonin Syndrome						
	Tremor						

Date:07/13/00ISR Number: 3531605-8Report Type:Expedited (15-DaCompany Report #2000-06-0664
Age:56 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Apathy	Foreign	Camcolit Tablets	PS		ORAL	1000 MG QD

Initial or Prolonged	Dehydration	Other			
ORAL					
	Diarrhoea		Furosemide Tablets	SS	ORAL
40 MG QD ORAL					
	Drug Toxicity		Intron A (Interferon		
	Sedation		Alfa-2b Recombinant)		
			Soluble Powder	SS	
SUBCUTANEOUS	15 MU QD				
SUBCUTANEOUS					
			Cardura Tablets	C	
			Metformin		
			Hydrochloride		
			Tablets	C	
			Zocor Tablets	C	

Date:07/14/00ISR Number: 3530011-XReport Type:Expedited (15-DaCompany Report #2000010163-1
Age:66 YR Gender:Male I/FU:F

Outcome	PT
Hospitalization -	Aggression
Initial or Prolonged	Agitation
	Asthenia
	Blood Creatinine
	Increased
	Blood Urea Decreased
	Coma
	Confusional State

		Cough					
		Cyanosis					
		Diabetes Mellitus	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
		Inadequate Control	Consumer	Eskalith	PS	Smithkline Beecham	
		Drug Level Above	Health			Pharmaceuticals	ORAL
ORAL							
		Therapeutic	Professional	Navane (Thiothixene)	C		
		Drug Toxicity		Lotensin			
		Dysphagia		(Benazepril)	C		
		Encephalopathy		Naproxen	C		
		Haematocrit Decreased		Bactrim			
		Haemoglobin Decreased		(Sulfamethoxzole/Rim			
		Hypertension		ethoprim	C		
		Hypotension		Insulin	C		
		Jaundice		Depakote (Divalrpoex			
		Malnutrition		Sodium	C		
		Muscle Rigidity		Zestril	C		
		Oliguria		Risperdal	C		
		Pco2 Decreased		Aspirin	C		
		Pneumonia		Iron	C		
		Pyrexia		Tegretol	C		
		Respiratory Failure		Keflex	C		
		Restlessness					
		Retching					
		Road Traffic Accident					
		Speech Disorder					
		Sputum Abnormal					
		Tachypnoea					
		Tremor					
		Urinary Incontinence					

Date:07/18/00ISR Number: 3531298-XReport Type:Expedited (15-DaCompany Report #2000015366-1
Age:52 YR Gender:Female I/FU:F

Outcome	PT
Hospitalization -	Arthralgia
Initial or Prolonged	Asthenia
Other	Bone Pain
Required	Carpal Tunnel Syndrome
Intervention to	Cerebellar Syndrome
Prevent Permanent	Cerebral Ischaemia
Impairment/Damage	Cerebrovascular Accident
	Choking
	Communication Disorder

Coordination Abnormal
Dehydration
Depression
Difficulty In Walking
Dysarthria
Encephalopathy
Faecal Incontinence
Fall
Feeling Abnormal
Gait Disturbance
Hypovolaemia
Laboratory Test Abnormal
Motor Dysfunction
Movement Disorder
Muscular Weakness
Neck Pain
Overdose

	Paraesthesia Renal Failure Renal Failure Acute	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
	Rhinorrhoea Urinary Incontinence	Consumer Health	Eskalith Cr	PS	Smithkline Beecham Pharmaceuticals	ORAL
ORAL 10 YR						
		Professional	Eskalith	SS	Smithkline Beecham	ORAL
675 MILLIGRAMS 2.0 DAILY ORAL						
			Depakote	C		
			Synthroid	C		
			Effexor	C		
			Restoril	C		

Date:07/19/00ISR Number: 3532073-2Report Type:Expedited (15-DaCompany Report #S00-FRA-00500-01
Age:51 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Blood Phosphorus Decreased	Foreign Health	Celexa	PS	Forest Laboratories Inc	ORAL
40 MG QD PO						
	Condition Aggravated Depression Hypercalcaemia	Professional Other	Hygroton (Chlortalidone) Tenormine (Atenolol)	SS SS		
100 MG QD						
	Hyperparathyroidism Nephrogenic Diabetes		Tercian (Cyamemazine)	SS		
25 MG QD						
	Insipidus Polydipsia Psychogenic		Teralithe (Lithium Carbonate)	SS		ORAL
1200 MG QD PO						
	Psychotic Disorder					

Date:07/20/00ISR Number: 3532645-5Report Type:Expedited (15-DaCompany Report #PHBS2000CA04064
Age:23 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Alanine Aminotransferase Increased	Foreign Literature	Clozaril	PS	Novartis Pharmaceuticals Corp	ORAL	ORAL	16 DAY
	Anorexia	Health Professional Other	Lithium (Lithium)	SS			12 DAY	
	Aspartate Aminotransferase Increased							
	Asthenia							
	Blood Alkaline Phosphatase Increased							
	Blood Creatinine Increased							
	Eosinophilia							
	Fatigue							
	Influenza Like Illness							
	Leukocytosis							
	Nausea							
	Pyrexia							
	Sinus Tachycardia							
	Vomiting							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/24/00ISR Number: 3533960-1Report Type:Direct Company Report #
Age:47 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged -LONG TERM	Akinesia		Lithium Co3 300mg	PS		ORAL	300MG TID PO	
	Dialysis							
	Drug Level Above		Lisinopril 5mg	SS		ORAL	5MG PO QD PO	
	Therapeutic		Haloperidol	C				
	Gait Disturbance		Benztropine	C				
	Mental Impairment		Asa	C				
	Parkinsonism		Hctz	C				
			Levothyroxine	C				

Date:07/24/00ISR Number: 3534842-1Report Type:Expedited (15-DaCompany Report #2000020093-1
Age:63 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged ORAL	Body Temperature Decreased	Foreign	Eskalith	PS	Smithkline Beecham Pharmaceuticals	ORAL		
	Bradycardia		Atenolol	C				
	Hypotension		Efexor (Venlafaxine)	C				
	Intentional Misuse		Thioridazine	C				
	Sedation							
	Tremor							
	Vomiting							

Date:07/25/00ISR Number: 3534900-1Report Type:Expedited (15-DaCompany Report #2000AP03298
Age:63 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Body Temperature Decreased	Foreign Health	Tenormin	PS	Astrazeneca Pharmaceuticals Lp		350 MG ONCE	
	Bradycardia	Professional	Efexor	SS		ORAL	1350 MG ONCE	

	Hypotension	Other					
PO							
	Overdose		Lithium	SS			
2800 MG							
	Sedation		Lithium	SS			ORAL
2800 MG DAILY							
	Tremor						
PO							
	Vomiting		Thioridazine	SS			
525 MG							
			Thioridazine	SS			ORAL
525 MG DAILY							
PO							

Date:07/25/00ISR Number: 3535280-8Report Type:Expedited (15-DaCompany Report #PHBS2000FR03434
Age:25 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Asthenia	Foreign	Clozaril	PS	Novartis			
Hospitalization -	Cardiac Failure	Health			Pharmaceuticals Corp	ORAL	400 MG/DAY,	
Initial or Prolonged	Congestive	Professional					ORAL	
Disability	Cardiomyopathy	Other	Teralithe (Lithium					
	Myocarditis		Carbonate) (Lithium					
	Pyrexia		Carbonate)	SS		ORAL	600 MG/DAY,	
ORAL								1 YR
			Depakine	C				
			Largactil	C				
			Tranxene	C				
			Kaleroid	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/26/00ISR Number: 3536218-XReport Type:Expedited (15-DaCompany Report #A025655
Age:51 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Blood Urea Increased	Foreign	Lithane	PS	Pfizer Inc	ORAL	750.00 MG TOTAL:DAILY:ORAL
	Confusional State	Literature					
	Coordination Abnormal	Health					
	Delirium	Professional	Valsartan	SS		ORAL	80.00 MG TOTAL:DAILY:ORAL
	Drug Interaction						
	Drug Level Above Therapeutic		Quetiapine	SS		ORAL	50.00 MG TOTAL:DAILY:ORAL
	Grandiosity						
	Mania						
	Medication Error		L-Tryptophan	C			
	Sedation		Lorazepam	C			
			Glyburide	C			
			Conjugated Estrogens	C			

Date:07/28/00ISR Number: 3537781-5Report Type:Expedited (15-DaCompany Report #LBID00200005232
Age:76 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Other	Accidental Overdose	Literature	Lithobid	PS	Solvay Pharmaceuticals	ORAL	900 MG QD PO, 600 MG QD PO
	Agitation	Health					
	Anxiety	Professional					
	Cognitive Disorder						
	Drug Level Above Therapeutic						
	Dysphoria						
	Feeling Of Despair						
	Thinking Abnormal						

Date:07/28/00ISR Number: 3537782-7Report Type:Expedited (15-DaCompany Report #LBID00200005226
Age:86 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Asthenia	Literature	Lithobid	PS	Solvay Pharmaceuticals	ORAL	300 MG QD PO	
	Hip Fracture	Health						
	Hypotonia	Professional	Levothyroxine (Levothyroxine)	C				
	Movement Disorder		Clopidogrel (Clopidogrel)	C				
	Tremor		Diltiazem (Diltiazem)	C				
			Fosinopril (Fosinopril)	C				
			Insulin (Insulin)	C				
			Vitamins (Vitamins)	C				
			Laxative (Laxative)	C				
			Oxycodone (Oxycodone)	C				

Date:07/31/00ISR Number: 3538613-1Report Type:Expedited (15-DaCompany Report #WAES 00060222
Age:68 YR Gender:Female I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Confusional State
	Coordination Abnormal
Other	Drug Interaction

		Dysarthria Speech Disorder Tremor	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
			Health Professional	Vioxx	PS	Merck Research Laboratories Div Merck Co Inc	ORAL
12.5							
MG/DAILY/PO							
				Lithium Carbonate	SS		ORAL
600							
MG/DAILY/PO							
				Allegra	C		
				Fosamax	C		
				Klonopin	C		
				Levoxyl	C		
				Calcium Supplement (Composition			
				Nortriptyline)	C		
				Thyroid	C		
				Nortriptyline	C		

Date:08/03/00ISR Number: 3541059-3Report Type:Expedited (15-DaCompany Report #2000022699-1
Age:66 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Death	Cardiac Arrest	Health Professional	Eskalith	PS	Smithkline Beecham Pharmaceuticals	ORAL
Life-Threatening	Drug Level Above					
2.0 DAILY						
Hospitalization - Initial or Prolonged	Therapeutic Drug Toxicity					
ORAL						
			Ranitidine	C		
			Amitriptyline	C		
			Prednisone	C		
			Enoxaparine	C		
			Aspirin (Acetylsalicylic Acid)	C		
			Lisinopril	C		

Date:08/03/00ISR Number: 3541083-0Report Type:Expedited (15-DaCompany Report #00-0860
Age:45 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Abnormal Behaviour	Consumer	Loxapine Succinate	PS	Watson Laboratories Inc	ORAL	30 MG; 60 MG;	
	Blister	Health					40 MG; 30 MG;	
	Brain Damage	Professional					DAILY, ORAL	
	Cerebral Cyst	Other					300 MG PO AM;	
	Memory Impairment		Lithium Carbonate 300 Mg	SS			600 MG PM	10 YR
	Mental Impairment							
	Peripheral Neuroepithelioma		Depakene	C				
	Rhinorrhoea		Prolixin	C				
	Sleep Disorder		Clozapine	C				
	Thrombocytopenia		Haldol	C				
	Tremor		Olanzapine	C				
			Seizure Medication	C				
			Antidepressant	C				
			L-Tryptophan, Many Years Through	C				
			Lithobid	C				
			One-A-Day Vitamin	C				
			5 Hydroxytryptophan	C				
			Vitamin C	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/04/00ISR Number: 3542745-1Report Type:Expedited (15-DaCompany Report #2000023069-1
Age:50 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Stevens-Johnson Syndrome	Health Professional	Eskalith	PS	Smithkline Beecham Pharmaceuticals			
			Erythromycin	SS				

Date:08/08/00ISR Number: 3544592-3Report Type:Direct Company Report #
Age:39 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Agraphia	Health	Serzone 200mg Po Qhs	PS		ORAL	200MG PO QHS	
	Cognitive Disorder	Professional	Lithium Carbonate	SS			900MG BID	
	Coordination Abnormal							
	Disturbance In Attention							
	Dysphemia							
	Dystonia							
	Hallucination							
	Muscular Weakness							

Date:08/08/00ISR Number: 3544665-5Report Type:Direct Company Report #
Age:53 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Asthenia	Health Professional	Lithium 300mg (Roxanne)	PS	Roxanne	ORAL	300 MG PO TID	
	Fall							
	Vision Blurred		Haloperodol	C				
			Aspirin Ec	C				
			Phenytoin	C				
			Bactrim Ds	C				
			Fluconazole	C				
			Clotrimazole Lotion	C				
			Betamethasone Oint	C				
			Theravite	C				

Date:08/09/00ISR Number: 3548405-5Report Type:Periodic Company Report #1357422A
Age:65 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Abnormal Dreams Hallucination	Foreign Consumer	Tylenol	PS	Mcneil Consumer Products Co Div Mcneilab Inc	ORAL	1000 MG, Q4H,	PO 8 DAY
			Lithium	SS		ORAL	1200 MG/DAY,	PO
			Diabeta	C				
			Lipidil	C				

Date:08/10/00ISR Number: 3548690-XReport Type:Expedited (15-DaCompany Report #001-0719-M0000140
Age:63 YR Gender:Female I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Blood Electrolytes Decreased Drug Interaction Drug Level Above Therapeutic

	Hyponatraemia Insomnia Oral Intake Reduced	Report Source	Product	Role	Manufacturer	Route	Dose Duration
		Consumer	Lopid	PS	Parke Davis Pharmaceuticals Ltd	ORAL	600 MG (DAILY), PER ORAL
			Eskalith (Lithium Carbonate)	SS		ORAL	450 MG (DAILY), PER ORAL
			Glucophage (Metformin Hydrochloride)	SS			
			Prempro (Medroxyprogesterone Acetate, Estrogens Conjugated)	SS			
			Benadryl (Diphenhydramine Hydrochloride)	C			
			Trazodone	C			

Date:08/14/00ISR Number: 3550378-6Report Type:Expedited (15-DaCompany Report #2000022369-1
Age:45 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Anaemia Megaloblastic Biopsy Bone Marrow	Foreign Health	Eskalith	PS	Smithkline Beecham Pharmaceuticals	ORAL	1350 MG, ORAL 3 YR
	Abnormal Macrocytosis	Professional Other	Stangyl (Trimipramine Maleate)	C			
			Zoloft (Sertraline Hydrochloride)	C			

Date:08/14/00ISR Number: 3550459-7Report Type:Expedited (15-DaCompany Report #2000015366-1
Age:52 YR Gender:Female I/FU:F

Outcome	PT
Hospitalization -	Abdominal Pain
Initial or Prolonged	Asthenia
Other	Back Pain
Required	Balance Disorder
Intervention to	Bipolar Disorder
Prevent Permanent	Chills
Impairment/Damage	Choking
	Confusional State
	Constipation
	Coordination Abnormal
	Decreased Activity
	Depressed Level Of
	Consciousness
	Depression
	Diabetes Insipidus
	Dialysis
	Difficulty In Walking
	Disorientation
	Disturbance In Attention
	Drug Toxicity

	Dysarthria						
	Dysphagia						
	Electrocardiogram St	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Segment Abnormal	Consumer	Eskalith Cr	PS	Smithkline Beecham		
	Encephalopathy	Health			Pharmaceuticals	ORAL	ORAL 10 YR
	Faecal Incontinence	Professional	Eskalith	SS		ORAL	675
	Fall						MILLIGRAMS
	Hyperglycaemia						2.0 DAILY
	Hypernatraemia						ORAL
	Hypokalaemia		Depakote (Valproate				
	Infection		Semisodium)	C			
	Medication Error		Synthroid				
	Memory Impairment		(Levothyroxine)	C			
	Metabolic Encephalopathy		Effexor (Venlafaxine				
	Paranoia		Hydrochloride)	C			
	Pneumonia Aspiration		Restoril	C			
	Psychotic Disorder						
	Pyrexia						
	Renal Failure Acute						
	Rhinorrhoea						
	Sepsis						
	Tremor						
	Urinary Incontinence						
	Urinary Retention						
	Verbigeration						
	Vitamin B12 Deficiency						

Date:08/17/00ISR Number: 3552006-2Report Type:Direct Company Report #
Age:52 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Life-Threatening	Dialysis		Lithium 300mg Caps	PS		ORAL	300MG CAPS PO
Hospitalization -	Drug Level Above						TID
Initial or Prolonged	Therapeutic		Tegretol	C			
	Drug Toxicity		Haldol	C			
	Emotional Distress		Lisinopril	C			

	Gastrointestinal Disorder					
	Tremor					

Date:08/21/00ISR Number: 3554398-7Report Type:Expedited (15-DaCompany Report #A028449
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Disability	Amnesia	Consumer	Sinequan	PS	Pfizer Laboratories	
Required	Depression				Div Pfizer Inc	
Intervention to	Mental Disorder		Sertraline	SS		
Prevent Permanent	Panic Attack		Lithium	SS		
Impairment/Damage	Weight Increased		Prozac	SS		
			Lotensin	C		
			Klonopin	C		

Date:08/21/00ISR Number: 3554447-6Report Type:Expedited (15-DaCompany Report #2000023739-1
Age:71 YR Gender:Female I/FU:I

Outcome	PT
Hospitalization -	Blood Creatinine
Initial or Prolonged	Increased
	Blood Lactate

	Dehydrogenase Increased					
	Blood Urea Increased					
	Coma					
	Computerised Tomogram	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
	Abnormal	Literature	Eskalith	PS	Smithkline Beecham	
	Coordination Abnormal	Health			Pharmaceuticals	
750						
	Csf Test Abnormal	Professional				
MILLIGRAMS						
	Dehydration					
	Dyskinesia					
	Escherichia Sepsis					
	Fall					
	Gait Disturbance					
	Hepatic Enzyme Increased					
	Hypernatraemia					
	Hyperparathyroidism					
	Hyperpyrexia					
	Hyporeflexia					
	Leukocytosis					
	Loss Of Consciousness					
	Nephrogenic Diabetes					
	Insipidus					
	Neutrophilia					
	Peripheral Sensory					
	Neuropathy					
	Polyuria					
	Psychiatric Symptom					
	Pyrexia					
	Pyuria					
	Quadriplegia					
	Renal Tubular Disorder					
	Sedation					
	Sensory Disturbance					
	Tachycardia					
	Tachypnoea					
	Urinary Incontinence					

Date:08/22/00ISR Number: 3555728-2Report Type:Expedited (15-DaCompany Report #EWC000807564
Age:55 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization -	Breast Pain	Foreign	Lithium	PS		
900 MG/DAY						

Initial or Prolonged	Bundle Branch Block Right	Study	Olanzapine	SS	
20 MG/DAY					
Other	Dyspnoea	Health	Lorazepam	C	
	Haematocrit Decreased	Professional			
	Haemoglobin Decreased	Other			
	Mean Cell Volume Decreased				
	Microcytic Anaemia				

Date:08/23/00ISR Number: 3556308-5Report Type:Direct Company Report #
Age:30 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Priapism		Lithium Carbonate	PS		ORAL
300 MG PO BID						
			Paroxetine	C		
			Hydroxyzine	C		
			Sumatriptan	C		
			Alprazolam	C		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/23/00ISR Number: 3556457-1Report Type:Expedited (15-DaCompany Report #L00-TWN-01201-01
Age:42 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Blood Creatinine Increased	Foreign Literature	Carbamazepine	PS	Inwood Laboratories Inc Sub Forest			
Hospitalization - Initial or Prolonged	Convulsion	Health			Laboratories Inc	ORAL	200 MG BID PO	
	Diarrhoea	Professional	Lithium	SS		ORAL	900 MG QD PO	
	Dizziness	Other	Clonazepam	C				
	Drug Level Above Therapeutic		Trazadone	C				
			Moperone	C				
	Drug Level Below Therapeutic		Bethanechol	C				
			Trihexyphenidyl	C				
	Electrocardiogram Abnormal							
	Electrocardiogram Qt Corrected Interval Prolonged							
	Electrocardiogram Qt Prolonged							
	Electrocardiogram T Wave Inversion							
	Fall							
	Hypokalaemia							
	Leukocytosis							
	Loss Of Consciousness							
	Sedation							
	Sinus Arrest							
	Sinus Arrhythmia							
	Sinus Bradycardia							

Date:08/24/00ISR Number: 3557700-5Report Type:Expedited (15-DaCompany Report #10498152
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Interaction	Foreign	Avapro	PS	Sanofi Synthelabo Inc	ORAL	ORAL	
	Drug Level Above Therapeutic	Health						
		Professional Other	Priadel (Lithium Carbonate)	SS		ORAL	400 MG, 1/1	

DAY ORAL

Date:08/24/00ISR Number: 3566371-3Report Type:Direct Company Report #
Age:14 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Blood Thyroid Stimulating Hormone Increased	Health Professional	Lithium	PS		ORAL	600 MG PO BID	
	Condition Aggravated		Thorazine	SS		ORAL	200 MG PO QID	
	Hypercholesterolaemia		Depakote	SS		ORAL	500 MG PO BID	
	Hypertriglyceridaemia		Seroquel	SS		ORAL	200 MG PO BID	
			Depakote	SS		ORAL	250-750 MG PO	
			Zyprexa	SS		ORAL	5MG PO HS	
			Ritalin	SS			20 MG PO TID	
			Tenex	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/25/00ISR Number: 3558701-3Report Type:Direct Company Report #
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Rash Macular		Clozapine	PS			350MG/D-DIVID	
	Skin Hyperpigmentation						ED	
			Lithium	SS		ORAL	300MG PO TID	
			Cogentin	C				
			Neurontin	C				
			Lithium	C				
			Prevacid	C				

Date:08/28/00ISR Number: 3560606-9Report Type:Expedited (15-DaCompany Report #2000024412-2
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Amoebic Dysentery	Literature	Eskalith	PS	Smithkline Beecham			
	Benign Congenital	Health			Pharmaceuticals			
TRANSPLACENTAL	TRANSPLACENTA							
	Hypotonia	Professional					RY,	
	Cardiac Murmur						TRANSMAMMARY	
	Complications Of Maternal		Chlorthalidone	C				
	Exposure To Therapeutic		Thyroglobulin	C				
	Drugs		Secobarbital	C				
	Cyanosis Neonatal		Chloramphenicol	C				
	Drug Level Above Therapeutic		Iodochlorhydroxyquin	C				
	Electrocardiogram T Wave Inversion							
	Hypoglycaemia Neonatal							
	Hypothermia							
	Insomnia							
	Lethargy							
	Pregnancy							

Date:08/29/00ISR Number: 3561571-0Report Type:Direct Company Report #
Age:60 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Asthenia	Health	Lithium Sr 450mg	PS		ORAL	450 MG PO TID	
	Dizziness	Professional	Asa	C				
	Drug Level Above Therapeutic		Lith Carb Sr	C				
			Vpa	C				
	Gait Disturbance		Cogentin	C				
			Chlorpramazine	C				
			Glyburide	C				
			Prazonin	C				
			Simvastatin	C				
			Fosinopril	C				

Date:08/29/00ISR Number: 3561792-7Report Type:Expedited (15-DaCompany Report #EWC000807564
Age:55 YR Gender:Female I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Breast Pain
	Bundle Branch Block Right
Other	Dyspnoea
	Haematocrit Decreased
	Mean Cell Volume Abnormal
	Microcytic Anaemia

Pulmonary Embolism

Dose	Duration	Report Source	Product	Role	Manufacturer	Route
UNKNOWN	900 MG DAY	Foreign Study	Lithium	PS		
UNKNOWN	20 MG DAY	Health Professional	Olanzapine	SS		
UNKNOWN		Other	Lorazepam	C		

Date:08/30/00ISR Number: 3562226-9Report Type:Expedited (15-DaCompany Report #HQ0130422AUG2000
Age:17 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Athetosis Cerebellar Syndrome Coma Coordination Abnormal Dysarthria Dysphagia Dystonia Electroencephalogram Abnormal Encephalopathy Enuresis Fall Grand Mal Convulsion Hypotension	Literature	Artane	PS	Lederle Laboratories Div American Cyanamid Co	ORAL	2 MG FOUR TIMES DAILY	
			Chlorpromazine	SS		ORAL	50 MG AS NEEDED	
			Clozapine	SS		ORAL	25 MG DAILY INCREASED TO 100 MG TWICE DAILY DECREASED TO 300 MG FOUR TIMES DAILY	
			Lithium	SS		ORAL		

	Hypotonia					
ORAL						
	Lethargy		Aspirin "Bayer"	C		
	Movement Disorder		Ceftriaxone	C		
	Neuroleptic Malignant Syndrome		Haloperidol	C		
	Orthostatic Hypotension					
	Pyrexia					
	Sedation					
	Tachycardia					
	Tremor					
	Vomiting					

Date:09/01/00ISR Number: 3564128-0Report Type:Expedited (15-DaCompany Report #243169
Age:45 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Blood Thyroid Stimulating Hormone Decreased	Foreign Other	Valium	PS	Hoffmann La Roche Inc	ORAL	3 DOSE FORM
	Dehydration						DAILY, ORAL
	Hypernatraemia		Lithium Microsol				
	Hyperthyroidism		(Lithium Bromide)	SS		ORAL	ORAL
	Hypotension		Zyprexa (Olanzapine)	SS		ORAL	1 DOSE FORM
	Nephrogenic Diabetes Insipidus						DAILY, ORAL
	Polydipsia		Tercian				
	Polyuria		(Cyamemazine) 40 Mg/Ml	SS		ORAL	25 MG 3 PER DAY ORAL

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/08/00ISR Number: 3568965-8Report Type:Expedited (15-DaCompany Report #2000023526-1
Age:53 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Amyotrophic Lateral Sclerosis	Health Professional	Eskalith Cr	PS	Smithkline Beecham Pharmaceuticals	ORAL	SEE IMAGE	
Other	Condition Aggravated		Haldol (Haloperidol)	C				
	Drug Ineffective		Cogentin (Benztropine Mesylate)	C				
	Headache		Dalmane (Flurazepam Hydrochloride)	C				
	Loss Of Libido							
	Mania							
	Polydipsia							
	Tremor							

Date:09/08/00ISR Number: 3573478-3Report Type:Periodic Company Report #2000026052-1
Age:27 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Interaction	Literature	Lithium Smithkline Beecham	PS	Smithkline Beecham		900	MILLIGRAMS
	Drug Toxicity						2.0	DAILY
			Lithium Smithkline Beecham	SS	Smithkline Beecham		600	MILLIGRAMS
							1.0	DAILY
			Lithium Smithkline Beecham	SS	Smithkline Beecham		900	MILLIGRAMS
							1.0	DAILY
			Sulindac	C				
			Nefazodone	C				
			Fluphenazine					

			Decanoate	C		
			Lorazepam	C		
			Gemfibrozil	C		

Date:09/08/00ISR Number: 3573484-9Report Type:Periodic Company Report #2000026032-1
Age:23 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Interaction Drug Toxicity	Literature	Lithium Smithkline Beecham	PS	Smithkline Beecham		600-900 MILLIGRAMS 1.0 DAILY	

(SEE NEXT PAGE)

4 MON

			Sulindac	C		
			Divalproex Sodium	C		
			Olanzapine	C		
			Tetracycline	C		

Date:09/13/00ISR Number: 3571247-1Report Type:Expedited (15-DaCompany Report #00P-083-0096941-00(1)
Age:33 YR Gender:Female I/FU:F

Outcome	PT	Report Source
Hospitalization - Initial or Prolonged	Fall Spinal Fracture	Foreign Health Professional

Other

Dose	Duration	Product	Role	Manufacturer	Route
525 MG, 1 IN 1 D, PER ORAL		Ferrograd (Fero-Gradumet Filmtab) (Ferrous Sulfate)	PS		ORAL
5 MG, 1 IN 1 D, PER ORAL		Zomig Rapimeld	SS		ORAL
600 MG, 1 IN 1 D, PER 0RAL		Lithium Carbonate (Lithium Carbonate)	SS		ORAL
20 MG, 1 IN 1 D, PER ORAL		Paroxetine (Par0xetine)	SS		ORAL

Date:09/13/00ISR Number: 3574873-9Report Type:Expedited (15-DaCompany Report #2000026382-1
Age:66 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged Other	Amnesia Clonic Convulsion Cognitive Disorder Coma Dementia Disorientation Drug Level Above Therapeutic Drug Toxicity Electroencephalogram Abnormal Encephalopathy Extrapyramidal Disorder Hyperreflexia	Literature Health Professional	Eskalith	PS	Smithkline Beecham Pharmaceuticals	

Parkinsonism
Pulmonary Congestion
Respiratory Distress
Speech Disorder
Tremor

Date:09/14/00ISR Number: 3570958-1Report Type:Direct Company Report #
Age:56 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Dyspnoea		Lithium	PS		ORAL	300MG PO Q 8	
	Hyperpyrexia		Droperidol	SS		INTRAVENOUS	1.25MG IV Q4	
	Renal Failure						PRN	
	Respiratory Failure							

Date:09/14/00ISR Number: 3571678-XReport Type:Expedited (15-DaCompany Report #239346
Age:60 YR Gender:Male I/FU:F

Outcome	PT
Death	Diabetes Mellitus
	Drug Level Above Therapeutic
	Mania

Pulse Absent
Respiratory Disorder
Stupor

Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Foreign Study	Valium	PS	Hoffmann La Roche Inc	ORAL	30 MG DAILY	
Health Professional	Valium (Diazepam)	SS		INTRATUMOR	10 MG DAILY	
				INTRAVENOUS		
	Quilonum Retard (Lithium Carbonate)	SS			1350 MG DAILY	
	Orfiril (Valproate Sodium)	SS			600 MG DAILY	
	Truxal (Chlorprothixene)	SS		ORAL	150 MG DAILY	
				ORAL		
	Truxal (Chlorprothixene)	SS		INTRAVENOUS	100 MG DAILY	
				INTRAVENOUS		
	Truxal (Chlorprothixene)	SS		ORAL	100 MG DAILY	
				ORAL		
	Risperdal (Risperidone)	SS			6 MG DAILY	
	Amaryl(Glimepiride)	C				
	Pirenzepine (Pirenzepine Hydrochloride)	C				
	Heparin (Heparin Sodium)	C				

Date:09/15/00ISR Number: 3572762-7Report Type:Expedited (15-DaCompany Report #LBID00200005688
Age:59 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Alpha 2 Globulin Increased	Foreign Literature	Lithobid	PS	Solvay Pharmaceuticals		800 MG DAILY	
	Anaemia	Health Professional Other	Haloperidol (Haloperidol)	C				
	Blood Urea Increased		Doxepin (Doxepin)	C				
	Cerebellar Ataxia		Biperiden (Biperiden)	C				
	Diarrhoea							
	Drug Level Above Therapeutic							
	Dysarthria							
	Glomerulonephritis Proliferative							
	Haemoglobin Decreased							
	Hypercholesterolaemia							
	Hypoproteinaemia							
	Lethargy							
	Leukopenia							
	Oedema							
	Pleural Effusion							
	Proteinuria							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/18/00ISR Number: 3573051-7Report Type:Direct Company Report #
Age:35 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Balance Disorder Confusional State Dehydration Drug Level Above Therapeutic Dysarthria Haemodialysis		Lithium	PS				

Date:09/18/00ISR Number: 3573108-0Report Type:Direct Company Report #
Age:45 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Hospitalization - Initial or Prolonged Disability Required Intervention to Prevent Permanent Impairment/Damage	Acne Alopecia Depression Drug Withdrawal Syndrome Epistaxis Hallucination, Gustatory Increased Appetite Insomnia Judgement Impaired Lethargy Mania Muscle Spasms Myalgia Nervous System Disorder Obesity Psychotic Disorder Scar Suicidal Ideation Tic Tremor Visual Acuity Reduced Weight Increased		Depakote, 1000 Mg Per Diem Lithium-1500 Mg Per Diem	PS SS		ORAL	500MG 2X/DIEM 1500MG 2X DIEM ORAL	6 MON 4 MON

Date:09/18/00ISR Number: 3574948-4Report Type:Expedited (15-DaCompany Report #2000026865-1
Age:68 YR Gender:Female I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Aggression
	Blood Calcium Increased
	Blood Chloride Decreased
	Blood Creatinine Increased
	Blood Parathyroid Hormone Increased
	Blood Thyroid Stimulating Hormone Decreased
	Calcium Ionised Increased
	Confusional State
	Coordination Abnormal
	Delirium
	Disinhibition
	Drug Toxicity
	Euthyroid Sick Syndrome
	Feeling Jittery

		Flight Of Ideas Hypercalcaemia Hypernatraemia	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
		Hyperreflexia Hyperthyroidism	Literature Health	Eskalith	PS	Smithkline Beecham Pharmaceuticals	
750							
		Hyponatraemia	Professional				
MILLIGRAMS							
		Mania		Carbamazepine	C		
		Nephrogenic Diabetes		Citalopram	C		
		Insipidus		Simvastatin	C		
		Pressure Of Speech		Temazepam	C		
		Speech Disorder		Thioridazine	C		
		Thyroiditis Chronic Thyroxine Increased Tri-Iodothyronine Increased					

Date:09/18/00ISR Number: 3574949-6Report Type:Expedited (15-DaCompany Report #2000026969-1
Age: Gender:Unknown I/FU:I

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Other		Overdose	Literature	Eskalith	PS	Smithkline Beecham Pharmaceuticals	
				Alimemazine	C		
				Benzodiazepines	C		
				Venlafaxine	C		

Date:09/18/00ISR Number: 3575039-9Report Type:Expedited (15-DaCompany Report #2000026461-1
Age:24 YR Gender:Female I/FU:I

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Hospitalization - Initial or Prolonged		Abdominal Pain Agitation	Literature	Eskalith	PS	Smithkline Beecham Pharmaceuticals	ORAL
ORAL							
Other		Cerebellar Atrophy Condition Aggravated Coordination Abnormal Depression Diarrhoea		Maprotiline	C		

	Disorientation
	Drug Toxicity
	Dry Mouth
	Dysarthria
	Gait Disturbance
	Headache
	Intentional Misuse
	Stress
	Suicidal Ideation
	Suicide Attempt
	Tremor
	Vomiting

Date:09/18/00ISR Number: 3575040-5Report Type:Expedited (15-DaCompany Report #2000026798-1
Age:34 YR Gender:Female I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Agitation
	Blood Bicarbonate Decreased
	Blood Creatinine

		Increased Blood Thyroid Stimulating Hormone Decreased Blood Urea Increased	Report Source	Product	Role	Manufacturer		Route
Dose	Duration							
		Clubbing Confusional State	Literature Health	Eskalith	PS	Smithkline Beecham Pharmaceuticals		
1500								
		Dehydration	Professional					
MILLIGRAMS	10 YR							
		Delirium		Diphenoxylate/Atropine	C			
		Dermatitis		Metoclopramide	C			
		Diarrhoea		Paroxetine	C			
		Drug Toxicity		Thioridazine	C			
		Extrasystoles						
		Faecal Incontinence						
		Haemodialysis						
		Hyperglycaemia						
		Hypernatraemia						
		Hyperosmolar State						
		Hyperreflexia						
		Hyperthyroidism						
		Hypertonia						
		Hypochloraemia						
		Hypokalaemia						
		Hyponatraemia						
		Hypothyroidism						
		Implant Site Infection						
		Iodine Uptake Increased						
		Lid Lag						
		Myopathy						
		Nephrogenic Diabetes Insipidus						
		Nervous System Disorder						
		Polyuria						
		Pyrexia						
		Renal Impairment						
		Renal Tubular Necrosis						
		Sepsis						
		Tachycardia						
		Thyrotoxic Crisis						
		Thyroxine Increased						
		Tremor						
		Tri-Iodothyronine Increased						
		Urinary Incontinence						
		Urinary Tract Infection						
		Vomiting						

Date:09/18/00ISR Number: 3575041-7Report Type:Expedited (15-DaCompany Report #2000026922-1
Age:78 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Metabolic Disorder Renal Disorder	Literature Health Professional	Eskalith	PS	Smithkline Beecham Pharmaceuticals	ORAL	ORAL	

Date:09/19/00ISR Number: 3574919-8Report Type:Expedited (15-DaCompany Report #00P-083-0096941-00 (1)
Age:33 YR Gender:Female I/FU:F

Outcome	PT	Report Source
Hospitalization - Initial or Prolonged	Fall Spinal Fracture	Foreign Health

Professional

Dose	Duration	Product	Role	Manufacturer	Route
525 MG , 1 IN 1 D, PER ORAL		Ferrograd Tablets (Fero-Gradumet Filmtab) (Ferrous Sulfate)	PS		ORAL
5 MG, 1 IN 1 D, PER ORAL; 2.5 MG 1 IN 1 D, PER ORAL		Zomig Rapimeld	SS		ORAL
600 MG, 1 IN 1 D, PER ORAL		Lithium Carbonate (Lithium Carbonate)	SS		ORAL
20 MG, 1 IN 1 D, PER ORAL		Paroxetine (Paroxetine)	SS		ORAL

Date:09/20/00ISR Number: 3575521-4Report Type:Expedited (15-DaCompany Report #LBID00200005755
Age:51 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Antibody Test Positive Electromyogram Abnormal Fatigue Muscular Weakness Myasthenia Gravis	Foreign Literature Health Professional Other	Lithobid Benzodiazepine Carbamazepine (Carbamazepine)	PS C C	Solvay Pharmaceuticals	ORAL	750 MG DAILY PO	

Date:09/20/00ISR Number: 3575733-XReport Type:Expedited (15-DaCompany Report #2000027172-1
Age:60 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Chronic Lymphocytic Leukaemia	Foreign Health	Eskalith	PS	Smithkline Beecham Pharmaceuticals	ORAL		
Other	Leukocytosis	Professional						
	Thrombocythaemia	Other						

Date:09/20/00ISR Number: 3575734-1Report Type:Expedited (15-DaCompany Report #2000018615-1
Age:60 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Diabetes Mellitus	Foreign	Eskalith	PS	Smithkline Beecham			
	Drug Level Above Therapeutic	Health Professional			Pharmaceuticals	ORAL	1125 MILLIGRAMS	3 DAY
	Nervous System Disorder	Other	Amaryl (Glimepirid)	C				
	Pulse Absent		Heparin	C				
	Respiratory Arrest		Orfiril (Valproat)	C				
	Sedation		Pirenzepin (Pirenzepin)	C				
			Risperdal (Reisperidon)	C				
			Truxal (Chlorprothixen)	C				
			Valium (Diazepam)	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/20/00ISR Number: 3575803-6Report Type:Expedited (15-DaCompany Report #LBID00200005748
Age:63 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Blood Creatine Phosphokinase Increased	Literature Health	Lithobid	PS	Solvay Pharmaceuticals	ORAL	300 MG TID PO
	Blood Creatinine Increased	Professional	Amoxapine (Amoxapine)	SS			
	Blood Urea Increased		Lorazepam	C			
	Blunted Affect		Benztropine	C			
	Decreased Activity		Atenolol	C			
	Dementia		Verapamil	C			
	Depressed Level Of Consciousness						
	Disorientation						
	Disturbance In Attention						
	Hyperhidrosis						
	Hypernatraemia						
	Hypertension						
	Judgement Impaired						
	Leukocytosis						
	Muscle Rigidity						
	Myoglobinuria						
	Neuroleptic Malignant Syndrome						
	Pyrexia						
	Sensory Disturbance						
	Tachycardia						

Date:09/21/00ISR Number: 3576882-2Report Type:Expedited (15-DaCompany Report #LBID00200005776
Age:27 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Drug Interaction Drug Level Above Therapeutic	Literature Health Professional	Lithobid	PS	Solvay Pharmaceuticals	ORAL	900 MG BID PO, 1500 MG DAILY PO
			Sulindac (Sulindac)	SS		ORAL	150 MG BID PO

			Gemfibrozil	C		
			Nefazodone	C		
			Fluphenazine			
			Deconate	C		
			Lorazepam	C		

Date:09/22/00ISR Number: 3576365-XReport Type:Expedited (15-DaCompany Report #245208
Age:68 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Agitation		Rivotril	PS	Roche			25 DAY
Initial or Prolonged	Anxiety		Silece	SS	Roche			660 DAY
	Depressed Level Of		Limas	SS				60 DAY
	Consciousness		Lodopin	SS				257 DAY
	Disorientation							
	Drug Level Above Therapeutic							
	Electroencephalogram Abnormal							
	Therapeutic Agent Toxicity							

Date:09/22/00ISR Number: 3578319-6Report Type:Expedited (15-DaCompany Report #A031176
Age:59 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anaemia	Foreign	Lithium Carbonate	PS	Pfizer Inc	ORAL	800.00 MG	TOTAL:ORAL
	Blood Albumin Decreased	Literature						
	Blood Urea Decreased	Health	Haloperidol	C				
	Cerebellar Ataxia	Professional	Doxepin	C				
	Diarrhoea		Biperiden	C				
	Drug Level Above Therapeutic							
	Drug Toxicity							
	Dysarthria							
	Glomerulonephritis Proliferative							
	Hypercholesterolaemia							
	Lethargy							
	Leukopenia							
	Nephrotic Syndrome							
	Oedema							
	Pleural Effusion							
	Proteinuria							
	Red Blood Cell Count Abnormal							
	Renal Impairment							
	White Blood Cell Count Abnormal							

Date:09/22/00ISR Number: 3578847-3Report Type:Expedited (15-DaCompany Report #245208
Age:68 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agitation	Foreign	Clonopin	PS	Hoffmann La Roche Inc	ORAL	0.5 MG DAILY	ORAL
	Anxiety	Health						
	Depressed Level Of Consciousness	Professional						
		Other	Silece	SS		ORAL	2 MG DAILY	ORAL
	Disorientation							

	Drug Level Above		Limas	SS		ORAL
800 MG DAILY						
	Therapeutic					
ORAL						
	Electroencephalogram		Lodopin	SS		ORAL
25 MG DAILY						
	Abnormal					
ORAL						
	Therapeutic Agent Toxicity					

Date:09/25/00ISR Number: 3579360-XReport Type:Expedited (15-DaCompany Report #2000022369-1
Age:45 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Anaemia Macrocytic	Health Professional	Eskalith Cr	PS	Smithkline Beecham Pharmaceuticals	ORAL
1350						
	Abnormal					
MILLIGRAMS						
	Hyperchromic Anaemia					
ORAL						
	Macrocytosis		Stangyl	C		
			Vitamin B12	C		
			Zoloft	C		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/25/00ISR Number: 3579365-9Report Type:Expedited (15-DaCompany Report #DEU003143
Age:69 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Life-Threatening	Aggression	Foreign	Akineton	PS	Knoll Pharmaceutical		
Hospitalization -	Bipolar I Disorder	Health			Co	ORAL	3 MG DAILY PO
Initial or Prolonged	Cerebellar Ataxia	Professional	Limas	SS		ORAL	1000 MG DAILY
	Condition Aggravated	Other					PO
	Excitability		Lodopin	SS		ORAL	50 MG DAILY
	Insomnia						PO
	Neuroleptic Malignant Syndrome		Silece	C			
	Stupor						
	Therapeutic Agent Toxicity						
	Urinary Incontinence						

Date:09/25/00ISR Number: 3579463-XReport Type:Expedited (15-DaCompany Report #EWC000506839
Age:33 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Depression	Foreign	Lithium	PS			3600 MG/DAY
Initial or Prolonged	Mania	Study	Olanzapine	SS			7.5 MG/DAY
	Mood Altered	Health	Lorazepam	C			
	Psychomotor Hyperactivity	Professional					
	Suicide Attempt	Other					

Date:09/25/00ISR Number: 3581811-1Report Type:Expedited (15-DaCompany Report #2000026922-1
Age:76 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Anxiety	Literature	Eskalith	PS	Smithkline Beecham		

Initial or Prolonged	Bipolar Disorder	Health	Pharmaceuticals	ORAL
250 MILLIGRAM				
	Blood Amylase Increased	Professional		
ORAL				
	Blood Creatinine Increased			
	Blood Urea Increased			
	Dehydration			
	Depression			
	Extrapyramidal Disorder			
	Hypercalcaemia			
	Hyperparathyroidism			
	Hypothyroidism			
	Lipase Increased			
	Nephrogenic Diabetes Insipidus			
	Polyuria			
	Proteinuria			
	Psychomotor Retardation			
	Renal Failure			
	Suicidal Ideation			
	Urinary Incontinence			

Date:09/25/00ISR Number: 3583140-9Report Type:Expedited (15-DaCompany Report #2000-06-0664
Age:56 YR Gender:Female I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Apathy
	Dehydration

	Diarrhoea Drug Toxicity Sedation	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
		Foreign	Camcolit	PS		ORAL
1000 MG QD						
		Other				
ORAL						
			Furosemide Tablets	SS		ORAL
40 MG QD ORAL						
			Intron A (Interferon Alfa-2b Recombinant Soluble Powder)	SS		
SUBCUTANEOUS 15 MU QD						
SUBCUTANEOUS						
			Cardura Tablets	C		
			Metformin	C		
			Zocor Tablets	C		
			Artane Tablets	C		
			Temazepam Capsules	C		
			Trilafon	C		

Date:09/27/00ISR Number: 3581293-XReport Type:Direct Company Report #
Age:56 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Confusional State Diabetes Insipidus Hypernatraemia Tremor	Health Professional	Lithium	PS		

Date:09/28/00ISR Number: 3582576-XReport Type:Direct Company Report #
Age:65 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Athetosis Coordination Abnormal Dyskinesia Muscle Rigidity Tremor		Lithium	PS		

Date:09/28/00ISR Number: 3582787-3Report 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	Confusional State Drug Toxicity		Lithium Carbonate 300mg Cap	PS				
			Acetaminophen	C				
			Guaifenesin	C				
			Sertraline Hcl	C				
			Valsartan	C				
			Beclomethasone	C				
			Benztropine Mesylate	C				
			Thiothixene Hcl	C				
			Atenolol	C				

Date:09/28/00ISR Number: 3584447-1Report Type:Expedited (15-DaCompany Report #8-99092-033A
Age:62 YR Gender:Male I/FU:I

Outcome
Hospitalization -
Initial or Prolonged

Other

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Blood Lactate Dehydrogenase Increased	Health Professional	Effexor	PS	Wyeth Ayerst Laboratories Inc	ORAL	SEE IMAGE,	
	Coma						ORAL	14 DAY
	Drug Interaction Electrocardiogram Abnormal		Alimemazine (Alimemazine	SS		ORAL	SEE IMAGE,	
	Electrocardiogram Qrs Complex Prolonged		Lithium (Lithium)	SS		ORAL	SEE IMAGE,	
	Hypotension Intentional Misuse Respiratory Depression Suicide Attempt Toxicologic Test Abnormal		Noctran 10 (Acepromazine/ Aceprometazine/ Clorazepate Dipotassium,)	SS		ORAL	300 MG,	
							OVERDOSE	
AMOUNT, ORAL								1 DAY
			Imovane (Zopiclone)	C				

Date:09/28/00ISR Number: 3585804-XReport Type:Expedited (15-DaCompany Report #2000026301-1
Age:59 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Corneal Disorder		Eskalith	PS	Smithkline Beecham Pharmaceuticals	ORAL	900	
	Keratoconjunctivitis Sicca						MILLIGRAMS	
	Retinopathy						ORAL	
	Visual Acuity Reduced		Jodthyrox (Levothyroxine)	C				
			Vioxx (Rofecoxib)	C				

Date:09/29/00ISR Number: 3582977-XReport Type:Direct Company Report #
Age:63 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Confusional State		Lithium	PS				
	Dysphagia		Tegretol	C				
	Dyspnoea		Atenolol	C				
	Hyperhidrosis							
	Mental Impairment							
	Tremor							

Date:09/29/00ISR Number: 3583116-1Report Type:Direct Company Report #
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Blood Potassium Increased		Lithium	PS				
	Renal Impairment							

Date:09/29/00ISR Number: 3584982-6Report Type:Periodic Company Report #8-99230-153A
Age:45 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Interaction	Health Professional	Premarin	PS	Wyeth Ayerst Laboratories Inc	ORAL	ORAL	3 DAY
			Lithobid (Lithium)	SS				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/29/00ISR Number: 3585123-1Report Type:Expedited (15-DaCompany Report #WAES 00064287
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Interaction	Consumer	Vioxx	PS	Merck Research Laboratories Div			
	Injury							
Disability	Pain				Merck Co Inc	ORAL	PO	4 WK
	Tremor		Lithiumco3	SS				

Date:10/02/00ISR Number: 3584575-0Report Type:Direct Company Report #
Age:83 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Confusional State	Health	Lithium Cn750	PS		ORAL	225 AM + 450 PM PO	
	Dehydration	Professional						
			Ec Asa	C				
			Furosemide	C				
			Lisinopril	C				
			Malindone	C				
			Salsalate	C				
			Mvi	C				
			Vit E	C				

Date:10/02/00ISR Number: 3585280-7Report Type:Direct Company Report #
Age:60 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Asthenia		Lithium Cn 750	PS		ORAL	600 BID 1200 MG PO QD	
	Dysarthria							
	Syncope		Atenolol	C				
			Diltiazem	C				
			Diphenhydramine	C				
			Haloperidol	C				

Date:10/02/00ISR Number: 3586254-2Report Type:Direct Company Report #
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Level Above Therapeutic	Health Professional	Fosinopril 10mg Lithium Carbonate	PS SS			1 BID 2 BID	
Other			300 Mg					

Date:10/03/00ISR Number: 3585402-8Report Type:Direct Company Report #
Age:52 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abnormal Behaviour Medication Error Sedation Speech Disorder		Lithium Cn750	PS				

Date:10/04/00ISR Number: 3587785-1Report Type:Expedited (15-DaCompany Report #9947674
Age: Gender:Female I/FU:F

Outcome
Required Intervention to

Prevent Permanent
Impairment/Damage

	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Abdominal Pain	Study	Zoloft	PS	Pfizer			
	Convulsion	Consumer			Pharmaceuticals Inc	ORAL	50.00 MG	
	Dizziness							TOTAL:DAILY:O
	Drug Ineffective							RAL
	Liver Disorder		Lithium	SS				
	Loss Of Consciousness		Prometazine	C				
	Nervousness		Diazepam	C				
	Nightmare		Thoridazine	C				
	Paraesthesia		Maprotiline	C				
	Syncope							
	Vomiting							
	Weight Decreased							

Date:10/05/00ISR Number: 3589152-3Report Type:Expedited (15-DaCompany Report #LBID00200005889
Age:49 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Agitation	Foreign	Lithobid	PS	Solvay			
Initial or Prolonged	Blood Creatinine	Literature			Pharmaceuticals	ORAL	DAILY PO	
	Increased	Other						
	Blood Ph Decreased							
	Cerebellar Ataxia							
	Dialysis							
	Disorientation							
	Drug Level Above Therapeutic							
	Drug Toxicity							
	Hyperkalaemia							
	Hypothermia							
	Intentional Misuse							
	Nausea							

Date:10/06/00ISR Number: 3592056-3Report Type:Expedited (15-DaCompany Report #2000026969-1
Age: Gender:Unknown I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Overdose	Literature	Eskalith	PS	Smithkline Beecham Pharmaceuticals			
			Alimemazine	C				
			Benzodiazepines	C				
			Venlafaxine	C				

Date:10/10/00ISR Number: 3592545-1Report Type:Expedited (15-DaCompany Report #JAOCAN2000000938
Age: Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Unevaluable Event	Foreign Health Professional	Risperdal	PS	Janssen Research Fdn Div Johnson And Johnson	ORAL	ORAL	
			Lithium (Lithium)	SS		ORAL	ORAL	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/10/00ISR Number: 3592730-9Report Type:Expedited (15-DaCompany Report #LBID00200005900
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Drug Interaction Drug Level Above Therapeutic Renal Disorder	Health Professional Company Representative	Lithobid	PS	Solvay Pharmaceuticals	ORAL	300 MG BID PO, 300 MG QD PO
			Vioxx	SS		ORAL	DAILY PO

Date:10/11/00ISR Number: 3592893-5Report Type:Direct Company Report #
Age:61 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Asthenia Balance Disorder Decreased Activity Dizziness		Lithium Carbonate (300mg Qid)(Roxane) Sinemet Olanzapine Fluoxetine Insulin Regular Hctz Albuterol Metformin Lisinopril	PS C C C C C C C C	Roxane	ORAL	ORAL MG QID

Date:10/13/00ISR Number: 3595482-1Report Type:Expedited (15-DaCompany Report #PHFR2000GB01523
Age:60 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Atrioventricular Block Complete Coordination Abnormal	Foreign Health Professional	Tegretol	PS	Novartis Pharmaceuticals Corp	ORAL	400MG/DAY, ORAL

	Drug Interaction	Other	Lithium(Lithium)	SS		ORAL 800MG/DAY, ORAL
	Nodal Arrhythmia					
			Anafranil(Clomipramine Hydrochloride) Tablet	SS		ORAL 300MG/DAY, ORAL
			Bendrofluazide(Bendrofluazide)	SS		ORAL 2.5MG/DAY, ORAL
			Thyroxine	C		
			Fluoxetine (Fluoxetine)	C		

Date:10/16/00ISR Number: 3595805-3Report Type:Expedited (15-DaCompany Report #2000027172-1
Age:60 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Leukocytosis	Foreign	Quilonum (Lithium)	PS	Smithkline Beecham Pharmaceuticals	ORAL	1125	
Other	Lymphocytic Leukaemia	Health					MILLIGRAMS	
	Thrombocythaemia	Professional						

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/17/00ISR Number: 3596701-8Report Type:Expedited (15-DaCompany Report #LBID00200006014
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hyperparathyroidism Hypocalcaemia Mania Post Procedural Complication	Foreign Literature Health Professional Other	Lithobid	PS	Solvay Pharmaceuticals	ORAL	PO, 1400 MG DAILYPO	9 YR

Date:10/17/00ISR Number: 3596713-4Report Type:Expedited (15-DaCompany Report #LBID00200006026
Age:57 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agitation Blood Creatinine Increased Blood Urea Increased Clonic Convulsion Confusional State Coordination Abnormal Drug Toxicity Encephalopathy Hypertension Sedation	Foreign Literature Other	Lithobid Captopril (Captopril) Nifedipine (Nifedipine) Haloperidol (Haloperidol)	PS SS C C	Solvay Pharmaceuticals	ORAL	1000 MG DAILY PO 50 MG TID PO	

Date:10/17/00ISR Number: 3596731-6Report Type:Expedited (15-DaCompany Report #LBID00200006021
Age:51 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Urea Increased Confusional State Coordination Abnormal	Foreign Literature Health	Lithobid	PS	Solvay Pharmaceuticals	ORAL	750 MG DAILY PO, 600 MG	

Delirium Professional

DAILY PO, 750

Drug Interaction

MG DAILY PO 5 YR

Drug Level Below Diovan (Valsartan) SS ORAL

80 MG DAILY

Therapeutic

PO, 80 MG

Grandiosity

DAILY PO 2 WK

Medication Error

Quetiapine (Quetiapine)	C
Zopiclone (Zopiclone)	C
L-Tryptophan (L-Tryptophan)	C
Lorazepam (Lorazepam)	C
Glyburide (Glyburide)	C
Conjugated Estrogen (Estrogens Conjugated)	C
Ciprofloxacin (Ciprofloxacin)	C

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/18/00ISR Number: 3597622-7Report Type:Expedited (15-DaCompany Report #A033638
Age:63 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Autonomic Nervous System Imbalance	Literature Health	Lithium Carbonate	PS	Pfizer Inc	ORAL	900.00 MG TOTAL:TID:ORAL
	Blood Creatine Phosphokinase Increased	Professional	Amoxapine	SS		ORAL	300.00 MG TOTAL:TID:ORAL
	Blunted Affect						
	Decreased Activity						
	Disturbance In Attention		Benztropine	SS		ORAL	3.00 MG TOTAL:TID:ORAL
	Extrapyramidal Disorder						
	Hyperhidrosis						
	Hypertension		Lorazepam	C			
	Judgement Impaired		Atenolol	C			
	Leukocytosis		Verapamil	C			
	Major Depression						
	Muscle Rigidity						
	Myoglobinuria						
	Neuroleptic Malignant Syndrome						
	Pyrexia						
	Renal Impairment						
	Tachycardia						

Date:10/23/00ISR Number: 3599834-5Report Type:Direct Company Report #
Age:68 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Other	Diabetes Insipidus		Lithium	PS		ORAL	150MG PO TID

Date:10/23/00ISR Number: 3599848-5Report Type:Direct Company Report #
Age:61 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Confusional State		Lithium	PS				
	Feeling Jittery							
	Lethargy							
	Leukocytosis							
	Tachycardia							

Date:10/24/00ISR Number: 3600441-6Report Type:Direct Company Report #
Age:44 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Hepatic Cirrhosis	Health	Depakote 250mg					
Life-Threatening	Hepatic Steatosis	Professional	Abbott	PS	Abbott		250MG	2 WK
Hospitalization -	Liver Disorder		Lithium 1200mg					
Initial or Prolonged	Nephrolithiasis		Ciba-Geigy Co	SS	Ciba-Geigy Co		1200 MG	10 MON
Other	Renal Cyst							
	Renal Neoplasm							
	Urinary Incontinence							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/24/00ISR Number: 3600790-1Report Type:Periodic Company Report #2000022074-1
Age:58 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Therapeutic Agent Toxicity	Health Professional	Eskalith Cr	PS	Smithkline Beecham Pharmaceuticals	ORAL	1 TABLET	2.0
DAILY ORAL	20	YR						
			Marplan (Isocarboxid)	C				
			Tegretol (Carbamazepine)	C				
			Cozaar (Losartain Potassium)	C				
			Seroquel (Quetiapine Fumurate)	C				

Date:10/24/00ISR Number: 3600791-3Report Type:Periodic Company Report #2000024320-1
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hypercalcaemia Hyperparathyroidism	Health Professional	Eskalith	PS	Smithkline Beecham Pharmaceuticals	ORAL	ORAL	

Date:10/24/00ISR Number: 3600792-5Report Type:Periodic Company Report #2000003113-1
Age:53 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dermatitis Pruritus	Health Professional	Eskalith	PS	Smithkline Beecham Pharmaceuticals	ORAL	300	
MILLIGRAMS								
3.0 DAILY								
ORAL								

Date:10/24/00ISR Number: 3601132-8Report Type:Expedited (15-DaCompany Report #EWC000807564
Age:55 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Breast Pain	Foreign	Zyprexa	PS	Eli Lilly And Co		20 MG/DAY	
Initial or Prolonged	Bundle Branch Block Right	Study	Lithium	SS			900 MG/DAY	
Other	Deep Vein Thrombosis	Health	Lorazepam	C				
	Delusion Of Reference	Professional						
	Dyspnoea	Other						
	Electrocardiogram Abnormal							
	Erotomanic Delusion							
	Escherichia Sepsis							
	Haematocrit Decreased							
	Haemoglobin Decreased							
	Iron Deficiency Anaemia							
	Lung Disorder							
	Mean Cell Volume Decreased							
	Pulmonary Embolism							
	Streptococcal Sepsis							
	Therapeutic Agent Toxicity							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/25/00ISR Number: 3601251-6Report Type:Direct Company Report #
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Asthenia Drug Toxicity		Lithium	PS		ORAL	300MG PO BID	PRIOR TO ADMISSION
			Zoloft	C				
			Phenobarbital	C				
			Claritin	C				
			Aspirin	C				
			Prilosec	C				
			Kcl	C				
			Lasix	C				
			Synthroid	C				
			Miacalcin	C				
			Detrol	C				
			Atacand	C				

Date:10/26/00ISR Number: 3602189-0Report Type:Expedited (15-DaCompany Report #WAES 00064287
Age:73 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Condition Aggravated Drug Interaction Tremor	Consumer Other	Vioxx	PS	Merck Research Laboratories Div Merck Co Inc	ORAL	25MG/DAILY/PO	
			Lithiniumco3 450 Mg	SS			450 MG/DAILY	
			Avapro	C				
			Deseril	C				
			Fosamax	C				
			Lipitor	C				
			Premarin	C				
			Aspirin	C				

Date:10/26/00ISR Number: 3602202-0Report Type:Expedited (15-DaCompany Report #LITH00200006065
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Overdose	Health	Lithonate	PS	Solvay			
Life-Threatening	Renal Failure	Professional			Pharmaceuticals	ORAL	UNK	DAILY PO
Hospitalization - Initial or Prolonged		Company Representative						

Date:10/26/00ISR Number: 3605756-3Report Type:Expedited (15-DaCompany Report #SP-200001922
Age:52 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Interaction	Foreign	Remicade	PS		INTRAVENOUS INFUSION	INTRAVENOUS	
	Hypercalcaemia	Study						
Required Intervention to Prevent Permanent Impairment/Damage		Health Professional	Remicade	SS		INTRAVENOUS INFUSION	INTRAVENOUS	
			Remicade	SS		INTRAVENOUS INFUSION	INTRAVENOUS	
			Lithium	SS		ORAL	ORAL 600MG AT BEDTIME	
			Acetaminophen With Codeine	C				
			Eltroxin	C				
			Losec	C				

Medroxyprogesterone	C
Timolol	C
Motilium	C
Vita-Vim	C
Vitamin E	C
Zyprexa	C
Clonazepam	C
Oxazepam	C
Pantoloc	C
Prednisone	C
Premarin	C
Fluconazole	C
Insulin Humulin Ultralente	C
Vasotec	C
Mobiflex	C
Humalog	C
Amoxicillin	C
Clonazepam	C
Cytotec	C
Biaxin	C

Date:10/30/00ISR Number: 3604211-4Report Type:Expedited (15-DaCompany Report #WAES 00101917
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Interaction	Health Professional	Vioxx	PS	Merck Research Laboratories Div Merck Co Inc	ORAL	DAILY/PO	
	Drug Level Above Therapeutic							
	Drug Toxicity		Lithobid 300 Mg	SS		ORAL	300 MG/BID/PO	
	Renal Disorder							

Date:10/31/00ISR Number: 3604996-7Report Type:Expedited (15-DaCompany Report #LBID00200005900
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Interaction	Health Professional	Lithobid	PS	Solvay Pharmaceuticals	ORAL	300 MG BID PO	10 YR
	Drug Level Above Therapeutic							

	Therapeutic	Company	Vioxx (Rofecoxib)	SS		ORAL
UNKNOWN DAILY						
	Dysarthria	Representative				
PO						
	Hemiparesis					
	Renal Disorder					

Date:11/02/00ISR Number: 3605796-4Report Type:Direct Company Report #
Age:45 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Disability	Amnesia		Aspartame In Diet			
	Feeling Abnormal		Coke	PS		ORAL
5 DIET COKES						
	Feeling Drunk					
/ DAY						
	Headache		Klonipin	SS		
	Vision Blurred		Lithium	SS		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/02/00ISR Number: 3606454-2Report Type:Expedited (15-DaCompany Report #2000030745-1
Age:56 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Electrocardiogram Abnormal	Foreign Health Professional	Eskalith Cr	PS	Smithkline Beecham Pharmaceuticals	ORAL	1350 MILLIGRAMS
			Carbamazepine (Tegretal)	C			
			Zotepin (Nipolept)	C			

Date:11/06/00ISR Number: 3607731-1Report Type:Expedited (15-DaCompany Report #2000031294-1
Age:73 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Other	Drug Interaction Drug Level Above Therapeutic		Eskalith	PS	Smithkline Beecham Pharmaceuticals	ORAL	450 MILLIGRAMS
			Celecoxib	C			
			Venlafaxine	C			

Date:11/07/00ISR Number: 3607759-1Report Type:Direct Company Report #
Age:50 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Confusional State Diarrhoea Mental Impairment		Lithium	PS			450 MG AM 900MG Q PM

Date:11/07/00ISR Number: 3607777-3Report Type:Direct Company Report #
Age:47 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Blood Creatinine		Lico3	PS			600MG BID	
	Increased		Lisinopril	SS			10MG QAM	
	Blood Urea Increased Diarrhoea Dizziness Drug Toxicity Hypotension Nausea Vomiting							

Date:11/07/00ISR Number: 3608645-3Report Type:Expedited (15-DaCompany Report #FLUV00300006081
Age:44 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Difficulty In Walking Dizziness	Foreign Health	Luvox	PS	Solvay Pharmaceuticals	ORAL	75 MG DAILY	
	Drug Level Below Therapeutic	Professional Other					PO, 100 MG DAILY PO,	
	Medication Error Nausea Oral Intake Reduced		Limas (Lithium Carbonate)	SS		ORAL	DAILY PO 200 MG TID PO	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/08/00ISR Number: 3608744-6Report Type:Direct Company Report #
Age:43 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Blood Creatinine		Lithium	PS		ORAL	300MG PO BID	
Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Increased Convulsion Hyperglycaemia Hypernatraemia Hypochloraemia Pneumonia Aspiration							

Date:11/09/00ISR Number: 3610283-3Report Type:Expedited (15-DaCompany Report #2000031588JP
Age:55 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Convulsion	Foreign	Xanax	PS	Pharmacia And Upjohn Co	ORAL	BID, ORAL	
	Depressed Level Of Consciousness	Health Professional	Prothiaden(Dosulepin)Tablet	SS		ORAL	TID, ORAL	
	Excitability	Other						
	Haemodialysis		Limas(Lithium Carbonate) Tablet	SS		ORAL	BID, ORAL	
	Hyperhidrosis							
	Pyrexia		Propranolol Hydrochloride(Propra nolol Hydrochloride)	C				
	Restlessness							
	Therapeutic Agent Toxicity							
	Tremor							

Date:11/13/00ISR Number: 3611163-XReport Type:Periodic Company Report #FLUV00299000297
Age:23 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Psychotic Disorder	Consumer	Luvox	PS	Solvay Pharmaceuticals	ORAL	100 MG QD PO	
			Lithonate (Lithium					

			Carbonate)	SS		ORAL
DAILY PO,						
1500 MG DAILY						
PO						
			Sinequan (Doxepin Hydrochloride)	C		
			Thyroid Hormones (Thyroid Hormones)	C		

Date:11/13/00ISR Number: 3611270-1Report Type:Periodic Company Report #FLUV00299001176
Age:37 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Vomiting	Health Professional	Luvox	PS	Solvay Pharmaceuticals	ORAL
PO						
			Lithobid (Lithum Carbonate)	SS		ORAL
DAILY PO						
			Ativan (Lorazepam)	C		
			Ambein (Zolpidem Tartrate)	C		
			Navane (Tiotixene)	C		
			Cogentin (Benzatropine Mesilate)	C		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/13/00ISR Number: 3611336-6Report Type:Periodic Company Report #FLUV00299000236
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Amblyopia	Health	Luvox	PS	Solvay Pharmaceuticals	ORAL	100 MG TID PO	
	Drug Level Above Therapeutic	Professional						
	Speech Disorder	Company Representative	Lithium Carbonate (Lithium Carbonate)	SS		ORAL	600 MG BID PO, 300 MG QD PO	
			Mellaril (Thioridazine Hydrochloride)	C				
			Buspar (Buspirone Hydrochloride)	C				
			Zyprexa (Olanzapine)	C				

Date:11/13/00ISR Number: 3612451-3Report Type:Expedited (15-DaCompany Report #SP-200001922
Age:52 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Interaction Hypercalcaemia	Foreign Study	Remicade	PS		INTRAVENOUS INFUSION	INTRAVENOUS INFUSION	
Required Intervention to Prevent Permanent Impairment/Damage	Nausea Polyuria Vomiting	Health Professional	Remicade	SS		INTRAVENOUS INFUSION	INTRAVENOUS INFUSION	
			Lithium	SS		ORAL	ORAL 600MG AT BEDTIME	
			Acetaminophen With Codeine	C				

Amoxicillin	C
Clonazepam	C
Cytotec	C
Biaxin	C
Eltroxin	C
Humalog (Insulin Analog)	C
Losec	C
Mobiflex	C
Medroxyprogesterone	C
Vasotec	C
Timolol	C
Premarin	C
Prednisone	C
Pantoloc	C
Oxazepam	C
Zyprexa	C
Vitamin E	C
Vita-Vim	C
Motilium	C
Insulin Humulin Ultralente	C
Fluconazole	C

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/13/00ISR Number: 3614248-7Report Type:Periodic Company Report #FLUV00299001066
Age:25 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hyperglycaemia Leukocytosis	Health Professional	Luvox	PS	Solvay Pharmaceuticals	ORAL	50 MG QD PO	
	Myasthenic Syndrome		Lithium	SS		ORAL	DAILY PO	
			Ativan	C				
			Zyprexa	C				

Date:11/14/00ISR Number: 3611476-1Report Type:Expedited (15-DaCompany Report #WAES 00110445
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Level Above Therapeutic	Health Professional	Vioxx	PS	Merck Research Laboratories Div Merck Co Inc	ORAL	25 MG/DAILY/PO	5 DAY
			Lithium Carbonate (Roxane)	SS			900 MG/DAILY/UNK	

Date:11/14/00ISR Number: 3613302-3Report Type:Periodic Company Report #A027306
Age:26 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hypertonia	Health Professional	Sinequan	PS	Pfizer Laboratories Div Pfizer Inc	ORAL	75.00 MG	TOTAL:DAILY:O RAL

			Depakote	SS		
1500.00 MG TOTAL:BID						
			Lithobid	SS		
600 MG TOTAL BID						
			Seroquel	SS		
25MG TOTAL DAILY						

Date:11/14/00ISR Number: 3613322-9Report Type:Periodic Company Report #A020603
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Ineffective	Consumer	Sinequan	PS	Pfizer Laboratories			
	Gastrointestinal	Health			Div Pfizer Inc	ORAL	125.00 MG	
	Candidiasis	Professional					TOTAL:DAILY:O	
	Personality Disorder						RAL	
	Thinking Abnormal		Eskalith Cr	SS		ORAL	675.00 MG	
							TOTAL:DAILY:O	
							RAL	

Date:11/15/00ISR Number: 3611776-5Report Type:Direct Company Report #
Age:40 YR Gender:Male I/FU:I

Outcome	PT
Death	Circulatory Collapse
	Dermatitis
	Drug Toxicity
	Fatigue
	Fear

		Nervousness						
		Panic Disorder						
		Renal Failure	Report Source	Product	Role	Manufacturer		Route
Dose	Duration							
		Swelling		Lithium - Pills	PS			
3X PER DAY								

Date:11/16/00ISR Number: 3612801-8Report Type:Expedited (15-DaCompany Report #2000032410-1
Age: Gender:Male I/FU:I

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Disability		Amyotrophic Lateral	Health	Eskalith	PS	Smithkline Beecham	
Other		Sclerosis	Professional			Pharmaceuticals	ORAL
ORAL							
		Bulbar Palsy		Flupentixol	C		
		Extrapyramidal Disorder					

Date:11/16/00ISR Number: 3612895-XReport Type:Expedited (15-DaCompany Report #2000032527-1
Age:45 YR Gender:Male I/FU:I

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Other		Confusional State	Foreign	Eskalith	PS	Smithkline Beecham	
		Delirium	Health			Pharmaceuticals	ORAL
2144							
		Dysarthria	Professional				
MILLIGRAMS							
		Judgement Impaired	Other	Biperiden (Akineton)	C		
		Restlessness		Chloral			
				(Chloradurat)	C		
				Clomipramine			
				(Anafranil)	C		
				Diazepam	C		
				Risperidone			
				(Risperdal)	C		

Date:11/16/00ISR Number: 3613082-1Report Type:Expedited (15-DaCompany Report #PHNU2000DE02101
Age:54 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Level Above Therapeutic	Foreign Study	Clozaril	PS	Novartis Pharmaceuticals Corp	ORAL		
	Fall	Health Professional	Hypnorex - Slow Release (Lithium Carbonate)	SS		ORAL		
	Hypotonia	Other	Saroten	SS		ORAL		
			Torem (Torasemide)	SS		ORAL		
			Allopurinol	C				

Date:11/16/00ISR Number: 3613084-5Report Type:Expedited (15-DaCompany Report #PHNU2000DE02098
Age:69 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Atrioventricular Block First Degree	Foreign Study	Clozaril	PS	Novartis Pharmaceuticals Corp	ORAL		
	Cold Sweat	Health Professional	Hypnorex (Lithium Carbonate)	SS		ORAL		
	Electrocardiogram Qt Prolonged	Other	Akineton(Biperiden Hydrochloride)	SS		ORAL		
	Heart Rate Decreased		Haldol (Haloperidol)	SS		ORAL		
	Sick Sinus Syndrome		Saroten	SS		ORAL		
	Sinoatrial Block							
	Sinus Bradycardia							

Date:11/16/00ISR Number: 3613086-9Report Type:Expedited (15-DaCompany Report #2000033402FR
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Anal Atresia	Foreign	Xanax	PS	Pharmacia And Upjohn			
Congenital Anomaly	Apgar Score Low	Health			Co			
	Caesarean Section	Professional	Tercian(Cyamemazine)	SS				
	Complications Of Maternal Exposure To Therapeutic Drugs	Other	Teralithe(Lithium Carbonate)	SS		ORAL		ORAL
	Congenital Genitourinary Abnormality							
	Congenital Renal Cyst							
	Diabetes Insipidus							
	Heart Disease Congenital							
	Hypercalcaemia							
	Hyponatraemia							
	Kidney Small							
	Multiple Congenital Abnormalities							
	Neonatal Disorder							
	Pregnancy							

Date:11/17/00ISR Number: 3613556-3Report Type:Expedited (15-DaCompany Report #JACGER2000001716
Age:68 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Arrhythmia	Foreign	Haldol	PS	Rw Johnson Pharmaceutical Research Institute Div Ortho Pharm	ORAL	MG, DAILY,	ORAL
	Atrioventricular Block Bradycardia	Health Professional						
	Bundle Branch Block Right							
	Cold Sweat							
	Electrocardiogram Qt Prolonged		Hypnorex (Lithium Carbonate)	SS		ORAL	MG, DAILY,	ORAL
	Sick Sinus Syndrome							
	Sinus Bradycardia		Akineton (Biperiden Hydrochloride)	SS		ORAL	MG, DAILY,	

ORAL

Leponex (Clozapine)	SS		ORAL

MG, DAILY,

ORAL

Saroten (Amitriptyline Hydrochloride)	SS		ORAL

MG, DAILY,

ORAL

Fluanxol (Flupentixol)	C		

Date:11/20/00ISR Number: 3615374-9Report Type:Expedited (15-DaCompany Report #2000027172-1
Age:60 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Chronic Lymphocytic Leukaemia	Health Professional	Eskalith	PS	Smithkline Beecham Pharmaceuticals	ORAL	1125	
Other	Thrombocythaemia						MILLIGRAMS	

ORAL

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/21/00ISR Number: 3615628-6Report Type:Expedited (15-DaCompany Report #PRIUSA2000012580
Age:54 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Creatinine Increased Coordination Abnormal Creatinine Renal Clearance Decreased Drug Interaction Drug Level Above Therapeutic Dysarthria Mania Medication Error Tremor Upper Respiratory Tract Infection Vomiting	Foreign Literature Health Professional	Levaquin Lithium Carbonate (Lithium Carbonate)	PS SS	Rw Johnson Pharmaceutical Research Institute Div Ortho Pharm	ORAL ORAL	300 MG, DAILY 1200 MG, DAILY	

Date:11/21/00ISR Number: 3615802-9Report Type:Expedited (15-DaCompany Report #2000032060-1
Age:61 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Interaction Drug Level Above Therapeutic Drug Toxicity		Eskalith Bisoprolol Carbamazepine (Tegretol) Lithium (Priadel) Ramipril Risperidone Thyroxine	PS C C C C C C	Smithkline Beecham Pharmaceuticals			

Date:11/22/00ISR Number: 3616651-8Report Type:Expedited (15-DaCompany Report #2000032060-1
Age:61 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Interaction Drug Level Above Therapeutic Drug Toxicity		Eskalith Bisoprolol Carbamazepine Lithium Ramipril Risperidone Thyroxine	PS C C C C C C	Smithkline Beecham Pharmaceuticals			

Date:11/24/00ISR Number: 3616392-7Report Type:Expedited (15-DaCompany Report #LITH00200006356
Age: Gender:Female I/FU:I

Outcome	PT
Death Hospitalization - Initial or Prolonged	Abnormal Behaviour Agitation Diarrhoea Drug Level Above Therapeutic Drug Toxicity Lethargy Psychotic Disorder

	Vomiting						
		Report Source	Product	Role	Manufacturer	Route	Dose Duration
		Health Professional	Lithonate	PS	Solvay Pharmaceuticals	ORAL	DAILY PO

Date:11/27/00ISR Number: 3617526-0Report Type:Expedited (15-DaCompany Report #A035977
Age:47 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Required Intervention to Prevent Permanent Impairment/Damage	Abdominal Pain Diarrhoea Drug Interaction Drug Toxicity Flatulence Intervertebral Disc Degeneration Pain Polyp Proctalgia	Consumer Health Professional	Zithromax Metronidazole Lithium Klonopin Artane Ultram Moban	PS SS SS C C C C	Pfizer Chemicals Div Pfizer Inc	ORAL	ORAL

Date:11/27/00ISR Number: 3622964-6Report Type:Periodic Company Report #PHEH1999US03798
Age:26 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Life-Threatening Hospitalization - Initial or Prolonged	Convulsion Coordination Abnormal Disorientation Fall Leukocytosis Sedation Stupor Tachycardia Tremor		Clozaril Lithium Risperdal Effexor (Venlafaxine Hydrochloride) Lithobid (Lithium Carbonate) Depakene (Valproate Sodium) Tavist (Clemastine	PS SS C C C C	Novartis Pharmaceuticals Corp	ORAL	450 MG ORAL 900 MG 3 MON

Fumarate)	C	
Ddavap (Desmopressin)	C	
Prednisone	C	

Date:11/27/00ISR Number: 3631312-7Report Type:Periodic Company Report #PHEH2000US08188
Age:46 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Interaction	Health	Clozaril	PS	Novartis			
	Parotid Gland Enlargement	Professional			Pharmaceuticals Corp	ORAL	100 MG AM+300 MG HS, ORAL	730 DAY
			Lithium(Lithium)	SS			751 DAY	
			Zoloft	SS			751 DAY	

Date:11/30/00ISR Number: 3620070-8Report Type:Expedited (15-DaCompany Report #17812-117
Age: Gender:Male I/FU:I

Outcome	PT
Death	Circulatory Collapse
	Completed Suicide

	Dermatitis Drowning Drug Toxicity	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Fatigue Hallucination	Consumer Other	Lithium Carbonate	PS	Roxane Laboratories Inc		TID
	Nervousness Renal Failure Swelling						

Date:11/30/00ISR Number: 3627155-0Report Type:Periodic Company Report #A0116644A
Age:54 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Disability	Tic	Health	Wellbutrin Sr	PS	Glaxo Wellcome Inc	ORAL	400 MG / PER
	Tremor	Professional					DAY / ORAL 6 WK
			Lithium Salt	SS			
			Methadone Hydrochloride	SS		ORAL	250 MG / FOUR
							TIMES PER DAY
							ORAL
			Tamsulosin Hcl	C			
			Psychiatric Consultation	C			

Date:12/07/00ISR Number: 3624704-3Report Type:Expedited (15-DaCompany Report #LBID00200006463
Age:37 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Death Life-Threatening	Dermatitis Drug Toxicity Fatigue	Consumer	Lithobid	PS	Solvay Pharmaceuticals, Inc.	ORAL	DAILY PO
	Nervousness Panic Reaction						

	Renal Failure Swelling					

Date:12/08/00ISR Number: 3625507-6Report Type:Expedited (15-DaCompany Report #LBID00200006500
Age:37 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Mania	Foreign Literature Health Professional	Lithobid	PS	Solvay Pharmaceuticals	ORAL	450 MG BID PO

Date:12/08/00ISR Number: 3625593-3Report Type:Expedited (15-DaCompany Report #A032735
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Arthritis Bipolar I Disorder Blood Cholesterol Increased Cystitis Erectile Dysfunction Middle Insomnia Overdose	Consumer Health Professional	Cardura Lithium Depakote	PS SS C	Pfizer Laboratories Div Pfizer Inc		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/11/00ISR Number: 3626495-9Report Type:Expedited (15-DaCompany Report #A035977
Age:47 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Required Intervention to Prevent Permanent Impairment/Damage	Colitis	Consumer Health Professional	Zithromax	PS	Pfizer Chemicals Div Pfizer Inc	ORAL	
	Colonic Polyp						
	Drug Interaction		Metronidazole	SS			
	Drug Toxicity		Lithium	SS			
			Klonopin	C			
			Artane	C			
			Ultram	C			
			Moban	C			

Date:12/11/00ISR Number: 3626949-5Report Type:Expedited (15-DaCompany Report #AU_000501403
Age:23 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Affective Disorder	Foreign Study Health Professional Other	Lithium	PS			6 DSG FORM/DAY 33 DAY
	Aggression						
	Agitation		Placebo	SS			4 DSG FORM/DAY
	Alanine Aminotransferase Increased		Olazapine	SS			20 MG/DAY
	Anxiety						
	Depression						
	Irritability						
	Mania						

Date:12/11/00ISR Number: 3627141-0Report Type:Expedited (15-DaCompany Report #2000033870-1
Age:63 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Disability	Arthralgia	Foreign Health Professional	Eskalith	PS	Smithkline Beecham Pharmaceuticals	ORAL	
	Arthropathy						
	Blood Disorder		Tibolone (Liviella)	C			

	Blood Uric Acid Increased Diarrhoea Hypoaesthesia Joint Swelling Peripheral Vascular Disorder Weight Increased	Other				

Date:12/12/00ISR Number: 3628775-XReport Type:Expedited (15-DaCompany Report #WAES 00101917
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Interaction Drug Level Above Therapeutic	Health Professional	Vioxx	PS	Merck Research Laboratories Div Merck Co Inc	ORAL	DAILY/PO	
	Renal Disorder		Lithobid 300 Mg	SS		ORAL	300 MG/BID/PO	
			Lithobid 300 Mg	SS		ORAL	300 MG/DAILY/PO	

Date:12/14/00ISR Number: 3630247-3Report Type:Expedited (15-DaCompany Report #2000022195-1
Age:30 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Abortion Induced	Health	Eskalith	PS	Smithkline Beecham			
	Pregnancy	Professional			Pharmaceuticals	ORAL	ORAL	

Date:12/18/00ISR Number: 3633315-5Report Type:Expedited (15-DaCompany Report #JACFRA2000000803
Age:69 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Coma	Foreign	Risperdal 7-Day					
	Hypercalcaemia	Health	Starter Pack	PS	Janssen Research Fdn			
	Hypernatraemia	Professional			Div Johnson And			
					Johnson	ORAL	ORAL	
			Lithium Microsol	SS		ORAL	ORAL	

Date:12/19/00ISR Number: 3632893-XReport Type:Expedited (15-DaCompany Report #A0134381A
Age:33 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Alcoholism		Lamictal	PS	Glaxo Wellcome	ORAL	200MG Twice	
Initial or Prolonged	Anxiety							
per day							2	YR
	Bipolar Disorder		Zyprexa	SS				
	Condition Aggravated		Lithium	SS				
	Drug Effect Decreased		Norvasc	C				
	Mood Altered							

Date:12/20/00ISR Number: 3635106-8Report Type:Expedited (15-DaCompany Report #A038831
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Hospitalization - Initial or Prolonged Required	Depressed Level Of Consciousness Drug Interaction	Health Professional	Zoloft Tikosyn	PS SS	Pfizer Pharmaceuticals Inc		
500.00 Intervention to TOTAL:BID	Dysphagia						
Prevent Permanent 600.00 MG Impairment/Damage TOTAL:BID:ORA	Hepatitis Lethargy		Lithium	SS		ORAL	
L			Pepcid Atrovent Lasix Digoxin Ventolin Plavix Aspirin	C C C C C C C			

Date:12/20/00ISR Number: 3635124-XReport Type:Expedited (15-DaCompany Report #A0134381A
Age:33 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Bipolar Disorder Drug Ineffective	Health Professional	Lamictal	PS	Glaxo Wellcome Inc	ORAL	200 MG/ TWICE PER DAY/ ORAL 2 YR
			Olanzapine (Formulation Unknown) (Olanzapine) Lithium Salt	SS			

				(Formulation Unknown) (Lithium Salt)	SS		
				Amlodipine	C		

Date:12/20/00ISR Number: 3635728-4Report Type:Expedited (15-DaCompany Report #2000035222-1
Age:64 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anxiety	Literature	Eskalith	PS	Smithkline Beecham Pharmaceuticals			
Other	Asthenia	Health						
	Depression	Professional	Fluoxetine	C				
	Diarrhoea		Sertraline	C				
	Fatigue							
	Headache							
	Hypersomnia							
	Insomnia							
	Restlessness							

Date:12/26/00ISR Number: 3638132-8Report Type:Expedited (15-DaCompany Report #PHEH2000US10807
Age:80 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardiac Arrest	Study	Exelon	PS	Novartis Pharmaceuticals Corp	ORAL	3 MG, BID, ORAL	
Life-Threatening	Cerebrovascular Accident	Health						
Hospitalization - Initial or Prolonged	Myocardial Infarction	Professional	Lithium (Lithium)	SS			500 MG, QD	110 DAY
			Cardura (Doxazosin Mesilate)	C				

Date:12/28/00ISR Number: 3639207-XReport Type:Expedited (15-DaCompany Report #HQ5230622DEC2000
Age:52 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Drug Interaction	Foreign	Effexor	PS	Wyeth Ayerst			

Initial or Prolonged		Pulmonary Embolism	Health			Laboratories	ORAL	150 MG DAILY
		Pyrexia	Professional					
ORAL	4 DAY							
			Other	Teralithe (Lithium Carbonate)	SS			
400 MG DAILY	2 DAY							

Date:12/29/00ISR Number: 3638664-2Report Type:Direct Company Report #
Age:62 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Dehydration		Lithium (300mg)	PS			TID	
	Depressed Level Of Consciousness		Tegretol	C				
	Nephrogenic Diabetes Insipidus							
	Pneumonia Aspiration							

Date:12/29/00ISR Number: 3640251-7Report Type:Expedited (15-DaCompany Report #HQ5204122DEC2000
Age:70 YR Gender:Female I/FU:I

Outcome
Hospitalization -
Initial or Prolonged

Other

	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Level Above Therapeutic	Health Professional	Effexor	PS	Wyeth Ayerst Laboratories	ORAL	200 MG 1 X	
	Fall	Other					PER 1 DAY,	
	Serotonin Syndrome						ORAL	
			Teralithe (Lithium Carbonate)	SS		ORAL	1000 MG 1X	
							PER 1 DAY,	
							ORAL	

Date:01/02/01ISR Number: 3640473-5Report Type:Expedited (15-DaCompany Report #2000AU03968
Age:51 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Blood Potassium Decreased	Health	Prilosec	PS	Astrazeneca Lp	ORAL	20 MG QD PO	
Initial or Prolonged	Drug Interaction	Professional	Lithium	SS				
	Drug Toxicity		Trazodone	SS				
	Heart Rate Increased		Wellbutrin	SS				

Date:01/10/01ISR Number: 3645451-8Report Type:Direct Company Report #
Age:58 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Neurotoxicity		Lithium Carbonate 300 Mg Bid	PS				
Initial or Prolonged			Vioxx	C				
			Ultram	C				

Date:01/11/01ISR Number: 3646483-6Report Type:Expedited (15-DaCompany Report #2000037052-1
Age:40 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Psychotic Disorder	Health Professional	Lithium	PS	Smithkline Beecham Pharmaceuticals			
	Thrombocythaemia							
	White Blood Cell Count Increased		Granulocyte Colony-Stimulating Factor	C				

Date:01/11/01ISR Number: 3647836-2Report Type:Periodic Company Report #17812-114
Age:34 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Convulsion	Health Professional	Lithium Carbonate	PS	Roxane Laboratories Inc	ORAL	300 MG QAM & 600 MG QPM, PO	
			Klonopin	C				
			Vistaril	C				
			Chlorpromazine	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/11/01ISR Number: 3647837-4Report Type:Periodic Company Report #17812-109
Age:61 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Asthenia	Health Professional	Lithium Carbonate	PS	Roxane Laboratories Inc	ORAL	300 MG. QID, PO	
	Coordination Abnormal							
	Dizziness							
	Overdose		Sinemet	C				
			Olanzapine	C				
			Fluoxetine	C				
			Metformin	C				
			Insulin	C				
			Albuterol/Beclometha sone Mdi	C				
			Lisinopril	C				

Date:01/11/01ISR Number: 3647838-6Report Type:Periodic Company Report #17812-107
Age:41 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Arrhythmia	Consumer	Lithium Carbonate	PS	Roxane Laboratories Inc	ORAL	300 MG, BID, PO	10 YR
	Dizziness						Other	
			Trazadone	C				
			Klonopin	C				
			Motrin	C				

Date:01/11/01ISR Number: 3647839-8Report Type:Periodic Company Report #17812-098
Age:53 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Asthenia	Health Professional	Lithium Carbonate	PS	Roxane Laboratories Inc	ORAL	300 MG, PO, TID	
	Overdose							
	Vision Blurred							

			Haloperidol	C		
			Aspirin Ec	C		
			Phenytoin	C		
			Fluconazole	C		
			Bactrin Ds	C		
			Clotrimazole Lotion	C		
			Betamethasone Oint	C		
			Theravite	C		

Date:01/11/01ISR Number: 3647840-4Report Type:Periodic Company Report #17812-094
Age:46 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Coordination Abnormal Speech Disorder	Consumer	Lithium Carbonate	PS	Roxane Laboratories Inc	ORAL	900 MG/QD/PO	
			Prozac	C				
			Depakote	C				
			Xanax	C				
			Neurontin	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/11/01ISR Number: 3647841-6Report Type:Periodic Company Report #17812-095
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Overdose	Other	Lithium Carbonate	PS	Roxane Laboratories Inc			
			Nsaids	C				

Date:01/11/01ISR Number: 3647842-8Report Type:Periodic Company Report #17812-096
Age:44 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Vomiting	Consumer	Lithium Carbonate	PS	Roxane Laboratories Inc	ORAL	1200 MG, QHS,	PO 11 YR

Date:01/11/01ISR Number: 3647843-XReport Type:Periodic Company Report #17812-092
Age:46 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dermatitis	Consumer	Lithium Carbonate	PS	Roxane Laboratories Inc	ORAL	300 MG, TID,	PO
			Prozac	C				

Date:01/11/01ISR Number: 3647844-1Report Type:Periodic Company Report #17812-088
Age:48 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Confusional State Overdose	Health Professional	Lithium Carbonate	PS	Roxane Laboratories Inc	ORAL	300 MG, TID,	

	Sedation					
PO						
	Speech Disorder		Chlorpromazine	C		
			Valproate Sodium	C		
			Olanzapine	C		
			Furosemide	C		
			Oxybutin	C		
			Ipratropium	C		
			Albuterol	C		
			Theophylline	C		
			Lansoprazole	C		
			Digoxin	C		
			Kcl	C		
			Triamcinolone Aerosol	C		

Date:01/11/01ISR Number: 3647845-3Report Type:Periodic Company Report #17812-085
Age:71 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dehydration Drug Toxicity	Health Professional	Lithium Carbonate	PS	Roxane Laboratories Inc		1500 MG QD,	
	Overdose						PO; >600 MG,	
	Stupor						QD PO	
			Captopril	C				
			Asa	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/15/01ISR Number: 3650370-7Report Type:Expedited (15-DaCompany Report #2001000474-1
Age:10 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dermatitis	Health Professional	Eskalith	PS	Smithkline Beecham Pharmaceuticals	ORAL	SEE IMAGE	38 DAY
	Hepatic Failure							
	Pyrexia		Zyprexa	C				
	Renal Failure		Klonopin	C				
			Adderall	C				

Date:01/16/01ISR Number: 3648374-3Report Type:Expedited (15-DaCompany Report #2001000229-1
Age:21 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dialysis	Health Professional	Eskalith	PS	Smithkline Beecham Pharmaceuticals	ORAL	675	
Required Intervention to Prevent Permanent Impairment/Damage	Drug Level Above Therapeutic						MILLIGRAMS	
	Lethargy						2.0 DAILY	
	Medication Error						ORAL	
	Oedema							

Date:01/16/01ISR Number: 3648770-4Report Type:Expedited (15-DaCompany Report #LBID00201000032
Age:62 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Atrophy	Foreign Literature	Lithobid	PS	Solvay Pharmaceuticals	ORAL	PO	
	Bipolar Disorder							
	Brain Scan Abnormal	Other	Zuklopentixol ()	C				
	Mania		Biperiden (Biperiden)	C				
	Tardive Dyskinesia							

Date:01/16/01ISR Number: 3648823-0Report Type:Expedited (15-DaCompany Report #A040563
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Atrioventricular Block	Foreign	Zoloft	PS	Pfizer			
	Sick Sinus Syndrome	Health			Pharmaceuticals Inc	ORAL	100.00 MG	
		Professional					TOTAL DAILY	
ORAL								
			Lithium	SS				
			Olanzapine	C				
			Aricept	C				
			Mirtazapine	C				
			Unat	C				

Date:01/22/01ISR Number: 3652920-3Report Type:Expedited (15-DaCompany Report #2001000611-1
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Agranulocytosis	Foreign	Eskalith	PS	Smithkline Beecham			
		Health			Pharmaceuticals	ORAL	ORAL	
		Professional						

Date:01/22/01ISR Number: 3652923-9Report Type:Expedited (15-DaCompany Report #2001000604-1
Age:46 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Atelectasis	Foreign	Eskalith	PS	Smithkline Beecham			
Hospitalization - Initial or Prolonged	Brain Oedema	Literature			Pharmaceuticals			
	Coma	Health						
	Completed Suicide	Professional						
	Heart Rate Increased							
	Hepatic Necrosis							
	Hypernatraemia							
	Hypokalaemia							
	Hyporeflexia							
	Intentional Misuse							
	Leukocytosis							
	Muscle Rigidity							
	Pneumonia							
	Pulmonary Congestion							
	Pulmonary Oedema							
	Purulence							
	Renal Disorder							
	Renal Tubular Disorder							
	Therapeutic Agent Toxicity							

Date:01/22/01ISR Number: 3652933-1Report Type:Expedited (15-DaCompany Report #LBID00200006014
Age:40 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Aggression	Foreign	Lithobid	PS	Solvay Pharmaceuticals	ORAL	DAILY PO,	
	Anxiety	Literature					1200 MG DAILY	
	Condition Aggravated	Health					PO, 1400 MG	
	Dehydration	Professional					DAILY PO	
	Drug Ineffective	Other						
	Dysphoria		Valproic Acid (Valproic Acid)	C				
	Epilepsy		Zuclopenthixol (Zuclopenthixol)	C				
	Euphoric Mood		Haloperidol					
	Hostility							
	Hypernatraemia							

Hyperparathyroidism	(Haloperidol)	C
Hypocalcaemia	Risperidone	
Logorrhoea	(Risperidone)	C
Mania	Clozapine	
Oral Intake Reduced	(Clozapine)	C
Polydipsia	Levomepromazine	
Polyuria	(Levomepromazine)	C
Post Procedural	Oxazepam (Oxazepam)	C
Complication	Clorazepinic Acid	C
Skin Disorder	Flurazepam	
	(Flurazepam)	C

Date:01/25/01ISR Number: 3653991-0Report Type:Direct Company Report #
Age:69 YR Gender:Male I/FU:I

Outcome	PT
Life-Threatening	Acute Psychosis
	Balance Disorder
	Blood Creatine
	Phosphokinase Increased
	Blood Creatinine

	Increased					
	Condition Aggravated					
	Confusional State					
	Oral Intake Reduced	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
	Parkinsonism		Haloperidol	PS		
REFER TO						
	Pneumonia					
SUMMARY						
	Respiratory Arrest		Lithium Carbonate	SS		
	Speech Disorder					

Date:01/25/01ISR Number: 3656041-5Report Type:Expedited (15-DaCompany Report #2001UW00195
Age:48 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization -	Decreased Appetite	Foreign	Elavil	PS	Astrazeneca	
Initial or Prolonged	Delusion	Literature			Pharmaceuticals Lp	
	Depression	Health	Lithium	SS		
	Drug Level Above	Professional				
	Therapeutic	Other				
	Electroencephalogram					
	Abnormal					
	Insomnia					
	Intentional Misuse					
	Nervous System Disorder					
	Psychotic Disorder					
	Sinus Tachycardia					
	Suicide Attempt					

Date:01/29/01ISR Number: 3656866-6Report Type:Expedited (15-DaCompany Report #2001001133-1
Age:41 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization -	Coma	Literature	Eskalith	PS	Smithkline Beecham	
Initial or Prolonged	Convulsion	Health			Pharmaceuticals	
Other	Drug Toxicity	Professional				
	Renal Failure					
	Respiratory Failure					
	Shock					

Date:01/29/01ISR Number: 3656869-1Report Type:Expedited (15-DaCompany Report #2001001043-1
Age:52 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Agitation Blood Albumin Increased Body Temperature Decreased Confusional State Disorientation Drug Level Above Therapeutic Heart Rate Increased Hyperreflexia Hypertonia Intentional Misuse Nausea	Literature Health Professional	Eskalith	PS	Smithkline Beecham Pharmaceuticals			

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/31/01ISR Number: 3657967-9Report Type:Expedited (15-DaCompany Report #HQ5204122DEC2000
Age:70 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agitation	Foreign	Effexor	PS	Wyeth Ayerst			
	Confusional State	Health			Laboratories	ORAL	200 MG 1X PER	
Other	Depressed Level Of	Professional						1 DAY
	Consciousness	Other	Modopar (Benserazide					
	Diarrhoea		Hydrochloride/Levodo					
	Drug Interaction		pa,)	SS			250 MG 1X PER	
	Drug Level Above							1 DAY
	Therapeutic		Teralithe (Lithium					
	Fall		Carbonate,)	SS		ORAL	1000 MG 1X	
	Hyperhidrosis							PER 1 DAY
	Hypertonia		Theralene	C				
	Logorrhoea		Atarax	C				
	Malaise		Avlocardyl	C				
	Serotonin Syndrome							
	Tremor							
	Vomiting							

Date:02/01/01ISR Number: 3658393-9Report Type:Expedited (15-DaCompany Report #2001000611-1
Age:35 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agranulocytosis	Foreign	Eskalith	PS	Smithkline Beecham			
	Haematoma	Health			Pharmaceuticals	ORAL	1072	
Other	Myelodysplastic Syndrome	Professional						
							MILLIGRAMS	32 DAY
			Ciatyl Depot(Zuclopenthixol e)	C				
			Lyogen Depot (Fluphenazine)	C				

Date:02/01/01ISR Number: 3660273-XReport Type:Expedited (15-DaCompany Report #WAES 00110445
Age:62 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Confusional State	Health Professional	Vioxx	PS	Merck Research Laboratories Div Merck Co Inc	ORAL	25 MG/DAILY/PO	
	Drug Level Above Therapeutic							
	Urinary Tract Infection							
			Lithium Carbonate (Roxane) 300 Mg	SS		ORAL	200 MG/TID/PO	

Date:02/02/01ISR Number: 3660347-3Report Type:Direct Company Report #
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Mental Impairment	Health Professional	Eskalith (450 Mg Tablets)	PS		ORAL	1 1/2 TABS PO	
							@ HS / PTA	
			Klonopin	C				
			Effexor	C				
			Glucotrol	C				
			Accupril	C				
			Pilocarpine	C				
			Prilosec	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/02/01ISR Number: 3661501-7Report Type:Periodic Company Report #FLUV00200006556
Age:7 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Pain	Consumer	Luvox	PS		ORAL	50 MG BID PO	
	Tremor		Lithobid (Lithium Carbonate)	SS		ORAL	300 MG BID PO	
	Vomiting		Zyprexa (Olanzapine)	C				
			Risperdal (Risperidone)	C				

Date:02/02/01ISR Number: 3701957-4Report Type:Periodic Company Report #FLUV00200002752
Age:40 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Abdominal Pain	Consumer	Luvox	PS	Solvay Pharmaceuticals	ORAL	25MG BID PO,	
	Anorectal Disorder						25 MG QD PO	
	Chills							
	Diarrhoea		Lithonate	SS		ORAL	1200 MG QD	
	Gastrointestinal Disorder						PO, 900 MG QD	
	Hernia						PO, UNK DAILY	
	Keratoconjunctivitis						PO	
	Sicca							
	Pharyngitis							

Date:02/05/01ISR Number: 3660438-7Report Type:Periodic Company Report #9952521
Age:30 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Interaction	Health	Zyrtec Tablets	PS		ORAL	5.00 MG TOTAL	

	Drug Level Below Therapeutic	Professional	Lithium	SS		ORAL 1125.00 MG DAILY ORAL TOTAL TID ORAL
			Synthroid	C		

Date:02/05/01ISR Number: 3661309-2Report Type:Expedited (15-DaCompany Report #LBID00200006463
Age:37 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Death Life-Threatening	Dermatitis Drug Hypersensitivity	Consumer	Lithobid	PS	Solvay Pharmaceuticals	ORAL PO
	Fatigue Nervousness Overdose Panic Attack Renal Failure Swelling		Neuroleptic Medication	C		

Date:02/05/01ISR Number: 3661539-XReport Type:Expedited (15-DaCompany Report #2000037052-1
Age:40 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Hospitalization - Initial or Prolonged	Leukocytosis Thrombocythaemia	Health Professional	Eskalith	PS	Smithkline Beecham Pharmaceuticals	ORAL ORAL
			Granulocyte Colony-Stimulating Factor	C		

				Zyprexa (Olanzapine)	C		
				Ambien (Zolpidem Tartrate)	C		
				Cogentin (Benztropine Mesylate)	C		

Date:02/06/01ISR Number: 3660904-4Report Type:Direct Company Report #
Age:51 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Alcoholism		Lithium Carbonate (300mg)	PS		ORAL	300MG PO BID	
	Fall							
	Hypotension							
	Medication Error							
	Myocardial Infarction							
	Therapeutic Agent Toxicity							
	Tremor							

Date:02/09/01ISR Number: 3664384-4Report Type:Expedited (15-DaCompany Report #2001000474-1
Age:10 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Dermatitis	Health Professional	Eskalith Cr	PS	Smithkline Beecham Pharmaceuticals	ORAL		
Hospitalization - Initial or Prolonged	Hepatic Failure							
	Infectious Mononucleosis		Eskalith	SS	Smithkline Beecham	ORAL	450 MG 2	
	Pyrexia						DAILY ORAL	34 DAY
	Renal Disorder		Zyprexa (Olanzapine)	C				
			Clonidine	C				
			Adderall	C				
			Bisperdal (Bisperidone)	C				

Date:02/13/01ISR Number: 3664975-0Report Type:Expedited (15-DaCompany Report #A101960
Age:57 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agitation	Foreign	Lithane Tablets	PS		ORAL	1000.00 MG	TOTAL:TID:ORAL
	Clonic Convulsion	Literature						
	Confusional State	Health						
	Coordination Abnormal	Professional	Captopril	SS		ORAL	150.00 MG	TOTAL:TID:ORAL
	Drug Interaction							
	Drug Level Above Therapeutic		Nifedipine	C				
	Encephalopathy		Lisinopril	C				
	Haemorrhagic Stroke							
	Hydrocephalus							
	Hypertension							
	Renal Impairment							
	Sedation							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/14/01ISR Number: 3665059-8Report Type:Direct Company Report #
Age:49 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Level Below		Agenerase	PS			6 CAPSULES X2	
	Therapeutic		Lithium	SS			4 PILL DAILY	

Date:02/16/01ISR Number: 3666101-0Report Type:Direct Company Report #
Age:84 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Coma		Lithium	PS			150 MG QID	
	Drug Level Above		Synthroid	C				
	Therapeutic		Prevacid	C				
	Dysarthria		Colace	C				
	Facial Palsy		Risperidol	C				
	Hemiparesis		Depakote	C				
			Buspar	C				
			Donnatal	C				

Date:02/16/01ISR Number: 3667786-5Report Type:Expedited (15-DaCompany Report #2000015366-1
Age:52 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Affective Disorder	Consumer	Eskalith Cr	PS	Smithkline Beecham Pharmaceuticals	ORAL	ORAL	10 YR
Other	Anaemia Vitamin B12	Professional	Eskalith	SS	Smithkline Beecham	ORAL	675 MG 2.0	
Required	Deficiency						DAILY	
Intervention to Prevent Permanent Impairment/Damage	Anger		Depakote (Valproate Semisodium)	C				
	Asthenia		Synthroid (Levothyroxine)	C				
	Bipolar Disorder		Effexor (Venlafaxine					
	Choking							
	Coordination Abnormal							
	Delirium							

Delusion	Hydrochloride)	C
Depressed Level Of Consciousness	Restoril (Famotidine)	C
Depression		
Dialysis		
Difficulty In Walking		
Disorientation		
Drug Toxicity		
Dysarthria		
Dysphagia		
Encephalopathy		
Faecal Incontinence		
Fall		
Hypokalaemia		
Paranoia		
Pernicious Anaemia		
Pneumonia Aspiration		
Pressure Of Speech		
Renal Failure Acute		
Rhinorrhoea		
Urinary Incontinence		
Urinary Retention		
Urinary Tract Infection		
Wheelchair User		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/16/01ISR Number: 3667793-2Report Type:Expedited (15-DaCompany Report #2001003226-1
Age:60 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Mania	Consumer	Lithium Carbonate	PS		ORAL	300	MILLIGRAMS
							3.0	DAILY
			Prilosec (Omeprazole)	SS		ORAL		
ORAL			Zoloft (Sertraline)	C				
			Ranitidine (Ranitidine Hcl)	C				
			Buspar (Buspirone Hcl)	C				

Date:02/16/01ISR Number: 3668301-2Report Type:Expedited (15-DaCompany Report #A040563
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Atrioventricular Block Sick Sinus Syndrome	Foreign Health Professional	Zoloft Tablets	PS	Pfizer Pharmaceuticals Inc	ORAL	100.00 MG	TOTAL:DAILY:O
RAL								
			Lithium	SS				
			Olanzapine	C				
			Aricept	C				
			Mirtazapine	C				
			Unat	C				

Date:02/16/01ISR Number: 3668368-1Report Type:Expedited (15-DaCompany Report #2001002462-1
Age:39 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agitation Bipolar I Disorder	Literature Health	Eskalith	PS	Smithkline Beecham Pharmaceuticals			1 DAY
Other	Blood Pressure Decreased Depressed Level Of Consciousness Disorientation Drug Interaction Drug Level Above Therapeutic Intentional Misuse Mania Neuroleptic Malignant Syndrome Oral Intake Reduced Suicide Attempt Tachycardia Vomiting	Professional	Haloperidol Sulpiride	C C				

Date:02/20/01ISR Number: 3668365-6Report Type:Expedited (15-DaCompany Report #LBID00201000436
Age:34 YR Gender:Female I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Abdominal Distension Depression Overdose

		Tremor Vomiting Weight Increased	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
			Consumer	Lithobid	PS	Solvay Pharmaceuticals	ORAL
600 MG PO , 1800 MG PO, 2100 MG PO							
				Klonopin (Clonazepam)	C		

Date:02/21/01ISR Number: 3668691-0Report Type:Expedited (15-DaCompany Report #PHBS1996SE02492
Age:33 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization - Initial or Prolonged	Cardiomyopathy Diarrhoea	Foreign Health	Clozaril	PS	Novartis Pharmaceuticals Corp	ORAL
300 MG, ORAL						
	Eosinophilia Headache Hepatic Function Abnormal Neutropenia Pyrexia	Professional Other	Lithium(Lithium) Truxal	SS C		

Date:02/21/01ISR Number: 3668828-3Report Type:Expedited (15-DaCompany Report #A102364
Age:72 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization - Initial or Prolonged	Coma Drug Level Above Therapeutic Drug Toxicity Haemodialysis Hypotension Hypotonia Rebound Effect Renal Failure	Literature Health Professional	Lithane Tablets	PS	Pfizer Inc	

Date:02/23/01ISR Number: 3669766-2Report Type:Expedited (15-DaCompany Report #NSADSS2001003698
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Confusional State	Health	Risperdal	PS	Janssen Research Fdn	ORAL	ORAL	
Required Intervention to Prevent Permanent Impairment/Damage	Delirium	Professional	Lithium (Lithium)	SS		ORAL	ORAL	
	Diabetes Insipidus							
	Platelet Count Decreased							
	Thrombotic Thrombocytopenic Purpura							

Date:02/26/01ISR Number: 3670311-6Report Type:Expedited (15-DaCompany Report #WAES 01020666
Age:44 YR Gender:Female I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Balance Disorder
	Burning Sensation
	Dialysis
	Diarrhoea
	Drug Level Above Therapeutic

		Dyspnoea Photopsia					
			Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
			Consumer	Vioxx	PS	Merck Research Laboratories Div Merck Co Inc	ORAL
UNK/UNK/PO							
				Lithiumco3 Unk	SS		
				Avandia	C		
				Celexa	C		
				Glucotrol	C		
				Lopid	C		
				Seroquel	C		
				Zestril	C		
				Metoprolol	C		

Date:02/26/01ISR Number: 3670865-XReport Type:Expedited (15-DaCompany Report #PHRM2001FR00611
Age:45 YR Gender:Female I/FU:I

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Other		Diabetes Insipidus Diabetes Mellitus	Foreign Health	Tegretol-Xr	PS	Novartis Pharmaceuticals Corp	ORAL
400MG, QD,							
		Inadequate Control	Professional				
ORAL							
		Drug Withdrawal Syndrome Hypernatraemia Inappropriate Antidiuretic Hormone Secretion Polydipsia	Other	Lithium (Lithium) Anxiolytics (No Ingredients/Substances)	SS C		

Date:02/28/01ISR Number: 3676196-6Report Type:Periodic Company Report #9835901
Age:60 YR Gender:Female I/FU:F

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Other		Bone Pain Depression	Consumer Health	Zoloft	PS	Pfizer Pharmaceuticals Inc	ORAL
25.00 MG							

	Dyspepsia	Professional				
TOTAL: DAILY:						
	Hyperhidrosis					
ORAL						
	Nausea		Lithium	SS		
675.00 MG						
	Visual Disturbance					
TOTAL: DAILY						
	Weight Increased		Ibuprofen	C		

Date:02/28/01ISR Number: 3677281-5Report Type:Periodic Company Report #A018510
Age:27 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Headache	Health	Zoloft	PS	Pfizer	
	Nausea	Professional			Pharmaceuticals Inc	ORAL
100.00 MG						
	Pyrexia					
TOTAL:ORAL						
			Eskalith	SS		ORAL
300.00 MG						
TOTAL:TID:ORA						
L						
			Klonopin	C		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/28/01ISR Number: 3677326-2Report Type:Periodic Company Report #A035493
Age: Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Skin Discolouration	Health Professional	Zoloft	PS	Pfizer Pharmaceuticals Inc			
		Company Representative	Lithium	SS				
			Wellbutrin	C				

Date:02/28/01ISR Number: 3677358-4Report Type:Periodic Company Report #A004670
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Nausea	Health Professional	Zoloft	PS	Pfizer Pharmaceuticals Inc			
	Vomiting		Lithium	SS				

Date:02/28/01ISR Number: 3677522-4Report Type:Periodic Company Report #A001056
Age:13 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Abdominal Pain	Health Professional	Zoloft	PS	Pfizer Pharmaceuticals Inc	ORAL	25.00 MG	TOTAL: DAILY
	Agitation							
	Drug Ineffective							
	Dysgeusia							
	Hypertonia		Lithium	SS		ORAL	300.00 MG	TOTAL:DAILY:O
	Muscle Twitching							
	Myalgia							
	Osteoarthritis		Neurontin	SS		ORAL	900.00 MG	TOTAL:TID:ORA
	Pain							
	Thinking Abnormal							

	Vasodilatation		Haldol	SS		ORAL
1.00 MG						
TOTAL:BID:ORA						
L						
			Adderall	C		
			Tenex	C		
			Claritin	C		

Date:03/01/01ISR Number: 3672392-2Report Type:Expedited (15-DaCompany Report #LBID00201000567
Age:58 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Life-Threatening	Bone Marrow Depression	Health Professional	Lithobid	PS	Solvay Pharmaceuticals	ORAL
900 MG DAILY						
PO						
			Zoloft (Sertraline Hydrochloride)	C		
			Synthroid (Levothyroxine Sodium)	C		
			Gemfibrozil (Gemfibrozil)	C		
			Procrit (Erythopoietin)	C		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/01/01ISR Number: 3672393-4Report Type:Expedited (15-DaCompany Report #LBID00201000527
Age:81 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Cardiac Pacemaker Insertion	Consumer	Lithobid	PS	Solvay Pharmaceuticals	ORAL	900 MG DAILY	
	Cerebrovascular Accident						PO	
	Dysarthria		Sular (Nisoldipine)	C				
	Heart Rate Decreased		Bladder Medication	C				
	Muscular Weakness							

Date:03/02/01ISR Number: 3672944-XReport Type:Expedited (15-DaCompany Report #2000037052-1
Age:40 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Leukocytosis	Health Professional	Eskalith	PS	Smithkline Beecham Pharmaceuticals	ORAL	900 MILLIGRAMS ,	
	Psychotic Disorder						1.0 DAILY	
	Thrombocythaemia						ORAL	
			Granulocyte Colony-Stimulating Factor	C				
			Zyprexa (Olanzapine)	C				
			Ambien (Zolpidiem Tartrate)	C				
			Cogentin(Benztropine Mesylate)	C				
			Lodine (Etodolac)	C				

Date:03/06/01ISR Number: 3675613-5Report Type:Expedited (15-DaCompany Report #A104073
Age:64 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Required	Alanine Aminotransferase	Foreign	Lithium Carbonate	PS	Pfizer Inc	ORAL
ORAL						
Intervention to	Increased	Other	Ranitidine	SS		ORAL
300.00 MG						
Prevent Permanent	Aspartate					
TOTAL:DAILY:O						
Impairment/Damage	Aminotransferase					
RAL						
	Increased		Nefazodone	SS		ORAL
300.00 MG						
	Blood Alkaline					
TOTAL:DAILY:O						
	Phosphatase Increased					
RAL						
	Blood Lactate		Olanzapine	SS		ORAL
DAILY:ORAL						
	Dehydrogenase Increased					
	Gamma-Glutamyltransferase					
	Increased					
	Pyrexia					

Date:03/09/01ISR Number: 3678213-6Report Type:Expedited (15-DaCompany Report #LBID00201000770
Age:56 YR Gender:Male I/FU:I

Outcome	PT
Hospitalization -	Asthenia
Initial or Prolonged	Confusional State
	Coordination Abnormal
	Dizziness
	Drug Level Above
	Therapeutic
	Dysarthria
	Fall

	Nervous System Disorder Renal Impairment Tremor	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
	Vomiting	Foreign Literature	Lithobid	PS	Solvay Pharmaceuticals	ORAL
1200 MG DAILY						
		Other				
PO						
			Levofloxacin (Levofloxacin)	SS		
300 MG DAILY						

Date:03/12/01ISR Number: 3680592-0Report Type:Expedited (15-DaCompany Report #WAES 00101917
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Drug Interaction Drug Toxicity Renal Disorder	Health Professional	Vioxx	PS	Merck Research Laboratories Div Merck Co Inc	ORAL
DAILY/PO						
			Lithobid 300 Mg	SS		ORAL
300 MG						
/BID/PO;						
300MG/DAILY/P						
O						

Date:03/12/01ISR Number: 3680848-1Report Type:Expedited (15-DaCompany Report #17812-124
Age:56 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Confusional State Coordination Abnormal	Foreign Literature	Lithium Carbonate	PS	Roxane Laboratories Inc	ORAL
1200MG,						
	Dizziness	Health				
DAILY, ORAL						
	Drug Level Above	Professional	Levofloxacin	SS		
300MG, DAILY 2 DAY						

	Therapeutic					
	Dysarthria					
	Fall					
	Nervous System Disorder					
	Renal Impairment					
	Tremor					
	Vomiting					

Date:03/14/01ISR Number: 3680760-8Report Type:Direct Company Report #
Age:8 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Condition Aggravated Enuresis		Valproic Acid / 250mg	PS		ORAL	250 MG / QID	Other
			Lithium	SS		ORAL	300MG / BID / ORAL	
			Clonidine	C				
			Risperidone	C				
			Synthroid	C				
			Ddavp	C				

Date:03/15/01ISR Number: 3682477-2Report Type:Expedited (15-DaCompany Report #LBID00201000994
Age:25 YR Gender:Male I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Electromyogram Abnormal Hypokalaemia

		Hyporeflexia Paralysis Flaccid					
			Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
			Literature	Lithobid	PS	Solvay	
			Health			Pharmaceuticals	
600 MG DAILY	5 YR						
			Professional	Buspirone (Buspirone)	C		
				Fluoxetine (Fluoxetine)	C		

Date:03/16/01ISR Number: 3681922-6Report Type:Direct Company Report #
Age:64 YR Gender:Female I/FU:I

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Hospitalization -		Back Pain		Lithium (300mg)	PS		ORAL
PO BID							
Initial or Prolonged		Dry Mouth		Synthroid	C		
				Estrace	C		
				Ditropan	C		
				Risperdal	C		
				Pepcid	C		

Date:03/16/01ISR Number: 3681975-5Report Type:Direct Company Report #
Age:47 YR Gender:Male I/FU:I

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Hospitalization -		Body Temperature		Lithium 300mg Po	PS		ORAL
300MG PO							
Initial or Prolonged		Increased					
DAILY							
		Drug Level Above Therapeutic					
		Electrocardiogram Change					
		Fatigue					
		Feeling Jittery					
		Hypoaesthesia					
		Mental Impairment					
		Pollakiuria					
		Tremor					

Date:03/19/01ISR Number: 3682878-2Report Type:Direct Company Report #
Age:66 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anxiety		Lithium (450 Mg)	PS		ORAL	PO DAILY	
	Confusional State		Clonidine	C				
	Decreased Appetite		Lopressor	C				
	Headache		Lipitor	C				
	Insomnia		Clonazepam	C				
	Tremor		Celexa	C				

Date:03/19/01ISR Number: 3684374-5Report Type:Expedited (15-DaCompany Report #LBID00201000994
Age:25 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Electromyogram Abnormal	Literature	Lithobid	PS	Solvay Pharmaceuticals		600 MG DAILY	5 YR
	Hypokalaemia	Health						
	Hyporeflexia	Professional	Buspirone					
	Paralysis Flaccid		(Buspirone)	C				
			Fluoxetine					

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

(Fluoxetine) C

Date:03/19/01ISR Number: 3684503-3Report Type:Expedited (15-DaCompany Report #A104932
Age:56 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Creatine Increased Bronchitis Confusional State Coordination Abnormal Creatinine Renal Clearance Decreased Dizziness Drug Interaction Drug Level Above Therapeutic Drug Toxicity Dysarthria Fall Renal Impairment Tremor Vomiting	Foreign Consumer Health Professional	Lithium Carbonate Levofloxacin	PS SS	Pfizer Inc	ORAL ORAL	1200.00 MG 300.00 MG	TOTAL:ORAL TOTAL:ORAL

Date:03/19/01ISR Number: 3685630-7Report Type:Direct Company Report #
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Hospitalization - Initial or Prolonged	Catatonia Dehydration Drug Level Above Therapeutic Electrocardiogram Abnormal		Lithium (600mg) (Roxane) Zestril (20mg) Lithium 300 Mg	PS SS C	Roxane	ORAL ORAL ORAL	LI 6OO MG PO BID ZESTRIL 20MG PO QD 300 MG BID	

	Lethargy					
LIQUID						
	Medication Error					

Date:03/20/01ISR Number: 3685074-8Report Type:Direct Company Report #
Age:57 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hypernatraemia		Lithium	PS			300 QID	
Required Intervention to Prevent Permanent Impairment/Damage	Nephrogenic Diabetes Insipidus		Lithium	SS			300 QID	

Date:03/20/01ISR Number: 3685085-2Report 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	Asthenia		Lithium	PS			450MG AT HS	
	Drug Toxicity							
	Renal Impairment							
	Tremor							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/20/01ISR Number: 3685087-6Report Type:Direct Company Report #
Age:46 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Circulatory Collapse Confusional State Coordination Abnormal Disorientation Drug Level Above Therapeutic Muscle Rigidity Speech Disorder		Lithium (300mg In Am)	PS			1 AT NOON, 3Q HS	

Date:03/20/01ISR Number: 3686404-3Report Type:Expedited (15-DaCompany Report #2001006204-1
Age:60 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Chest Pain Drug Toxicity Electrocardiogram T Wave Inversion Sinus Bradycardia	Literature Health Professional	Eskalith	PS	Smithkline Beecham Pharmaceuticals		750 MILLIGRAMS	

Date:03/21/01ISR Number: 3687358-6Report Type:Expedited (15-DaCompany Report #2001006495-1
Age:64 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Balance Disorder Dizziness Electrocardiogram Abnormal Photopsia Sinus Arrhythmia Supraventricular Extrasystoles	Literature Health Professional	Eskalith	PS	Smithkline Beecham Pharmaceuticals			

Date:03/22/01ISR Number: 3687952-2Report Type:Expedited (15-DaCompany Report #WAES 01031627
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Interaction Drug Toxicity	Health Professional Company Representative	Vioxx	PS	Merck Research Laboratories Div Merck Co Inc	ORAL	UNK / UNK / PO	
			Lithiumco3	SS				

Date:03/22/01ISR Number: 3687991-1Report Type:Expedited (15-DaCompany Report #NSADSS2001006935
Age:38 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Level Above Therapeutic	Consumer	Risperdal	PS	Janssen Research Fdn	ORAL	2 MG, 2 IN 1	DAY(S), ORAL
Disability	Pneumonia		Lithium (Lithium)	SS		ORAL	900 MG,	DAILY, ORAL
	Tongue Disorder Tremor		Synthroid (Levothyroxine Sodium) Cogentin	C				

(Benzatropine Mesilate)	C	
Neurontin (Gabapentin)	C	
Depakote (Valproate Semisodium)	C	

Date:03/22/01ISR Number: 3688189-3Report Type:Expedited (15-DaCompany Report #2001006525-1
Age:80 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain Upper	Literature	Eskalith	PS	Smithkline Beecham Pharmaceuticals	ORAL	900	MILLIGRAMS
	Akinesia	Health						
	Blood Creatinine Increased	Professional	Acetylsalicylic Acid	C				
	Blood Potassium Decreased		Isosorbital Dinitrate	C				
	Blood Sodium Increased		Theophylline	C				
	Blood Uric Acid Increased		Thiazide Diuretic (Nos)	C				
	Bradycardia		Trimipramine	C				
	Cardiac Disorder							
	Dehydration							
	Depressed Level Of Consciousness							
	Difficulty In Walking							
	Disturbance In Attention							
	Drug Level Above Therapeutic							
	Drug Toxicity							
	Dysarthria							
	Extrapyramidal Disorder							
	Haematocrit Increased							
	Haemoglobin Increased							
	Hepatitis							
	Hypotension							
	Leukocytosis							
	Metabolic Acidosis							
	Muscle Rigidity							
	Nausea							
	Pancreatitis							
	Paresis							
	Sedation							
	Sinus Arrhythmia							
	Sinus Bradycardia							

Tachypnoea
Urinary Retention

Date:03/23/01ISR Number: 3705663-1Report Type:Periodic Company Report #WAES 01020184
Age:56 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Level Above Therapeutic	Health Professional	Vioxx	PS	Merck Research Laboratories Div Merck Co Inc	ORAL	PO	
			Lithiumco3	SS				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/23/01ISR Number: 3705674-6Report Type:Periodic Company Report #WAES 00120968
Age:48 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Toxicity	Consumer	Vioxx	PS	Merck Research Laboratories Div			
	Muscular Weakness							
	Pain				Merck Co Inc	ORAL	PO	
			Lithium-Duriles	SS				
			Ambien	C				
			Singulair	C				
			(Therapy Unspecified)	C				
			Doxepin	C				

Date:03/26/01ISR Number: 3689883-0Report Type:Expedited (15-DaCompany Report #ZONI000389 (0)
Age:17 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Drug Interaction	Health	Zonegran	PS	Dainippon Pharmaceutical Usa Corp	ORAL	700 MG DAILY	
Hospitalization - Initial or Prolonged	Drug Toxicity	Professional						
Required Intervention to Prevent Permanent Impairment/Damage	Haemodialysis							
	Renal Impairment							
			Lithium (Lithium)	SS			1800 MG DAILY	
			Topamax	C				
			Seroquel	C				

Date:03/26/01ISR Number: 3690166-3Report Type:Expedited (15-DaCompany Report #1999004849NL
Age:72 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Arrhythmia	Foreign	Detrol	PS	Pharmacia And Upjohn Co	ORAL	2 MG QD ORAL	
	Cardiomyopathy	Health						
	Cardiovascular Disorder	Professional	Theolin - Slow Release					
	Dizziness	Other						

		Malaise	(Theophylline)	SS	
UNKNOWN	300 MG BID	Nausea			
UNK	8 DAY	Pulse Pressure Decreased	Clomipramine		
		Syncope	(Clomipramine)	SS	
UNKNOWN	25 MG TID 8 DAY	Tremor	Priadel (Lithium		
		Urinary Incontinence	Carbonate)	SS	
UNKNOWN	400 MG BID 8 DAY	Urinary Retention	Ventoline		
		Ventricular Tachycardia	(Salbutamol)	SS	
UNKNOWN	8 DAY		Zestril (Lisinopril)	C	
			Aspirine	C	
			Acetylcysteine	C	

Date:03/27/01ISR Number: 3691107-5Report Type:Expedited (15-DaCompany Report #2001006729-1
Age:75 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Bradycardia	Literature	Eskalith	PS	Smithkline Beecham Pharmaceuticals			
	Drug Level Above Therapeutic	Health Professional	Carbamazepine	C				
	Nodal Arrhythmia		Haloperidol	C				
	Sinus Arrest							
	Sinus Arrhythmia							
	Supraventricular Extrasystoles							
	Vomiting							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/27/01ISR Number: 3691108-7Report Type:Expedited (15-DaCompany Report #2001006210-1
Age:13 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Cardiac Failure Congestive	Literature Health	Eskalith	PS	Smithkline Beecham Pharmaceuticals		2400	MILLIGRAMS
	Cardiomyopathy	Professional						
	Chest Pain		Imipramide	C				
	Drug Level Above Therapeutic							
	Drug Level Below Therapeutic							
	Dyspnoea							
	Ejection Fraction Abnormal							
	Fatigue							
	Heart Rate Increased							
	Hepatomegaly							
	Hyperhidrosis							
	Hypothyroidism							
	Mitral Valve Incompetence							
	Oedema							
	Pallor							
	Pulmonary Oedema							
	Rales							
	Respiratory Distress							
	Respiratory Rate Increased							
	Ventricular Extrasystoles							
	Weight Decreased							

Date:03/28/01ISR Number: 3691190-7Report Type:Expedited (15-DaCompany Report #01P-163-0104719-00
Age:42 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Chronic Obstructive Airways Disease Exacerbated	Health Professional	Kaletra Amprenavir Lithium (Lithium)	PS SS	Abbott Laboratories	ORAL PER ORAL		
	Delirium Tremens		(Lithium)	SS				YR

	Drug Interaction	Coumadin (Warfarin		
	Metabolic Acidosis	Sodium) (Warfarin		
	Pulmonary Oedema	Sodium)	SS	ORAL

11 MG, 1 IN 1

	Renal Tubular Acidosis

D, PER ORAL

	Respiratory Alkalosis

Date:03/28/01ISR Number: 3692387-2Report Type:Expedited (15-DaCompany Report #2001006888-1
Age:57 YR Gender:Male I/FU:I

Outcome	PT
Hospitalization -	Asthenia
Initial or Prolonged	Atrial Fibrillation
Other	Bradycardia
	Cardiac Arrest
	Chest Pain
	Grandiosity
	Hyperhidrosis
	Hypomania
	Loss Of Consciousness
	Myocardial Infarction
	Nausea

	Syncope						
	Tachycardia						
		Report Source	Product	Role	Manufacturer	Route	Dose Duration
		Literature	Eskalith	PS	Smithkline Beecham		
		Health			Pharmaceuticals		
900							
		Professional					
MILLIGRAMS 4 YR							

Date:03/28/01ISR Number: 3692390-2Report Type:Expedited (15-DaCompany Report #2001006648-1
Age:53 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Bradycardia	Health	Eskalith	PS	Smithkline Beecham		
Initial or Prolonged	Drug Level Above	Professional			Pharmaceuticals		
	Therapeutic		Carbamazepine	C			
	Sinus Arrest		Cogentin	C			
	Sinus Arrhythmia		Haloperidol	C			
	Syncope						

Date:03/28/01ISR Number: 3692397-5Report Type:Expedited (15-DaCompany Report #2001006659-1
Age:75 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Chorea	Health	Eskalith	PS	Smithkline Beecham		
Initial or Prolonged	Coordination Abnormal	Professional			Pharmaceuticals		
1200							
	Drug Level Above						
MILLIGRAMS							
	Therapeutic						
	Dysarthria						
	Electrocardiogram T Wave Inversion						
	Sinus Arrhythmia						
	Sinus Bradycardia						

Date:03/28/01ISR Number: 3692399-9Report Type:Expedited (15-DaCompany Report #2001006738-1
Age:40 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Atrioventricular Block Complete Dysarthria Heart Rate Irregular Mania Nausea Sedation Sinus Bradycardia Toxicologic Test Abnormal Vomiting	Literature Health Professional	Eskalith	PS	Smithkline Beecham Pharmaceuticals			

Date:03/29/01ISR Number: 3692517-2Report Type:Expedited (15-DaCompany Report #01-0459
Age:29 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Aggression Blood Alcohol Increased	Foreign Health	Loxitane Im	PS	Watson Laboratories Inc	INTRAMUSCULAR	50 MG 1 X PER	
	Condition Aggravated	Professional					1 DAY, IM	1 DAY
	Drug Ineffective	Company	Alcohol (Ethanol)	SS		ORAL		
	Head Injury	Representative	Bromazepam	SS				
	Pulmonary Embolism		Lysanxia (Prazepam)	SS			40 MG 1 X PER	

1 DAY

			Marijuana (Cannabis)	SS		
RECTAL	INHALATION					
			Netux (Codeine/Phenyltoloxamine)	SS		
			Rivotril (Clonazepam)	SS		
ONE VIAL	1 DAY					
			Solian (Amisulpride)	SS		
400 MG 1 X						
PER 1 DAY,						
			Teralithe (Lithium Carbonate)	SS		ORAL
400 MG 3 X						
PER 1 DAY,						
ORAL						
			Tercian (Cyamemazine)	SS		
ONE VIAL	1 DAY					

Date:04/02/01ISR Number: 3694324-3Report Type:Expedited (15-DaCompany Report #2001004210-1
Age:53 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Loss Of Consciousness	Health Professional	Eskalith Cr	PS	Smithkline Beecham Pharmaceuticals		450	
	Narcolepsy						MILLIGRAMS	
	Road Traffic Accident						3.0	DAILY
	Sedation							

Date:04/03/01ISR Number: 3695596-1Report Type:Expedited (15-DaCompany Report #2001006666-1
Age:65 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Atrioventricular Block	Literature	Eskalith	PS	Smithkline Beecham			

Initial or Prolonged	First Degree	Health			Pharmaceuticals	ORAL
SEE IMAGE						
	Electrocardiogram Qt	Professional	Benztropine Mesylate	C		
	Prolonged		Haloperidol	C		
	Electrocardiogram T Wave		Temazepam	C		
	Amplitude Decreased		Thioridazine	C		
	Hypokalaemia					
	Hypotension					
	Lethargy					
	Sinus Bradycardia					
	Syncope					
	Tardive Dyskinesia					
	Torsade De Pointes					
	Urinary Incontinence					

Date:04/04/01ISR Number: 3696995-4Report Type:Expedited (15-DaCompany Report #NSADSS2001005642
Age: Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Dialysis	Health	Topamax	PS	Rw Johnson	
Initial or Prolonged	Dizziness	Professional			Pharmaceutical	
Required	Drug Toxicity				Research Institute	ORAL
SEE IMAGE						
Intervention to	Speech Disorder		Lithium (Lithium)	SS		
900 MG, 2 IN						
Prevent Permanent						
1 DAILY						
Impairment/Damage			Zonisamide (Zonisamide)	C		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/04/01ISR Number: 3697042-0Report Type:Expedited (15-DaCompany Report #A035541
Age:53 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Chills	Foreign	Zoloft	PS	Pfizer Pharmaceuticals Inc	ORAL	150.00 MG TOTAL:DAILY:ORAL
	Clonic Convulsion	Health					
	Electroencephalogram	Professional					
	Normal						
	Serotonin Syndrome		Lithium	SS		ORAL	750.00 MG TOTAL:TID:ORAL
	Sleep Disorder						
			Buspirone	C			
			Bromazepam	C			
			Meprobamate + Aceprometazine	C			
			Zolpidem	C			

Date:04/04/01ISR Number: 3697228-5Report Type:Expedited (15-DaCompany Report #2001046151FR
Age:77 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Coordination Abnormal	Foreign	Celebrex	PS	Gd Searle And Co	ORAL	200 MG, QD, ORAL
	Drug Interaction	Health					
	Fall	Professional	Teralithe (Lithium Carbonate)	SS		ORAL	250 MG, BID, ORAL
	Malaise	Other					
	Overdose						
			Prothiaden	C			
			Sermion	C			

Date:04/05/01ISR Number: 3696975-9Report Type:Direct Company Report #
Age:30 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Pruritus Urticaria		Lithobid 300mg (Mfg: Solvay)	PS	Solvay	ORAL	ONE TAB Q AM 300 MG (ORAL); TWO TABS Q HS 300 MG	

Date:04/06/01ISR Number: 3700172-8Report Type:Expedited (15-DaCompany Report #LBID00201001421
Age:83 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Pressure Diastolic Decreased	Literature Health	Lithobid	PS	Solvay Pharmaceuticals	ORAL	1200 MG DAILY	
	Blood Urea Increased	Professional					PO 1200 MG	
	Drug Level Above Therapeutic		Clonazepam (Clonazepam)	SS		ORAL	DAILY PO 1 MG QD PO	
	Hypothermia							
	Lethargy		Olanzapine	SS		ORAL	5 MG QD PO	
	Mental Impairment		Piroxicam (Piroxicam)	C				
	Oedema Peripheral							
	Oral Intake Reduced		Trazodone Hydrochloride (Trazodone Hydrochloride)	C				
	Platelet Count Decreased							
			Lactulose (Lactulose)	C				

			Sulfamethoxazole (Sulfamethoxazole)	C		
			Trimethoprim (Trimethoprim)	C		

Date:04/06/01ISR Number: 3700179-0Report Type:Expedited (15-DaCompany Report #2001007381-2
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Ascites	Literature	Eskalith	PS	Smithkline Beecham			
Other	Caesarean Section	Health			Pharmaceuticals			
	Cardio-Respiratory Arrest	Professional						
	Neonatal							
	Complications Of Maternal							
	Exposure To Therapeutic Drugs		Pre-Natal Vitamins	C				
	Congenital Aortic Valve Incompetence							
	Congenital Jaw Malformation							
	Congenital Mitral Valve Incompetence							
	Congenital Pulmonary Valve Disorder							
	Developmental Delay							
	Foetal Distress Syndrome							
	Limb Malformation							
	Neonatal Apnoeic Attack							
	Oedema							
	Pericardial Effusion							
	Pleural Effusion							
	Pregnancy							
	Small For Dates Baby							
	Tricuspid Valve Incompetence							

INTRA-UTERINE 900 MILLIGRAMS INTERUTERINE (SEE IMAGE)

Date:04/06/01ISR Number: 3700227-8Report Type:Expedited (15-DaCompany Report #2001003226-1
Age:60 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Interaction	Consumer	Eskalith	PS	Smithkline Beecham			
	Drug Level Below Therapeutic	Health Professional			Pharmaceuticals	ORAL	300 MILLIGRAMS	
	Mania						3.0 DAILY	
						ORAL		
			Prilosec (Omeprazole)	SS		ORAL		
			Zoloft	C				
			Ranitidine	C				
			Buspar	C				

Date:04/06/01ISR Number: 3700652-5Report Type:Expedited (15-DaCompany Report #2001007676-1
Age:37 YR Gender:Female I/FU:I

Outcome	PT
Other	Cognitive Disorder
	Confusional State
	Delirium

		Delusion Of Grandeur					
		Dementia					
		Depersonalisation	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
		Disorientation	Health	Eskalith	PS	Smithkline Beecham	
		Disturbance In Attention	Professional			Pharmaceuticals	ORAL
900							
		Electroencephalogram					
MILLIGRAMS							
		Abnormal					
		Flight Of Ideas					
		Hallucinations, Mixed					
		Memory Impairment					
		Mood Altered					
		Renal Impairment					
		Restlessness					
		Urinary Incontinence					

Date:04/12/01ISR Number: 3703926-7Report Type:Direct Company Report #
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Other	Acne Cystic		Lithium	PS		
			Benztropine	C		

Date:04/16/01ISR Number: 3705888-5Report Type:Expedited (15-DaCompany Report #2001008586-1
Age:50 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization -	Condition Aggravated	Foreign	Eskalith	PS	Smithkline Beecham	
Initial or Prolonged	Keratosis Follicular	Literature			Pharmaceuticals	ORAL
1200						
	Mania	Health				
MILLIGRAMS						
	Seborrhoea	Professional				
ORAL						
		Other	Maprotiline	C		

Date:04/17/01ISR Number: 3706303-8Report Type:Direct Company Report #
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Interaction		Lithium / 300mg /					
	Drug Level Above Therapeutic		Roxane	PS	Roxane	ORAL	300 MG TID	
	Medication Error		Zestril 10 Mg Astrazenica	SS	Astrazenica	ORAL	10 MG DAILY ORAL	

Date:04/17/01ISR Number: 3707186-2Report Type:Expedited (15-DaCompany Report #FLUV00301000004
Age:34 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blood Alkaline Phosphatase Increased	Foreign Health	Luvox	PS	Solvay Pharmaceuticals	ORAL	150 MG DAILY	
	Fall	Professional					PO	
	Gamma-Glutamyltransferase Increased	Other	Linton (Haloperidol)	SS		ORAL	12 MG DAILY PO	
	Injury Loss Of Consciousness		Hirnamin (Levomepromazine)	SS		ORAL	200 MG DAILY PO	
			Anafranil (Clomipramine					

			Hydrochloride)	SS		ORAL
150 MG DAILY						
PO						
			Tegretol (Carbamazepine)	SS		ORAL
800 MG DAILY						
PO						
			Limas (Lithium Carbonate)	SS		ORAL
1200 MG DAILY						
PO						

Date:04/17/01ISR Number: 3707967-5Report Type:Expedited (15-DaCompany Report #01P-163-0104719-00
Age:42 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Chronic Obstructive Airways Disease Exacerbated Delirium Tremens Drug Interaction Dyspnoea Pulmonary Oedema Renal Tubular Acidosis Respiratory Alkalosis	Health Professional	Kaletra Amprenavir Lithium (Lithium) (Lithium)	PS SS SS	Abbott Laboratories	ORAL PER ORAL		

Date:04/19/01ISR Number: 3708109-2Report Type:Expedited (15-DaCompany Report #LBID00201001744
Age:85 YR Gender:Female I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Anorexia Apraxia Blood Alkaline Phosphatase Increased Blood Chloride Increased Blood Magnesium Decreased Blood Potassium Increased Blood Sodium Increased Blood Thyroid Stimulating

Hormone Decreased
Cheyne-Stokes Respiration
Coma
Condition Aggravated
Confusional State
Dehydration
Depression
Drug Level Above
Therapeutic
Drug Toxicity
Drug Withdrawal Syndrome
Electrocardiogram Qt
Corrected Interval
Prolonged
Grandiosity
Granuloma
Hepatic Encephalopathy
International Normalised
Ratio Increased
Keratitis Herpetic
Meningitis
Muscle Rigidity
Myocardial Infarction
Myocardial Ischaemia

	Nephrogenic Diabetes Insipidus					
	Neutrophil Count Increased	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
	Pupil Fixed	Literature Health	Lithobid	PS	Solvay Pharmaceuticals	ORAL
150 MG BID PO						
	Uveitis	Professional	Divalproex Sodium			
	White Blood Cell Count Increased		(Divalproex Sodium)	C		
			Thioridazine (Thioridazine)	C		
			Oxybutynin (Oxybutynin)	C		
			Probantheline	C		
			Erythromycin (Erythromycin)	C		
			Temazepam (Temazepam)	C		
			Levothyroxine (Levothyroxine)	C		

Date:04/23/01ISR Number: 3709751-5Report Type:Periodic Company Report #2001000383-1
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Condition Aggravated	Health Professional	Eskalith	PS	Smithkline Beecham Pharmaceuticals	ORAL
1200 MILLIGRAMS, ORAL	Drug Toxicity					
	Mental Disorder					

Date:04/24/01ISR Number: 3709261-5Report Type:Direct Company Report #
Age:58 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Required Intervention to Prevent Permanent	Coma		Lithium Carb. (300mg Caps)	PS		ORAL
300MG PO TID	Depressed Level Of Consciousness		Clonazepam	C		

Impairment/Damage	Drug Level Above Therapeutic Sedation	Depakote	C	
		Colace	C	
		Fosinopril	C	
		Gabapentin	C	
		Hctz	C	
		Levothyroxine	C	
		Lorazepam	C	
		Miconazole Powder	C	
		Mom	C	
		Olanzepine	C	
		Nifedipine	C	

Date:04/24/01ISR Number: 3710199-8Report Type:Direct Company Report #
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Memory Impairment		Lithium	PS		ORAL	225MG PO BID	
Hospitalization -	Speech Disorder							30 YRS OF
Initial or Prolonged								LITHIUM USE 30 YR
			Synthroid	C				
			Lithium Carbonate	C				
			Ferrous Sulfate	C				
			Flomax	C				

			Baycol	C		

Date:04/24/01ISR Number: 3710201-3Report Type:Direct Company Report #
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Coma		Lithium	PS				
Hospitalization - Initial or Prolonged	Rhabdomyolysis							

Date:04/24/01ISR Number: 3710204-9Report Type:Direct Company Report #
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Cardiac Failure		Lithium	PS		ORAL	300MG 2	
	Congestive						TABLETS BID	
	Diabetes Mellitus						PO	
	Drug Toxicity		Pyridium	C				
	Mental Impairment		Pepcid	C				
	Pulmonary Oedema		Metoprolol	C				
	Renal Failure Acute		Hydralazine	C				
			Avandia	C				
			Amlodipine	C				
			Divalprovex	C				
			Insulin	C				
			Oxybutynin	C				
			Actron	C				

Date:04/24/01ISR Number: 3710496-6Report Type:Direct Company Report #
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Toxicity		Lithium	PS				
	Rhabdomyolysis		Sertraline	C				
			Clonazepam	C				

				Zyprexa	C		

Date:04/24/01ISR Number: 3710497-8Report Type:Direct Company Report #
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Depressed Level Of Consciousness		Lithium	PS				
	Drug Toxicity		Diltizem	C				
	Lethargy		Estrogens	C				
	Loss Of Consciousness		Pepcid	C				
			Neurontin	C				
			Levothyroxine	C				
			Colace	C				

Date:04/25/01ISR Number: 3710668-0Report Type:Expedited (15-DaCompany Report #C2001-0972.01
Age: Gender:Female I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Constipation
	Decreased Activity
	Depressed Level Of

	Consciousness Hyperreflexia Hypothermia Lethargy	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
	Mental Impairment Oedema Peripheral	Literature Other	Clonazepam	PS	Mylan Pharmaceuticals Inc	ORAL
1 MG QD, ORAL						
	Oral Intake Reduced		Lithium	SS		ORAL
300 MG BID						
	Social Avoidant Behaviour					
AND 600 MG						
QHS, ORAL						
			Olanzapine Lilly	SS	Lilly	ORAL
5 MG QD, ORAL						
			Piroxicam	C		
			Sulfamethoxazole/Trimethoprim	C		

Date:04/25/01ISR Number: 3710919-2Report Type:Expedited (15-DaCompany Report #WAES 01031627
Age:69 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Abdominal Pain Balance Disorder Blood Pressure Increased	Health Professional Company	Vioxx	PS	Merck Research Laboratories Div Merck Co Inc	ORAL
PO						
	Confusional State	Representative	Lithiumco3 300 Mg	SS		
DAILY						
	Drug Interaction		Fosamax	C		
	Drug Toxicity		Lortab	C		
	Gait Disturbance		Prempro	C		
	Haematocrit Decreased		Prevacid	C		
	Haemoglobin Decreased		Zestril	C		
	Hallucination Headache Memory Impairment Mental Impairment Oliguria Peripheral Sensory Neuropathy Pollakiuria Sedation Speech Disorder					

	Thirst					
	Tremor					
	Visual Acuity Reduced					
	Weight Decreased					

Date:04/26/01ISR Number: 3711545-1Report Type:Direct Company Report #
Age:47 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Creatinine		Lithium	PS			255 MG TID AND 450 HS	
	Increased							
	Cough		Depakote Er	C				
	Diabetes Insipidus		Synthroid	C				
	Lethargy		Clozaril	C				
	Mental Impairment		Haldol	C				
	Oral Intake Reduced		Allopurinol	C				
	Pyrexia		Glucophage	C				
			Flomax	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/27/01ISR Number: 3712931-6Report Type:Direct Company Report #
Age:45 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Bradycardia Dizziness Nausea Vomiting		Lithium Atropine Rosiglitazone Medisense Precision Qid Strips Nortriptyline Diltiazem Gemfibrozil Insulin 70/30 Insulin Syringe Isopropyl Alcohol Lancets Lithium Carbonate Maxzide Olanzapine Terazosin Hcl Lisinopril Isopropyl Alcohol Lancets Lithium Carbonate Maxzide Olanzapine Terazosin Hcl Lisinop	PS C C C C C C C C C C C				

Date:04/30/01ISR Number: 3714306-2Report Type:Expedited (15-DaCompany Report #033-0982-M0100006
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Coma Drug Level Above Therapeutic Hypotension Overdose Sinus Bradycardia	Foreign Consumer Other	Cerebyx Daonil (Glibenclamide) Terlithe (Lithium Carbonate) Lovenox (Heparin F-Raction, Sodium Salt)	PS SS SS C	Parke Davis Div Warner Lambert Co		1200 MG, INTRAVENOUS INTRAVENOUS PER ORAL PER ORAL	

			Augmentin Injection (Amoxicillin Sodium, Clavulanate Potassium)	C		
			Actrapid (Insulin)	C		

Date:04/30/01ISR Number: 3715011-9Report Type:Expedited (15-DaCompany Report #01-0459 FOLLOW-UP
Age:29 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Abnormal Behaviour	Foreign	Loxitane Im	PS	Watson Laboratories Inc	INTRAMUSCULAR	50 MG 1 X PER 1 DAY, IM	1 DAY
	Aggression	Health						
	Agitation	Professional						
	Alcoholism	Company	Alcohol (Ethanol)	SS		ORAL	ORAL	1 DAY
	Drug Abuser	Representative	Bromazepam (Bromazepam)	SS				
	Drug Ineffective		Lysanxia (Prazepam)	SS			40 MG 1 X PER 1 DAY	
	Head Injury							
	Toxicologic Test Abnormal							
			Marijuana (Cannabis)	SS			RESPIRATORY (INHALATION)	INHALATION 1 DAY
			Netux					

				(Codeine/Phenyltoloxamine)	SS		
				Rivotril (Clonazepam)	SS		
ONE VIAL	1	DAY					
				Solian (Amisulpride)	SS		
400 MG 1 X							
PER 1 DAY,							
				Teralithe (Lithium Carbonate)	SS		ORAL
400 MG 3 X							
PER 1 DAY,							
ORAL							
				Tercian (Cyamemazine)	SS		
ONE VIAL	1	DAY					

Date:05/03/01ISR Number: 3717245-6Report Type:Expedited (15-DaCompany Report #1818977-2001-00264
Age:40 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Alkaline Phosphatase Increased	Foreign Literature	Proloprim	PS	Monarch Pharmaceuticals Inc	ORAL	300	
	Blood Creatinine Increased		Lithium Carbonate	SS		ORAL	1200 MG /D	AILY/ORAL
	Diarrhoea							
	Disturbance In Attention		Olanzapine	C				
	Drug Level Above Therapeutic		Diazepan	C				
	Gait Disturbance		Oxazepam	C				
	Malaise							
	Movement Disorder							
	Tremor							
	Urinary Tract Infection							

Date:05/03/01ISR Number: 3717553-9Report Type:Expedited (15-DaCompany Report #NSADSS2001003698
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Confusional State	Health	Risperdal	PS	Janssen Research Fdn	ORAL	ORAL	
Initial or Prolonged	Delirium	Professional	Lithium (Lithium)	SS		ORAL	ORAL	
Required Intervention to Prevent Permanent Impairment/Damage	Diabetes Insipidus							
	Thrombotic Thrombocytopenic Purpura							

Date:05/04/01ISR Number: 3716894-9Report Type:Expedited (15-DaCompany Report #259433
Age:59 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Granuloma		Rivotril	PS	Roche			
Initial or Prolonged	Hepatic Fibrosis		Laroxyl	SS	Roche			
	Hepatic Necrosis		Depamide	SS				
	Hepatic Steatosis		Tiapridal	SS				
	Hepatitis		Seropram	SS				
			Lithium	SS				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/04/01ISR Number: 3716903-7Report Type:Expedited (15-DaCompany Report #259430
Age:60 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Alanine Aminotransferase Increased		Rivotril	PS	Roche			
			Isoptine	SS				
			Teralithe	SS				
			Innohep	SS				
			Opium Tincture	SS				
	Aspartate Aminotransferase Increased							9 DAY
	Blood Alkaline Phosphatase Increased							
	Gamma-Glutamyltransferase Increased							

Date:05/07/01ISR Number: 3718784-4Report Type:Expedited (15-DaCompany Report #259430
Age:60 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Alanine Aminotransferase Increased	Foreign Other	Clonopin	PS	Hoffmann La Roche Inc	ORAL	6 MG	ORAL
	Aspartate Aminotransferase Increased		Isoptine (Verapamil Hydrochloride) 240 Mg	SS		ORAL	120 MG	1 PER DAY ORAL
	Blood Alkaline Phosphatase Increased		Teralithe (Lithium Carbonate) 400 Mg	SS		ORAL	200 MG	1 PER DAY ORAL
	Gamma-Glutamyltransferase Increased		Innohep (Tinzaparin Sodium) 2500 Iu	SS		SUBCUTANEOUS	SUBCUTANEOUS	
			Opium Tincture (Opium Tincture)	SS		ORAL	ORAL	

Date:05/07/01ISR Number: 3718809-6Report Type:Expedited (15-DaCompany Report #259433
Age:59 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Glucose Increased	Foreign	Clonopin	PS	Hoffmann La Roche Inc	ORAL	ORAL	
	Granulomatous Liver Disease	Other	Laroxyl (Amitriptyline Hydrochloride)	SS		ORAL	ORAL	
	Hepatic Fibrosis		Depamide (Valpromide)	SS		ORAL	ORAL	
	Hepatic Necrosis		Tiapridal (Tiapride)	SS		ORAL	ORAL	
	Hepatic Steatosis		Seropram (Citalopram)	SS		ORAL	ORAL	
	Hepatitis		Lithium (Lithium Nos)	SS		ORAL	ORAL	

Date:05/08/01ISR Number: 3719128-4Report Type:Direct Company Report #
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dermatitis		Lithobid 300 Mg Bid	PS		ORAL	300 MG 2 PO	
	Diarrhoea						BID	
	Eczema							
	Vomiting							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/14/01ISR Number: 3723723-6Report Type:Expedited (15-DaCompany Report #PHEH1990US01495
Age:17 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Accident	Health	Clozaril	PS	Novartis			
Hospitalization -	Coma	Professional			Pharmaceuticals Corp	ORAL	SEE IMAGE	
Initial or Prolonged	Convulsion		Lithium(Lithium)	SS				
	Coordination Abnormal		Haldol (Haloperidol)					
	Dermatitis		(Haloperidol)	SS				
	Encephalopathy		Artane					
	Fall		(Trihexypenidyl					
	Head Injury		Hydrochloride	SS			"HIGH DOSE"	
	Hypotension		Thorazine	SS			HIGH DOSE	
	Loss Of Consciousness						UNK	
	Nephropathy Toxic							
	Orthostatic Hypotension							
	Pyrexia							
	Simple Partial Seizures							
	Syncope							
	Tachycardia							
	White Blood Cell Count Increased							

Date:05/14/01ISR Number: 3723940-5Report Type:Expedited (15-DaCompany Report #S01-FRA-00867-01
Age:59 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Granuloma	Foreign	Celexa	PS	Forest Laboratories			
Initial or Prolonged	Hepatic Fibrosis	Health			Inc		UNKNOWN	
	Hepatic Necrosis	Professional	Depamide					
	Hepatic Steatosis	Other	(Valpromide)	SS			UNKNOWN	
			Laroxyl (Amitriptyline Hydrochloride)	SS			UNKNOWN	
			Rivotril					

(Clonazepam)	SS	
Tiapridal (Tiapride)	SS	
Lithium	SS	

UNKNOWN

UNKNOWN

UNKNOWN

Date:05/14/01ISR Number: 3724104-1Report Type:Expedited (15-DaCompany Report #2001010454-1
Age:47 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Accommodation Disorder Bradycardia	Health Professional	Eskalith	PS	Smithkline Beecham Pharmaceuticals		4500	
Other	Drug Toxicity Intentional Misuse Muscle Spasms Sedation Vomiting						MILLIGRAMS	

Date:05/17/01ISR Number: 3724419-7Report Type:Direct Company Report #
Age: Gender:Female I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Blood Creatinine Increased Blood Sodium Increased Coma

Diabetes Insipidus

			Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
				Lithium	PS		ORAL
300 MG QD PO							
				Zyprexa	C		

Date:05/18/01ISR Number: 3724571-3Report Type:Direct Company Report #
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization -	Acalculia		Lithium	PS		ORAL
300 MG PO BID						
Initial or Prolonged	Asthenia		Prednisone	C		
Required	Clonic Convulsion		Bactrim	C		
Intervention to	Cognitive Disorder		Mn	C		
Prevent Permanent	Difficulty In Walking		Nystatin	C		
Impairment/Damage	Drug Level Above		Imuran	C		
	Therapeutic		Cya	C		
	Fall		Actigall	C		
	Intention Tremor		Mg Ox	C		
	Memory Impairment		Acyclovir	C		
	Tremor		Inderal	C		
	Urinary Incontinence		Lasix	C		
			Zantac	C		

Date:05/18/01ISR Number: 3726310-9Report Type:Expedited (15-DaCompany Report #LBID00201002158
Age:26 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization -	Amnesia	Consumer	Lithobid	PS	Solvay	
Initial or Prolonged	Confusional State				Pharmaceuticals	ORAL
300 MG PO						
	Disturbance In Social		Seroquel (Seroquel)	C		
	Behaviour		Lorazepam			
	Speech Disorder		(Lorazepam)	C		

Date:05/22/01ISR Number: 3727647-XReport Type:Expedited (15-DaCompany Report #HQ6750129NOV1999
Age:40 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Arrhythmia	Health	Effexor Xr	PS	Wyeth Ayerst			
	Drug Interaction	Professional			Laboratories	ORAL	300 MG 1X PER	1 DAY
	Drug Level Above	Other						
	Therapeutic		Dromyl					
	Sudden Death		(Dimenhydrinate,)	SS			"LARGE DOSE"	
			Lithium (Lithium,)	SS			300 MG 2X PER	1 DAY 9 DAY
			Nozinan					
			(Levomepromazine,)	SS			MAXIMUM 20 MG	AT BEDTIME 9 DAY

Date:05/23/01ISR Number: 3728079-0Report Type:Expedited (15-DaCompany Report #A110876
Age:47 YR Gender:Female I/FU:I

Outcome
Hospitalization -
Initial or Prolonged
Required
Intervention to

Prevent Permanent
Impairment/Damage

	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Abdominal Distension	Foreign	Pfi-Lith	PS	Pfipharmecs Div			
	Amnesia	Consumer			Pfizer Inc	ORAL	1200.00 MG	
	Arthritis						TOTAL: ORAL	
	Breast Engorgement		Sertraline	C				
	Bronchitis Acute		Levothyroxine	C				
	Diarrhoea		Clonazepam	C				
	Difficulty In Walking		Lansoprazole	C				
	Drug Level Above Therapeutic		Conjugated Estrogens	C				
	Drug Toxicity		Morphine	C				
	Eyelid Oedema		Hydromorphone	C				
	Haemodialysis							
	Hair Disorder							
	Pruritus							

Date:05/24/01ISR Number: 3728570-7Report Type:Expedited (15-DaCompany Report #HQ6750129NOV1999
Age:40 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Arrhythmia	Health	Effexor Xr	PS	Wyeth Ayerst			
	Drug Interaction	Professional			Laboratories	ORAL	300 MG 1X PER	
	Drug Level Above Therapeutic	Other					1 DAY ORAL	
	Sudden Death		Diphenhydramine (Diphenydramine)	SS			"LARGE DOSE"	
			Lithium (Lithium)	SS			300 MG 2X PER	
							1 DAY	9 DAY
			Nozinan (Levomepromazine)	SS			MAXIMUM 20 MG	
							AT BEDTIME	
			Methotrimeprazine (Levomepromazine)	C				

Date:05/25/01ISR Number: 3729185-7Report Type:Expedited (15-DaCompany Report #A111268
Age: Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Intentional Misuse	Foreign	Lithium Carbonate	PS	Pfizer Inc	ORAL	ORAL	
		Literature	Ssri Unspecified	SS		ORAL	ORAL	
		Health Professional						

Date:05/25/01ISR Number: 3729186-9Report Type:Expedited (15-DaCompany Report #A111269
Age: Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Intentional Misuse	Foreign	Lithium Carbonate	PS	Pfizer Inc	ORAL	ORAL	
		Literature	Ssri Unspecified	SS		ORAL	ORAL	
		Health Professional						

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/25/01ISR Number: 3729188-2Report Type:Expedited (15-DaCompany Report #A111270
Age: Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Intentional Misuse	Foreign	Lithium Carbonate	PS	Pfizer Inc	ORAL	ORAL	
		Literature	Ssri Unspecified	SS		ORAL	ORAL	
		Health Professional						

Date:05/25/01ISR Number: 3729190-0Report Type:Expedited (15-DaCompany Report #A111271
Age: Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Cardiovascular Disorder	Foreign	Lithium Carbonate	PS	Pfizer Inc	ORAL	ORAL	
		Literature	Ssri Unspecified	SS		ORAL	ORAL	
		Health Professional						

Date:05/25/01ISR Number: 3729191-2Report Type:Expedited (15-DaCompany Report #A111272
Age: Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Cardiovascular Disorder	Foreign	Lithium Carbonate	PS	Pfizer Inc	ORAL	ORAL	
		Literature	Ssri Unspecified	SS		ORAL	ORAL	
		Health Professional						

Date:05/25/01ISR Number: 3729258-9Report Type:Expedited (15-DaCompany Report #A111273
Age: Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Required	Cardiovascular Disorder	Foreign	Lithium Carbonate	PS	Pfizer Inc	ORAL ORAL
Intervention to Prevent Permanent Impairment/Damage		Literature Health Professional	Ssri Unspecified	SS		ORAL ORAL

Date:05/25/01ISR Number: 3729259-0Report Type:Expedited (15-DaCompany Report #A111274
Age: Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Required	Cardiovascular Disorder	Foreign	Lithium Carbonate	PS	Pfizer Inc	ORAL ORAL
Intervention to Prevent Permanent Impairment/Damage		Literature Health Professional	Ssri Unspecified	SS		ORAL ORAL

Date:05/25/01ISR Number: 3729261-9Report Type:Expedited (15-DaCompany Report #A111276
Age: Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Required	Cardiovascular Disorder	Foreign	Lithium Carbonate	PS	Pfizer Inc	ORAL ORAL
Intervention to Prevent Permanent Impairment/Damage		Literature Health Professional	Ssri Unspecified	SS		ORAL ORAL

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/29/01ISR Number: 3729221-8Report Type:Direct Company Report #
Age:53 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Asthenia		Lithium Carbonate	PS			600MG QAM AND PM	
	Polydipsia							
	Polyuria							
	Tremor							

Date:05/30/01ISR Number: 3729386-8Report Type:Expedited (15-DaCompany Report #B0109422A
Age:29 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Abortion		Lamotrigine	PS	Glaxo Wellcome	ORAL		
			Lithium	SS			UNKNOWN	

Date:05/30/01ISR Number: 3730831-2Report Type:Expedited (15-DaCompany Report #A109699
Age:37 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Coordination Abnormal	Foreign	Lithium Carbonate	PS	Pfizer Inc			
	Wheelchair User	Health Professional	Edronax	C				
			Atenolol	C				
			Singulair	C				
			Lastrix	C				
			Stilnoct	C				
			Bcom Forte	C				
			Tradeloan	C				
			Losec	C				
			Atarax	C				
			Atrovent	C				
			Ventoline	C				
			Stesolid	C				
			Panocod	C				
			Malsine	C				
			Pulmicort	C				
			Lactipex	C				

Date:06/01/01ISR Number: 3731280-3Report Type:Direct Company Report #
Age:12 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Eye Movement Disorder Tremor		Lithium	PS	Varries/Month To Month	ORAL	250MG/AM/PM/O RAL	
			Risperdal	SS		ORAL	1MG/ 2 TIMES/ORAL	

Date:06/04/01ISR Number: 3733242-9Report Type:Expedited (15-DaCompany Report #B0109422A
Age:29 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Abortion	Foreign	Lamictal	PS	Glaxo Wellcome Inc	ORAL	ORAL	
			Lithium Salt (Formulation Unknown) (Lithium Salt)	SS				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/04/01ISR Number: 3733259-4Report Type:Expedited (15-DaCompany Report #A040222
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Arrhythmia	Foreign Health Professional	Zoloft	PS	Pfizer Pharmaceuticals Inc	ORAL	50.00 MG	TOTAL; DAILY;
			Lithium	SS		ORAL		

Date:06/04/01ISR Number: 3733639-7Report Type:Periodic Company Report #A109062
Age:37 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Interaction Movement Disorder	Health Professional	Geodon	PS	Pfizer Central Research		40.00 MG	
	Sedation	Company Representative	Lithium Carbonate	SS			900.00 MG	TOTAL BID
			Lithium	C				TOTAL

Date:06/04/01ISR Number: 3733640-3Report Type:Periodic Company Report #A109963
Age:15 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Grand Mal Convulsion Sedation	Health Professional	Geodon	PS	Pfizer Central Research		40.00 MG Required	TOTAL BID
Intervention to			Lithium Carbonate	SS			1500.00 MG	

Prevent Permanent
TOTAL BID
Impairment/Damage Clozaril C

Date:06/04/01ISR Number: 3733643-9Report Type:Periodic Company Report #A105389
Age:19 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Agitation	Consumer	Geodon	PS	Pfizer Central			
	Drug Ineffective	Health			Research	ORAL	40.00 MG	
	Insomnia	Professional					TOTAL DAILY	
	Mania						ORAL	
	Nausea		Lithium Carbonate	SS		ORAL	4500.00 MG	
	Nervousness						TOTAL/ TID	
	Psychotic Disorder						ORAL	
	Vomiting		Clonazepam	C				

Date:06/04/01ISR Number: 3733668-3Report Type:Periodic Company Report #A109347
Age:23 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Acne	Health	Geodon	PS	Pfizer Central			
	Dyspnoea	Professional			Research		40.00 MG	
	Epistaxis						TOTAL:BID	
	Hallucination		Lithium Carbonate	SS				
	Sedation		Seroquel	C				
	Tachycardia		Restoril	C				
			Klonopin	C				
			Topamax	C				
			Wellbutrin Sr	C				

			Colace	C		
			Antibiotic	C		

Date:06/04/01ISR Number: 3733771-8Report Type:Periodic Company Report #A036785
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Neurosis	Consumer	Lithium Carbonate	PS	Pfizer Inc	ORAL	900.00 MG	
	Paraesthesia						TOTAL; TID:	
	Unevaluable Event						ORAL	
			Zoloft	SS		ORAL	150.00 MG	

TOTAL: TID:

ORAL

Date:06/04/01ISR Number: 3733772-XReport Type:Periodic Company Report #A100681
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dizziness	Consumer	Lithium Carbonate	PS	Pfizer Inc			
	Thinking Abnormal		Gabapentin	SS				
			Divalproex	SS				

Date:06/05/01ISR Number: 3735326-8Report Type:Expedited (15-DaCompany Report #A109962
Age:37 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Monoparesis	Health Professional	Geodon	PS	Pfizer Central Research		40.00 MG	
	Sedation						TOTAL:BID	

			Lithium Carbonate	SS		
900.00 MG						
TOTAL:DAILY						
			Naltrexone	C		

Date:06/06/01ISR Number: 3735495-XReport Type:Expedited (15-DaCompany Report #2001013043-1
Age:29 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Abortion		Eskalith	PS	Smithkline Beecham Pharmaceuticals			
	Acne							
	Complications Of Maternal Exposure To Therapeutic Drugs		Lamotrigine	C				
	Pregnancy							

Date:06/06/01ISR Number: 3735707-2Report Type:Expedited (15-DaCompany Report #LBID00201002549
Age:42 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Depression	Literature	Lithobid	PS	Solvay Pharmaceuticals	ORAL	900 MG DAILY	
	Fatigue	Health					PO	
	Hallucination, Auditory	Professional						
	Sleep Disorder		Fluoxetine (Fluoxetine)	SS		ORAL	40 MG DAILY	
	Suicidal Ideation						PO	
			Imipramine (Imipramine)	SS		ORAL	50 MG DAILY	

PO, 100 MG

DAILY PO

		Thioridazine (Thioridazine)	SS	ORAL

75 MG DAILY

PO, 150 MG

DAILY PO

Date:06/07/01ISR Number: 3735563-2Report Type:Direct Company Report #
Age:49 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Coordination Abnormal Diabetes Insipidus Drug Level Above Therapeutic Lethargy		Lithium	PS				

Date:06/08/01ISR Number: 3737126-1Report Type:Expedited (15-DaCompany Report #2000027543-1
Age:34 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Bradycardia Complications Of Maternal Exposure To Therapeutic Drugs Neonatal Disorder Oxygen Saturation Decreased Pregnancy Premature Rupture Of Membranes Skin Discolouration Weight Increased	Health Professional	Eskalith Cr	PS	Smithkline Beecham Pharmaceuticals	ORAL	450 MILLIGRAMS	238 DAY

Date:06/11/01ISR Number: 3737116-9Report Type:Periodic Company Report #2001-01-0940
Age:30 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Infertility	Consumer	Claritin					
		Other	(Loratadine)	PS	Schering Corp Sub Schering Plough Corp	ORAL	10 MG QD	ORAL
			Synthroid	SS		ORAL	75 MCG QD	ORAL
			Eskalith	SS		ORAL	675 MG QD	ORAL
			Nortriptyline	SS		ORAL	150 MG QD	ORAL

Date:06/11/01ISR Number: 3737209-6Report Type:Periodic Company Report #2000-08-2046
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Interaction Sexual Dysfunction	Consumer	Claritin	PS	Schering Corp Sub Schering Plough Corp	ORAL	UNKNOWN	ORAL
			Risperdal	SS				
			Dilantin	SS			600 MG	UNKNOWN
			Lithium	SS			1200 MG	

UNKNOWN

Date:06/11/01ISR Number: 3738146-3Report Type:Expedited (15-DaCompany Report #2001013629-1
Age:32 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Grand Mal Convulsion	Health Professional	Eskalith	PS	Smithkline Beecham Pharmaceuticals			
	White Blood Cell Count Increased		Clozapine	SS				
			Navane (Tiotixene)	C				

Date:06/12/01ISR Number: 3738482-0Report Type:Expedited (15-DaCompany Report #A109961
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Akathisia	Health Professional	Geodon	PS	Pfizer Central Research			
	Blood Creatine Phosphokinase Increased		Lithium	SS			1200.00 MG	TOTAL:
	Coordination Abnormal							
	Dystonia		Seroquel (Quetiapine)	SS			200.00 MG	TOTAL
	Extrapyramidal Disorder							
	Hyperhidrosis		Propranolol	SS			60.00 MG	
	Hypomania		Paxil (Paroxetine)	C				
	Muscle Rigidity		Nortriptyline	C				
	Muscle Spasms							
	Neuroleptic Malignant Syndrome							
	Psychomotor Hyperactivity							
	Pyrexia							
	Restlessness							
	Sleep Talking							
	Tongue Disorder							
	Urinary Incontinence							

Date:06/13/01ISR Number: 3738239-0Report Type:Direct Company Report #
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Confusional State Drug Level Above Therapeutic Feeling Jittery		Lithium	PS			1200 MG/DAY IN DIVIDED DOESES	

Date:06/14/01ISR Number: 3740037-9Report Type:Expedited (15-DaCompany Report #A109699
Age:37 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Condition Aggravated Coordination Abnormal	Foreign Health Professional	Lithium Carbonate	PS	Pfizer Inc			
			Edronax	C				
			Atenolol	C				
			Singulair	C				
			Lastrix	C				
			Stilnoct	C				
			Bcom Forte	C				
			Tradeloan	C				
			Losec	C				
			Atarax	C				
			Atrovent	C				

				Ventoline	C		
				Stesolid	C		
				Panocod	C		
				Malsine	C		
				Pulmicort	C		
				Lactipex	C		

Date:06/14/01ISR Number: 3740106-3Report Type:Expedited (15-DaCompany Report #A112898
Age:38 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Bradycardia Cholelithiasis Diarrhoea Drug Level Above Therapeutic Fatigue Heart Rate Increased Malaise Mood Swings Pleural Effusion Thyroid Function Test Abnormal	Foreign Consumer	Pfi-Lith Unspecified Medication	PS C	Pfipharmecs Div Pfizer Inc	ORAL	1200.00 MG TOTAL:DAILY:O	Required Intervention to Prevent Permanent Impairment/Damage

Date:06/18/01ISR Number: 3741640-2Report Type:Periodic Company Report #LBID00200003144
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Diarrhoea	Health Professional Company Representative	Lithobid	PS	Solvay Pharmaceuticals	ORAL	DAILY PO	

Date:06/18/01ISR Number: 3741641-4Report Type:Periodic Company Report #LBID00200005241
Age:38 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Alopecia	Health Professional	Lithobid	PS	Solvay Pharmaceuticals	ORAL	600 MG QD PO	
			Eskalith (Lithium Carbonate)	C				

Date:06/18/01ISR Number: 3741643-8Report Type:Periodic Company Report #LBID00200005242
Age:61 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Sedation	Consumer	Lithobid	PS	Solvay Pharmaceuticals	ORAL	900 MG DAILY	
			Neurontin (Gabapentin)	C			PO	
			Roxicet	C				
			Zyprexa (Olanzapine)	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/18/01ISR Number: 3741644-XReport Type:Periodic Company Report #LBID00200005258
Age:34 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Bradycardia Hypotension Weight Decreased	Consumer	Lithobid	PS	Solvay Pharmaceuticals	ORAL	1600 MG DAILY PO	

Date:06/18/01ISR Number: 3741647-5Report Type:Periodic Company Report #LBID00200005294
Age:52 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Alopecia	Consumer	Lithobid	PS	Solvay Pharmaceuticals	ORAL	300 MG QD PO	
			Eskalith (Lithium Carbonate)	SS		ORAL	450 MG QD PO	
			Synthroid (Levothyroxine Sodium)	C				
			Wellbutrin (Amfebutamone Hydrochloride)	C				
			Benadryl (Diphenhydramine Hydrochloride)	C				
			Prevacid (Lansoprazole)	C				
			Neurontin (Gabapentin)	C				

Date:06/18/01ISR Number: 3741649-9Report Type:Periodic Company Report #LBID00200005465
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Acne	Health	Lithobid	PS	Solvay			

		Professional			Pharmaceuticals	ORAL

DAILY PO

Date:06/18/01ISR Number: 3741650-5Report Type:Periodic Company Report #LBID00200005483
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Acne	Health Professional	Lithobid	PS	Solvay Pharmaceuticals	ORAL

DAILY PO

		Company Representative				

Date:06/18/01ISR Number: 3741651-7Report Type:Periodic Company Report #LBID00200005490
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Dry Mouth Thirst	Consumer	Lithobid	PS	Solvay Pharmaceuticals	ORAL

300 MG QD PO

			Zoloft (Sertraline Hydrochloride)	SS		ORAL

DAILY PO

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/18/01ISR Number: 3741653-0Report Type:Periodic Company Report #LBID00200005502
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Anorexia Dry Mouth		Lithobid	PS	Solvay Pharmaceuticals	ORAL	300 MG QD PO	
			Risperdal (Risperidone)	C				

Date:06/18/01ISR Number: 3741654-2Report Type:Periodic Company Report #LBID00200005516
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Asthenia Nausea	Consumer	Lithobid	PS	Solvay Pharmaceuticals	ORAL	DAILY PO	
			Antidepressant	C				

Date:06/18/01ISR Number: 3742189-3Report Type:Periodic Company Report #LBID00200005519
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Effect Decreased	Health Professional	Lithobid	PS	Solvay Pharmaceuticals		SEE IMAGE	
		Company Representative	Prempro	C				

Date:06/18/01ISR Number: 3742192-3Report Type:Periodic Company Report #LBID00200005787
Age:30 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Alopecia	Health Professional	Lithobid	PS	Solvay Pharmaceuticals	ORAL	900 MG QD PO	
			Haldol (Haloperidol)	C				

Wellbutrin (Amfebutamone Hydrochloride)	C
Zyprexa (Olanzapine)	C
Vistaril (Hydroxyzine Embonate)	C

Date:06/18/01ISR Number: 3742195-9Report Type:Periodic Company Report #LBID00200006151
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Alopecia	Consumer	Lithobid	PS	Solvay Pharmaceuticals	ORAL	DAILY , PO	

Date:06/18/01ISR Number: 3742197-2Report Type:Periodic Company Report #LBID00200006157
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Acne Alopecia	Consumer	Lithobid	PS	Solvay Pharmaceuticals	ORAL	DAILY PO	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/18/01ISR Number: 3742199-6Report Type:Periodic Company Report #LBID00200006394
Age:44 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Alopecia	Consumer	Lithobid	PS	Solvay Pharmaceuticals	ORAL	300 MG TID PO	
			Meridia (Sibutranmine Hydrochloride)	SS		ORAL	DAILY PO	
			Depakote (Valproate Semisodium)	C				
			Seroquel (Seroquel)	C				

Date:06/18/01ISR Number: 3742201-1Report Type:Periodic Company Report #LBID00200006732
Age:78 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Abdominal Pain	Consumer	Lithobid	PS	Solvay Pharmaceuticals	ORAL	300 MG DAILY	
			Nadolol (Nadolol)	C			PO	

Date:06/18/01ISR Number: 3742203-5Report Type:Periodic Company Report #LBID00200006762
Age:49 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Diarrhoea Dizziness	Health Professional	Lithobid	PS	Solvay Pharmaceuticals	ORAL	SEE IMAGE	

Date:06/18/01ISR Number: 3742205-9Report Type:Periodic Company Report #LBID00201000033
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Tremor	Health Professional	Lithobid	PS	Solvay Pharmaceuticals	ORAL
900 MG PO						

Date:06/18/01ISR Number: 3742206-0Report Type:Periodic Company Report #LBID00201000196
Age:27 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Asthenia Diarrhoea	Consumer	Lithobid	PS	Solvay Pharmaceuticals	ORAL
1800 MG DAILY PO						
			Depakote (Valproate Semisodium)	SS		ORAL
1000MG QD PO						
			Seroquel (Seroquel)	C		

Date:06/18/01ISR Number: 3742207-2Report Type:Periodic Company Report #LBID00201000271
Age:54 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Depression Drug Ineffective	Consumer	Lithobid	PS	Solvay Pharmaceuticals	ORAL
600 MG DAILY PO						
			Xanax (Alprazolam)	C		

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Freedom Of Information (FOI) Report

Date:06/18/01ISR Number: 3742209-6Report Type:Periodic Company Report #LBID00201000286
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Tremor	Health Professional	Lithobid	PS	Solvay Pharmaceuticals	ORAL	PO	
			Luvox (Fluvoxamine Maleate)	SS		ORAL	PO	
			Buspar (Buspirone Hydrochloride)	C				

Date:06/18/01ISR Number: 3742222-9Report Type:Periodic Company Report #LBID00201000500
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Level Above Therapeutic	Foreign Literature	Lithobid	PS	Solvay Pharmaceuticals		SEE IMAGE	
	Tremor	Health Professional						

Date:06/18/01ISR Number: 3742224-2Report Type:Periodic Company Report #LBID00201000538
Age:51 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Alopecia	Consumer	Lithobid	PS	Solvay Pharmaceuticals	ORAL	400 MG BID PO	
	Amblyopia							
	Diarrhoea		Glucotrol Xl (Glipizide)	C				
			Glucophage (Metformin Hydrochloride)	C				

Date:06/18/01ISR Number: 3742228-XReport Type:Periodic Company Report #LBID00201000586
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Mania	Health Professional	Lithobid	PS	Solvay Pharmaceuticals	ORAL	DAILY PO	

Date:06/18/01ISR Number: 3742230-8Report Type:Periodic Company Report #LBID00201000645
Age:11 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Alopecia	Health Professional	Lithobid	PS	Solvay Pharmaceuticals	ORAL	1200 MG DAILY PO	
			Bisperdal (Risperidone)	C				
			Prozac (Fluoxetine Hydrochloride)	C				
			Concerta (Methylphenidate-Slow Release)	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/18/01ISR Number: 3742232-1Report Type:Periodic Company Report #LBID00201001255
Age:21 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Depression	Consumer	Lithobid	PS	Solvay Pharmaceuticals	ORAL	PO	
			Luvox (Fluvoxamine Maleate)	SS		ORAL	PO, PO	
			Risperdal (Risperidone)	SS		ORAL	PO	

Date:06/18/01ISR Number: 3742234-5Report Type:Periodic Company Report #LBID00201001469
Age:16 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Tremor	Health Professional	Lithobid	PS	Solvay Pharmaceuticals	ORAL	PO, PO	
		Company Representative						

Date:06/18/01ISR Number: 3742239-4Report Type:Periodic Company Report #LBID00201001658
Age:49 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Alopecia	Consumer	Lithobid	PS	Solvay Pharmaceuticals	ORAL	300 MG BID PO	

Date:06/18/01ISR Number: 3742257-6Report Type:Periodic Company Report #LBID00201001670
Age:37 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Alopecia	Consumer	Lithobid	PS	Solvay			

	Hair Disorder				Pharmaceuticals	ORAL
1200 MG DAILY						
PO						
			Depakote (Valproate Semisodium)	C		

Date:06/18/01ISR Number: 3742258-8Report Type:Periodic Company Report #LBID00200002853
Age:30 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Hormone Level Abnormal	Health Professional	Lithobid	PS	Solvay Pharmaceuticals	ORAL
2400 MG DAILY						
PO		Company Representative				

Date:06/18/01ISR Number: 3742271-0Report Type:Periodic Company Report #LBID00200005347
Age:20 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Alopecia Mania	Consumer	Lithobid	PS	Solvay Pharmaceuticals	ORAL
600 MG DAILY						
PO, 1200 MG DAILY PO						

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/18/01ISR Number: 3742274-6Report Type:Periodic Company Report #LBID00200005485
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Paraesthesia Oral	Consumer	Lithobid	PS	Solvay Pharmaceuticals	ORAL	300 MG DAILY	PO
			Risperdal (Risperidone)	SS		ORAL	0.5 MG DAILY	PO, 0.25 MG
			Synthroid (Levothyroxine Sodium)	C				DAILY PO

Date:06/18/01ISR Number: 3742277-1Report Type:Periodic Company Report #LBID00200005517
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Level Below Therapeutic	Health Professional	Lithobid	PS	Solvay Pharmaceuticals	ORAL	PO DAILY	
		Company Representative	Vitamin B (Vitamin B)	C				

Date:06/18/01ISR Number: 3742283-7Report Type:Periodic Company Report #LBID00200005571
Age:51 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Visual Field Defect	Health Professional	Lithobid	PS	Solvay Pharmaceuticals	ORAL	900MG DAILY	PO

Date:06/18/01ISR Number: 3742285-0Report Type:Periodic Company Report #LBID00200005600
Age:17 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hormone Level Abnormal Weight Increased	Health Professional	Lithobid	PS	Solvay Pharmaceuticals	ORAL	DAILY PO	

Date:06/18/01ISR Number: 3742286-2Report Type:Periodic Company Report #LBID00200005690
Age:55 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Amnesia Constipation Headache Hypokinesia Pollakiuria Visual Disturbance	Consumer	Lithobid Synthroid (Levothyroxine Sodium) Premarin (Estrogens Conjugated Baycol (Cerivastatin Sodium) Klonopin (Clonazepam)	PS C C C C	Solvay Pharmaceuticals	ORAL	900 MG DAILY PO	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/18/01ISR Number: 3742288-6Report Type:Periodic Company Report #LBID00200005737
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Ineffective	Health Professional	Lithobid	PS	Solvay Pharmaceuticals	ORAL	DAILY PO	
		Company Representative						

Date:06/18/01ISR Number: 3742291-6Report Type:Periodic Company Report #LBID00200005826
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Diarrhoea Haemorrhagic	Consumer	Lithobid	PS	Solvay Pharmaceuticals	ORAL	900 MG DAILY	PO
			Celebrex (Celecoxib)	SS		ORAL	DAILY PO	
			Vasotec (Enalapril Maleate)	C				

Date:06/18/01ISR Number: 3742294-1Report Type:Periodic Company Report #LBID00200006123
Age:40 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hyperhidrosis	Health Professional	Lithobid	PS	Solvay Pharmaceuticals	ORAL	DAILY PO	
		Company Representative						

Date:06/18/01ISR Number: 3742295-3Report Type:Periodic Company Report #LBID00200006190
Age:57 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Asthenia	Consumer	Lithobid	PS	Solvay Pharmaceuticals	ORAL
300 MG BID PO	Drug Level Below Therapeutic					
	Skin Disorder		Synthroid (Levothyroxine Sodium)	C		
	Weight Increased					

Date:06/18/01ISR Number: 3742339-9Report Type:Periodic Company Report #LBID00200006195
Age:32 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Pollakiuria	Consumer	Lithobid	PS	Solvay Pharmaceuticals	ORAL
1500 MG DAILY PO						
			Topamax (Topiramate)	C		
			Risperdal (Risperidone)	C		
			Loxapine (Loxapine)	C		

Date:06/18/01ISR Number: 3742341-7Report Type:Periodic Company Report #LBID00200006354
Age:23 YR Gender:Female I/FU:I

Outcome	PT	Report Source
Other	Oedema Peripheral	Health Professional

		Company Representative					
			Product	Role	Manufacturer		Route
Dose	Duration						
			Lithobid	PS	Solvay Pharmaceuticals		ORAL
DAILY PO							

Date:06/18/01ISR Number: 3742343-0Report Type:Periodic Company Report #LBID00200006540
Age:65 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Other	Urine Abnormality	Health Professional	Lithobid	PS	Solvay Pharmaceuticals	ORAL
30 MG BID PO						
			Lipitor (Atorvastatin)	C		
			Prevacid (Lansoprazole)	C		
			Synthroid (Levothyroxine Sodium)	C		
			Claritin (Loratadine)	C		
			Vioxx (Rofecoxib)	C		

Date:06/18/01ISR Number: 3742345-4Report Type:Periodic Company Report #LBID00200006555
Age:7 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Other	Pain	Consumer	Lithobid	PS	Solvay Pharmaceuticals	ORAL
300 MG BID PO	Tremor					
	Vomiting		Luvox (Fluvoxamine Maleate)	SS		ORAL
50 MG BID PO						
			Zyprexa (Olanzapine)	C		
			Risperidal (Risperidone)	C		

Date:06/18/01ISR Number: 3742348-XReport Type:Periodic Company Report #LBID00200006631
Age:28 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dermatitis	Health Professional	Lithobid	PS	Solvay Pharmaceuticals	ORAL	300MG BID PO,	
	Diarrhoea						300 MG BID PO	
	Eczema							
	Leukocytosis		Benadryl (Diphenhyrdramine Hydrochloride)	C				
	Vomiting		Tagamet (Cimetidine)	C				
			Zyrtec (Cetirizine Hydrochloride)	C				
			Xanax (Alprazolam)	C				
			Depakote (Valproate Semisodium)	C				
			Proventil Tablet (Salbutamol Sulfate)	C				
			Serevent (Salmeterol Xinafoate)	C				
			Singulair (Montelukast Sodium)	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/18/01ISR Number: 3742350-8Report Type:Periodic Company Report #LBID00200006657
Age:23 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Level Above Therapeutic	Literature Health	Lithobid	PS	Solvay Pharmaceuticals	ORAL	1500 MG PO	
		Professional	Suldox (Suldinac)	C		ORAL	150 MG BID PO	
			Divalproex Sodium (Divalproex Sodium)	C				
			Olanzapine (Olanzapine)	C				

Date:06/18/01ISR Number: 3742353-3Report Type:Periodic Company Report #LBID00200006661
Age:27 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Interaction	Literature	Lithobid	PS	Solvay			
	Drug Level Above Therapeutic	Health Professional	Suldox (Suldinac)	SS	Pharmaceuticals	ORAL	900 MG BID PO	
	Pain		Nefazodone (Nefazodone Hydrochloride)	C		ORAL	150 MG BID PO	
			Fluphenazine Deconate (Fluphenazine)	C				

Date:06/18/01ISR Number: 3742354-5Report Type:Periodic Company Report #LBID00200006696
Age:15 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Urinary Incontinence	Health Professional	Lithobid	PS	Solvay Pharmaceuticals	ORAL	DAILY PO	
		Company Representative						

Date:06/18/01ISR Number: 3742356-9Report Type:Periodic Company Report #LBID00201000023
Age:27 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Alopecia Insomnia Pollakiuria Tremor Urinary Retention	Consumer	Lithobid	PS	Solvay Pharmaceuticals	ORAL	1200 MG DAILY PO	

Date:06/18/01ISR Number: 3742358-2Report Type:Periodic Company Report #LBID00201000031
Age:33 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dermatitis Bullous	Health Professional	Lithobid	PS	Solvay Pharmaceuticals	ORAL	SEE IMAGE	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/18/01ISR Number: 3742492-7Report Type:Periodic Company Report #LBID00201000153
Age:56 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Gout	Consumer	Lithobid	PS	Solvay Pharmaceuticals	ORAL	900 MG DAILY	PO

Date:06/18/01ISR Number: 3742493-9Report Type:Periodic Company Report #LBID00201000346
Age:52 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Anorexia	Health Professional	Lithobid	PS	Solvay Pharmaceuticals	ORAL	300 MG BID PO	
	Hallucination							
	Hyperhidrosis		Meridia (Sibutramine Hydrochloride)	SS		ORAL	10 MG DAILY	
	Insomnia							
	Weight Increased							
			Unk ()	SS		ORAL	DAILY PO	
			Zoloft (Sertraline Hydrochloride)	C				
			Synthroid (Levothyroxine Sodium)	C				
			(Lorazepam)	C				
			Estrace (Estradiol)	C				
			(Progesterone)	C				

Date:06/18/01ISR Number: 3742494-0Report Type:Periodic Company Report #LBID00201000348
Age:13 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Asthenia	Consumer	Lithobid	PS	Solvay Pharmaceuticals	ORAL	1200 MG DAILY	
	Eye Disorder							

	Personality Disorder					
PO						
			Ritalin (Methylphenidate Hydrochloride)	C		
			Clonidine (Clonidine)	C		

Date:06/18/01ISR Number: 3742495-2Report Type:Periodic Company Report #LBID00201000428
Age:55 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Amblyopia	Consumer	Lithobid	PS	Solvay Pharmaceuticals	ORAL	300 MG QD PO	
	Arthralgia							
	Drug Interaction		Calcium W/Magnesium ()	SS		ORAL	DAILY PO	
	Muscle Spasms							
	Tendon Disorder							
	Tongue Disorder							

Date:06/18/01ISR Number: 3742496-4Report Type:Periodic Company Report #LBID00201000448
Age:48 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Laboratory Test Abnormal	Consumer	Lithobid	PS	Solvay Pharmaceuticals	ORAL	900 MG DAILY PO	
	Vasodilatation							

			Levoxyl (Levothyroxine Sodium)	C			

Date:06/18/01ISR Number: 3742497-6Report Type:Periodic Company Report #LBID00201000894
Age:52 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Conjunctivitis Dry Mouth	Consumer	Lithobid	PS	Solvay Pharmaceuticals	ORAL	300 MG TID PO	
	Keratoconjunctivitis Sicca		Tolvon (Mianserin Hydrochloride)	C				

Date:06/18/01ISR Number: 3742498-8Report Type:Periodic Company Report #LBID00201001077
Age:22 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Thrombocytopenia	Health Professional	Lithobid	PS	Solvay Pharmaceuticals	ORAL	900 MG DAILY	
							PO	
			Clozapine (Clozapine)	SS		ORAL	25 MG DAILY	
							PO, 300 MG	
							DAILY PO	
			Dilantin (Phenytoin Sodium)	C				
			(Propranolol)	C				
			Aricept (Donepezil Hydrochloride)	C				

Date:06/18/01ISR Number: 3742499-XReport Type:Periodic Company Report #LBID00201001484
Age:56 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Glossitis	Health Professional	Lithobid	PS	Solvay Pharmaceuticals	ORAL	900 MG DAILY	
			Levothroid (Levothyroxine Sodium)	C			PO	
			Cyclobenzaprine (Cyclobenzaprine)	C				
			Arthritis Medication	C				

Date:06/18/01ISR Number: 3742500-3Report Type:Periodic Company Report #LBID00201001665
Age:41 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Emotional Disorder Insomnia	Consumer	Lithobid	PS	Solvay Pharmaceuticals	ORAL	300 MG WD PO	
			Nortriptyline (Nortriptyline)	C				
			Doxepin (Doxepin)	C				
			Klonopin (Clonazepam)	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/18/01ISR Number: 3742501-5Report Type:Periodic Company Report #LBID00201001823
Age:54 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Anorgasmia	Consumer	Lithobid	PS	Solvay Pharmaceuticals	ORAL	300 MG QD PO	
			Risperdal (Risperidone)	SS		ORAL	1 MG DAILY PO	
			Estrace (Estradiol)	C				
			Levoxyl (Levothyroxine Sodium)	C				
			Atenolol (Atenolol)	C				
			Furosemide (Furosemide)	C				
			Detrol (Tolterodine L-Tartrate)	C				

Date:06/18/01ISR Number: 3742502-7Report Type:Periodic Company Report #LBID00200003054
Age:6 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Speech Disorder Tremor	Health Professional	Lithobid	PS	Solvay Pharmaceuticals	ORAL	DAILY PO	
		Company Representative						

Date:06/18/01ISR Number: 3742503-9Report Type:Periodic Company Report #LBID00200006013
Age:65 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Sinus Bradycardia	Foreign Literature	Lithobid	PS	Solvay Pharmaceuticals	ORAL	SEE IMAGE	2 YR
		Health Professional Other	Sotalol (Sotalol)	C				
			Atenolol (Atenolol)	C				

Date:06/18/01ISR Number: 3742504-0Report Type:Periodic Company Report #LBID00201000651
Age:61 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Bradycardia Dizziness	Consumer	Lithobid	PS	Solvay Pharmaceuticals	ORAL	DAILY PO	
	Overdose		Paxil (Paroxetine Hydrochloride)	C				
			Risperdal (Risperidone)	C				

Date:06/18/01ISR Number: 3742505-2Report Type:Periodic Company Report #LBID00201000991
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Overdose	Health Professional	Lithobid	PS	Solvay Pharmaceuticals	ORAL	DAILY PO	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/18/01ISR Number: 3742507-6Report Type:Periodic Company Report #LBID00200000725
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Accidental Overdose Drug Level Above Therapeutic	Consumer	Lithobid	PS	Solvay Pharmaceuticals	ORAL	DAILY PO	

Date:06/18/01ISR Number: 3742508-8Report Type:Periodic Company Report #LBID00200002723
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Level Below Therapeutic	Health Professional Company Representative	Lithobid	PS	Solvay Pharmaceuticals	ORAL	1800 MG DAILY PO	

Date:06/18/01ISR Number: 3742510-6Report Type:Periodic Company Report #LBID00200002757
Age:57 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Diarrhoea	Health Professional	Lithobid	PS	Solvay Pharmaceuticals	ORAL	900 MG QD PO	

Date:06/18/01ISR Number: 3742512-XReport Type:Periodic Company Report #LBID00200002784
Age:35 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Tremor	Health Professional	Lithobid	PS	Solvay Pharmaceuticals	ORAL	300 MG DAILY PO	

			Neurontin (Gabapentin)	C		
			Parmate (Tranylcypromide)	C		

Date:06/18/01ISR Number: 3742513-1Report Type:Periodic Company Report #LBID00200002908
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Level Below Therapeutic	Foreign Health Professional	Lithobid	PS	Solvay Pharmaceuticals	ORAL	1800 MG DAILY PO	

Company Representative
Other

Date:06/18/01ISR Number: 3742515-5Report Type:Periodic Company Report #LBID00200003100
Age:21 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Tremor	Health Professional	Lithobid	PS	Solvay Pharmaceuticals	ORAL	300 MG DAILY PO	
			Paxil ([Aroxetine Hydrochloride)	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/18/01ISR Number: 3743548-5Report Type:Periodic Company Report #LBID00201001851
Age:37 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Constipation Dyspepsia Sedation	Consumer	Lithobid	PS	Solvay Pharmaceuticals	ORAL	1200 MG DAILY	PO
			Thyroid Hormones (Thyroid)	C				
			St John'S Wort (St. John'S Wort)	C				

Date:06/18/01ISR Number: 3743549-7Report Type:Periodic Company Report #LBID00201001922
Age:13 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Accident Impaired Healing	Health Professional	Lithobid	PS	Solvay Pharmaceuticals	ORAL	900 MG DAILY	PO
			Concerta	C				

Date:06/18/01ISR Number: 3743550-3Report Type:Periodic Company Report #LBID00201001555
Age:30 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Coordination Abnormal Paranoia Speech Disorder	Health Professional	Lithobid	PS	Solvay Pharmaceuticals	ORAL	900 MG DAILY	PO
			Seroquel (Seroquel)	SS		ORAL	600 MG DAILY	PO
			Wellbutrin - Slow Release					

			(Amfebutamone Hydrochloride)	SS		ORAL
150 MG DAILY PO						
			Klonopin (Clonazepam)	SS		ORAL
2 MG DAILY PO						
			Celebrex (Celecoxib)	SS		ORAL
UNK DAILY PO						

Date:06/19/01ISR Number: 3742477-0Report Type:Expedited (15-DaCompany Report #A113136
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	Blood Creatinine Increased	Consumer	Geodon	PS	Pfizer Central Research	ORAL	120.00 MG TOTAL;BID;ORA
	Blood Urea Increased						
	Drug Level Above Therapeutic		Lithium	SS		ORAL	180.00 MG TOTAL;TID;ORA
	Muscle Rigidity						
	Tremor						
			Sinemet	C			
			Premarin	C			
			Pepcid	C			
			Flovent	C			
			Levothyroxine	C			
			Primidone	C			
			Triazolam	C			

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/26/01ISR Number: 3747221-9Report Type:Direct Company Report #
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Depression		Lithium Carb 300 Mg					
	Suicidal Ideation		Roxa	PS	Roxa	ORAL	900 MG	
	Tremor						EVERDAY	ORAL
			Remeron 15 Mg Org	SS	Org	ORAL	15 MG	
							EVERYDAY	ORAL

Date:06/26/01ISR Number: 3748084-8Report Type:Expedited (15-DaCompany Report #A110238
Age:41 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Neuroleptic Malignant	Health	Geodon	PS	Pfizer Central			
Hospitalization -	Syndrome	Professional			Research	ORAL	BID PO	
Initial or Prolonged	Psychotic Disorder	Company	Clozapine	SS			DAILY	
Required	Urinary Tract Infection	Representative	Lithium	SS				
Intervention to			Lipitor	C				
Prevent Permanent			Depakote Er	C				
Impairment/Damage			Zyprexa	C				

Date:06/26/01ISR Number: 3750582-8Report Type:Expedited (15-DaCompany Report #2001015107-1
Age:33 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Drug Level Above	Health	Eskalith Cr	PS	Smithkline Beecham			
Hospitalization -	Therapeutic	Professional			Pharmaceuticals	ORAL	450	
Initial or Prolonged	Haemodialysis						MILLIGRAMS	
Other	Overdose						DAILY	ORAL 1 DAY
	Renal Failure Acute							

Date:06/27/01ISR Number: 3748388-9Report Type:Direct Company Report #
Age:56 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Coordination Abnormal		Lithium 300mg	PS			600 MG BID	
Hospitalization - Initial or Prolonged	Dehydration		Hctz	C				
	Drooling		Lisinopril	C				
Required Intervention to Prevent Permanent Impairment/Damage	Drug Toxicity		Arthrotec	C				
	Parkinsonian Gait		Fluticasone	C				
	Renal Failure Acute		Asa	C				
	Speech Disorder		Verapamil Sr	C				
	Tremor		Thioridazine	I				

Date:06/27/01ISR Number: 3749453-2Report Type:Expedited (15-DaCompany Report #LBID00201002834
Age:43 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Back Pain	Literature	Lithobid	PS	Solvay Pharmaceuticals	ORAL	DAILY PO	
	Diabetes Mellitus	Health						
	Non-Insulin-Dependent	Professional	Tegretol					
	Drug Effect Decreased		(Carbamazepine)	SS		ORAL	DAILY PO, 1 G	
	Hypertension						DAILY PO	
	Obesity		Valproate (Valproate					
	Paraesthesia		Sodium)	SS		ORAL	DAILY PO	
			Clozapine					
			(Clozapine)	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/27/01ISR Number: 3770379-2Report Type:Periodic Company Report #2001010864-1
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Interaction	Health	Avandia	PS		ORAL		
	Drug Toxicity	Professional	Lithium	SS				
			Hydrochlorothiazide	SS				

Date:06/28/01ISR Number: 3748664-XReport Type:Expedited (15-DaCompany Report #262790
Age:35 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Interaction Schizophrenia	Health Professional	Xenical Zyprexa	PS I	Roche			
			Teralithe	I				

THE LONG TERM

TREATMENT OF

SCHIZOPHRENIA

HAS BEEN

LOWERED BY

THE LONG TERM

TREATMENT OF

SCHIZOPHRENIA

HAS BEEN

LOWERED BY

Date:06/29/01ISR Number: 3750293-9Report Type:Expedited (15-DaCompany Report #17812-136
Age:54 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Hallucination	Consumer	Lithium Carbonate	PS	Roxane Laboratories			

Initial or Prolonged	Imprisonment				Inc	ORAL
600						
	Road Traffic Accident					
MG,BID,ORAL 10 YR						
			Zyprexa(Olanzapine)Tablet, 10mg Eli Lilly	SS	Eli Lilly	ORAL
10MG,QHS,ORAL						
			Trazadone	C		
			Ativan (Lorazepam)	C		
			Inderal (Propranolol)	C		

Date:07/02/01ISR Number: 3751054-7Report Type:Expedited (15-DaCompany Report #262790
Age:35 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Condition Aggravated	Foreign	Xenical	PS	Hlr Technology	ORAL
ORAL						
Initial or Prolonged	Drug Interaction	Health	Zyprexa (Olanzapine)	SS		ORAL
ORAL						
	Medication Error	Professional	Teralithe (Lithium Carbonate)	SS		ORAL
	Persecutory Delusion					
ORAL						
	Schizophrenia					

Date:07/03/01ISR Number: 3752520-0Report Type:Periodic Company Report #TAP2001Q00302
Age:62 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Condition Aggravated	Health	Prevacid			
	Gastritis	Professional	(Lansoprazole) (30 Milligram, Capsules)	PS	Tap Pharmaceutical Products Inc	ORAL
30 MG, 1 IN 1						
D, PER ORAL						

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Lithium (Lithium) SS

Date:07/05/01ISR Number: 3752569-8Report Type:Direct Company Report #
Age:66 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anxiety		Lithium 450 Mg	PS		ORAL	450 MG PO	DAILY
	Confusional State							
	Decreased Appetite		Clonidine	C				
	Headache		Lopressor	C				
	Insomnia		Lipitor	C				
	Tremor		Clonazepam	C				
			Celexa	C				

Date:07/05/01ISR Number: 3753625-0Report Type:Expedited (15-DaCompany Report #A115588
Age:48 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Angina Pectoris	Foreign	Lithium Carbonate	PS	Pfizer Inc	ORAL	ORAL	
	Coronary Artery Disease	Health Professional	Ziprasidone	C				
	Dyspnoea							
	Electrocardiogram Abnormal							
	Electrocardiogram T Wave Inversion							
	Myocardial Ischaemia							
	Sinus Bradycardia							

Date:07/05/01ISR Number: 3753660-2Report Type:Expedited (15-DaCompany Report #2001AP03089
Age:58 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agitation	Foreign	Atacand	PS	Astrazeneca Pharmaceuticals Lp		16 MG DAILY	8 WK
	Confusional State	Literature						

	Coordination Abnormal	Health	Lithium	SS			
900 MG DAILY							
	Disorientation	Professional					
	Drug Interaction	Other					

Date:07/06/01ISR Number: 3754375-7Report Type:Expedited (15-DaCompany Report #A115201
Age:36 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Required	Anorgasmia	Foreign	Lithium Carbonate	PS	Pfizer Inc		1200.00 MG
Intervention to	Ejaculation Failure	Literature					TOTAL;DAILY
Prevent Permanent	Hypomania	Health					
Impairment/Damage	Orgasm Abnormal	Professional					

Date:07/09/01ISR Number: 3754671-3Report Type:Expedited (15-DaCompany Report #2001015445-1
Age:16 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Dialysis	Literature	Eskalith	PS	Smithkline Beecham		
Initial or Prolonged	Dysarthria	Health			Pharmaceuticals	ORAL	ORAL
Other	Overdose	Professional	...	C			
	Sedation		Clonazepam				
	Suicide Attempt		(Klonopin)	C			

			Chlopromazine Hydrochloride (Thorazine)	C			

Date:07/11/01ISR Number: 3756472-9Report Type:Expedited (15-DaCompany Report #200111619BWH
Age:60 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Other	Condition Aggravated	Consumer	Adalat Cc	PS	Bayer Corp	ORAL	60 MG QD ORAL
	Coordination Abnormal	Other	Adalat Cc	SS		ORAL	30 MG QD ORAL
	Difficulty In Walking Drug Interaction		Lithobid (Lithium Carbonate)	SS		ORAL	600 MG DAILY
	Drug Level Above						ORAL
	Therapeutic		Depakote	C			
			Ticlid	C			
			Temazepam	C			
			Atenolol	C			
			Glyburide	C			
			Tamoxifen	C			

Date:07/11/01ISR Number: 3756561-9Report Type:Expedited (15-DaCompany Report #2001015737-1
Age:40 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Blood Pressure Decreased Cognitive Disorder	Consumer	Paxil	PS	Smithkline Beecham Pharmaceuticals	ORAL	20 MILLIGRAMS
	Convulsion						1.0 DAILY
	Feeling Abnormal						ORAL
	Headache		Lithium	SS			
	Nausea						
	Oral Discomfort						
	Oral Intake Reduced						
	Tremor						

Date:07/11/01ISR Number: 3756729-1Report Type:Expedited (15-DaCompany Report #FLUV00301003007
Age:65 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anxiety Cerebral Atrophy Communication Disorder Decreased Appetite Depression Insomnia Irritability Lethargy Mental Impairment Nuclear Magnetic Resonance Imaging Abnormal Parkinsonism Suicidal Ideation	Foreign Literature Other	Luvox Lithium (Lithium) Sulpiride (Sulpiride) Imipramine (Imipramine)	PS SS C C	Solvay Pharmaceuticals	ORAL	100 MG DAILY PO, 150 MG DAILY PO, DAILY PO 400 MG DAILY, 200 MG DAILY	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/11/01ISR Number: 3756812-0Report Type:Expedited (15-DaCompany Report #10902245
Age:26 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Delirium Drug Level Above Therapeutic Haemodialysis Intentional Misuse Respiratory Failure Suicide Attempt	Foreign Health Professional Company Representative Other	Serzone Alprazolam Cyproheptadine Cyproheptadine Hcl) Lithium (Lithium Salts)	PS SS SS SS	Bristol Myers Squibb Co Pharmaceutical Research Institute		2.8 GRAM 1/ TOTAL 2 GRAM 1 TOTAL 2.4 GRAM 1 TOTAL 1 TOTAL	

Date:07/20/01ISR Number: 3761971-XReport Type:Expedited (15-DaCompany Report #262790
Age:31 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Interaction Schizophrenia		Xenical Seresta Risperdal Teralithe	PS C I I	Roche		31 DAY THE LONG TERM TREATMENT OF SCHIZOPHRENIA HAS BEEN LOWERED BY THE LONG TERM	

TREATMENT OF

SCHIZOPHRENIA

HAS BEEN

LOWERED BY

Date:07/23/01ISR Number: 3762411-7Report Type:Direct Company Report #
Age:13 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Malaise		Lithium 100 Ml	PS		ORAL	100ML TWICE	DAILY ORAL
			Tegratol	C				

Date:07/23/01ISR Number: 3775454-4Report Type:Periodic Company Report #2001053231US
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Orgasm Abnormal	Consumer	Detrol La	PS	Pharmacia And Upjohn Co	ORAL		ORAL
			Lithobid (Lithium Carbonate)	SS			300 MG QD	UNK
			Estrace	C				
			Levoxyl (Levothyroxine Sodium)	C				
			Risperdal	C				
			Atenolol	C				
			Lasix	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/24/01ISR Number: 3764232-8Report Type:Expedited (15-DaCompany Report #200111619BWH
Age:60 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Other	Condition Aggravated	Consumer	Adalat Cc	PS	Bayer Corp	ORAL	60 MG QD ORAL
	Coordination Abnormal	Other	Lithobid (Lithium Carbonate)	SS		ORAL	600 MG DAILY
	Difficulty In Walking						
	Drug Interaction						ORAL
	Drug Level Above		Adalat Cc	SS		ORAL	30 MG QD ORAL
	Therapeutic		Depakote	C			
	Facial Palsy		Ticlid	C			
	Fall		Temazepam	C			
			Atenolol	C			
			Glyburide	C			
			Tamoxifen	C			
			Cozaar	C			

Date:07/24/01ISR Number: 3764263-8Report Type:Expedited (15-DaCompany Report #262790
Age:31 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Condition Aggravated	Foreign	Xenical	PS	Hlr Technology	ORAL	ORAL
	Drug Interaction	Health Professional	Risperdal(Risperidone)	SS		ORAL	1 MG DAILY
	Medication Error						ORAL
	Persecutory Delusion						
	Schizophrenia		Teralithe (Lithium Carbonate)	SS		ORAL	ORAL
			Seresta	C			

Date:07/25/01ISR Number: 3764348-6Report 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	Drug Level Below Therapeutic		Lithium Carbonate 300mg	PS		ORAL	600 MG BID	
	Mania						ORAL	
			Aspirin	C				
			Carbamazepine	C				
			Ibuprofen	C				
			Lisinopril	C				
			Simvastatin	C				
			Terazosin	C				

Date:07/25/01ISR Number: 3765246-4Report Type:Expedited (15-DaCompany Report #LBID00201003129
Age:80 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Delusion	Literature	Lithobid	PS	Solvay Pharmaceuticals	ORAL	DAILY PO	
	Hallucination	Health						
	Tremor	Professional						

Date:07/25/01ISR Number: 3765695-4Report Type:Expedited (15-DaCompany Report #264199
Age:35 YR Gender:Male I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Arthralgia
	Drug Interaction
Disability	Psoriasis

	Thyroiditis					
Dose	Duration	Report Source	Product	Role	Manufacturer	Route
		Foreign Health Professional	Lariam	PS	Hoffmann La Roche Inc	ORAL
1 DOSE FORM PER ONE DOSE						
ORAL						
			Effexor	SS		ORAL
2 DOSE FORM DAILY ORAL						
			Lexomil	SS		ORAL
2 PER DAY ORAL						
			Teralithe	SS		ORAL
400 MG 3 PER DAY ORAL						
			Seropram	SS		ORAL
2 DOSE FORM DAILY ORAL						
			Havlane	C		
			Plaquenil	C		

Date:07/25/01ISR Number: 3765810-2Report Type:Direct Company Report #
Age:51 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization - Initial or Prolonged	Dehydration		Lithium Citrate 300mg/5ml	PS		ORAL
TAKE 1 TSP TID PO	Diarrhoea					
	Drug Level Above Therapeutic		Benztropine	C		
	Tremor		Risperidone	C		
	Vomiting		Fluphenazine	C		

Date:07/26/01ISR Number: 3765375-5Report Type:Direct Company Report #USP 54201
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Fall		Lithium Carbonate	PS				
	Head Injury		Lithium Carbonate	SS				
	Medication Error							

Date:07/26/01ISR Number: 3766176-4Report Type:Expedited (15-DaCompany Report #A117130
Age:33 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Amnesia	Consumer	Geodon	PS	Pfizer Central Research	ORAL	120.00 MG	
	Difficulty In Walking							
	Drug Interaction							
	Drug Level Above Therapeutic		Lithium	SS		ORAL	1600.00 MG	
	Hallucination							
			Zyprexa (Olanzapine)	SS		ORAL	30.00 MG	
			Tegretol (Carbamazepine)	SS		ORAL		
			Sleeping Medication	C				
			Blood Pressure Medication	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/26/01ISR Number: 3766180-6Report Type:Expedited (15-DaCompany Report #A117132
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Coordination Abnormal Drug Interaction Drug Level Above Therapeutic Dysarthria	Consumer	Geodon Lithium	PS SS	Pfizer Central Research			

Date:07/26/01ISR Number: 3766560-9Report Type:Expedited (15-DaCompany Report #LEID00201003144
Age:67 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Bladder Cancer Hypercalcaemia Hyperparathyroidism Primary Laboratory Test Abnormal Nephrogenic Diabetes Insipidus Renal Cell Carcinoma Stage Unspecified Transient Ischaemic Attack	Literature Health Professional	Lithobid Nifedipine (Nifedipine) Fosinopril (Fosinopril) Levothyroxine (Levothyroxine)	PS C C C	Solvay Pharmaceuticals	ORAL	300 MG TID PO	

Date:07/30/01ISR Number: 3767686-6Report Type:Expedited (15-DaCompany Report #2001017851-1
Age:53 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Pancreatitis	Health Professional	Eskalith	PS	Smithkline Beecham Pharmaceuticals			

Date:07/30/01ISR Number: 3767699-4Report Type:Expedited (15-DaCompany Report #200111619BWH
Age:60 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Condition Aggravated	Consumer	Adalat Cc	PS	Bayer Corp	ORAL	60 MG QD	
	Coordination Abnormal	Other				ORAL		
	Difficulty In Walking		Adalat Cc	SS		ORAL	30 MG QD	ORAL
	Drug Level Above Therapeutic		Lithobid (Lithium Carbonate)	SS		ORAL	600 MG DAILY	
	Eye Infection					ORAL		
	Facial Palsy		Depakote	C				
	Fall		Ticlid	C				
			Temazepam	C				
			Atenolol	C				
			Glyburide	C				
			Tamoxifen	C				
			Cozaar	C				

Date:07/30/01ISR Number: 3767729-XReport Type:Expedited (15-DaCompany Report #01-0052
Age:34 YR Gender:Male I/FU:F

Outcome	PT
Death	Anaphylactic Shock
Hospitalization - Initial or Prolonged	Atelectasis
	Cardiac Failure

	Diarrhoea Disseminated Intravascular Coagulation	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Duodenal Ulcer Enteritis	Other	Ponstel	PS	First Horizon Pharmaceutical Corp	ORAL	250 MG, TID,
	Haemodialysis						PO
	Hypogammaglobulinaemia Hypoproteinaemia		Serenace (Haloperidol)	SS			33MG, TID, PO
	Oesophagitis Pleural Effusion		Limas (Lithium Carbonate)	SS		ORAL	200MG;TID;PO
	Pneumonia Pulmonary Embolism Pulmonary Mycosis Rash Erythematous Renal Failure Acute Rhabdomyolysis Sepsis Staphylococcal Infection		Depas (Etizolam) Artane (Trihexyphenidyl Hydrochloride) Silece (Flunitrazepam) Impromen (Bromperidol) Remark (Betahistine Mesilate)	C C C C C			

Date:07/30/01ISR Number: 3769107-6Report Type:Expedited (15-DaCompany Report #2001017719-1
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Other	Thyroid Gland Cancer	Consumer	Eskalith	PS	Smithkline Beecham Pharmaceuticals	ORAL	ORAL

Date:07/30/01ISR Number: 3769108-8Report Type:Expedited (15-DaCompany Report #2001016845-1
Age:55 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Other	Acanthosis Alopecia	Literature Health	Lithium Smithkline Beecham	PS	Smithkline Beecham		11 YR

	Antibody Test Positive Antinuclear Antibody Positive Atelectasis Biopsy Skin Abnormal Drug Level Below Therapeutic Inflammation Laboratory Test Abnormal Mycosis Fungoides Rash Erythematous Rash Papular Skin Lesion	Professional	Haloperidol	C			

Date:07/31/01ISR Number: 3777716-3Report Type:Periodic Company Report #2001056168US
Age:30 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Coordination Abnormal	Health	Celebrex	PS	Gd Searle And Co	ORAL	ORAL	
	Paranoia Speech Disorder	Professional	Lithobid (Lithium Carbonate)	SS		ORAL	900 MG, QD,	ORAL
			Seroquel (Quetiapine)	SS		ORAL	600 MG, QD,	

ORAL							
			Klonopin (Clonazepam)	SS			ORAL
2 MG, QD,							
ORAL							
			Wellbutrin-Slow Release (Amfebutamone Hydrochloride)	SS			ORAL
150 MG, QD,							
ORAL							

Date:08/01/01ISR Number: 3769304-XReport Type:Expedited (15-DaCompany Report #M2001.0463/LBIDO0201003074
Age:25 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Acne	Consumer	Lonox	PS	Geneva Pharmaceuticals Inc	ORAL	DAILY PO	
	Convulsion							
	Drug Interaction		Lithobid (Lithium Carbonate)	SS		ORAL	1500 MG DAILY	
	Fall							
	Scar						PO	
	Syncope		Celexa (Citalopram Hydrobromide)	C				

Date:08/02/01ISR Number: 3770162-8Report Type:Expedited (15-DaCompany Report #A109961
Age:45 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Ecchymosis	Health Professional	Geodon	PS	Pfizer Central Research	ORAL	40.00	
	Fall							
	Neuroleptic Malignant Syndrome		Lithium	SS			TOTAL:ORAL 1200.00 MG	

TOTAL						
			Seroquel (Quetiapine)	SS		
200.00 MG						
TOTAL						
			Propranolol	SS		
60.00 MG						
TOTAL						
			Paxil (Paroxetine)	C		
			Nortriptyline	C		

Date:08/02/01ISR Number: 3770300-7Report Type:Expedited (15-DaCompany Report #S01-SWI-01503-01
Age:70 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Coma	Foreign	Celexa	PS	Forest Laboratories			
Hospitalization -	Drug Interaction	Health			Inc	ORAL	30 MG QD PO	
Initial or Prolonged	Encephalopathy	Professional	Priadel (Lithium					
Disability		Other	Carbonate)	SS		ORAL	1200 MG QD PO	
			Tolvon(Mianserin Hydrochloride)	SS		ORAL	30 MG QD PO	
			Entumin(Clotiapine)	SS		ORAL	80 MG QD PO	
			Sotalex(Sotalol Hydrochloride)	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/03/01ISR Number: 3770209-9Report Type:Direct Company Report #
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Abdominal Pain		Eskalith 300mg Capsules	PS		ORAL	2 CAPSU	BID
	Vomiting						ORAL	
			Vioxx 25mg Tablets	SS		ORAL	1 TABLE	DAILY
			Levothyroid	C				

Date:08/03/01ISR Number: 3771546-4Report Type:Expedited (15-DaCompany Report #LBID00201003224
Age:17 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Aggression	Literature	Lithobid	PS	Solvay Pharmaceuticals	ORAL	SEE IMAGE	
	Condition Aggravated	Health						
	Depersonalisation	Professional	Risperidone (Risperidone)	C				
	Depression							
	Derealisation		Paroxetine (Paroxetine)	C				
	Disturbance In Attention							
	Hallucination, Auditory							
	Increased Appetite							
	Insomnia							
	Mania							
	Nightmare							
	Persecutory Delusion							
	Post-Traumatic Stress Disorder							
	Suicidal Ideation							
	Thinking Abnormal							

Date:08/06/01ISR Number: 3772057-2Report Type:Expedited (15-DaCompany Report #A117865
Age:46 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other Required Intervention to Prevent Permanent Impairment/Damage	Abdominal Pain Blood Creatinine Increased Blood Urea Increased Chills Confusional State Dehydration Drug Level Above Therapeutic Dysarthria Extrapyramidal Disorder Hallucination Hypomania Malaise Paraplegia Sedation Tremor Urinary Incontinence Vomiting	Foreign Literature Health Professional	Lithium Carbonate Nifedipine Enalapril Hydrochlorothiazide Amiloride Hydrochloride Metoprolol	PS C C C C C	Pfizer Inc		1200.00 MG	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/06/01ISR Number: 3772347-3Report Type:Expedited (15-DaCompany Report #2001013746-1
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Condition Aggravated Tremor	Consumer Health Professional	Eskalith	PS	Smithkline Beecham Pharmaceuticals	ORAL	450 MILLIGRAMS 2.0 DAILY	
			Prozac (Fluoxetne Hcl)	C				
			Xanax (Alprazolam)	C				
ORAL								108 DAY

Date:08/09/01ISR Number: 3775048-0Report Type:Expedited (15-DaCompany Report #2001018512-1
Age:41 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Pollakiuria Schizophrenia Thirst	Consumer	Eskalith Cr	PS	Smithkline Beecham Pharmaceuticals	ORAL	1350 MILLIGRAMS	
ORAL								

Date:08/13/01ISR Number: 3776132-8Report Type:Expedited (15-DaCompany Report #PHEH2001USA06234
Age:51 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Hospitalization - Initial or Prolonged	Anaemia Diabetes Mellitus Hyponatraemia Renal Disorder Renal Failure	Health Professional	Clozaril	PS	Novartis Pharmaceuticals Corp	ORAL	300 MG, ORAL	
			Lithium Carbonate (Lithium Carbonate)	SS				
			Lipitor (Atorvastatin)	C				

			Synthroid	C		
			Prandin "Kuhn" (Defglazacort)	C		
			Acupril (Quinapril)	C		
			Boestrol	C		

Date:08/14/01ISR Number: 3777360-8Report Type:Expedited (15-DaCompany Report #2001UW09272
Age:23 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Headache	Foreign	Seroquel	PS	Astrazeneca Lp	ORAL	25 MG DAILY	
	Insomnia	Health					PO	
	Paraesthesia	Professional	Seroquel "Zeneca"	SS	Zeneca	ORAL	25 MG DAILY	
	Serotonin Syndrome	Other					PO	
	Vision Blurred		Sertraline	SS		ORAL	100 MG PO	
	Vitamin B12 Abnormal		Lithium	SS			900 MG HS	
			Valproic Acid	C				

Date:08/14/01ISR Number: 3777375-XReport Type:Direct Company Report #
Age:62 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dysarthria		Lithium Carbonate (300 Mg)	PS			600MG QD	
	Feeling Jittery							
	Movement Disorder		Lisinopril (20mg)	SS			20MG QD	
	Tremor							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/15/01ISR Number: 3778644-XReport Type:Direct Company Report #
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Chorea		Lithium Carbonate 300 Mg	PS		ORAL	600 MG BID	Other
			Quetiapine	C				
			Vpa	C				
			Clonidine	C				
			Levothyroxine	C				

Date:08/17/01ISR Number: 3780326-5Report Type:Expedited (15-DaCompany Report #A109905
Age:45 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Neuroleptic Malignant Syndrome	Health Professional	Geodon	PS	Pfizer Central Research	ORAL	ORAL	
			Lithium	SS				
			Nortryptiline	C				
			Seroquel	C				
			Propanolol	C				
			Benadryl	C				

Date:08/20/01ISR Number: 3780769-XReport Type:Expedited (15-DaCompany Report #200114104DE
Age:71 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death Life-Threatening	Atherosclerosis Blood Creatinine Increased	Foreign Health Professional	Lasix	PS	Aventis Pharmaceuticals Inc		INTRAVENOUS	40 MG/DAY IV 3 DAY
	Body Temperature Increased	Other	Ramipril (Delix) Tablets	SS		ORAL	2.5 MG / DAY	
	Dialysis		Lithium Carbonate				PO	2 DAY

			Disseminated	(Quilonum - Slow		
			Intravascular Coagulation	Release)	SS	ORAL
450 MG/ DAY						
			Dizziness			
PO	11	MON				
			Dyspnoea	Xipamide	SS	ORAL
10 MG / DAY						
			Gastrointestinal Necrosis			
PO	11	MON				
			Hypotension	Pantoprazole	C	
			Hypovolaemia	Paraffin	C	
			Ileus Paralytic	Petrolatum	C	
			Inflammation	Wool Alcohols	C	
			Intestinal Ischaemia	(Mineral Oil Light)		
			Leukocytosis	(Aquaphor)	C	
			Multi-Organ Failure	Valproic Acid	C	
			Myocardial Infarction	Mirtazapine		
			Peritonitis	(Remergil)	C	
			Renal Artery Stenosis	Venlafaxine		
			Renal Failure Acute	Hydrochloride		
			Respiratory Failure	(Trevilor)	C	
			Rhabdomyolysis	Atorvastatin Calcium		
			Sepsis	(Sortis)	C	
			Shock	Bisoprolol Fumarate		
			Urea Urine Increased	(Concor)	C	
				Allopurinol		
				(Zyloric)	C	
				Clopidogrel Sulfate		
				(Iscover)	C	
				Valproate Sodium		

			(Ergenyl)	C		
			Isosorbide Mononitrate (Ismo)	C		
			Vitamin Nos, Amino Acids Nos, Electrolytes Nos (Tutofusin)	C		
			Lithium Acetate (Quilonum)	C		

Date:08/23/01ISR Number: 3781908-7Report Type:Expedited (15-DaCompany Report #A0125593A
Age:54 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - 29 DAY	Blood Pressure Decreased		Lotronex	PS	Glaxo Wellcome	ORAL	
Initial or Prolonged 15 YR	Dehydration		Lithium	SS			
	Drug Interaction		Nsaids	SS			
	Drug Toxicity						
	Pyelonephritis						
	Renal Failure Acute						

Date:08/24/01ISR Number: 3782930-7Report Type:Expedited (15-DaCompany Report #A113136
Age:50 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Required	Blood Creatinine	Consumer	Ziprasidone Po	PS		ORAL	120.00 MG
Intervention to	Increased						TOTAL:BID:ORA
Prevent Permanent	Blood Urea Increased						L
Impairment/Damage	Drug Level Above		Lithium	SS		ORAL	1800.00 MG
	Therapeutic						TOTAL:TID:ORA
	Muscle Rigidity						L
	Tremor		Sinemet	C			
			Premarin	C			
			Pepcid	C			

			Flovent	C		
			Levothyroxine	C		
			Primidone	C		
			Triazolam	C		

Date:08/24/01ISR Number: 3783662-1Report Type:Periodic Company Report #PHEH2001US00585
Age:54 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Life-Threatening	Dehydration	Consumer	Lotensin(Benazepril				
Hospitalization -	Diarrhoea	Health	Hydrochloride)	PS		ORAL	20 MG, QD,
Initial or Prolonged	Drug Toxicity	Professional					ORAL
	Vomiting	Company	Lithium	SS			107 DAY
		Representative	Periactin (Cyproheptadine Hydrochloride)	C			
			Amoxicillin	C			
			Neurontin (Gabapentin)	C			
			Glucophage "Merck"	C			
			Synthroid	C			
			Olanzapine	C			
			Ativan	C			

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/27/01ISR Number: 3783442-7Report Type:Expedited (15-DaCompany Report #A0125593A
Age:54 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Dehydration Drug Interaction Drug Toxicity	Consumer	Lotronex Tablet (Alosetron Hydrochloride)	PS		ORAL	ORAL
	Proteinuria Pyelonephritis Renal Failure Acute		Lithium Salt (Formulation Unknown)	SS			15 YR
	Staphylococcal Infection		Nsaid (Formulation Unknown)	SS			

Date:08/29/01ISR Number: 3785217-1Report Type:Direct Company Report #
Age:8 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Required Intervention to Prevent Permanent Impairment/Damage	Blood Pressure Decreased Heart Rate Increased Hypotension		Ziprasidone 20mg Pfizer	PS	Pfizer	ORAL	60MG/DAY 40MG AM/20P / ORAL
	Mental Impairment Sluggishness Tachycardia		Lithium 150mg	SS		ORAL	750/DAY DIVIDE D TID / ORAL
	Tremor		Clonidine	C			

Date:08/29/01ISR Number: 3785591-6Report Type:Expedited (15-DaCompany Report #A119878
Age:66 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Life-Threatening Required	Arrhythmia Bundle Branch Block Right	Foreign Literature	Lithane Tablets	PS		ORAL	300.00 MG TOTAL; DAILY;

Intervention to	Cardiomegaly	Health			
ORAL					
Prevent Permanent	Drug Level Above	Professional	Haloperidol	C	
Impairment/Damage	Therapeutic		Carbamazepine	C	
	Electrocardiogram Qt		Unspecified		
	Prolonged		Benzodiazepines	C	
	Feeling Jittery		Enalapril	C	
	Heart Rate Decreased		Thyroxine	C	
	Hyperhidrosis				
	Hypotension				
	Sedation				
	Syncope				

Date:08/31/01ISR Number: 3786710-8Report Type:Expedited (15-DaCompany Report #HQ5326329AUG2001
Age:42 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Decreased Appetite	Consumer	Effexor Xr					
	Endometriosis		(Venlafaxine					
	Menorrhagia		Hydrochloride,					
	Neoplasm Malignant		Capsule, Extended					
	Ovarian Cyst		Release)	PS		ORAL		
			Effexor Xr					
			(Venlafaxine					
			Hydrochloride,					
			Capsule, Extended					
			Release)	SS		ORAL	375 MG 1X PER	1 DAY
			Lithium (Lithium,)	SS		ORAL	900 MG 1X PER	

1 DAY			Lithium (Lithium)	SS		ORAL
600 MG 1X PER						
1 DAY			Vitamins	C		

Date:08/31/01ISR Number: 3787083-7Report Type:Expedited (15-DaCompany Report #01-0052
Age:34 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Anaphylactic Shock	Other	Pontal (Mefenamic			
Hospitalization -	Atelectasis		Acid 250mg Capsules)	PS		ORAL
250 MG, BID,						
Initial or Prolonged	Cardiac Failure					
PO						
	Diarrhoea		Serenace			
	Disseminated		(Haloperidol)	SS		ORAL
33MG, TID, PO						
	Intravascular Coagulation		Limas (Lithium			
	Duodenal Ulcer		Carbonate)	SS		ORAL
200 MG, TID,						
	Enteritis					
PO						
	Erythema		Depas (Efizolam)	C		
	Haematemesis		Artane			
	Haemodialysis		(Trihexyphenidyl			
	Liver Function Test		Hydrochloride)	C		
	Abnormal		Silece			
	Melaena		(Flunitrazepam)	C		
	Muscular Weakness		Impromen			
	Oesophagitis		(Bromperidol)	C		
	Oliguria		Remark (Betahistine			
	Pleural Effusion		Mesilate)	C		
	Pulmonary Embolism					
	Pulmonary Mycosis					
	Renal Failure Acute					
	Rhabdomyolysis					
	Sepsis					
	Shock					
	Staphylococcal Infection					
	Vomiting					

Date:08/31/01ISR Number: 3787736-0Report Type:Periodic Company Report #A109963
Age:15 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Required	Grand Mal Convulsion	Health	Ziprasidone Po	PS			40.00 MG
Intervention to	Sedation	Professional					TOTAL:BID
Prevent Permanent			Lithium Carbonate	SS			1500.00 MG
Impairment/Damage							TOTAL:BID
			Clozaril	C			

Date:08/31/01ISR Number: 3787818-3Report Type:Periodic Company Report #A105389
Age:19 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Other	Agitation	Consumer	Ziprasidone Po	PS	Pfizer Regulatory		
	Drug Ineffective	Health			Safety	ORAL	80.00 MG
	Insomnia	Professional					TOTAL:BID:ORA
	Mania						L
	Nausea		Lithium Carbonate	SS		ORAL	4500.00 MG
	Nervousness						TOTAL:TID:ORA
	Psychotic Disorder						L
	Vomiting		Clonazepam	C			

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/31/01ISR Number: 3788333-3Report Type:Periodic Company Report #A109262
Age:22 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Other	Nausea	Health	Ziprasidone Po	PS		ORAL	20.00 MG
	Vomiting	Professional					TOTAL:BID:ORAL
			Lithium Carbonate	SS		ORAL	1200.00 MG TOTAL:DAILY:ORAL
			Risperdal	SS		ORAL	4.00 MG TOTAL:BID:ORAL

Date:09/03/01ISR Number: 3787682-2Report Type:Expedited (15-DaCompany Report #2001SE06327
Age:29 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Life-Threatening	Convulsion	Foreign	Seroquel "Zeneca"	PS		ORAL	600 MG DAILY
Hospitalization - Initial or Prolonged	Drug Interaction	Health Professional					PO
	Epilepsy		Lithium	SS		ORAL	800 MG DAILY
Required Intervention to Prevent Permanent Impairment/Damage		Other					PO
			Depakine	C			

Date:09/05/01ISR Number: 3788594-0Report Type:Expedited (15-DaCompany Report #01P-028-0110397-00
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Glomerulonephritis	Foreign Health Professional	Epival Tablets (Depakote) (Divalproex Sodium) (Divalproex Sodium)	PS		ORAL	1.5 GM, 1 IN	1 D, PER ORAL
			Lithium	SS				

Date:09/05/01ISR Number: 3788670-2Report Type:Expedited (15-DaCompany Report #2001018512-1
Age:41 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Mania	Consumer	Eskalith	PS	Smithkline Beecham	ORAL	1350 MILLIGRAMS	
Other	Pollakiuria							
	Schizophrenia						ORAL	
	Thirst							

Date:09/06/01ISR Number: 3788781-1Report Type:Direct Company Report #
Age:11 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Abdominal Pain Upper		Lithium Carbonate	PS		ORAL	1200 MG / DAY	
	Pain							
PO	Psychogenic Pain Disorder		Dexedrine	C			1	DAY
			Risperidone	C				
			Ddavp	C				
			Hydroxyzine	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/07/01ISR Number: 3789907-6Report Type:Expedited (15-DaCompany Report #17812-141
Age:33 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dehydration Mania	Foreign Literature	Lithium: Strength & Manufacturer Unknown	PS				18 MON
	Muscle Twitching Nephritis Interstitial Oliguria	Health Professional	Carbamazepine: Strength & Manufacturer Unknown	SS			300 MG	
	Renal Failure						BID-ROUTE NOT	
	Sedation						STATED	3 WK
	Stupor Tremor							

Date:09/10/01ISR Number: 3790263-8Report Type:Direct Company Report #
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Level Above Therapeutic		Lithium 300 Mg	PS		ORAL	300 MG TID	
Required Intervention to Prevent Permanent Impairment/Damage	Dysarthria Gait Disturbance		Sulindac 200 Mg	SS		ORAL	200 MG BID	

Date:09/11/01ISR Number: 3791435-9Report Type:Expedited (15-DaCompany Report #A120276
Age:26 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Confusional State	Health	Ziprasidone Po	PS		ORAL	80.00 MG	

Initial or Prolonged	Coordination Abnormal	Professional				
TOTAL:BID:ORA						
	Drug Level Above					
L						
	Therapeutic		Lithium	SS		ORAL
1200.00 MG						
	Gastrointestinal Disorder					
TOTAL:BID:ORA						
	Lethargy					
L						
			Effexor Xr	C		
			Wellbutrin	C		
			Topamax	C		
			Parlodel	C		

Date:09/12/01ISR Number: 3792286-1Report Type:Expedited (15-DaCompany Report #2001018512-1
Age:41 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Mania	Consumer	Eskalith	PS	Smithkline Beecham	ORAL	1350	
Initial or Prolonged	Schizophrenia						MILLIGRAMS	
Other								
ORAL	5 YR							
			Risperdal (Risperidone)	C				

Date:09/13/01ISR Number: 3792490-2Report Type:Direct Company Report #
Age:60 YR Gender:Male I/FU:I

Outcome	PT
Hospitalization -	Aphasia
Initial or Prolonged	Clumsiness
	Dysphagia
	Movement Disorder

	Myotonia Tremor					
		Report Source	Product	Role	Manufacturer	Route
Dose Duration						
			Lithium(300mg)	PS		
300MG 2 BID						

Date:09/14/01ISR Number: 3793838-5Report Type:Expedited (15-DaCompany Report #FLUV00301003707
Age:52 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Blood Calcium Decreased Blood Potassium Decreased Convulsion	Foreign Health Professional	Depromel 50 (Fluvoxamine Maleate)	PS		ORAL
200 MG DAILY PO	Depressed Level Of Consciousness Hyponatraemia	Other	Rohypnol (Flunitrazepam)	SS		ORAL
4 MG DAILY PO			Contomin (Chlorpromazine Hydrochloride)	SS		ORAL
DAILY PO			Limas (Lithium Carbonate)	SS		ORAL
DAILY PO						

Date:09/14/01ISR Number: 3794038-5Report Type:Expedited (15-DaCompany Report #A120681
Age:64 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - 600.00 MG Initial or Prolonged TOTAL: DAILY	Confusional State Hallucination	Foreign Literature	Lithane Tablets	PS		
Required Intervention to Prevent Permanent Impairment/Damage	Nephrogenic Diabetes Insipidus Renal Tubular Disorder Restlessness Sleep Disorder	Health Professional	Thyroxine	C		

Date:09/17/01ISR Number: 3794033-6Report Type:Direct Company Report #
Age:56 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Required	Dizziness Drug Toxicity Nausea		Lithium Carbonate 300 Mg	PS		ORAL	900 MG QHS	
Intervention to Prevent Permanent Impairment/Damage	Sinus Bradycardia		Furosemide 40 Mg	SS		ORAL	40 MG QAM	

Date:09/17/01ISR Number: 3795971-0Report Type:Expedited (15-DaCompany Report #HQ5706209SEP2001
Age:3 MON Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Complications Of Maternal Exposure To Therapeutic Drugs Hypotonia	Health Professional	Efexor (Venlafaxine Hydrochloride)	PS		TRANSPLACENTAL	300 MG 1X PER 1 DAY	
			Efexor (Venlafaxine Hydrochloride	SS		TRANSPLACENTAL	75 MG 1X PER 1 DAY	

L

Diazepam (Diazepam) SS

TRANSPLACENTAL 20 MG 1X PER

1 DAY

TRANSPLACENTA

L

Lithium (Lithium) SS

TRANSPLACENTAL 400 MG 1X PER

1 DAY

TRANSPLACENTA

L

Date:09/18/01ISR Number: 3794161-5Report Type:Direct Company Report #
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged CHRONIC	Confusional State Mental Impairment Tremor		Lithium	PS		ORAL	300MG PO TID	

Date:09/19/01ISR Number: 3795097-6Report Type:Direct Company Report #
Age:18 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Grand Mal Convulsion		Seroquel Eskalith	PS SS			200MG TID 450MG 2 Q 4PM	

Date:09/19/01ISR Number: 3795422-6Report Type:Direct Company Report #
Age:64 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Difficulty In Walking Drug Level Above Therapeutic		Lithium Carbonate Trazodone Risperidone Divalproex Restoril	PS C C C C		ORAL	900MG PO BID	

Date:09/19/01ISR Number: 3796333-2Report Type:Expedited (15-DaCompany Report #EMADSS2001005392
Age:55 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Hypernatraemia	Foreign Health Professional	Risperdal (Unspecified) (Risperidone) Lithium (Lithium) Perphenan (Perphenazine)	PS SS C		ORAL	2 MG, DAILY, ORAL	

Date:09/20/01ISR Number: 3796131-XReport Type:Direct Company Report #
Age:29 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Drug Level Above Therapeutic Dysarthria Tremor		Geodon (Ziprasidone) Pfizer Lithium 300mg Po Bid	PS SS	Pfizer	ORAL ORAL	60 MG PO BID STARTED 8/10 AT 20 MG PO 300MG PO BID AND THEN	

INCREASED

SLOWLY

			Trilafon	C		
			Haldol	C		
			Lamictal	C		
			Cogentin	C		
			Synthroid	C		
			Klonopin	C		
			Rocaltrol	C		
			Oystcal	C		
			Mg Oxide	C		

Date:09/20/01ISR Number: 3796132-1Report Type:Direct Company Report #
Age:26 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Drug Toxicity		Geodon	PS		ORAL	20 MG PO BID	
Hospitalization -	Extrapyramidal Disorder		Lithium	SS		ORAL	600 MG PO BID	1 MON
Initial or Prolonged			Effexor	C				
Required			Wellbutrin Sr	C				
Intervention to			Topamax	C				
Prevent Permanent			Parlodel	C				
Impairment/Damage								

Date:09/20/01ISR Number: 3796557-4Report Type:Expedited (15-DaCompany Report #LBID00201003825
Age:26 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Diarrhoea	Literature	Lithium (Lithium)	PS		ORAL	900 MG BID PO	
Initial or Prolonged	Dizziness	Health	Herbal Diurectic Otc	SS			DAILY/ A FEW	
	Drug Level Above	Professional					WEEKS	
	Therapeutic		Sinus Medication Otc					
	Gait Disturbance		(Sinus Medication					
	Nausea		Otc)	SS			DAILY/ A FEW	

	Nystagmus						
DAYS							
	Sedation			Risperidone			
	Tremor			(Risperidone)	C		
				Propranolol			
				(Propranolol)	C		
				Lorazepam			
				(Lorazepam)	C		
				Sertraline			
				(Sertraline)	C		
				Hydroxyzine			
				(Hydroxyzine)	C		

Date:09/20/01ISR Number: 3796864-5Report Type:Expedited (15-DaCompany Report #LBID00201003849
Age:46 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Coordination Abnormal	Literature	Lithium (Lithium)	PS		ORAL	PO	
	Drug Level Above Therapeutic	Health Professional						
	Intentional Misuse							
	Renal Failure Acute							
	Suicide Attempt							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/24/01ISR Number: 3797916-6Report Type:Expedited (15-DaCompany Report #2001021576-1
Age:58 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agitation	Literature	Lithium Smithkline Beecham	PS	Smithkline Beecham		900	MILLIGRAMS
	Confusional State	Health						
	Coordination Abnormal	Professional						
	Disorientation		Candesartan	C				
	Drug Interaction							
	Drug Level Above Therapeutic							
	Drug Toxicity							

Date:09/24/01ISR Number: 3798162-2Report Type:Expedited (15-DaCompany Report #2001015173-1
Age:70 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Disorientation	Consumer	Relafen Smithkline Beecham	PS	Smithkline Beecham	ORAL	ORAL	
	Drug Interaction	Health						
	Dyspnoea	Professional	Esaklith Cr (Lithium Carbonate) Smithkline Beecham	SS	Smithkline Beecham	ORAL	450	MILLIGRAMS
	Memory Impairment							
	Oedema Peripheral							
	Tremor							
							1.0	DAILY
							ORAL	
			Flomax (Tamsulosin Hcl)	C				

Date:09/24/01ISR Number: 3799647-5Report Type:Periodic Company Report #WAES 01082050
Age:70 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

	Tremor	Consumer	Tab Vioxx 12.5 Mg	PS		ORAL
12.5						
MG/DAILY/PO						
			Eskalith Unk	SS		
			Sinement	C		

Date:09/25/01ISR Number: 3798365-7Report Type:Expedited (15-DaCompany Report #2001018512-1
Age:41 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Depression	Consumer	Eskalith Smithkline			
Initial or Prolonged	Mania		Beecham	PS	Smithkline Beecham	ORAL
1350						
Other	Pollakiuria					
MILLIGRAMS,						
	Schizophrenia					
ORAL 5 YR						
	Sedation		Risperdal			
	Thirst		(Risperidone)	C		

Date:09/25/01ISR Number: 3800113-9Report Type:Direct Company Report #
Age:65 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Blood Creatinine		Lithium 300mg	PS		ORAL
300MG TWICE						
Initial or Prolonged	Increased					
DAILY ORAL						
	Diabetes Insipidus		Olanzapine	C		
	Fall		Hydrochlorothiazide	C		
	Tremor		Ranitidine	C		
	Urinary Incontinence		Hytrin	C		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/25/01ISR Number: 3801247-5Report Type:Expedited (15-DaCompany Report #2001021764-1
Age:25 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Electromyogram Abnormal Hypokalaemia	Literature Health	Lithium Smithkline Beecham	PS	Smithkline Beecham		600	MILLIGRAMS 5 YR
	Muscular Weakness	Professional						
	Paralysis Flaccid		Buspirone	C				
			Fluoxetine (Fluoxetine)	C				

Date:09/25/01ISR Number: 3801301-8Report Type:Expedited (15-DaCompany Report #PHEH2001US07720
Age:15 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Creatinine Increased	Health Professional	Clozaril(Clozapine) Tablet	PS		ORAL	200 MG, ORAL	
	Drug Level Above		Lithium(Lithium)	SS			900 MG	13 DAY
	Therapeutic Leukocytosis Pyrexia Red Blood Cell Sedimentation Rate Increased		Geodon (Ziprasidone Hydrochloride)	C				
			Depakote (Valproate Semisodium)	C				
			Acetaminophen (Paracetamol)	C				
			Ibuprofen	C				
			Chloral Hydrate	C				

Date:09/26/01ISR Number: 3799914-5Report Type:Expedited (15-DaCompany Report #0519635A
Age:76 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Medication Error Tremor	Consumer	Gas-X Simethicone 125mg Nvch	PS	Nvch	ORAL	1	SOFTGEL/PRN/P

O

			Lithium-Smithkline Beecham	SS	Smithkline Beecham	ORAL
UNK/UNK/PO						
			Lithium	C		
			Synthroid	C		
			Fosamax	C		

Date:09/26/01ISR Number: 3799915-7Report Type:Expedited (15-DaCompany Report #0519635A
Age:76 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Medication Error	Consumer	Gas-X-Simethicone 125mg Nvch	PS	Nvch	ORAL
Tremor						
1						
SOFTGEL/PRN/P						

O

		Lithium Smithkline Beecham	SS	Smithkline Beecham	ORAL
UNK/UNK/PO					
		Lithium	C		
		Synthroid	C		
		Fosamax	C		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/26/01ISR Number: 3800305-9Report Type:Direct Company Report #
Age:65 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Delirium		Lithium	PS				
	Drug Toxicity		Oxcarbamazepine	C				
	Hypovolaemia		Olanzepine	C				
	Movement Disorder		Lisinopril	C				
	Muscle Twitching		Felodipine	C				
			Glyburide	C				

Date:09/26/01ISR Number: 3801892-7Report Type:Expedited (15-DaCompany Report #FLUV00301003707
Age:54 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Convulsion	Foreign	Depromel 50	PS		ORAL	200 MG DAILY PO	2 YR
	Depressed Level Of Consciousness	Health Professional	Rohypnol (Flunitrazepam)	SS		ORAL	2 MG DAILY PO	2 YR
	Electrolyte Imbalance	Other	Contomin (Chlorpromazine Hydrochloride)	SS		ORAL	DAILY PO	2 YR
	Hypocalcaemia		Limas (Lithium Carbonate)	SS		ORAL	DAILY PO	2 YR
	Hypochloraemia							
	Hypokalaemia							
	Hyponatraemia							
	Polyuria							

Date:09/27/01ISR Number: 3800426-0Report Type:Expedited (15-DaCompany Report #2001022226-1
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Pancreatitis	Health Professional	Eskalith Smithkline Beecham	PS	Smithkline Beecham			

Date:09/28/01ISR Number: 3802136-2Report Type:Expedited (15-DaCompany Report #NSADSS2001028418
Age:57 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Confusional State Coordination Abnormal	Study Health	Topiramate (Tablet) (Topiramate)	PS		ORAL	SEE IMAGE	
	Decreased Appetite Drug Toxicity Dysgeusia	Professional	Lithium Carbonate (Lithium Carbonate)	SS		ORAL	900 MG, 2 IN	1 DAY (S),

ORAL

Date:09/28/01ISR Number: 3803107-2Report Type:Direct Company Report #
Age: Gender:Not SpecifiI/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Intentional Misuse Lethargy Sedation Suicide Attempt		Lithium	PS				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/01/01ISR Number: 3803159-XReport Type:Expedited (15-DaCompany Report #A121985
Age:33 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Pressure Decreased	Foreign	Lithane Tablets	PS			600.00 MG	TOTAL:BID
	Blood Sodium Decreased	Literature	Carbamazepine	SS				
	Dehydration	Health						
	Haemodialysis	Professional						
	Mania							
	Muscle Twitching							
	Nephritis Interstitial							
	Oliguria							
	Pulmonary Oedema							
	Renal Failure							
	Sedation							
	Sinus Tachycardia							
	Stupor							
	Therapeutic Agent							
	Toxicity							
	Tremor							

Date:10/01/01ISR Number: 3804122-5Report Type:Expedited (15-DaCompany Report #LBID00201003893
Age:59 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agitation	Literature	Lithium	PS		ORAL	300 MG BID PO	
	Delirium	Health	Fluphenazine					
	Dizziness	Professional	(Fluphenazine)	C				
	Dyspnoea		(Benztropine					
	Electrocardiogram		Mesylate)	C				
	Abnormal		Aspirin Compound	C				
	Electrocardiogram Qt							
	Shortened							
	Headache							
	Hypercalcaemia							
	Hypermagnesaemia							
	Hyperparathyroidism							
	Hypertension							
	Hypophosphataemia							
	Nausea							

	Polyuria
	Tachycardia
	Urine Abnormality

Date:10/01/01ISR Number: 3804162-6Report Type:Expedited (15-DaCompany Report #LBID00201003889
Age:59 YR Gender:Male I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Abnormal Behaviour
	Constipation
	Diarrhoea
	Disorientation
	Disturbance In Attention
	Electroencephalogram Abnormal
	Encephalopathy
	Medication Error
	Memory Impairment
	Obsessive Thoughts
	Paranoia

Urinary Incontinence

		Report Source	Product	Role	Manufacturer	Route	Dose Duration
		Literature Health Professional	Lithium, Manufacturer Unknown (Lithium)	PS		ORAL	900 MG DAILY PO
			Olanzapine (Olanzapine)	SS		ORAL	5 MG DAILY PO
			Haloperidol (Haloperidol)	SS		ORAL	20 MG DAILY PO
			(Carbamazepine)	C			

Date:10/02/01ISR Number: 3803393-9Report Type:Direct Company Report #
Age:40 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Coordination Abnormal		Lithium	PS			300MG QD 1 YR
	Depressed Level Of Consciousness		Cogentin	C			
	Drug Level Above Therapeutic		Haldol	C			
	Renal Failure Acute		Olanzapine	C			
	Tremor		Propranolol	C			
			Bactrim	C			

Date:10/03/01ISR Number: 3803376-9Report Type:Expedited (15-DaCompany Report #B0121705A
Age:55 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Death	Agitation	Foreign	Salbutamol	PS	Glaxo Wellcome	RESPIRATORY (INHALATION)	
	Arrhythmia						

	Bipolar I Disorder	Procyclidine	SS	Glaxo Wellcome	
UNKNOWN	5MG Three				
	Blood Phosphorus				
times per day					
	Increased	Flupenthixol	SS		
UNKNOWN	60MG Weekly				
	Confusional State	Quetiapine	SS		
UNKNOWN	225MG See				
	Coronary Artery Disease				
text					
	Delusion	Sandocal	SS		
UNKNOWN	400MG Three				
	Drug Level Above				
times per day					
	Therapeutic	Ramipril	SS		
UNKNOWN	1.25MG In the				
	Irritability				
morning					
	Speech Disorder	Alfacalcidol	SS		
UNKNOWN	1MCG Per day				
	Sudden Death	Diazepam	SS		
UNKNOWN	5MG Three				
times per day					
		Chlorpromazine Hydrochloride	SS	Glaxo Wellcome	
UNKNOWN					
		Lorazepam	SS		
PARENTERAL					
		Lithium	SS		
UNKNOWN	15 DAY				

Date:10/03/01ISR Number: 3803422-2Report Type:Direct Company Report #
Age: Gender:Male I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Bradycardia
	Dialysis
	Drug Toxicity
	Dysarthria
	Mental Impairment

	Nausea						
	Nephrogenic Diabetes Insipidus	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Vomiting		Lithium	PS		ORAL	240 MG TID PO
			Carbamzepine	C			
			Gemfibrozil	C			
			Resperidone	C			
			Terazosin	C			
			Acetaminophen	C			
			Lantoprost Opth	C			
			Timolol Opth	C			

Date:10/03/01ISR Number: 3803697-XReport Type:Direct Company Report #
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Life-Threatening	Anxiety		Lithium	PS		ORAL	900MG PO QD
Hospitalization - Initial or Prolonged	Confusional State		Cotrimoxazole	C			
Required Intervention to Prevent Permanent Impairment/Damage	Diarrhoea		Citalopram	C			
	Dissociation		Fluconazole	C			
	Drug Toxicity		Mirtazipine	C			
	Dry Mouth						
	Dysarthria						
	Fatigue						
	Mental Impairment						
	Micturition Urgency						
	Movement Disorder						
	Nausea						
	Polyuria						
	Renal Failure						
	Speech Disorder						
	Thirst						
	Tongue Disorder						
	Tremor						
	Vomiting						

Date:10/03/01ISR Number: 3804320-0Report Type:Expedited (15-DaCompany Report #01P-163-0104719-00
Age:42 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Chronic Obstructive Airways Disease Exacerbated Delirium Tremens Drug Interaction Dyspnoea Renal Tubular Acidosis Respiratory Alkalosis	Health Professional	Kaletra Soft Gelatin Capsules (Kaletra) (Lopinavir/Ritonavir) (Lopinavir/Ritonavir Amprenavir Lithium (Lithium) Coumadin (Warfarin Sodium) Agenerase Ipratropium Bromide Salmeterol Xinafoate Lithium Carbonate Metoprolol Benazepril Hydrochloride	PS SS SS C C C C C C		ORAL ORAL	3 TABLET, 2 IN 1 D, PER ORAL 11 MG, IN 1 D, PER ORAL	

				Amfebutamone Hydrochloride	C		
				Combivir	C		
				Warfarin Sodium	C		
				Salbutamol	C		

Date:10/03/01ISR Number: 3804463-1Report Type:Expedited (15-DaCompany Report #2001018512-1
Age:41 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Condition Aggravated	Consumer	Eskalith Smithkline Beecham	PS	Smithkline Beecham	ORAL	1350 Other MILLIGRAMS	
	Depression							
	Hallucination, Visual							
	Libido Decreased						ORAL	5 YR
	Mania		Eskalith Smithkline Beecham	SS	Smithkline Beecham			
	Pollakiuria							
	Psychotic Disorder		Risperdal (Risperidone)	C				
	Schizophrenia							
	Sedation							
	Thirst							

Date:10/03/01ISR Number: 3806839-5Report Type:Expedited (15-DaCompany Report #EMADSS2001005486
Age:48 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Blood Creatine Phosphokinase Increased	Foreign Study	Topiramate	PS		ORAL	10 CAP, DAILY ORAL	
	Body Temperature Increased	Health Professional	Placebo (Placebo)	SS		ORAL	10 CAP, DAILY, ORAL	
	Catatonia		Risperidone (Risperidone)	SS			PATIENT HAD PREVIOUSLY	
	Headache							
	Muscle Rigidity							

Neuroleptic Malignant
RECEIVED
Syndrome
RISPERIDONE
Respiratory Failure
FROM

	Lithium (Lithium)	SS	ORAL

10 CAP,

DAILY, ORAL

	Lorazepam (Lorazepam)	C
	Chloral Hydrate (Chloral Hydrate)	C
	Diazepam (Diazepam)	C
	Olanzapine (Olanzapine)	C
	Senna (Senna)	C
	Lactulose (Lactulose)	C
	Haloperidol (Haloperidol)	C
	Lithium Carbonate (Lithium Carbonate)	C

Date:10/04/01ISR Number: 3805329-3Report Type:Expedited (15-DaCompany Report #LBID00201003968
Age:64 YR Gender:Female I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Dehydration
	Drug Level Above

		Therapeutic Inappropriate Affect					
			Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
			Literature	Lithium (Lithium)	PS		ORAL
DAILY PO							
			Health Professional				

Date:10/04/01ISR Number: 3805518-8Report Type:Expedited (15-DaCompany Report #LBID00201003969
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Drug Level Above	Literature	Lithium (Lithium)	PS		ORAL
DAILY PO						
Initial or Prolonged	Therapeutic	Health Professional				
	Euphoric Mood					
	Haemodialysis					
	Tremor					

Date:10/05/01ISR Number: 3806077-6Report Type:Direct Company Report #
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Tremor		Lithium Carbonate	PS		

Date:10/05/01ISR Number: 3806078-8Report Type:Direct Company Report #
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Drug Level Above		Lithium	PS		
	Therapeutic					

Date:10/05/01ISR Number: 3806816-4Report Type:Expedited (15-DaCompany Report #2001022308-1
Age:36 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Crying	Health	Lithium Smithkline					
	Disturbance In Attention	Professional	Beecham	PS	Smithkline Beecham			
SEE IMAGE							5	DAY
	Drug Interaction		Fluoxetine	C				
	Fatigue							
	Serotonin Syndrome							

Date:10/05/01ISR Number: 3807415-0Report Type:Expedited (15-DaCompany Report #2001UW12244
Age:51 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required	Blood Urea Increased	Foreign	Seroquel "Zeneca"	PS		ORAL	50 MG DAILY	
Intervention to	Confusional State	Other						
PO							8	DAY
Prevent Permanent	Coordination Abnormal		Lithium	SS		ORAL	750 MG DAILY	
Impairment/Damage	Delirium							
PO							5	YR
	Delusion		Diovan	SS		ORAL	80 MG DAILY	
	Drug Level Above							
PO							2	WK
	Therapeutic		Lorazepam	C				
	Mania		Ciproflaxacin	C				
	Sedation		Conjugated Estrogens	C				
			Glyburide	C				
			L-Typtophan	C				
			Zopiclone	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/08/01ISR Number: 3806864-4Report Type:Expedited (15-DaCompany Report #1633168A
Age:39 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Death	Activated Partial	Literature	Acetaminophen				
Hospitalization -	Thromboplastin Time	Health	Product	PS		ORAL	PO
Initial or Prolonged	Prolonged	Professional	Lithium	SS		ORAL	PO
Required Intervention to Prevent Permanent Impairment/Damage	Acute Respiratory Distress Syndrome Ammonia Increased Anion Gap Increased Aspartate Aminotransferase Increased Blood Bicarbonate Decreased Blood Bilirubin Increased Blood Calcium Decreased Blood Glucose Decreased Brain Oedema Drug Level Above Therapeutic Electroencephalogram Abnormal Encephalopathy Gastrointestinal Haemorrhage Hyperreflexia Orthostatic Hypotension Vomiting White Blood Cell Count Increased						

Date:10/08/01ISR Number: 3806865-6Report Type:Expedited (15-DaCompany Report #1633417A
Age:44 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Death	Bradycardia	Literature	Unspecified Tylenol				
Hospitalization -	Coagulopathy	Health	Product	PS		ORAL	"3 MONTHS

Initial or Prolonged	Coma	Professional				
WORTH" PO;						
Required	Drug Level Above					
ACUTE-ON-CHRO						
Intervention to	Therapeutic					
NIC						
Prevent Permanent	Gastrointestinal Disorder		Lithium	SS		ORAL
"3 MONTHS						
Impairment/Damage	Hepatic Failure					
WORTH" PO;						
	Hypotension					
ACUTE-ON-CHRO						
NIC						
			Effexor (Venlafaxine)	C		
			Stelazine (Trifluoperazine)	C		
			Metoprolol	C		
			Lamictal (Lamotrigine)	C		
			Unspecified Valproic Acid Product	C		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/08/01ISR Number: 3807641-0Report Type:Expedited (15-DaCompany Report #NSADSS2001029546
Age:41 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Literature	Haldol (Unspecified)					
		Health	(Haloperidol)	PS		ORAL		
ORAL								
		Professional	Lithium (Lithium)	SS				

Date:10/09/01ISR Number: 3805423-7Report Type:Expedited (15-DaCompany Report #A0162626A
Age:50 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Balance Disorder		Wellbutrin	PS	Glaxo Wellcome	ORAL		
Initial or Prolonged	Blood Potassium Abnormal		Eskalith Cr	SS	Glaxo Wellcome	ORAL		
900MG Per day	5 YR							
	Blood Sodium Abnormal		Zyprexa	SS				
UNKNOWN								
	Condition Aggravated		Prilosec	SS				
UNKNOWN								
	Diplopia							
	Disorientation							
	Electrolyte Imbalance							
	Fall							
	Tremor							

Date:10/09/01ISR Number: 3805617-0Report Type:Direct Company Report #
Age:66 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Dehydration		Lithium	PS		ORAL		
ORAL								
Initial or Prolonged	Drug Toxicity							
	Hypercalcaemia							
	Hypernatraemia							
	Mental Impairment							
	Nephrogenic Diabetes							
	Insipidus							
	Pneumonia Aspiration							

Date:10/10/01ISR Number: 3809150-1Report Type:Expedited (15-DaCompany Report #2001023091-1
Age:50 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Balance Disorder	Consumer	Eskalith	PS	Smith Beecham	ORAL	SEE IMAGE	5 YR
Initial or Prolonged	Condition Aggravated		Wellbutrin					
	Diplopia		(Bupropion)	SS	Glaxowellcome			
	Disorientation		Zyprexa	SS	Lilly			
	Electrolyte Imbalance		Prilosec					
	Fall		(Omeprazole)	SS	Astrazeneca			
	Tremor							

Date:10/10/01ISR Number: 3810020-3Report Type:Expedited (15-DaCompany Report #2001AP03838
Age:55 YR Gender:Male I/FU:I

Outcome	PT
Death	Agitation
	Arrhythmia
	Bipolar I Disorder
	Blood Phosphorus Increased
	Chest Pain
	Confusional State

		Coronary Artery Disease Delusion					
		Drug Level Above	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
		Therapeutic	Foreign	Salbutamol	PS	Astrazeneca	
		Dyspnoea	Health			Pharmaceuticals	
		Emotional Distress	Professional	Ramipril	SS		ORAL
1.25 MG DAILY							
		Irritability	Other				
PO							
		Left Ventricular Failure		Quetiapine	SS		ORAL
75 MG HS PO							
		Mania		Quetiapine	SS		ORAL
150 MG HS PO							
		Respiratory Failure		Depixol	SS		
60 MG WEEK							
		Speech Disorder		Sandocal "Novartis"	SS		ORAL
400 MG TID PO							
		Sudden Death		Alfacalcidol	SS		ORAL
1 UG DAILY PO							
				Diazepam	SS		ORAL
5 MG TID PO							
				Procyclidine	SS		
5 MG TID							
				Chlorpromazine	SS		
				Lorazepam	SS		
				Lithium	SS		

Date:10/10/01ISR Number: 3810507-3Report Type:Expedited (15-DaCompany Report #B0121705A
Age:55 YR Gender:Male I/FU:I

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Death		Agitation	Foreign	Ventolin Unspecified			
		Arrhythmia		Inhaler Device			
		Bipolar I Disorder		(Albuterol Sulfate)	PS		
RESPIRATORY							
		Blood Phosphorus					
(INHALATION)	INHALED						
		Increased		Kemadrin			
		Confusional State		(Formulation			
		Coronary Artery Disease		Unknown)			
		Delusion		(Procyclidine Hcl)	SS		
5 MG / THREE							

TIMES PER DAY /	Irritability Speech Disorder Sudden Death		
60 MG / WEEKLY		Flupenthixol (Formulation Unknown) (Flupenthixol)	SS
225 MG / SEE TEXT		Quetiapine (Formulation Unknown) (Quetiapine)	SS
400 MG / THREE TIMES PER DAY		Sandocal (Formulation Unknown) (Sandocal)	SS
1.25 MG / IN THE MORNING /		Ramipril (Formulation Unknown) (Ramipril)	SS
1 MCG / PER DAY		Alfacalcidol (Formulation Unknown) (Alfacalcidol)	SS
5 MG / THREE TIMES PER DAY		Diazepam (Formulation Unknown) (Diazepam)	SS

				Lorazepam (Formulation Unknown) (Lorazepam)	SS		
PARENTERAL	PARENTERAL						
				Lithium Salt (Formulation Unknown) (Lithium Salt)	SS		
				Chlorpromazine Hcl (Formulation Unknown) (Chlorpromazine Hcl)	SS		

Date:10/11/01ISR Number: 3807612-4Report Type:Direct Company Report #
Age:54 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Agitation		Lithium	PS				
	Delirium							

Date:10/11/01ISR Number: 3807702-6Report Type:Direct Company Report #
Age:49 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Drug Level Above		Lithium (300mg)	PS		ORAL	300 MG PO BID	
	Therapeutic		Lisinopril	SS		ORAL	10 MG PO	DAILY
	Feeling Jittery							
	Hypotension							
	Lethargy							
	Mental Impairment							
	Polyuria							

Date:10/11/01ISR Number: 3808265-1Report Type:Expedited (15-DaCompany Report #NSADSS2001028418
Age:57 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Confusional State Coordination Abnormal Decreased Appetite Drug Toxicity Dysgeusia	Study Health Professional	Topiramate (Tablet) (Topiramate)	PS		ORAL	1) 25 MG, 2 IN 1 DAY(S), PO; 2) 50 MG, 2 IN 1 DAY(S), PO;	
			Lithium Carbonate (Lithium Carbonate)	SS		ORAL	900 MG, 2 IN 1 DAY(S), ORAL	

Date:10/16/01ISR Number: 3809852-7Report Type:Direct Company Report #
Age:33 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Leukocytosis		Lithobid (600 Mg) (Solvay Pharmaceuticals)	PS	Solvay Pharmaceuticals	ORAL	600 MG QHS PO	
			Clozapine (400mg)	SS		ORAL	(400 MG) BID PO	
			Klonopin	C				

				Clonidine	C		
				Cogentin	C		

Date:10/16/01ISR Number: 3809867-9Report Type:Direct Company Report #
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Tremor		Lithium	PS				

Date:10/16/01ISR Number: 3809913-2Report Type:Expedited (15-DaCompany Report #2001-08-1173
Age:55 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Agitation	Foreign	Salbulin Hfa					
Hospitalization -	Arrhythmia	Health	(Salbutamol) Oral					
Initial or Prolonged	Blood Phosphorus	Professional	Aerosol	PS				
RESPIRATORY								
	Increased	Other						
(INHALATION)						ORAL	AER INH	
	Delusion		Depixol Injectable	SS				
INTRAMUSCULAR							60MG	QWEEK*
	Irritability							
INTRAMUCULAR								
	Mania		Ramipril Capsules	SS		ORAL		
1.25 MG QAM								
	Speech Disorder							
ORAL								
	Sudden Death		Alfacalcidol Tablets	SS		ORAL		
1MCG QD ORAL								
			Diazepam Tablets	SS		ORAL		
15MG TID ORAL								
			Procyclidine Tablets	SS		ORAL		
15MG TID ORAL								
			Quetiapine Fumurate	SS				
225MG QD								
			Sandocal Tablets	SS		ORAL		
400MG TID								
ORAL								
			Lorazepam Injectable	SS				

			Lithium	SS		ORAL
ORAL						
			....	C		
INTRAMUSCULAR	60MG QWEEK					
INTRAMUSCULAR						

Date:10/16/01ISR Number: 3810213-5Report Type:Expedited (15-DaCompany Report #11008554
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Leukocytoclastic Vasculitis	Foreign Health	Nefadar Tabs(Nefazodone Hcl)	PS		ORAL	500	MILLIGRAM, 1 DAY, ORAL
	Liver Function Test	Professional						
	Abnormal	Company						
	Pyrexia	Representative Other	Quilonum Ilithium Carbonate)	SS		ORAL	450	MILLIGRAM, 1 DAY , ORAL
			Ximovan (Zopiclone)	SS		ORAL	7.5	MILLIGRAM, 1 DAY , ORAL
			Diazepam (Diazepam)	C				
			Calcium (Calcium)	C				

Date:10/16/01ISR Number: 3810407-9Report Type:Expedited (15-DaCompany Report #2001021558-1
Age: Gender:Male I/FU:I

Outcome	PT
Other	Bone Marrow Depression
	Haematocrit Decreased
	Megakaryocytes Abnormal

		Myeloproliferative Disorder					
			Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
			Health Professional	Eskalith Smithkline Beecham	PS	Smithkline Beecham	ORAL
300							
MILLIGRAMS							
4.0 DAILY							
ORAL							
				Cogentin (Benztropine Mesylate)	C		
				Norvasc (Amlodipine Besylate)	C		
				Diovan (Valsartan)	C		
				Potassium Chloride	C		

Date:10/16/01ISR Number: 3810515-2Report Type:Expedited (15-DaCompany Report #A0162626A
Age:50 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization - Initial or Prolonged	Balance Disorder Condition Aggravated Diplopia Disorientation	Consumer	Wellbutrin Unspecified Tablet (Bupropion Hydrochloride)	PS		ORAL
ORAL						
	Electrolyte Imbalance Fall Tremor		Lithium Carbonate (Formulation Unknown) (Lithium Carbonate)	SS		ORAL
900 MG / PER						
DAY / ORAL						
			Olanzapine (Formulation Unknown) (Olanzapine)	SS		
			Omeprazole (Formulation Unknown)			

				(Omeprazole)	SS		

Date:10/18/01ISR Number: 3811418-XReport Type:Expedited (15-DaCompany Report #2001023197-1
Age:55 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Agitation		Lithium Smithkline					
	Arrhythmia		Beecham	PS	Smithkline Beecham			15 DAY
	Confusional State		Alfacalcidol	C				
	Delusion		Calcium Carbonate					
	Drug Level Above		X/Calcium Carbonate					
	Therapeutic		(Sandocal)	C				
	Irritability		Chlorpromazine	C				
	Mental Impairment		Diazepam	C				
	Speech Disorder		Flupenthixol					
			(Depixol)	C				
			Lorazepam	C				
			Procyclidine	C				
			Quetiapine	C				
			Ramipril	C				
			Salbutamol	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/18/01ISR Number: 3811572-XReport Type:Expedited (15-DaCompany Report #HQ6829008OCT2001
Age:55 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Agitation	Health	Ativan (Lorazepam,					
	Arrhythmia	Professional	Injection)	PS		PARENTERAL	PARENTERAL	
	Coronary Artery	Other	Chlorpromazine					
	Atherosclerosis		(Chlorpromazine)	SS				
	Delusion		Depixol (Flupentixol					
	Drug Level Above		Decanoate)	SS			60 MG 1 X PER	
	Therapeutic							1 WK
	Irritability		Diazepam (Diazepam)	SS			5 MG 3 X PER	
	Medication Error							1 DAY
	Mental Impairment		Lithium (Lithium)	SS				15 DAY
	Speech Disorder		Procyclidine					
	Sudden Death		(Procyclidine)	SS			5 MG 3 X PER	
								1 DAY
			Quetiapine					
			(Quetiapine)	SS			225 MG 1 X	
								PER 1 DAY
			Salbutamol					
			(Salbutamol)	SS			RESPIRATORY	
(INHALATION)	INHALATION							
			Sandocal (Calcium					
			Glubionate)	SS			400 MG 3 X	
								PER 1 DAY

Date:10/18/01ISR Number: 3811730-4Report Type:Expedited (15-DaCompany Report #001-0902-M0100096
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Balance Disorder Bipolar Disorder	Consumer	Nardil (Phenelzine Sulfate)	PS		ORAL	15 MG	Other (DAILY), PER
	Cardiac Disorder Coordination Abnormal							ORAL
	Diabetes Mellitus Non-Insulin-Dependent Difficulty In Walking Drug Ineffective Fear Pain Weight Increased		Zoloft (Sertraline Hydrochloride) Prozac (Fluoxetine Hydrochloride) Lithium (Lithium) Effexor Xr (Venlafaxine) Paxil (Paroxetine Hydrochloride) Pamate (Tranylcypromine) (Unspecified Thyroid Medication) Effexor (Venlafaxine Hydrochloride)	SS SS SS SS SS SS SS			375 MG

Date:10/18/01ISR Number: 3811775-4Report Type:Expedited (15-DaCompany Report #A123617
Age: Gender:Male I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Balance Disorder Bipolar Disorder Coordination Abnormal Diabetes Mellitus Non-Insulin-Dependent

	Difficulty In Walking					
	Drug Ineffective					
	Fear	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
	Pain	Consumer	Zoloft Tablets	PS		
	Palpitations		Lithium	SS		
	Weight Increased		Phenelzine	SS		ORAL
15.00 MG						
TOTAL: DAILY:						
ORAL						
			Prozac (Fluoxetine)	SS		
			Effexor Xr	C		
			Paxil (Paroxetine)	C		
			Tranylcypromine	C		
			Unspecified Thyroid Medication	C		
			Effexor (Venlafaxine)	C		

Date:10/19/01ISR Number: 3812211-4Report Type:Expedited (15-DaCompany Report #EMADSS2001006022
Age: Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Other	Blood Disorder	Foreign	Risperdal			
		Health	(Unspecified)			
		Professional	(Risperidone)	PS		
			Mirtazapine (Mirtazapine)	SS		
			Lithium	SS		

Date:10/19/01ISR Number: 3812213-8Report Type:Expedited (15-DaCompany Report #APCDSS2001001339
Age:93 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization - Initial or Prolonged	Clonic Convulsion	Foreign	Risperdal			
	Coma	Health	(Unspecified)			
	Depressed Level Of	Professional	(Risperidone)	PS		ORAL
0.5 MG, 2 IN						

	Consciousness	Company		
1 DAY (S),				
	Drug Interaction	Representative		
ORAL; 1 MG, 2				
	Lethargy			
IN 1 DAY (S),				
	Muscle Rigidity			
ORAL				
		Lithium (Lithium)	SS	ORAL
250 MG, 2 IN				
1 DAY (S),				
ORAL; 500 MG,				
2 IN 1 DAY				
(S), ORAL				

Date:10/19/01ISR Number: 3812574-XReport Type:Expedited (15-DaCompany Report #K200100247
Age:55 YR Gender:Male I/FU:F

Outcome	PT
Death	Abnormal Behaviour
	Agitation
	Arrhythmia
	Bipolar I Disorder
	Condition Aggravated
	Coronary Artery Disease
	Drug Level Above
	Therapeutic
	Irritability

Medication Error
Speech Disorder

Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Foreign Health Professional	Altace Capsules (Ramipril)	PS		ORAL	1.25 MG, QD,	ORAL
Other	Diazepam (Diazepam)	SS		ORAL	5 MG, TID,	ORAL
	Salbutamol (Salbutamol)	SS		ORAL		ORAL
	Depixol (Flupentixol Decanoate)	SS			60 MG, Q WEEK	
	Quetiapine (Quetiapine)	SS		ORAL	225 MG, QD,	ORAL
	Sandocal (Calcium Carbonate, Colecaliferol, Sodium)	SS	Novartis		400 MG, TID	
	Alfacalidol (Alfacalcidol)	SS			1 UG	
	Procyclidine (Procyclidine)	SS			15 MG, QD	
	Chlorpromazine (Chlorpromazine)	SS				
	Lorazepam (Lorazepam)	SS				
	Lithium (Lithium)	SS				

Date:10/24/01ISR Number: 3817627-8Report Type:Periodic Company Report #1998007471-1
Age:58 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Coronary Artery Disease Heart Rate Decreased	Health Professional	Eskalith Smithkline Beecham Eskalith Smithkline Beecham Lithobid (Lithium Carbonate)	PS C C	Smithkline Beecham Smithkline Beecham	ORAL ORAL	450 MILLIGRAMS 2.0 DAILY ORAL	8 YR

Date:10/24/01ISR Number: 3818948-5Report Type:Expedited (15-DaCompany Report #2001024864-1
Age:46 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Coma Coordination Abnormal Drug Toxicity Intentional Misuse Renal Failure Acute Suicide Attempt	Literature Health Professional	Lithium Carbonate (Lithium) Glaxosmithkline	PS	Glaxosmithkline			

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/29/01ISR Number: 3817130-5Report Type:Expedited (15-DaCompany Report #01P-062-0111690-00
Age:52 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	Valproic Acid Iv (Depacon) (Valproate Sodium) (Valproate Sodium)	PS		INTRAVENOUS	1250 MG, 1 IN 1 D	INTRAVENOUS
	Blood Creatinine Increased	Literature						
	Blood Osmolarity Increased	Health Professional						
	Coma	Other	Lithium	SS				
	Diabetes Insipidus		Perazine	C				
	Drug Level Above Therapeutic		Zotepine	C				
	Hypernatraemia		Lorazepam	C				
	Mania							
	Paranoia							
	Sedation							
	Stupor							
	Urinary Retention							

Date:10/31/01ISR Number: 3818516-5Report Type:Expedited (15-DaCompany Report #FLUV00301003707
Age:54 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Body Temperature Increased	Foreign	Depromel 50 (Fluvoxamine Maleate)	PS		ORAL	200 MG DAILY	PO 2 YR
	Convulsion	Health Professional						
	Dehydration	Other						
	Depressed Level Of Consciousness		Rohypnol (Flunitrazepam)	SS		ORAL	2 MG DAILY PO	
	Diabetes Insipidus		Contomin (Chlorpromazine Hydrochloride)	SS		ORAL	DAILY PO	2 YR
	Electrolyte Imbalance							
	Hypocalcaemia							
	Hypochloraemia		Limas (Lithium Carbonate)	SS		ORAL	DAILY PO	2 YR
	Hypokalaemia							

	Hyponatraemia					
	Muscle Disorder					
	Neuroleptic Malignant Syndrome					
	Phlebitis					
	Rhabdomyolysis					

Date:10/31/01ISR Number: 3818598-0Report Type:Expedited (15-DaCompany Report #A124605
Age:15 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Agitation	Health	Ziprasidone Po	PS		ORAL	40.00 MG	
Hospitalization - Initial or Prolonged	Neuroleptic Malignant Syndrome	Professional					TOTAL; DAILY; ORAL	
Required Intervention to Prevent Permanent Impairment/Damage	Renal Impairment		Lithium Carbonate	SS				
			Eskalith	SS		ORAL		
			Vitamin B6 (Subject Drug)	SS		ORAL		
			Paxil	SS				
			Risperidone	C				
			Clonidine (Subject Drug)	C				
			Estradiol (Subject Drug)	C				
			Ferrous Sequels					

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

(Subject Drug)	C
Trazodone (Subject Drug)	C

Date:10/31/01ISR Number: 3818999-0Report Type:Expedited (15-DaCompany Report #NSADSS2001029546
Age:41 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Agitation	Literature	Haldol(Haloperidol)	PS		ORAL	ORAL	
	Blood Pressure Diastolic Decreased	Health Professional	Lithium (Lithium)	SS				
	Blood Pressure Systolic Increased							
	Clonic Convulsion							
	Completed Suicide							
	Drug Level Below Therapeutic							
	Heart Rate Increased							
	Mental Impairment							
	Pyrexia							
	Respiratory Rate Increased							
	Tremor							
	Ventricular Fibrillation							

Date:10/31/01ISR Number: 3819777-9Report Type:Periodic Company Report #2001066135US
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Interaction	Consumer	Celebrex (Celecoxib) Capsule	PS		ORAL	200 MG, QD,	
	Movement Disorder							
	Muscle Twitching							
			Lithium (Lithium)	SS				

Date:11/01/01ISR Number: 3817985-4Report Type:Direct Company Report #
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Clonic Convulsion		Lithium	PS		ORAL	300MG PO TID	
	Coordination Abnormal							
PTA Required Intervention to Prevent Permanent Impairment/Damage	Drug Interaction		Hctz	C				
	Drug Level Above Therapeutic		Sertraline	C				
	Hypernatraemia		Potassium Chloride	C				
	Multiple Sclerosis		Vit D	C				
	Nystagmus		L-Thyroxine	C				
	Psychotic Disorder		Olanzapine	C				
	Tremor		Zonisamide	C				
			Lorazepam	C				
			Mirapex	C				
			Nasocort	C				

Date:11/05/01ISR Number: 3820605-6Report Type:Expedited (15-DaCompany Report #17812-148
Age:57 YR Gender:Male I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Aspiration
	Asthenia
	Balance Disorder

	Coma						
	Coordination Abnormal						
	Cough	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Drooling	Consumer	Lithium Carbonate				
	Dysarthria		Capsules, 300 Mg				
	Hypertonia		Roxane Laboratories,				
	Overdose		Inc.	PS		ORAL	600 TO 900
	Pneumonia						MG, DAILY,
	Sepsis						ORAL
	Temperature Intolerance		Enalapril	SS		ORAL	ORAL

Date:11/05/01ISR Number: 3820799-2Report Type:Expedited (15-DaCompany Report #02708
Age:44 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Death	Completed Suicide	Literature	Trazodone	PS			
	Intentional Misuse		Lithium	SS			

Date:11/05/01ISR Number: 3820816-XReport Type:Expedited (15-DaCompany Report #02617
Age:80 YR Gender:Not SpecifiI/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Death	Completed Suicide	Literature	Temazepam	PS			
	Intentional Misuse		Lithium	SS			

Date:11/06/01ISR Number: 3820983-8Report Type:Expedited (15-DaCompany Report #NSADSS2001031572
Age:63 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Confusional State	Foreign	Topiramate (Tablet				
	Coordination Abnormal	Study	(Bipolar))				
	Drug Level Above	Health	(Topiramate)	PS		ORAL	200 MG ,

	Therapeutic	Professional					
DAILY, ORAL							
	Drug Toxicity		Lithium (Lithium)	SS			ORAL
900 MG, NIGHT							
	Mania						
(S), ORAL							
			Amantadine (Amatadine)	C			
			Propanolol (Propranolol)	C			
			Oxazepam (Oxazepam)	C			

Date:11/07/01ISR Number: 3822555-8Report Type:Expedited (15-DaCompany Report #A125617
Age:26 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Anxiety	Literature	Lithane Tablets	PS			1800.00 MG	
Hospitalization -	Diarrhoea	Health						
TOTAL; BID								
Initial or Prolonged	Dizziness	Professional	Herbal Diuretic	SS				
	Drug Toxicity		Sertraline	C				
	Gait Disturbance		Propranolol	C				
	Nausea		Risperidone	C				
	Nystagmus		Lorezepam	C				
	Sedation		Hydroxizine	C				
	Tremor		Over-The-Counter Sinus Medication (Unspecified)	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/07/01ISR Number: 3822762-4Report Type:Periodic Company Report #10760924
Age:57 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Level Above Therapeutic	Health Professional	Buspar Tabs (Buspirone Hcl)	PS		ORAL	15 MILLIGRAM, 3/1 DAY	
	Tremor	Company Representative	Buspar Tabs (Buspirone Hcl)	SS		ORAL	15 MILLIGRAM, 2/1 DAY	
			Lithium Carbonate	SS			300MG, 1/1 DAY	
			Trazodone Hcl	C				
			Effexor Xr	C				
			Depakote	C				

Date:11/07/01ISR Number: 3823503-7Report Type:Expedited (15-DaCompany Report #A125638
Age:51 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Fall Parkinson'S Disease	Foreign Health Professional	Zoloft Tablets	PS		ORAL	250.0 MG TOTAL:DAILY:ORAL	
			Melperone	SS		ORAL	25.00 MG TOTAL:DAILY: ORAL	
			Lithium Carbonate	SS		ORAL	900.00 MG TOTAL:DAILY:O	

RAL

Oxazepam	C
Chlormethiazole	C
Ass (Acetylsalicylic Acid)	C
Metoprolol	C
Diltiazem	C
Enalapril	C

Date:11/09/01ISR Number: 3822982-9Report Type:Direct Company Report #
Age:40 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Aggression		Lithium	PS				

Date:11/12/01ISR Number: 3824384-8Report Type:Expedited (15-DaCompany Report #01P-062-0111690-00
Age:52 YR Gender:Female I/FU:F

Outcome	PT
Required Intervention to Prevent Permanent Impairment/Damage	Blood Creatinine Increased
	Blood Osmolarity Increased
	Coma
	Diabetes Insipidus
	Drug Level Above Therapeutic
	Gait Disturbance
	Hypernatraemia
	Sedation
	Stupor

Therapeutic Agent Toxicity Urinary Retention	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Foreign Literature Health Professional	Valproic Acid Iv (Depacon) (Valproate Sodium) (Valproate Sodium)	PS		INTRAVENOUS	INTRAVENOUS
	Other	Sodium Valproate /Valproic Acid	SS		ORAL	PER ORAL 2 DAY
		Lithium	SS			1225 MG, 1 IN 1 D
		Perazine	C			
		Zotepine	C			
		Lorazepam	C			

Date:11/13/01ISR Number: 3824653-1Report Type:Expedited (15-DaCompany Report #LBID00201004554
Age:13 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Abdominal Tenderness	Literature	Lithium Sr (Lithium)	PS		ORAL	300 MG BID PO
	Blood Pressure Decreased	Health Professional	Olanzapine (Olanzapine)	SS			
	Body Temperature Increased		(Sertraline)	C			
	Differential White Blood Cell Count Abnormal						
	Fall						
	Haematuria						
	Heart Rate Increased						
	Influenza						
	Leukocytosis						
	Myocardial Infarction						
	Respiratory Rate Increased						
	Rhabdomyolysis						

Date:11/13/01ISR Number: 3825644-7Report Type:Expedited (15-DaCompany Report #A125836
Age:56 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agitation	Literature	Lithane Tablets	PS		ORAL	600.00 MG	TOTAL: BID: ORAL
	Blood Parathyroid Hormone Increased	Health Professional						
	Delirium		Fluphenazine Decanoate	C				
	Dizziness		Aspirin	C				
	Dyspnoea		Benztropine	C				
	Electrocardiogram Qt Shortened							
	Electrocardiogram St Segment Abnormal							
	Headache							
	Hypercalcaemia							
	Hypermagnesaemia							
	Hypertension							
	Hypophosphataemia							
	Nausea							
	Polyuria							
	Tachycardia							

Date:11/13/01ISR Number: 3829007-XReport Type:Expedited (15-DaCompany Report #2001025965-1
Age:51 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Condition Aggravated Drug Hypersensitivity Gait Disturbance Restlessness	Health Professional	Lithium Acetylsalicylic Acid Metoprolol Succinate Diltiazem Hydrochloride Distraneurin (Clomethiazol) Eunerpan (Melperon Hydrochloride Oxazepam Xanef (Elanapril Maleate) Zoloft (Sertralin Hydrochloride)	PS C C C C C C C C	Glaxosmithkline	ORAL	1) 900 MILLIGRAMS; 2) 675 MILLIGRAMS	3 MON

Date:11/13/01ISR Number: 3829010-XReport Type:Expedited (15-DaCompany Report #2001025863-1
Age:77 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Delirium Hypernatraemia Nephrogenic Diabetes Insipidus		Lithium Glaxosmithkline	PS	Glaxosmithkline			

Date:11/14/01ISR Number: 3825082-7Report Type:Expedited (15-DaCompany Report #2001UW14424
Age:50 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Balance Disorder	Other	Prilosec	PS				

Initial or Prolonged	Condition Aggravated		Zyprexa	SS		
	Disorientation		Eskalith	SS		
	Fall		Wellbutrin	SS		

Date:11/14/01ISR Number: 3825203-6Report Type:Expedited (15-DaCompany Report #1996008312-1
Age:47 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Blood Pressure Increased	Consumer	Parnate					
	Cold Sweat		Smithkline Beecham	PS	Smithkline Beecham	ORAL	SEE IMAGE	
	Dysarthria		Eskalith-Cr					
	Fluid Retention		(Lithium Carbonate)	SS		ORAL	450	
	Food Intolerance						MILLIGRAMS	
	Haemorrhage						2.0 DAILY	
	Headache						ORAL	
	Hepatitis B		Lithium Carbonate	C				
	Hypoaesthesia		Prilosec					
	Vision Blurred		(Omeprazole)	C				
			Vistaril (Hydroxyzine Pamoate)	C				
			Levsin (Hyoscyamine Sulfate)	C				

Vancenase (Beclomethasone Dipropionate, Monohydrate)	C
Serevent (Salmeterol Xinafoate)	C
Aerobid (Flunisolide)	C
Proventil (Albuterol Sulfate)	C
Claritin (Loratadine)	C
Niacin (Nicotinic Acid)	C
Omega-3 Fatty Acids	C
Tylenol #3 (Acetaminophen And Codeine Phosphate)	C
Valisone (Betamethasone Valerate)	C
Depakote (Divalproex Sodium)	C
Atarax (Hydroxyzine)	C

Date:11/14/01ISR Number: 3826532-2Report Type:Expedited (15-DaCompany Report #2001025809-1
Age:68 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Food Poisoning Gastrointestinal Disorder Hiatus Hernia Hypernatraemia Nephrogenic Diabetes Insipidus		Lithium Glaxosmithkline	PS	Glaxosmithkline			

Date:11/16/01ISR Number: 3824883-9Report Type:Expedited (15-DaCompany Report #11530912
Age:76 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Drug Interaction		Glucophage	PS	Bristol-Myers Squibb			

Initial or Prolonged	Therapeutic Agent Toxicity			Company	ORAL
		Lithium	SS		ORAL
		Nortriptyline	C		ORAL

Date:11/19/01ISR Number: 3827785-7Report Type:Expedited (15-DaCompany Report #FLUV00301003707
Age:54 YR Gender:Male I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	C-Reactive Protein Increased
	Convulsion
	Dehydration
	Depressed Level Of Consciousness
	Diabetes Insipidus
	Electrolyte Imbalance
	Hypocalcaemia

		Hypochloraemia Hypokalaemia Hyponatraemia	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
		Muscle Disorder Neuroleptic Malignant Syndrome	Foreign Health Professional	Depromel 50 (Fluvoxamine Maleate)	PS		ORAL
50 MG DAILY							
		Phlebitis	Other				
PO, 150 MG							
		Pollakiuria					
DAILY PO, 200							
		Rhabdomyolysis					
MG DAILY PO							
		Specific Gravity Urine Abnormal		Rohypnol (Flunitrazepam)	SS		ORAL
2 MG DAILY PO							
		Thirst		Contomin (Chlorpromazine Hydrochloride)	SS		ORAL
25 MG DAILY							
PO							
				Limas (Lithium Carbonate)	SS		ORAL
400 MG DAILY							
PO							
				Magnesium Oxide (Magnesium Oxide)	C		

Date:11/21/01ISR Number: 3828529-5Report Type:Expedited (15-DaCompany Report #LBID00201003988
Age:45 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Other	Benign Intracranial Hypertension	Health Professional	Lithium Carbonate (Lithium Carbonate)	PS		ORAL
300 MG Q4HR						
	Cyst	Company				
PO						
	Delusion Dementia Duodenal Operation Hypothyroidism	Representative	Tegretol (Carbamazepine) Flurazepam (Flurazepam)	C C		

	Nervous System Disorder		Clonazepam (Clonazepam)	C		
			Depakote (Valproate Semisodium)	C		

Date:11/21/01ISR Number: 3828641-0Report Type:Expedited (15-DaCompany Report #WAES 01111176
Age:47 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Abdominal Tenderness	Study	Tab Vasotec Unk	PS		ORAL	PO
Initial or Prolonged	Blood Creatinine	Health	Eskalith 675 Mg	SS		ORAL	675 MG/BID/PO
	Increased	Professional	Elavil	C			
	Blood Urea Increased		Tylenol	C			
	Confusional State		Wellbutrin Sr	C			
	Diarrhoea		Acetaminophen (+) Codeine	C			
	Dizziness		Estrogens (Unspecified)	C			
	Drug Interaction		Felodipine	C			
	Faecal Occult Blood Positive		Medroxyprogesterone Acetate	C			
	Haematocrit Decreased		Omeprazole	C			
	Haemoglobin Decreased		Ranitidine Hydrochloride	C			
	Hypotension		Terazosin Hydrochloride	C			
	Movement Disorder						
	Palpitations						
	Vomiting						

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/21/01ISR Number: 3830063-3Report Type:Expedited (15-DaCompany Report #11530912
Age:76 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Acidosis Bradycardia Drug Interaction Drug Toxicity Speech Disorder	Health Professional Company Representative	Glucophage (Metformin Hcl)	PS		ORAL	1000 MILLIGRAM, 2/1 DAY ORAL
			Lithium (Lithium Salts)	SS		ORAL	300 MILLIGRAM, 2/1 DAY ORAL
			Nortriptyline	C			

Date:11/27/01ISR Number: 3830709-XReport Type:Expedited (15-DaCompany Report #A125617
Age:26 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Life-Threatening	Anxiety	Literature	Lithane Tablets	PS			1800.00 MG TOTAL:BID
Hospitalization - Initial or Prolonged	Diarrhoea Dizziness Drug Level Above Therapeutic Drug Toxicity Gait Disturbance Nausea Nystagmus Sedation Tremor	Health Professional	Herbal Diuretic	SS			
			Sertraline	C			
			Propranolol	C			
			Risperidone	C			
			Lorezepam	C			
			Hydroxizine	C			
			Over-The-Counter Sinus Medication (Unspecified)	C			

Date:11/28/01ISR Number: 3831393-1Report Type:Expedited (15-DaCompany Report #LBID00201004755
Age:56 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Atrioventricular Block Complete Sick Sinus Syndrome	Health Professional Company Representative	Lithobid (Lithium Carbonate) Lamictal (Lamotrigine)	PS SS		ORAL ORAL	DAILY PO, 900 MG PO 25 MG QD PO, 25 MG BID PO, 250 MG PO	

Date:11/29/01ISR Number: 3832502-0Report Type:Direct Company Report #
Age:40 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anorexia Blood Pressure Increased Body Temperature Increased Cognitive Disorder Drug Level Above Therapeutic Heart Rate Increased Mental Impairment Nausea Tremor		Lithium	PS				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/04/01ISR Number: 3834464-9Report Type:Expedited (15-DaCompany Report #2001027385-1
Age:83 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Biopsy Kidney Abnormal	Literature	Lithium	PS	Glaxosmithkline		400 MILLIGRAMS	
	Inguinal Hernia	Health						
	Nephrotic Syndrome	Professional	Deflazacort	C				
			Enalapril	C				
			Gliclazide	C				
			Levomepromazine	C				
			Lorazepam	C				
			Paroxetine	C				
			Prednisone	C				

Date:12/04/01ISR Number: 3834701-0Report Type:Expedited (15-DaCompany Report #APCDSS2001001339
Age:93 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Depressed Level Of Consciousness	Foreign Health	Risperdal (Unspecified)					
	Drug Interaction	Professional	(Risperidone)	PS		ORAL	SEE IMAGE	
	Dysphagia	Company	Lithium (Lithium)	SS		ORAL	SEE IMAGE	
	Hyperreflexia	Representative						
	Lethargy							
	Muscle Rigidity							
	Muscle Twitching							
	Musculoskeletal Stiffness							
	Neuroleptic Malignant Syndrome							
	Urinary Tract Infection							

Date:12/11/01ISR Number: 3839114-3Report Type:Expedited (15-DaCompany Report #LBID00201005043
Age:31 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Hospitalization - DAILY	Chest Pain	Foreign	Lithium (Lithium)	PS
Initial or Prolonged	Clonic Convulsion	Literature	Fluvoxamine	
	Difficulty In Walking	Other	(Fluvoxamine)	SS
150 MG DAILY,				
	Disturbance In Attention			
200 MG DAILY				
	Drug Interaction		Triazolam	
	Fatigue		(Triazolam)	C
	Hyperreflexia		Nitrazepam	
	Lethargy		(Nitrazepam)	C
	Nausea			
	Pyrexia			
	Sensory Loss			
	Serotonin Syndrome			
	Urinary Tract Infection			
	Vomiting			

Date:12/12/01ISR Number: 3840014-3Report Type:Expedited (15-DaCompany Report #HQ9037403DEC2001
Age:77 YR Gender:Male I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Confusional State
	Drug Interaction
	Therapeutic Agent
	Toxicity
	Tremor

	Vomiting						
Dose	Duration	Report Source	Product	Role	Manufacturer	Route	
		Health Professional	Effexor Xr (Venlafaxine Hydrochloride, Capsule, Extended Release)	PS		ORAL	
300 MG 1X PER 1 DAY, ORAL							
			Lithium (Lithium,)	SS			
			Toradol (Ketorolac Tromethamine,)	SS			
			Unspecified Non-Steroidal Anti-Inflammatory Agent(Unspecified)	SS			

Date:12/12/01ISR Number: 3840058-1Report Type:Expedited (15-DaCompany Report #2001-UK-02032UK(0)
Age:69 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	
Dose	Duration						
Hospitalization - Initial or Prolonged	Difficulty In Walking	Foreign	Micardis (Bibr 277)				
	Drug Level Increased	Health	(Nr) (Telmisartan)	PS		ORAL	
40 MG (40 MG DAILY)	2 MON						
	Fall	Professional					
		Other	Lithium Carbonate (Lithium Carbonate (Nr)	SS		ORAL	
400 MG (400 MG DAILY)							
			Clopixol (Clopenthixol Decanoate) (Nr)	C			
			Co-Amilofruse (Frumil) (Nr)	C			
			Procyclidine (Procyclidine) (Nr)	C			
			Glimepiride (Nr)	C			

Date:12/13/01ISR Number: 3838288-8Report Type:Expedited (15-DaCompany Report #303320
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Suicidal Ideation		Xenical	PS	Roche			
			Lithium	SS				
			Efexor	SS				

Date:12/13/01ISR Number: 3840331-7Report Type:Expedited (15-DaCompany Report #EMADSS2001005486
Age:48 YR Gender:Female I/FU:F

Outcome	PT
Life-Threatening	Blood Creatine Phosphokinase Increased
	Body Temperature Increased
	Catatonia
	Dysphagia
	Headache
	Muscle Rigidity
	Neuroleptic Malignant

Syndrome
Respiratory Failure
Speech Disorder

Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Foreign Study Health Professional	Risperidone (Unspecified) (Risperidone)	PS				
	Topiramate (Capsule) (Topiramate)	SS		ORAL	3 CAP, DAILY,	
	Placebo (Placebo)	SS		ORAL	3 CAP, DAILY,	
	Lithium (Lithium)	SS		ORAL	3 CAP, DAILY,	
	Lorazepam (Lorazepam)	C				
	Chloral Hydrate (Chloral Hydrate)	C				
	Diazepam (Diazepam)	C				
	Olanzapine (Olanzapine)	C				
	Senna (Senna)	C				
	Lactulose (Lactulose)	C				
	Haloperidol (Haloperidol)	C				
	Lithium Carbonate (Lithium Carbonate)	C				

PATIENT HAD PREVIOUSLY RECEIVED RISPERIDONE FROM

Date:12/17/01ISR Number: 3840327-5Report Type:Expedited (15-DaCompany Report #303320
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Suicidal Ideation	Foreign Health Professional	Xenical (Orlistat)	PS				
			Lithium (Lithium Nos)	SS				
			Efexor (Venlafaxine Hydrochloride)	SS				

Date:12/17/01ISR Number: 3841709-8Report Type:Direct Company Report #
Age:56 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged (DON'T KNOW STRENGTH)	Dehydration		Lithium	PS			1 QAM 2Q HRS	
	Drug Toxicity							
	Mental Impairment							
			Thiothixene	C				
			Depakote	C				
			Amoxicillin	C				
			Zoloft	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/18/01ISR Number: 3841098-9Report Type:Expedited (15-DaCompany Report #FLUV00301004962
Age:31 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Asthenia Chest Pain Clonic Convulsion	Foreign Literature Health	Depromel 50 (Fluvoxamine Maleate)	PS		ORAL	150 MG DAILY	
	Csf Protein Increased	Professional					PO	
	Depressed Level Of Consciousness	Other	Limas (Lithium Carbonate)	SS		ORAL	400 MG DAILY	
	Difficulty In Walking						PO	
	Disorientation		Halcion (Triazolam)	SS		ORAL	0.25 MG DAILY	
	Hyperreflexia						PO	
	Lethargy Medication Error		Benzalin (Nitrazepam)	SS		ORAL	10 MG DAILY	
	Memory Impairment						PO	
	Nausea Pyrexia Sensory Disturbance Serotonin Syndrome Urinary Tract Infection Vomiting White Blood Cell Count Increased							

Date:12/18/01ISR Number: 3841100-4Report Type:Expedited (15-DaCompany Report #LBID00201005043
Age:31 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Asthenia Chest Pain	Foreign Literature	Limas (Lithium Carbonate)	PS		ORAL	400 MG DAILY	
	Clonic Convulsion	Health					PO	
	Csf Protein Increased	Professional	Fluvoxamine					

	Depressed Level Of Consciousness Difficulty In Walking Disorientation Hyperreflexia Lethargy Medication Error Memory Impairment Nausea Pyrexia Sensory Disturbance Serotonin Syndrome Urinary Tract Infection Vomiting White Blood Cell Count Increased	Other	(Fluvoxamine) Halcion (Triazolam) Benzalin (Nitrazepam)	SS SS SS		ORAL 0.25 MG DAILY PO ORAL 10 MG DAILY PO	

Date:12/18/01ISR Number: 3841824-9Report Type:Expedited (15-DaCompany Report #2001-BP-04987RO (0)
Age:66 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Cerebrovascular Accident Fatigue Therapeutic Agent Toxicity	Consumer	Lithium Carbonate Capsules (Lithium Carbonate) Zyprexa (Olanzapine) Aspirin	PS C C		ORAL	PO/"ABOUT 2 YEARS"

Advair (Fluticasone/Salmetrol)	C
Ativan(Lorazepam)	C
Celexa (Citalopram)	C
Spironolactone (Spironolactone)	C
Sonata (Zaleplon)	C
Vioxx (Rofecoxib)	C
Vitamin C(Ascorbic Acid)	C
Vitamin D (Ergocalciferol)	C

Date:12/18/01ISR Number: 3841832-8Report Type:Expedited (15-DaCompany Report #2001-BP-05079RO (0)
Age:1 DY Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Congenital Anomaly	Congenital Anomaly Craniosynostosis Drug Level Above Therapeutic Maternal Drugs Affecting Foetus Spine Malformation	Consumer	Lithium Carbonate Capsules (Lithium Carbonate) Vitamins (Vitamins)	PS C		INTRA-UTERINE	IU	

Date:12/19/01ISR Number: 3842299-6Report Type:Expedited (15-DaCompany Report #A129287
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Anxiety Obsessive-Compulsive Disorder Renal Disorder Suicidal Ideation Weight Decreased	Consumer	Lithane Tablets	PS				

Date:12/19/01ISR Number: 3842307-2Report Type:Expedited (15-DaCompany Report #A126997
Age:39 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Convulsion	Health Professional	Ziprasidone Po	PS		ORAL	120.00 MG	TOTAL: DAILY:
Required	Drug Interaction							
Intervention to Prevent Permanent Impairment/Damage	Drug Level Above Therapeutic		Desipramine	SS		ORAL	300.00 MG	TOTAL: DAILY:
	Epilepsy							
	Medication Error							
			Lithobid	SS				
			Lorazepam	C				
			Synthroid (Levothyroxine)	C				
			Wellbutrin (Bupropion)	C				
			Loestrin	C				
			Chinese Herbs	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/19/01ISR Number: 3842564-2Report Type:Expedited (15-DaCompany Report #NSADSS2001031572
Age:63 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Condition Aggravated Confusional State Coordination Abnormal	Foreign Study Health Professional	Topiramate (Tablet (Bipolar) (Topiramate)	PS		ORAL	200 MG DAILY, ORAL	
	Drug Level Increased							
	Mania		Lithium (Lithium)	SS		ORAL	900 MG, NIGHT (S), ORAL	
			Amantadine (Amantadine)	C				
			Propanolol (Propanolol)	C				
			Oxazepam (0xazepam)	C				

Date:12/19/01ISR Number: 3842681-7Report Type:Expedited (15-DaCompany Report #2001028574-1
Age:56 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Accidental Overdose Confusional State Dehydration	Health Professional	Lithium	PS			909 MILLIGRAMS 2.0 DAILY	30 YR
	Drug Level Above Therapeutic Drug Toxicity							

Date:12/20/01ISR Number: 3843291-8Report Type:Direct Company Report #
Age:24 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hallucination, Auditory		Haldol Decanoate	PS		INTRAMUSCULAR	75MG IM	

	Suicidal Ideation		Lithium Carbonate	SS		ORAL

600-600-300MG

PO (SEE

IMAGE)

Date:12/24/01ISR Number: 3843957-XReport Type:Expedited (15-DaCompany Report #LBID00201004755
Age:56 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Atrioventricular Block Complete	Health Professional	Lithobid (Lithium Carbonate)	PS		ORAL	900 MG DAILY	
	Sick Sinus Syndrome	Company					PO	
		Representative	Lamictal (Lamotrigine)	SS		ORAL	SEE IMAGE	2 WK
			Folic Acid (Folic Acid)	C				
			Synthroid (Levothyroxine Sodium)	C				
			Prozac (Fluoxetine Hydrochloride)	C				
			Trazodone (Trazodone)	C				
			Concerta (Methylphenidate - Slow Release)	C				

Date:12/24/01ISR Number: 3843965-9Report Type:Expedited (15-DaCompany Report #LBID00201005124
Age:55 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Drug Level Below Therapeutic	Health Professional	Lithobid (Lithium Carbonate)	PS		ORAL	PO
	Drug Toxicity		Trazodone				
	Dry Skin		(Trazodone)	C			
	Haemorrhage Subcutaneous		Nortriptyline (Nortriptyline)	C			
			Nexium (Omeprazole)	C			
			Trileptal (Oxcarbazepine)	C			
			Norvasc (Amlodipine Besilate)	C			
			Hyzaar	C			

Date:12/24/01ISR Number: 3844430-5Report Type:Expedited (15-DaCompany Report #LBID00201005103
Age:10 MON Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Congenital Anomaly	Complications Of Maternal Exposure To Therapeutic	Consumer	Lithobid (Lithium Carbonate)	PS			DAILY PL
	Drugs						
	Maternal Drugs Affecting Foetus						
	Pregnancy						
	Skull Malformation						
	Spine Malformation						

Date:12/26/01ISR Number: 3844970-9Report Type:Expedited (15-DaCompany Report #A125638
Age:51 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Demyelination	Foreign	Zoloft Tablets	PS		ORAL	250.00 MG TOTAL:DAILY:O
	Fall	Health					

	Gait Disturbance	Professional			
RAL					
	Parkinson'S Disease		Melperone	SS	ORAL
25.00 MG					
	Restlessness				
TOTAL:DAILY:O					
RAL					
			Lithium Carbonate	SS	ORAL
900.00 MG					
TOTAL:DAILY:O					
RAL					
			Oxazepam	C	
			Chlormethiazole	C	
			Ass (Acetylsalicylic Acid)	C	
			Metoprolol	C	
			Diltiazem	C	
			Enalapril	C	

Date:12/26/01ISR Number: 3844982-5Report Type:Expedited (15-DaCompany Report #A129265
Age:41 YR Gender:Male I/FU:I

Outcome
Hospitalization -
Initial or Prolonged
Required
Intervention to

Prevent Permanent
Impairment/Damage

	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Aggression	Literature	Lithane Tablets	PS				
	Cushingoid	Health	Clozapine	SS				
	Leukocytosis	Professional	Thioridiazine	C				
	Paranoia							
	Psychiatric Symptom							

Date:12/26/01ISR Number: 3845293-4Report Type:Expedited (15-DaCompany Report #FLUV00301004962
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Chest Pain	Foreign	Depromel 50					
	Difficulty In Walking	Literature	(Fluvoxamine					
	Fatigue	Health	Maleate)	PS		ORAL	150MG DAILY	
	Lethargy	Professional					PO	
	Pyrexia	Other	Limas (Lithium					
	Sensory Disturbance		Carbonate)	SS		ORAL	400 MG DAILY	
	Serotonin Syndrome						PO; 400 MG	
	Urinary Retention						DAILY PO	
	Urinary Tract Infection		Pollakisu					
	Vomiting		(Oxybutynin					
			Hydrochloride)	C				
			Halcion (Triazolam)	C				
			Benzalin					
			(Nitrazepam)	C				

Date:12/27/01ISR Number: 3864071-3Report Type:Periodic Company Report #WAES 01082050
Age:70 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Epigastric Discomfort	Consumer	Tab Vioxx 12.5 Mg	PS		ORAL	12.5	

	Tremor					
MG/DAILY/PO						
			Eskalith	SS		ORAL
12.5						
MG/DAILY/PO						
			Sinemet	C		
			Tums	C		
			Ultram	C		

Date:12/31/01ISR Number: 3845964-XReport Type:Direct Company Report #CTU 157967
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Decreased Activity		Lithium (300mg)	PS		ORAL	900MG/D PO	
Initial or Prolonged	Drug Toxicity		Risperidone (2mg)	SS		ORAL	2MG BID PO	
	Dysarthria		Propoxyphene	C				
	Swelling							
	Toxicologic Test Abnormal							

Date:12/31/01ISR Number: 3846020-7Report Type:Direct Company Report #CTU 158056
Age:81 YR Gender:Male I/FU:I

Outcome	PT
Hospitalization -	Diarrhoea
Initial or Prolonged	Drug Toxicity
	Gait Disturbance

		Medication Error Renal Failure Acute Tremor	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
			Health Professional	Lithium Carbonate 300mg	PS		ORAL
300MG BID							
ORAL							

Date:12/31/01ISR Number: 3847105-1Report Type:Expedited (15-DaCompany Report #A124605
Age:15 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Life-Threatening	Acute Prerenal Failure	Health	Ziprasidone Po	PS		ORAL
40.00 MG						
Hospitalization -	Agitation	Professional				
TOTAL:DAILY:O						
Initial or Prolonged	Anxiety					
RAL						
Disability	Blood Creatine		Lithium Carbonate	SS		ORAL
300.00 MG						
Required	Phosphokinase Increased					
TOTAL:DAILY:O						
Intervention to	Cognitive Disorder					
RAL						
Prevent Permanent	Depressed Level Of		Eskalith (Lithium			
Impairment/Damage	Consciousness		Carbonate)	SS		ORAL
450.00 MG						
	Disorientation					
TOTAL:DAILY:O						
	Dysarthria					
RAL						
	Dyskinesia		Paxil (Paroxetine)	SS		ORAL
25.00 MG						
	Dysphagia					
TOTAL:DAILY:O						
	Hallucination					
RAL						
	Hostility		Clonidine	C		
	Incoherent		Estradiol	C		
	Irritability		Trazodone	C		
	Motor Dysfunction		Vitamin B6	C		
	Muscle Twitching		Ferrous			

	Musculoskeletal Stiffness		Fumarate/Docusate	C	
	Neuroleptic Malignant Syndrome		Risperidone	C	
	Oliguria				
	Screaming				
	Tearfulness				
	Tic				
	White Blood Cell Count Increased				

Date:01/02/02ISR Number: 3847444-4Report Type:Expedited (15-DaCompany Report #2001025965-1
Age:51 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Areflexia	Health Professional	Quilonum Retard (Lithium)					
Other	Chills							
	Fall		Glaxosmithkline	PS	Glaxosmithkline	ORAL	900	MILLIGRAMS
	Gait Disturbance							
	Parkinsonism							
							ORAL	3 MON
	Restlessness		Ass (Acetylsalicylic Acid)	C				
			Beloc Zok (Metoprolol Succinate)	C				
			Dilzem (Diltiazem Hydrochloride)	C				
			Distraneurin (Clomethiazol)	C				
			Eunerpan (Melperon Hydrochloride)	C				

			Oxazepam	C		
			Xanef (Elanapril Maleate)	C		
			Zoloft (Sertralin Hydrochloride)	C		

Date:01/02/02ISR Number: 3847669-8Report Type:Expedited (15-DaCompany Report #2001029998-1
Age:59 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dizziness Dry Mouth Fatigue Memory Impairment		Lithium Glaxosmithkline	PS	Glaxosmithkline	ORAL	800 MILLIGRAMS ORAL	
			Citalopram (Cipramil)	C				
			Diclofenac	C				
			Dihydrocodeine	C				
			Oxybutynin	C				

Date:01/02/02ISR Number: 3847672-8Report Type:Expedited (15-DaCompany Report #2001030000-1
Age:86 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Disability	Confusional State Diabetes Insipidus Drug Level Increased Hypernatraemia		Lithium Glaxosmithkline	PS	Glaxosmithkline	ORAL	800 MILLIGRAMS ORAL	
			Frusemide	C				
			Haloperidol	C				
			Thyroxine	C				

Date:01/04/02ISR Number: 3847814-4Report Type:Expedited (15-DaCompany Report #304132
Age:40 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Large Intestinal Ulcer	Health	Tamiflu	PS	Roche			3 DAY
		Professional	Lexotan	SS	Roche			
			Limas	SS				
			Cefzon	SS				2 DAY
			Loxonin	SS				2 DAY

Date:01/04/02ISR Number: 3848250-7Report Type:Periodic Company Report #01-05-0261
Age:32 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Grand Mal Convulsion	Health	Clozapine - Ivax Pharmaceuticals,					
		Professional	Inc. Tablets	PS	Ivax Pharmaceuticals, Inc.	ORAL	700 MG QD	ORAL
			Lithium Tablets	SS		ORAL	900 MG QD	ORAL
			Navane	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/07/02ISR Number: 3849058-9Report Type:Direct Company Report #CTU 158487
Age:53 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abnormal Behaviour Delirium Drug Toxicity		Lithium Carbonate(300mg)	PS			900MG QD	

Date:01/07/02ISR Number: 3849070-XReport Type:Direct Company Report #CTU 158481
Age:51 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Coordination Abnormal Diarrhoea Fall Tremor		Lithium (300mg)	PS			1800MG QD	

Date:01/07/02ISR Number: 3849155-8Report Type:Direct Company Report #CTU 158477
Age:77 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Confusional State Dehydration Hypernatraemia Nausea Vomiting	Health Professional	Lithium Carbonate	PS			300 MG BID	

Date:01/07/02ISR Number: 3849157-1Report Type:Direct Company Report #CTU 158418
Age:44 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Toxicity Tremor		Lithium (300mg) Ibuprofen	PS C			600MG BID	

			Fluoxetine	C		

Date:01/08/02ISR Number: 3849931-1Report Type:Expedited (15-DaCompany Report #304132
Age:40 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Large Intestinal Ulcer	Foreign Health Professional	Tamiflu (Oseltamivir)	PS		ORAL	150 MG DAILY;	
			Lexotan (Bromazepam)	SS		ORAL	2 MG DAILY;	
			Limas (Lithium Carbonate)	SS		ORAL	400 MG DAILY;	
			Cefzon (Cefdinir)	SS		ORAL	300 MG DAILY;	
			Loxonin (Loxoprofen)	SS		ORAL	180 MG DAILY;	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/08/02ISR Number: 3850557-4Report Type:Direct Company Report #CTU 158695
Age:50 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Mental Status Changes Neck Pain		Lithium 900mg	PS				

Date:01/08/02ISR Number: 3850882-7Report Type:Expedited (15-DaCompany Report #2001030025-1
Age:68 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Hospitalization - Initial or Prolonged	Blood Creatinine Increased Blood Sodium Increased Blood Urea Increased Deep Vein Thrombosis Faecaloma Nephrogenic Diabetes Insipidus Tongue Coated Urine Osmolarity Decreased	Literature Health Professional	Lithium Glaxosmithkline	PS	Glaxosmithkline		600 MILLIGRAMS	

Date:01/10/02ISR Number: 3851473-4Report Type:Expedited (15-DaCompany Report #LBID00202000039
Age:45 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Anxiety Confusional State Convulsion Depression Insomnia Somnolence	Literature Health Professional	Lithium (Lithium) Venlafaxine	PS		ORAL	300 MG BID PO, 900 MG DAILY PO, 1200 MG DAILY	PO 1 DAY

		(Venlafaxine)	SS		ORAL
150 MG BID PO					
		Bupropion (Bupropion)	SS		ORAL
100 MG BID					
PO, 300 MG					
DAILY PO, 200					
MG DAILY PO					
		Gabapentin (Gabapentin)	C		
		Clonazepam (Clonazepam)	C		
		Glycopyrrolate (Glycophyrrolate)	C		
		Methotexital (Methohexital)	C		
		Succinylcholine (Succinylcholine Chloride)	C		
		Oxygen (Oxygen)	C		

Date:01/14/02ISR Number: 3852023-9Report Type:Direct Company Report #CTU 159017
Age:54 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Agitation Delirium		Lithium	PS				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/14/02ISR Number: 3852038-0Report Type:Direct Company Report #CTU 159050
Age:70 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Arrhythmia		Sulindac	PS				
	Dehydration		Lithium	SS				
	Diabetes Mellitus							
	Drug Toxicity							
	Pharmaceutical Product Complaint							
	Renal Failure Acute							

Date:01/16/02ISR Number: 3853273-8Report Type:Direct Company Report #CTU 159359
Age:53 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Mental Status Changes		Lithium	PS			300 MG TID	
			Temazepam	C				
			Risperidone	C				
			Terazosin	C				
			Hctz	C				

Date:01/16/02ISR Number: 3853379-3Report Type:Direct Company Report #CTU 159324
Age:24 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blood Prolactin Increased		Haldol Decanoate	PS				
INTRAMUSCULAR	75 MG IM							
	Hallucination, Auditory		Lithium Carbonate	SS		ORAL	600-600-300	
	Homicidal Ideation						MG PO	
	Suicidal Ideation		Haldol Decanoate	C				

Date:01/17/02ISR Number: 3855102-5Report Type:Expedited (15-DaCompany Report #WAES 0201FRA00016
Age:85 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Confusional State Drug Interaction Drug Level Above Therapeutic Haemodialysis Tremor Urinary Retention	Foreign Health Professional Other	Vaseretic (Enalapril Maleate-Hctz) Lithiumco3	PS SS		ORAL ORAL	20.12.5 MG/DAILY, PO 625 MG/DAILY, PO	

Date:01/17/02ISR Number: 3855724-1Report Type:Direct Company Report #CTU 159578
Age:59 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Cognitive Disorder Confusional State Coordination Abnormal Disorientation Drug Toxicity Memory Impairment Tremor		Lithium	PS		ORAL	600 MG BID ORAL	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/18/02ISR Number: 3854117-0Report Type:Expedited (15-DaCompany Report #A0171401A
Age:56 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Atrioventricular Block		Lamictal	PS	Glaxo Wellcome	ORAL	250MG Per day	MON
Initial or Prolonged	Complete		Lithobid	SS	Glaxo Wellcome	ORAL	900MG Per day	MON
	Sick Sinus Syndrome							

Date:01/22/02ISR Number: 3856677-2Report Type:Direct Company Report #CTU 159681
Age:78 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Asthenia		Lithium Carbonate					
Initial or Prolonged	Bradycardia		300 Mg	PS		ORAL	30MG BID	
	Decreased Appetite							
ORAL								
	Drug Level Above Therapeutic							
	Drug Toxicity							
	Dysarthria							
	Fatigue							
	Polydipsia							
	Polyuria							
	Tremor							
	Vomiting							

Date:01/23/02ISR Number: 3859351-1Report Type:Expedited (15-DaCompany Report #2002000438-1
Age:59 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Compulsions	Literature	Lithium					
Initial or Prolonged	Disorientation	Health	Glaxosmithkline	PS	Glaxosmithkline			
Other	Disturbance In Attention	Professional	Haloperidol	C				
	Electroencephalogram		Carbamazapine	C				
	Abnormal		Olnazapine	C				
	Encephalopathy							
	Faecal Incontinence							

	Memory Impairment
	Obsessive Thoughts
	Thinking Abnormal

Date:01/23/02ISR Number: 3859638-2Report Type:Direct Company Report #CTU 159954
Age:56 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Dialysis		Lithium 450 Mg	PS		ORAL	450 MG	BID
Hospitalization - Initial or Prolonged	Drug Effect Decreased					ORAL		
Required Intervention to Prevent Permanent Impairment/Damage	Therapeutic Agent Toxicity							

Date:01/23/02ISR Number: 3859796-XReport Type:Periodic Company Report #NSADSS2001003095
Age:78 YR Gender:Female I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Asthenia
	Confusional State

	Disturbance In Attention Extrapyramidal Disorder Infection	Report Source	Product	Role	Manufacturer	Route Dose Duration
	Mania	Health Professional	Risperdal (Tablet) (Risperidone)	PS		ORAL 0.5 MG, 1 IN 1 DAY(S), ORAL : 1.5 MG DAILY ORAL
		Company Representative				
			Eskalith (Lithium Carbonate)	SS		ORAL 450 MG, 2 IN 1 DAY(S), ORAL
			Neurontin (Gabapentin)	C		
			Paxil (Paroxetine Hydrochloride)	C		
			Premarin (Estrogens Conjugated)	C		
			Detrol (Tolterodine L-Tartrate)	C		
			Lorazepam (Lorazepam)	C		

Date:01/23/02ISR Number: 3860152-9Report Type:Expedited (15-DaCompany Report #A200759
Age:31 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Hospitalization - Initial or Prolonged	Asthenia Chest Pain Csf Protein Increased	Foreign Health Professional	Lithane Tablets	PS		ORAL 400.00 MG TOTAL:DAILY:O RAL
	Difficulty In Walking		Fluvoxamine	SS		150.00 MG

	Fatigue					
TOTAL:DAILY						
	Insomnia		Triazolam	SS		ORAL
0.25 MG						
	Lethargy					
TOTAL:DAILY:O						
	Medication Error					
RAL						
	Pyrexia		Nitrazepam	SS		ORAL
10.00 MG						
	Sensory Disturbance					
TOTAL:DAILY:O						
	Serotonin Syndrome					
RAL						
	Urinary Tract Infection					
	Vomiting					
	White Blood Cell Count Increased					

Date:01/23/02ISR Number: 3860474-1Report Type:Direct Company Report #CTU 160150
Age:47 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
	Medication Error		Lithium Carbonate 300mg Roxane Labs	PS	Roxane Labs	ORAL
300MG 2 X DAY						
ORAL						

Date:01/24/02ISR Number: 3858316-3Report Type:Expedited (15-DaCompany Report #2002000441-1
Age:45 YR Gender:Male I/FU:I

Outcome	PT
Other	Anxiety
	Confusional State
	Convulsion

	Insomnia						
	Somnolence						
		Report Source	Product	Role	Manufacturer	Route	Dose Duration
		Literature	Lithium				
		Health	Glaxosmithkline	PS	Glaxosmithkline	ORAL	300
		Professional					MILLIGRAMS
							2.0 DAILY
							ORAL ; ORAL ;
						ORAL	3 DAY
			Bupropion	C			
			Venlafaxine	C			
			Gabapentin	C			
			Clonazepam	C			
			Glycopyrrolate	C			
			Methohexital	C			
			Succinylcholine	C			

Date:01/24/02ISR Number: 3860064-0Report Type:Expedited (15-DaCompany Report #2002000437-1
Age:55 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Other	Clonic Convulsion		Lithium				
	Pyrexia		Glaxosmithkline	PS	Glaxosmithkline		
			Clozapril (Clozapine)	C			

Date:01/24/02ISR Number: 3860176-1Report Type:Expedited (15-DaCompany Report #2002000756-1
Age:52 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Bipolar Disorder	Literature	Lithium				
	Blood Creatine Increased	Health	Glaxosmithkline	PS	Glaxosmithkline		1225
	Blood Creatinine	Professional					MILLIGRAM

Increased	Carbamazepine	C	
Blood Osmolarity	Lorazepam	C	
Increased	Perazine	C	
Coma	Valproate	C	
Consciousness Fluctuating	Zotepine	C	
Drug Ineffective			
Drug Toxicity			
Hypernatraemia			
Mania			
Movement Disorder			
Nephrogenic Diabetes			
Insipidus			
Somnolence			

Date:01/25/02ISR Number: 3857889-4Report Type:Expedited (15-DaCompany Report #304132
Age:40 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Peritonitis		Tamiflu	PS	Roche		3	DAY
			Lexotan	SS	Roche		917	DAY
			Limas	SS			917	DAY
			Cefzon	SS			2	DAY
			Loxonin	SS			2	DAY

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/28/02ISR Number: 3858992-5Report Type:Expedited (15-DaCompany Report #A0171401A
Age:56 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Atrioventricular Block		Lamictal	PS	Glaxo Wellcome	ORAL	350MG Per day	MON
	Complete		Lithobid	SS	Glaxo Wellcome	ORAL	900MG Per day	YR
	Chest Pain		Folic Acid	C				
	Dizziness		Synthroid	C	Glaxo Wellcome			
	Drug Interaction		Prozac	C				
	Dyspnoea		Trazodone	C				
	Fatigue		Concerta	C				
	Heart Rate Decreased		Nsaid	C				
	Nausea							
	Sensation Of Heaviness							
	Sick Sinus Syndrome							

Date:01/28/02ISR Number: 3861159-8Report Type:Expedited (15-DaCompany Report #EMADSS2001005486
Age:48 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Blood Creatine Phosphokinase Increased	Foreign Study	Risperidone (Unspecified)					
	Body Temperature Increased	Health Professional	(Risperidone)	PS			PATIENT HAD PREVIOUSLY RECEIVED RISPERIDONE FROM	
	Catatonia							
	Dysphagia							
	Headache							
	Muscle Rigidity		Topiramate (Capsule)					
	Neuroleptic Malignant Syndrome		(Topiramate)	SS		ORAL	3 CAP DAILY, ORAL	
	Respiratory Failure		Placebo (Placebo)	SS		ORAL	3 CAP, DAILY, ORAL	
	Speech Disorder							

Lithium (Lithium)	SS
Lorazepam (Lorazepam)	C
Chloral Hydrate (Chloral Hydrate)	C
Diazepam (Diazepam)	C
Olanzapine (Olanzapine)	C
Senna (Senna)	C
Lactulose (Lactulose)	C
Haloperidol (Haloperidol)	C
Lithium Carbonate (Lithium Carbonate)	C

Date:01/28/02ISR Number: 3862202-2Report Type:Expedited (15-DaCompany Report #A0172394A
Age:45 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Anxiety	Literature	Wellbutrin Tablet (Bupropion Hydrochloride)	PS		ORAL	ORAL	
	Confusional State	Health Professional						
	Convulsion							
	Depression		Lithium Salt (Lithium Salt)	SS				
	Drug Ineffective							
	Insomnia		Venlafaxine Hydrochloride (Venalfaxine					
	Somnolence							

			Hydrochloride)	SS			
150 MG/TWICE PER DAY							
			Electroconvulsive Therapy (Electroconvulsive Therapy)	SS			
SEE DOSAGE TEXT							
			Gabapentin	C			
			Clonazepam	C			
			Glycopyrronium Bromide	C			
			Methohexitone	C			
			Suxamethonium	C			
			Oxygen	C			
			Citalopram	C			

Date:01/29/02ISR Number: 3861835-7Report Type:Expedited (15-DaCompany Report #304132
Age:40 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Abdominal Pain Upper	Foreign	Tamiflu					
	Diarrhoea	Health	(Oseltamivir) 75 Mg	PS		ORAL	75 MG 2 PER 1	DAY; ORAL
	Influenza	Professional						
	Laboratory Test Abnormal		Lexotan (Bromazepam)	SS		ORAL	1 MG 2 PER 1	DAY; ORAL
	Large Intestinal Ulcer							
	Peritonitis		Limas (Lithium					
	Shock		Carbonate)	SS		ORAL	200 MG 2 PER	1 DAY; ORAL
	White Blood Cell Count							
	Abnormal		Cefzon (Cefdinir)	SS		ORAL	100 MG 3 PER	1 DAY; ORAL
			Loxonin (Loxoprofen)					
			60 Mg	SS		ORAL	60 MG 3 PER 1	

DAY; ORAL

Date:02/01/02ISR Number: 3864566-2Report Type:Expedited (15-DaCompany Report #FLUV00301004962
Age: Gender:Female I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Angina Pectoris
	Asthenia
	Blood Lactate Dehydrogenase Decreased
	Blood Urea Decreased
	Blood Urine Present
	Csf Protein Increased
	Depression
	Difficulty In Walking
	Drug Interaction
	Drug Level Decreased
	Dysuria
	Electroencephalogram Abnormal
	Fatigue
	Headache
	Insomnia
	Lethargy
	Medication Error
	Overdose
	Sensory Disturbance
	Serotonin Syndrome

	Urinary Tract Infection Vomiting						
		Report Source	Product	Role	Manufacturer	Route	Dose Duration
		Foreign Literature Health Professional	Depromel 50 (Fluvoxamine Maleate)	PS		ORAL	150 MG DAILY PO
		Other	Limas (Lithium Carbonate)	SS		ORAL	400 MG DAILY PO, 400 MG DAILY PO
			Pollakisu (Oxybutynin Hydrochloride)	C			
			Halcion (Triazolam)	C			
			Benzalin (Nitrazepam)	C			

Date:02/04/02ISR Number: 3863835-XReport Type:Direct Company Report #CTU 160716
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Difficulty In Walking Hypotension Malaise		Lithium Carbonate Triamterene/Hctz Lisinopril	PS C C		ORAL	300MG PO BID 5 WK

Date:02/05/02ISR Number: 3863204-2Report Type:Expedited (15-DaCompany Report #B0117185A
Age:55 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Death	Agitation Arrhythmia		Salbutamol	PS	Glaxo Wellcome	RESPIRATORY (INHALATION)	

	Atherosclerosis	Depixol	SS		
UNKNOWN	60MG Weekly				
	Bipolar I Disorder	Quetiapine	SS		ORAL
225MG per day					
	Blood Phosphorus	Sandocal	SS		
UNKNOWN	400MG Three				
	Increased				
times per day					
	Confusional State	Ramipril	SS		
UNKNOWN	1.25MG In the				
	Delusion				
morning					
	Drug Level Above	Alfacalcidol	SS		
UNKNOWN	1MCG Per day				
	Therapeutic	Diazepam	SS		
UNKNOWN	5MG Three				
	Incoherent				
times per day					
	Irritability	Procyclidine	SS	Glaxo Wellcome	
UNKNOWN	5MG Three				
	Sudden Death				
times per day					
		Chlorpromazine Hydrochloride	SS	Glaxo Wellcome	
UNKNOWN					
		Lorazepam	SS		
PARENTERAL					
		Lithium	SS		
UNKNOWN	15 DAY				

Date:02/05/02ISR Number: 3863207-8Report Type:Expedited (15-DaCompany Report #B0121705A
Age:55 YR Gender:Male I/FU:F

Outcome	PT
Death	Agitation
	Arrhythmia
	Atherosclerosis
	Bipolar I Disorder
	Confusional State
	Incoherent

Irritability
Sudden Death

Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Salbutamol	PS	Glaxo Wellcome	RESPIRATORY (INHALATION)		
	Procyclidine	SS	Glaxo Wellcome	UNKNOWN	5MG	Three times per day
	Flupenthixol	SS		UNKNOWN	60MG	Weekly
	Quetiapine	SS		UNKNOWN	225MG	See dosage text
	Sandocal	SS		UNKNOWN	400MG	Three times per day
	Ramipril	SS		UNKNOWN	1.25MG	In the morning
	Alfacalcidol	SS		UNKNOWN	1MCG	Per day
	Diazepam	SS		UNKNOWN	5MG	Three times per day
	Chlorpromazine Hydrochloride	SS	Glaxo Wellcome	UNKNOWN		
	Lorazepam	SS		PARENTERAL		
	Lithium	SS		UNKNOWN	15	DAY

Date:02/05/02ISR Number: 3864130-5Report Type:Direct Company Report #CTU 160866
Age:49 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Hospitalization -	Aggression		Lithium Carbonate	PS		
300 MG CAP						
Initial or Prolonged	Akinesia					
BID						
	Apathy		Depakote	C		
	Catatonia		Trazodone	C		
	Confusional State		Albuterol	C		
	Coordination Abnormal		Beclomethasone	C		
	Disorientation		Prozac	C		
	Pupil Fixed		Glyburide	C		
	Sluggishness		Triamcinolone	C		
	Speech Disorder		Simvastatin	C		
			Lisinopril	C		

Date:02/06/02ISR Number: 3866412-XReport Type:Expedited (15-DaCompany Report #2002AP00267
Age:44 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Required	Drug Interaction	Foreign	Lithium	PS			1200 MG DAILY
Intervention to	Heart Rate Decreased	Literature	Propofol	SS			50 MG DAILY
Prevent Permanent	Hypothyroidism	Health	Fentanyl	SS			100 UG DAILY
Impairment/Damage	Sinus Arrhythmia	Professional Other	Unspecified	C			

Date:02/08/02ISR Number: 3866657-9Report Type:Direct Company Report #CTU 161280
Age:91 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Delirium		Lithium	PS		ORAL	225MG BID
Initial or Prolonged	Drug Level Increased						ORAL
	Dysarthria		Vioxx	C			
	Sedation						

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/12/02ISR Number: 3866887-6Report Type:Expedited (15-DaCompany Report #US-BRISTOL-MYERS SQUIBB COMPANY-11712270
Age:52 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Coma		Prolixin Inj	PS	Apothecon			"for years"
			Lithium	SS				"for years"

Date:02/12/02ISR Number: 3869605-0Report Type:Expedited (15-DaCompany Report #02P-087-0115047-00
Age:40 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Disability	Abdominal Pain Upper	Foreign	Cefzon (Omnicef)					
	Cough	Health	(Cefdinir)					
	Diarrhoea	Professional	(Cefdinir)	PS		ORAL	300 MG, 1 IN	1 D, PER ORAL
	Large Intestinal Ulcer	Other						
	Peritonitis		Lithium Carbonate	SS		ORAL	200 MG, 2 IN	1 D, PER ORAL
	Pharyngolaryngeal Pain							
	Pyrexia		Bromazepam	SS		ORAL	1 MG, 2 IN 1	D, PER ORAL
	Shock							
			Loxoprofen Sodium	SS		ORAL	60 MG, 3 IN 1	D, PER ORAL
			Oseltamivir	SS		ORAL	75 MG, 2 IN 1	D, PER ORAL

Date:02/13/02ISR Number: 3869989-3Report Type:Expedited (15-DaCompany Report #2002AP00330
Age:69 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Required	Alanine Aminotransferase	Foreign	Tenormin	PS		ORAL
50 MG QD PO						
Intervention to	Increased	Health	Sertraline	SS		ORAL
50 MG BID PO						
Prevent Permanent	Amnesia	Professional	Lithium Sulphate	SS		ORAL
42 MG BID PO						
Impairment/Damage	Aspartate	Other	Sibutramine	SS		ORAL
10 MG QD PO						
	Aminotransferase		Isradipine	C		
	Increased		Simvastatin	C		
	Blood Alkaline		Amiloride	C		
	Phosphatase Increased		Omeprazole	C		
	Blood Amylase Increased		Losartan	C		
	Blood Lactate		Furosemide	C		
	Dehydrogenase Decreased					
	Bradycardia					
	Dizziness					
	Dysphasia					
	Gamma-Glutamyltransferase					
	Abnormal					
	Hypotension					
	Tremor					

Date:02/13/02ISR Number: 3870278-1Report Type:Expedited (15-DaCompany Report #PHBS2002AU01746
Age:32 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Other	Blood Sodium Decreased	Foreign	Lamisil (Terbinafine			
	Drug Interaction	Health	Hydrochloride)			
	Drug Level Increased	Professional	Tablet	PS		ORAL
250 MG, QD,						
	Pitting Oedema	Other				
ORAL						
	Therapeutic Agent		Lithium (Lithium)	SS		
1) 1350 QD;						
	Toxicity					
2) 900 MG, QD						
	Water Intoxication		Modifast	C		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/13/02ISR Number: 3872280-2Report Type:Periodic Company Report #2014463
Age:30 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Intentional Misuse	Health	Oxycontin Cr Tablets	PS		ORAL	MG ONCE PO	
	Nausea	Professional	Oxyfast Oral Concentrate Solution					
	Somnolence	Other	20 Mg/1ml	SS		ORAL	25 ML ONCE PO	
	Vomiting		Citalopram	SS			MG ONCE	
			Darvocet (Propoxyphene/Acetaminophen)	SS		ORAL	MG ONCE PO	
			Effexor (Venlafaxine)	SS			150 MG	
			Eskalith (Lithium Carbonate)	SS		ORAL	5 MG QD PO	
			Proscar	C				

Date:02/13/02ISR Number: 3872400-XReport Type:Periodic Company Report #2014033
Age:19 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Consumer	Oxycontin Cr Tablets, 10 Mg (Oxycodone Hydrochloride)	PS			MG	
	Drug Interaction	Health Professional Other	Valium (Diazepam)	SS				
			Depakote (Divalproex Sodium)	SS				
			Valproic Acid	SS				
			Lithium	SS				

Date:02/19/02ISR Number: 3872924-5Report Type:Expedited (15-DaCompany Report #A129154
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Jaundice Weight Increased	Health Professional	Zoloft Tablets Lithium	PS SS			BID	
			Prolixin	SS			5.00 MG	
							TOTAL:DAILY	
			Depakote	SS				
			Cogentin	C				
			Paxil	C				
			Trazodone	C				
			Prozac	C				
			Celexa	C				
			Wellbutrin	C				
			Zyprexa	C				
			Ecstasy	C				

Date:02/20/02ISR Number: 3873391-8Report Type:Expedited (15-DaCompany Report #A0358791A
Age:49 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Communication Disorder Feeling Of Despair Loss Of Libido Suicidal Ideation Suicide Attempt	Consumer	Paxil (Paroxetine Hydrochloride) Paroxetine Hydrochloride 60 Mg (Paroxetine	PS		ORAL	20 MG/ORAL	

			Hydrochloride)	SS			ORAL
ORAL							
			Lithium Salt (Lithium Salt)	SS			
			Olanzapine (Olanzapine)	SS			

Date:02/21/02ISR Number: 3871497-0Report Type:Expedited (15-DaCompany Report #US-BRISTOL-MYERS SQUIBB COMPANY-11712270
Age:52 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Coma		Prolixin Decanoate Inj	PS	Apothecon			"for years"
			Lithium	SS				"for years"

Date:02/22/02ISR Number: 3874148-4Report Type:Expedited (15-DaCompany Report #A0358950A
Age:72 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Balance Disorder	Health Professional	Eskalith (Lithium Carbonate)	PS		ORAL	600 MG/ TWICE PER DAY/ ORAL	
	Confusional State							
	Drug Level Above Therapeutic	Company Representative	Paroxetine Hydrochloride	C				
	Mental Disorder Due To A General Medical Condition		Semisodium Valproate	C				
	Mental Impairment							
	Tremor							

Date:02/22/02ISR Number: 3874510-XReport Type:Expedited (15-DaCompany Report #A0358952A
Age:60 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Nephritis Interstitial	Health Professional	Eskalith (Lithium Carbonate)	PS		ORAL	ORAL	
	Nephrogenic Diabetes							

	Insipidus		Quetiapine Fumarate	C			
			Lamotrigine	C			
			Magnesium Hydroxide	C			
			Eye Medication (Unspec.)	C			
			Clonazepam	C			
			Centrum Silver	C			

Date:02/22/02ISR Number: 3874964-9Report Type:Expedited (15-DaCompany Report #001-0073-M0200071
Age: Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Nephritis Allergic	Health	Dilantin (Phenytoin)	PS				
	Nephritis Interstitial	Professional	(Lithium Carbonate)	SS				

Date:02/22/02ISR Number: 3879363-1Report Type:Periodic Company Report #HQ7950302NOV2001
Age:78 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Neuroleptic Malignant	Health	Effexor (Venlafaxine					
Hospitalization - Initial or Prolonged	Syndrome	Professional	Hydrochloride,					
	Pneumonia		Tablet)	PS		ORAL	200 MG	1X PER
	Pyrexia							1 DAY, ORAL
	Urinary Tract Infection		Lithium (Lithium,)	SS				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/25/02ISR Number: 3873251-2Report Type:Direct Company Report #CTU 162200
Age:47 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Level Above Therapeutic		Lithium Prinivil 10mg Merk	PS SS	Merk	ORAL	10MG DAILY ORAL	

Date:02/25/02ISR Number: 3874251-9Report Type:Expedited (15-DaCompany Report #D0037928A2002001836-1
Age:54 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Diarrhoea Drug Level Above Therapeutic Haemodialysis Overdose Renal Failure	Foreign Health Professional	Lithium Carbonate Tablet 450 Mg	PS		ORAL	450 MG/TWICE PER DAY/ORAL	

Date:02/26/02ISR Number: 3876007-XReport Type:Expedited (15-DaCompany Report #A126997
Age:39 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Convulsion Depression Drug Interaction Drug Level Increased Medication Error	Health Professional	Ziprasidone Po Desipramine Lithobid	PS SS SS		ORAL	120.00 MG TOTAL:DAILY:ORAL 300.00 MG TOTAL:DAILY:ORAL	

			Lorazepam	C			
			Synthroid (Levothyroxine)	C			
			Wellbutrin (Bupropion)	C			
			Loestrin	C			
			Chinese Herbs	C			

Date:02/27/02ISR Number: 3880842-1Report Type:Expedited (15-DaCompany Report #D0038002A
Age:58 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Chills Dyspnoea Euphoric Mood Hypertension Nervousness Serotonin Syndrome Vertigo Weight Decreased	Foreign Health Professional	Lithium Carbonate Tablet Paxil (Paroxetine Hydrochloride) Sibutramine Hydrochloride Capsule (Sibutramine Hyerochloride) Tibolone Thyroxine Sodium Lorazepam Noethist.Acet+Oestradiol Irbesartan Irbesartan Norethist.Acet+Oestradiol	PS SS SS C C C C C C C		ORAL ORAL ORAL		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/28/02ISR Number: 3875386-7Report Type:Expedited (15-DaCompany Report #WAES 0202GBR00256
Age:57 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Diplopia		Vioxx	PS	Merck & Co., Inc	ORAL	30	DAY
Other	Drug Interaction		Lithium Carbonate	SS		ORAL		
	Drug Level Increased		Sulfasalazine	C		ORAL		
	Therapeutic Agent		Methotrexate Sodium	C		ORAL		
	Toxicity		Oxybutynin Chloride	C		ORAL		
	Tremor							
	Vomiting							

Date:02/28/02ISR Number: 3878230-7Report Type:Expedited (15-DaCompany Report #D0037964A
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Intentional Misuse	Foreign	Eskalith					
Required	Suicide Attempt	Health	Tablet-Controlled					
Intervention to	Vomiting	Professional	Release (Lithium					
Prevent Permanent			Carbonate)	PS		ORAL	5	
Impairment/Damage								
TABLET/SINGLE								
DOSE/ORAL								
			Lithium Carbonate					
			Tablet 450 Mg					
			(Non-Us Product)	SS		ORAL	5	
TABLET/SINGLE								
DOSE/ORAL								

Date:03/01/02ISR Number: 3876821-0Report Type:Expedited (15-DaCompany Report #PHBS2002AU01746
Age:32 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blood Sodium Decreased	Foreign	Lamisil(Terbinafine					

	Condition Aggravated	Health	Hydrochloride)			
	Confusional State	Professional	Tablet	PS		ORAL
250 MG, QD,						
	Delusion	Other				
ORAL						
	Drug Interaction		Lithium(Lithium)	SS		
1350 QD, :						
	Drug Level Increased					
900 MG , QD,						
	Mental Disorder					
: 1125 MG ,						
	Pitting Oedema					
QD						
	Suicidal Ideation		Modifast	C		
	Therapeutic Agent		Olanzapine			
	Toxicity		(Olanzapine)	C		
	Water Intoxication		Fluvoxamine			
			(Fluvoxamine)	C		

Date:03/04/02ISR Number: 3879021-3Report Type:Expedited (15-DaCompany Report #D0038001A
Age:63 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Constipation	Foreign	Eskalith			
	Disorientation	Health	(Formulation			
	Hyperhidrosis	Professional	Unknown) (Lithium			
	Pain		Carbonate)	PS		ORAL
450 MG / ORAL						
	Restlessness		Tramadol			
	Serotonin Syndrome		Hydrochloride			
			(Formulatin Unknown)			
			(Tramadol			
			Hydrochloride)	SS		

			Mirtazapine (Formulation Unknown)			
			(Mirtazapine)	C		
			Celecoxib	C		
			Piretanide	C		
			Valerian	C		

Date:03/05/02ISR Number: 3882441-4Report Type:Expedited (15-DaCompany Report #B0260485A
Age:13 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Tenderness	Literature	Eskalith Tablet-Controlled Release (Lithium Carbonate)	PS		ORAL	300 MG / ORAL	
	Alanine Aminotransferase Increased	Health Professional						
	Aspartate Aminotransferase Increased		Olanzapine	C				
			Sertraline	C				
	Blood Albumin Decreased							
	Blood Pressure Decreased							
	Body Temperature Increased							
	Fall							
	Heart Rate Increased							
	Red Blood Cells Urine Positive							

Date:03/06/02ISR Number: 3879166-8Report Type:Direct Company Report #CTU 162858
Age:68 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Confusional State		Lithium 300mg	PS			1 BID	
	Drug Toxicity		Eskalith	SS			450MG HS	

Date:03/06/02ISR Number: 3879760-4Report Type:Expedited (15-DaCompany Report #HQ7224417OCT2001
Age:44 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Drug Abuser Intentional Misuse	Literature	Venlafaxine (Venlafaxine Hydrochloride, Unspec)	PS		ORAL		
OVERDOSE AMOUNT ,ORAL								
			Anacin Aspirin Free (Acetaminophen, Tablet)	SS		ORAL		
ORAL								
			Lithium (Lithium)	SS		ORAL		
OVERDOSE AMOUNT , ORAL								

Date:03/06/02ISR Number: 3880284-9Report Type:Expedited (15-DaCompany Report #MK200202-0370-1
Age:74 YR Gender:Female I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Agitation Drug Interaction Dystonia Hypertonia

Speech Disorder

		Report Source	Product	Role	Manufacturer	Route	Dose	Duration
		Foreign Health Professional	Tofranil-Pm 75 Mg Capsules 30	PS			75 MG	
			Plenur (Lithium Carbonate)	SS				
			Seroxat (Paroxetine Hydrochloride)	SS				

Date:03/07/02ISR Number: 3881249-3Report Type:Expedited (15-DaCompany Report #WAES 0202GBR00256
Age:57 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Other	Drug Interaction Drug Level Increased Drug Toxicity	Foreign Other	Tab Vioxx (Rofecoxib)	PS		ORAL	50 MG/DAILY PO	30 DAY
			Lithiumco3	SS		ORAL	600 MG/DAILY PO	
			Methotrexate Sodium	C				
			Oxybutynincl	C				
			Sulfasalazine	C				

Date:03/11/02ISR Number: 3882970-3Report Type:Expedited (15-DaCompany Report #LBID00202000638
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Asthma	Study Health Professional	Lithobid (Lithium Carbonate)	PS		ORAL	DAILY PO	

Date:03/11/02ISR Number: 3882978-8Report Type:Expedited (15-DaCompany Report #LBID00202000645
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Condition Aggravated Drug Abuser	Study Health Professional	Lithobid (Lithium Carbonate)	PS		ORAL	DAILY PO	

Date:03/13/02ISR Number: 3883225-3Report Type:Expedited (15-DaCompany Report #D0037852A2002000390-1
Age:61 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Required Intervention to Prevent Permanent Impairment/Damage	Bradycardia Intentional Misuse Somnolence Suicide Attempt	Foreign Health Professional	Lithium Acetate Tablet 536 Mg (Lithium Acetate)	PS		ORAL	SINGLE DOSE/ ORAL	

Date:03/13/02ISR Number: 3885854-XReport Type:Expedited (15-DaCompany Report #A0358952A
Age:60 YR Gender:Female I/FU:F

Outcome
Hospitalization - Initial or Prolonged Disability

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Dialysis Nephritis Interstitial Nephrogenic Diabetes Insipidus Renal Disorder	Health Professional	Eskalith Capsule (Lithium Carbonate)	PS		ORAL	SEE DOSAGE TEXT/ ORAL	
			Quetiapine Fumarate	C				
			Lamotrigine	C				
			Magnesium Hydroxide	C				
			Hypromellose	C				
			Clonazepam	C				
			Centrum Silver	C				
			Paracetamol	C				
			Maalox Suspension	C				
			Sodium Chloride	C				

Date:03/18/02ISR Number: 3890999-4Report Type:Expedited (15-DaCompany Report #A0358950A
Age:72 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Balance Disorder Bipolar Disorder Condition Aggravated Diarrhoea Drug Toxicity	Health Professional Company Representative	Eskalith (Formulation Unknown) (Lithium Carbonate)	PS		ORAL	600 MG/TWICE PER DAY/ ORAL	
			Paroxetine Hydrochloride	C				
			Semisodium Valproate	C				

Date:03/19/02ISR Number: 3885470-XReport Type:Expedited (15-DaCompany Report #A205704
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Depression	Consumer	Ziprasidone Po	PS		ORAL	160.00 MG	

Initial or Prolonged	Increased Appetite			
TOTAL:BID:ORA				
Required	Road Traffic Accident			
L				
Intervention to	Somnolence	Lithium	SS	
Prevent Permanent	Suicidal Ideation	Beer	SS	
Impairment/Damage	Treatment Noncompliance			
	Weight Increased			

Date:03/19/02ISR Number: 3885958-1Report Type:Expedited (15-DaCompany Report #001-0073-M0200071
Age:57 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Nephritis Allergic	Health	Dilantin (Phenytoin)	PS		ORAL	200 OR 300 MG	
	Nephritis Interstitial	Professional					(DAILY), PER	
	Renal Failure Acute						ORAL	
			(Lithium Carbonate)	SS		ORAL	900 MG (300	
							MG, TID), PER	
							ORAL	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/19/02ISR Number: 3886051-4Report Type:Expedited (15-DaCompany Report #A205342
Age:34 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Blood Glucose Abnormal	Health	Ziprasidone Po	PS		ORAL	PO
Initial or Prolonged	Drug Level Increased	Professional	Lithium Carbonate	SS		ORAL	900.00 MG
Required	Electrocardiogram Qt						TOTAL:BID/ORA
Intervention to	Corrected Interval						L
Prevent Permanent	Prolonged		Effexor	C			
Impairment/Damage	Glycosylated Haemoglobin		Zyprexa	C			
	Increased		Glucophage	C			
			Ambien	C			
			Thorazine	C			
			Actos	C			

Date:03/22/02ISR Number: 3886693-6Report Type:Expedited (15-DaCompany Report #B0262071A
Age:24 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Other	Dry Throat		Zovirax 800	PS	Glaxo Wellcome	ORAL	800MG per day
	Erythema		Lithium Oligosol	SS		ORAL	
	Face Oedema						
	Hypertension						
	Kidney Enlargement						

Date:03/22/02ISR Number: 3887587-2Report Type:Expedited (15-DaCompany Report #LBID00202000638
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Asthma	Study	Lithobid (Lithium				
		Health	Carbonate)	PS		ORAL	DAILY PO
		Professional					

Date:03/25/02ISR Number: 3888072-4Report Type:Direct Company Report #CTU 164096
Age:33 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Arthralgia		Lithium Carbonate					
	Muscular Weakness		300 Mg	PS			300MG	
	Myalgia						BID->TID	
			Lopid	C				
			Celebrex	C				
			Phentermine	C				
			Prilosec	C				

Date:03/26/02ISR Number: 3888241-3Report Type:Expedited (15-DaCompany Report #US-BRISTOL-MYERS SQUIBB COMPANY-11784766
Age:55 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Potassium Decreased		Coaprovel Tabs					
	Diabetes Mellitus		300mg/12.5mg	PS	Bristol-Myers Squibb			
	Non-Insulin-Dependent				Company	ORAL		
	Drug Interaction		Indapamide	SS		ORAL		
	Drug Level Increased		Teralithe	SS		ORAL		
	Mania		Atenolol	C	Apothecon			
	Tremor		Hyperium	C				
			Loxapac	C				
			Theralene	C				

			Parkinane	C		

Date:03/26/02ISR Number: 3888824-0Report Type:Direct Company Report #CTU 164183
Age:47 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	Confusional State Drug Level Increased Irritability Tremor Vomiting		Lithium	PS		ORAL	600MG QAM ORAL; 900MG QPM ORAL	

Date:03/27/02ISR Number: 3890274-8Report Type:Direct Company Report #CTU 164255
Age:50 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Hospitalization - Initial or Prolonged	Diarrhoea Drug Level Increased Renal Disorder Syncope Tremor		Lithium Carbonate Caprox Lomotil Generic-Diphenoxylate/Atropine Myl Synthroid	PS SS C	Roxanne Pharmaceuticals Myl		300 MGS TID	

Date:03/27/02ISR Number: 3890410-3Report Type:Direct Company Report #CTU 164326
Age:55 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Required Intervention to	Sinus Bradycardia		Lithium Rabeprazole Clonazepam Diphenhydramine Hcl	PS C C C		ORAL	600MG PO BID	

Prevent Permanent Impairment/Damage			Quetiapine Fumarate	C		
			Olanzapine	C		
			Mirtazapine	C		

Date:03/27/02ISR Number: 3890790-9Report Type:Expedited (15-DaCompany Report #2001UW03379
Age: Gender: I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Required Intervention to Prevent Permanent Impairment/Damage	Ascites	Health	Seroquel "Zeneca"	PS		ORAL	600 MG PO
	Polydipsia	Professional	Lithium	SS			1050 MG DAILY
	Polyuria						

Date:03/27/02ISR Number: 3891044-7Report Type:Expedited (15-DaCompany Report #PHRM2002FR00980
Age:32 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Disability	Retinal Detachment	Foreign	Tegretol (Carbamazepine)				
	Retinal Haemorrhage	Health					
	Visual Acuity Reduced	Professional	Tablet	PS		ORAL	1 DF, BID, ORAL
		Other					
			Teralithe(Lithium Carbonate) Slow				

			Release Tablet	SS		ORAL
400 MG, BID,						
ORAL						
			Zyprexa (Olanzapine) Tablet	SS		ORAL
27.5 MG/DAY,						
ORAL						
			Oral Contraceptive Nos	C		

Date:03/27/02ISR Number: 3891294-XReport Type:Expedited (15-DaCompany Report #D0038093A
Age:33 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Aspiration	Foreign	Lithium Carbonate					
Hospitalization - Initial or Prolonged	Caustic Injury	Health Professional	Tablet (Non-Us Product)	PS		ORAL	40	
Required Intervention to Prevent Permanent Impairment/Damage	Gastrointestinal Injury						TABLET/SINGLE	
	Haemorrhage						DOSE/ORAL	
	Intentional Misuse		Fluoxetine Tablet (Fluoxetine)	SS		ORAL	10	
	Mouth Injury						TABLET/SINGLE	
	Salivary Hypersecretion						DOSE, ORAL	
	Suicide Attempt		...	SS		ORAL	800 ML/SINGLE	
							DOSE/ORAL	

Date:03/27/02ISR Number: 3891319-1Report Type:Expedited (15-DaCompany Report #D0037928A
Age:54 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Accidental Overdose	Foreign Health	Lithium Carbonate Tablet (Non-Us					
	Coordination Abnormal							

Required	Diarrhoea	Professional	Product)	PS		ORAL
450 MG/TWICE						
Intervention to	Disorientation					
PER DAY /						
Prevent Permanent	Drug Level Increased					
ORAL						
Impairment/Damage	Drug Toxicity					
	Haemodialysis					
	Renal Failure					

Date:04/01/02ISR Number: 3893126-2Report Type:Expedited (15-DaCompany Report #D0037823A
Age:25 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Life-Threatening	Blister	Foreign	Lithium Carbonate			
Hospitalization -	Haemodialysis	Health	(Non-Us Product)	PS		ORAL
4500 MG/PER						
Initial or Prolonged	Intentional Misuse	Professional				
DAY/ ORAL						
Other	Somnolence		Venlafaxine			
Required	Suicide Attempt		Hydrochloride Tablet			
Intervention to			(Venlafaxine			
Prevent Permanent			Hydrochloride)	SS		ORAL
750 MG/ PER						
Impairment/Damage						
DAY/ ORAL						
			Stangyl Tablet			
			(Stangyl)	SS		ORAL
500 MG/ PER						
DAY/ ORAL						
			Valproate Sodium			
			Tablet (Valproate			
			Sodium)	SS		ORAL
1500 MG/PER						
DAY/ORAL						

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/01/02ISR Number: 3893415-1Report Type:Expedited (15-DaCompany Report #2002SE02099
Age:67 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Drug Interaction	Foreign	Kenzen	PS		ORAL	8 MG QD PO
	Drug Level Increased	Health	Theralithe	SS		ORAL	250 MG BID PO
	Fall	Professional Other	Glucophage	C			

Date:04/02/02ISR Number: 3893876-8Report Type:Expedited (15-DaCompany Report #A205704
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Depression	Consumer	Ziprasidone Po	PS		ORAL	160.00 MG TOTAL: BID:
	Increased Appetite						
Required	Road Traffic Accident						ORAL
Intervention to Prevent Permanent Impairment/Damage	Sedation		Lithium (Manufacturer Unknown)	SS			
	Somnolence						
	Suicidal Ideation						
	Weight Increased		Beer	SS			

Date:04/02/02ISR Number: 3894219-6Report Type:Expedited (15-DaCompany Report #A0358952A
Age:60 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Aspartate Aminotransferase Increased	Health Professional	Eskalith Capsule (Lithium Carbonate)	PS		ORAL	SEE DOSAGE TEXT / ORAL
Disability							
Required	Nephritis Interstitial		Quetiapine Fumarate	C			
Intervention to Prevent Permanent Impairment/Damage	Nephrogenic Diabetes Insipidus		Lamotrigine	C			
			Magnesium Hydroxide	C			
	Renal Disorder		Hypromellose	C			
			Clonazepam	C			

			Centrum Silver	C			
			Paracetamol	C			
			Maalox Suspension	C			
			Sodium Chloride	C			

Date:04/04/02ISR Number: 3894745-XReport Type:Direct Company Report #CTU 164952
Age:81 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Confusional State		Lithium 300mg	PS		ORAL	300MG TID	
	Diarrhoea							
	Drug Interaction		Sertraline	C				
	Drug Level Above Therapeutic		Glipizide	C				
			Potassium Chloride	C				
	Drug Toxicity		Celecoxib	C				
	Hallucination, Visual		Furosemide	C				
	Mental Status Changes		Lisipnopril	C				
	Somnolence		Quetiapine	C				
	Vomiting		Lorazepam	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/04/02ISR Number: 3896151-0Report Type:Expedited (15-DaCompany Report #D0037964A
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Hospitalization - Initial or Prolonged Required	Overdose Suicide Attempt Vomiting	Foreign Health Professional	Eskalith Tablet-Controlled Release (Lithium Carbonate)	PS		ORAL	5 Intervention to TABLET/SINGLE Prevent Permanent DOSE/ORAL Impairment/Damage	
			Lithium Carbonate Tablet 450 Mg (Non-Us Product)	SS		ORAL	5 TABLET/SINGLE DOSE/ORAL	

Date:04/04/02ISR Number: 3896161-3Report Type:Expedited (15-DaCompany Report #D0038195A
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Calculus Urethral Eye Operation Renal Colic	Foreign Health Professional	Eskalith Tablet-Controlled Release (Lithium Carbonate)	PS		ORAL	ORAL	

Date:04/05/02ISR Number: 3896325-9Report Type:Direct Company Report #CTU 165075
Age:56 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Asthenia		Lithium	PS			2(300MG) TID	
	Diarrhoea		Fluoxetine	C				
	Drug Level Above		Synthroid	C				

	Therapeutic		Trazodone	C		
	Gait Disturbance		Naproxen	C		
	Medication Error					
	Somnolence					
	Tremor					

Date:04/12/02ISR Number: 3900163-8Report Type:Expedited (15-DaCompany Report #D0038280A
Age:38 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Hallucination	Foreign	Eskalith					
Required	Hyperreflexia	Health	Tablet-Controlled					
Intervention to	Somnolence	Professional	Release (Lithium					
Prevent Permanent	Suicide Attempt		Carbonate)	PS		ORAL		
ORAL								
Impairment/Damage			Melperone					
			Hydrochloride Tablet					
			(Melperone					
			Hydrochloride)	SS		ORAL		
ORAL								
			Chlorprothixene					
			Tablet					
			(Chlorprothixene)	SS		ORAL		
ORAL								
			Mirtazapine Tablet					
			(Mirtazapine)	SS		ORAL		
ORAL								

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/12/02ISR Number: 3900164-XReport Type:Expedited (15-DaCompany Report #D0038278A
Age:28 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Bowel Sounds Abnormal	Foreign	Lithium Carbonate					
Hospitalization -	Intentional Misuse	Health	Tablet (Non-Us					
Initial or Prolonged	Somnolence	Professional	Product)	PS		ORAL	8 TABLET /	
	Suicide Attempt						SINGLE DOSE /	
	Vomiting						ORAL	
			Flunitrazepam	C				
			Promethazine	C				
			Carbamazepine	C				

Date:04/16/02ISR Number: 3900416-3Report Type:Expedited (15-DaCompany Report #WAES 0202DEU00068
Age:71 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Apathy		Vioxx	PS	Merck & Co., Inc	ORAL	6 DAY	
Initial or Prolonged	Clonic Convulsion		Lithium Carbonate	SS		ORAL		
	Drug Toxicity		Levothyroxine Sodium	C				
	Gait Disturbance		Hydrochlorothiazide					
	Hypertonia		And Ramipril	C		ORAL		
	Mood Altered		Allopurinol	C		ORAL		
			Elavil	C		ORAL		
			Bisoprolol Fumarate	C		ORAL		
			Ferrous Glycine Sulfate	C		ORAL		

Date:04/16/02ISR Number: 3900671-XReport Type:Direct Company Report #CTU 165768
Age:59 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Confusional State		Lithium Cr	PS			450 MG	
Initial or Prolonged	Coordination Abnormal						BID;1/25-3/4	

	Drug Level Above Therapeutic Hyperhidrosis Nasopharyngitis		Apap Carvedilol Chlorpromazine Clopidogrel Digoxin Folic Acid Lansoprazole Multiple Vitamin Thiamin Olanzapine	C C C C C C C C C C		

Date:04/17/02ISR Number: 3901101-4Report Type:Expedited (15-DaCompany Report #WAES 0204SWE00002
Age:81 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - 25 DAY	Blood Creatinine		Vioxx	PS	Merck & Co., Inc	ORAL
Initial or Prolonged	Increased Depressed Level Of Consciousness Drug Level Increased Extrapyramidal Disorder		Lithium Sulfate Zolpidem Tartrate Levothyroxine Sodium Lofepramine Hydrochloride Dipyridamole Calcium Carbonate And Cholecalciferol Tramadol	SS C C C C C		ORAL

				Hydrochloride	C		

Date:04/17/02ISR Number: 3903040-1Report Type:Expedited (15-DaCompany Report #2002101362US
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Interaction	Health	Medrol					
	Grand Mal Convulsion	Professional	(Methylprednisolone) Tablet	PS		ORAL	ORAL	1 DAY
			Zyprexa (Olanzapine)	SS				
			Lithium	SS				
			Propranolol	SS				
			Levothyroxine	SS				

Date:04/18/02ISR Number: 3902840-1Report Type:Expedited (15-DaCompany Report #K200200544
Age:79 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Blood Glucose Decreased	Foreign	Altace Capsules					
Hospitalization - Initial or Prolonged	Blood Pressure Decreased	Health	(Ramipril) Capsule,					
	Bradycardia	Professional	1.25 Mg	PS		ORAL	2.5 MG, QD,	
	Condition Aggravated	Other					ORAL	
	Cyanosis		Hydrochlorothiazide	SS		ORAL	2.5 MG, QD,	
	Hyperglycaemia						ORAL	
	Renal Impairment		Lithium-Duriles					
	Somnolence		(Lithium Sulfate)	SS		ORAL	42 MG, ORAL	
			Nebilet (Nebivolol Hydrochloride)	SS		ORAL	5 MG, ORAL	
			Ass "Ct-Arzneimittel" (Acetylsalicylic Acid)	SS		ORAL	100 MG, ORAL	
			Haloperidol-Ratiopha					

			rm (Haloperidol)	SS	Ratiopharm	ORAL	5 MG, ORAL
			Digitoxin "Awd" (Digitoxin)	SS		ORAL	0.07 MG, ORAL
			Sarptem "Bayer Vital" (Amitriptyline Hydrochloride)	SS		ORAL	25 MG, ORAL
			Allopurinol	SS		ORAL	100 MG, ORAL
			Akatinol (Memantine Hydrochloride)	C			
			Venoruton Retard (Troxerutin)	C			
			Amaryl (Glimepiride)	C			
			Diastabol (Miglitol)	C			
			Espa-Lipon (Thioctic Acid)	C			
			Nitrendipine	C			

Date:04/18/02ISR Number: 3903136-4Report Type:Expedited (15-DaCompany Report #A044-002-003658
Age:87 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Other	Drug Level Decreased	Foreign	Aricept (Donepezil)	PS		ORAL	5 MG 1 IN 1 D, PER ORAL
		Health Professional	Priadel (Lithium Carbonate)	SS		ORAL	400 MG, PER

ORAL

			Paroxetine (Paroxetine)	C		

Date:04/19/02ISR Number: 3903845-7Report Type:Direct Company Report #CTU 166158
Age:39 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 Convulsion Drug Level Above Therapeutic Pyrexia Vomiting		Lithium Valproic Acid Carbamazepine Sertraline Cenestin Risperidone Ranitidine Lomotil Zolpidem Clonazepam	PS C C C C C C C C C		ORAL 300MG TID ORAL

Date:04/20/02ISR Number: 3904190-6Report Type:Direct Company Report #CTU 166252
Age:61 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Hospitalization - Initial or Prolonged	Confusional State Drug Level Changed Lethargy Leukocytosis Mental Impairment Tremor		Lithium	PS		600 BID

Date:04/22/02ISR Number: 3904512-6Report Type:Direct Company Report #CTU 166326
Age:53 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration

Disability	Agitation	Lithium	PS
	Cerebellar Syndrome	Hydrochlorothiazide	C
	Coma	Synthroid	C
	Coordination Abnormal		
	Drug Level Increased		
	Eye Movement Disorder		
	Nephrogenic Diabetes Insipidus		
	Neurotoxicity		

Date:04/22/02ISR Number: 3904838-6Report Type:Expedited (15-DaCompany Report #WAES 0202DEU00068
Age:71 YR Gender:Female I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Apathy
	Clonic Convulsion
	Dehydration
	Drug Interaction
	Gait Disturbance
	Hypertonia
	Mood Altered
	Oligodipsia
	Therapeutic Agent

	Toxicity						
		Report Source	Product	Role	Manufacturer	Route	Dose Duration
		Foreign Health Professional	Tab Vioxx (Rofecoxib)	PS		ORAL	12.5 MG BID
			Tab Cr Lithiumco3	SS		ORAL	PO 6 DAY
							600 MG DAILY PO
			Elavil	C			
			Allopurinol	C			
			Bisoprolol Fumarate	C			
			Ferrous Glycine Sulfate	C			
			Hydrochlorothiazide (+) Ramipril	C			
			Levothyroxine Na	C			

Date:04/22/02ISR Number: 3904960-4Report Type:Expedited (15-DaCompany Report #A208620
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Anorexia	Foreign Health Professional	Lithane Tablets	PS		ORAL	ORAL
	Apathy		Lisinopril	SS		ORAL	ORAL
	Confusional State		Metformin	SS		ORAL	ORAL
	Depressed Level Of Consciousness		Furosemide	SS		ORAL	ORAL
	Drug Level Above Therapeutic		Acetylsalicylic Acid	C			
	Loss Of Consciousness		Codeine	C			

Date:04/22/02ISR Number: 3905069-6Report Type:Expedited (15-DaCompany Report #D0038195A
Age:63 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Calculus Ureteric Corneal Disorder Corneal Transplant Renal Colic Thermal Burn	Foreign Health Professional	Eskalith Tablet-Controlled Release (Lithium Carbonate)	PS		ORAL	450 MG / TWICE PER DAY / ORAL	
			Cyclosporin	C				
			Glibenclamide	C				
			Metoprolol Succinate	C				
			Clopidogrel Bisulphate	C				

Date:04/24/02ISR Number: 3907364-3Report Type:Expedited (15-DaCompany Report #A208548
Age:15 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Developmental Delay Pyelonephritis	Health Professional	Lithane Tablets Ziprasidone	PS SS		ORAL	80.00 MG TOTAL:BID: ORAL	
			Clozaril	C				
			Depakote	C				
			Cogentin	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/25/02ISR Number: 3912778-1Report Type:Periodic Company Report #A0352252A 2001021273-1
Age:39 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Disability	Nephrogenic Diabetes Insipidus	Health Professional	Lithium Carbonate Capsule 300 Mg (Lithium Carbonate)	PS		ORAL	600 MG / TWICE PER DAY / ORAL	
			Carbamazepine	C				
			Valproic Acid	C				
			Thyroxine Sodium	C				
			Paroxetine Hydrochloride	C				
			Loratadine	C				

Date:04/26/02ISR Number: 3907556-3Report Type:Direct Company Report #CTU 166665
Age:50 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Pressure Systolic Decreased		Metolazone 2.5mg	PS		ORAL	2.5MG BID ORAL	
	Dizziness Drug Level Above Therapeutic		Lithium Carbonate 300mg	SS		ORAL	300MG BID ORAL	
	Feeling Hot		Carvedilol	C				
	Hypertension		Furosemide	C				
	Syncope		Potassium	C				
			Pantopraxole	C				
			Ramipril	C				
			Valproic Acid	C				
			Glipizide	C				
			Insulin	C				

Date:04/26/02ISR Number: 3908176-7Report Type:Expedited (15-DaCompany Report #2001UW03379
Age: Gender: I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required	No Adverse Drug Effect	Health	Seroquel "Zeneca"	PS		ORAL	600 MG PO	
Intervention to		Professional	Lithium	SS			1050 MG DAILY	
Prevent Permanent Impairment/Damage								

Date:04/26/02ISR Number: 3908238-4Report Type:Expedited (15-DaCompany Report #D0038348A
Age:39 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Diarrhoea	Foreign	Lithium Carbonate					
Hospitalization - Initial or Prolonged	Nausea Overdose Suicidal Ideation Suicide Attempt Vomiting	Health Professional	Tablet (Non-Us Product)	PS		ORAL	22500 MG / SINGLE DOSE/	ORAL

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/29/02ISR Number: 3908377-8Report Type:Direct Company Report #CTU 166764
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Abdominal Pain		Lithium	PS				
			Tylenol	C				
			Glyburide	C				
			Levoxyl	C				
			Wellbutrin Sr	C				
			Klor-Con	C				
			Prevacid	C				
			Claritin	C				
			Seroquel	C				
			Vioxx	C				

Date:04/29/02ISR Number: 3909852-2Report Type:Expedited (15-DaCompany Report #A205342
Age:34 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Diabetes Mellitus	Health	Ziprasidone Po	PS		ORAL		
Initial or Prolonged	Drug Level Below	Professional	Lithium Carbonate	SS		ORAL	900.00 MG	
Required	Therapeutic							
Intervention to	Electrocardiogram Qt							
Prevent Permanent	Prolonged		Venlafaxine	SS		ORAL	225.00 MG	
Impairment/Damage	Glycosylated Haemoglobin							
	Increased							
	Medication Error		Thorazine	SS		ORAL	100.00 MG	
			Zyprexa	C				
			Glucophage	C				
			Ambien	C				
			Actos	C				

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Date:04/30/02ISR Number: 3908287-6Report Type:Expedited (15-DaCompany Report #B0262071A
Age:24 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Dry Throat		Zovirax 200	PS	Glaxo Wellcome	ORAL	200MG Twice	
	Erythema						per day	1 DAY
	Face Oedema		Lithium Oligosol	SS		ORAL	1AMP Per day	
	Hypertension							
	Kidney Enlargement							

Date:05/01/02ISR Number: 3909437-8Report Type:Expedited (15-DaCompany Report #WAES 0204USA02770
Age:72 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Asthenia		Vioxx	PS	Merck & Co., Inc	ORAL		
Initial or Prolonged	Dehydration		Lithium Carbonate	SS				
	Dizziness							
	Nausea							
	Toxicologic Test Abnormal							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/01/02ISR Number: 3909996-5Report Type:Direct Company Report #CTU 167014
Age:38 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Confusional State		Lithium 4t (300mg)					
	Drug Level Changed		Qhs	PS				
	Memory Impairment		Lorazepam 1mg Tid	SS				

Date:05/01/02ISR Number: 3911066-7Report Type:Expedited (15-DaCompany Report #PHBS2002CH05281
Age:79 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Accidental Exposure	Foreign	Leponex(Clozapine)					
	Coma	Health	Tablet	PS		ORAL		
	Disturbance In Attention	Professional	Lithium (Lithium)	SS				
	Drug Interaction	Other	Glucophage Forte	C				
	Hypothermia		Tiatral	C				
	Miosis		Fosamax (Alendronate Sodium)	C				
	Stupor		Calcimagon	C				
	Toxicologic Test Abnormal		Importal	C				
			Xalatan (Latanoprost)	C				
			Amiodarone (Amiodarone)	C				
			Nitroderm	C				

Date:05/02/02ISR Number: 3911540-3Report Type:Direct Company Report #CTU 167231
Age:72 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Medication Error		Lithium Salts 8 Meq/5 Ml Syrup					
	Overdose		Roxane	PS	Roxane		100 MG Q8H	
							PER TUBE	

Date:05/07/02ISR Number: 3913277-3Report Type:Expedited (15-DaCompany Report #B0266535A
Age:37 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Dialysis	Foreign	Eskalith					
Hospitalization - Initial or Prolonged	Drug Toxicity	Literature	(Formulation					
	Neurotoxicity	Health	Unknown) (Lithium					
	Sepsis	Professional	Carbonate)	PS				
			Clopenthixol Decanoate	C				
			Haloperidol	C				
			Maprotiline	C				

Date:05/07/02ISR Number: 3913484-XReport Type:Expedited (15-DaCompany Report #A0360110A
Age:59 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Confusional State	Foreign	Paxil (Paroxetine					
	Disorientation	Health	Hydrochloride)	PS		ORAL	ORAL/SEE DOSAGE TEXT	
	Drug Toxicity	Professional						
	Hallucination		Eskalith (Lithium					
	Tremor		Carbonate)	SS		ORAL	ORAL/SEE	

DOSAGE TEXT

	Lansoprazole	C
	Oxazepam	C

Date:05/07/02ISR Number: 3913492-9Report Type:Expedited (15-DaCompany Report #D0038405A
Age:48 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Creatinine Increased Clonic Convulsion Convulsion Drug Toxicity Dysarthria Somnolence Tremor	Foreign Health Professional	Eskalith Tablet-Controlled Release (Lithium Carbonate)	PS		ORAL	ORAL	

Date:05/07/02ISR Number: 3913680-1Report Type:Expedited (15-DaCompany Report #A0367112A
Age:36 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Distension Abdominal Pain Upper Asthenia Fatigue Gastrointestinal Disorder Gastrointestinal Ulcer Myalgia Nausea Overdose Pain	Consumer	Lithium Salt (Formulation Unknown) (Generic) (Lithium Salt Multiple Medication (Formulation Unknown) (Multiple Medication)	PS SS		ORAL	PER DAY ORAL	

Date:05/07/02ISR Number: 3913746-6Report Type:Expedited (15-DaCompany Report #B0266433A
Age:45 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Death	Asthenia	Foreign	Eskalith (Lithium	
Hospitalization -	Blood Sodium Decreased	Literature	Carbonate)	PS
Initial or Prolonged	Blood Urea Increased	Health	Haloperidol	C
	Coma	Professional	Antidepressant	C
	Depression			
	Diabetic Ketoacidosis			
	Diarrhoea			
	Dizziness			
	Drug Interaction			
	Drug Toxicity			
	Electrocardiogram T Wave			
	Inversion			
	Mania			
	Sepsis			
	Somnolence			
	Vomiting			

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/07/02ISR Number: 3913963-5Report Type:Expedited (15-DaCompany Report #A209649
Age:56 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Required	Dizziness	Consumer	Lithane Tablets	PS		ORAL	TID:ORAL
Intervention to	Fatigue		Gabapentin	SS		ORAL	300.00 MG
Prevent Permanent	Nausea						TOTAL:DAILY:O
Impairment/Damage	Osteoporosis						RAL
	Parkinson'S Disease		Prevacid	C			
			Unknown Stool Softener	C			

Date:05/07/02ISR Number: 3915181-3Report Type:Expedited (15-DaCompany Report #WAES 0204USA02770
Age:72 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Asthenia	Health	Tab Vioxx 25 Mg	PS		ORAL	25
Initial or Prolonged	Dehydration	Professional					MG/DAILY/PO
	Dizziness		Lithiumco3 Unk	SS			
	Nausea						

Date:05/10/02ISR Number: 3914864-9Report Type:Direct Company Report #CTU 167830
Age:59 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Confusional State		Lithium Carbonate				
Initial or Prolonged	Drug Interaction		300mg Roxane	PS	Roxane		900MG BEDTIME
	Drug Level Increased		Prinivil 10mg Merck	SS	Merck		10MG DAILY
	Dysarthria		Neurontin	C			
			Topamax	C			
			Lorazepam	C			
			Clonazepam	C			

			Lipitor	C		
			Premarin	C		
			Glucophage	C		

Date:05/13/02ISR Number: 3916546-6Report Type:Expedited (15-DaCompany Report #D0038482A
Age:53 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hypertension Somnolence Suicide Attempt	Foreign Health Professional	Eskalith Tablet-Controlled Release (Lithium Carbonate)	PS		ORAL	SINGLE DOSE / ORAL	
			Galantamine Hydrobromide Tablet (Galantamine Hydrobromide)	SS		ORAL	SINGLE DOSE / ORAL	
			Olanzapine Tablet (Olanzapine)	SS		ORAL	SINGLE DOSE / ORAL	
			Venlafaxine Hydrochloride Tablet (Venlafaxine Hydrochloride)	SS		ORAL	SINGLE DOSE / ORAL	
			Amitriptyline Hcl					

			Tablet (Amitriptyline Hcl)	SS		ORAL
SINGLE DOSE / ORAL						

Date:05/16/02ISR Number: 3918250-7Report Type:Expedited (15-DaCompany Report #D0038479A
Age:53 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Creatine Phosphokinase Increased Head Injury Intentional Misuse Muscle Spasms Somnolence Suicide Attempt Therapeutic Agent Toxicity	Foreign Health Professional	Eskalith Tablet-Controlled Release (Lithium Carbonate)	PS		ORAL	50 TABLET/SINGLE DOSE/ORAL	1 DAY
			Carbamazepine Tablet	SS		ORAL	100 TABLET/SINGLE DOSE/ORAL	1 DAY
			Prothipendyl Hc1 Tablet	SS			20 TABLET/SINGLE DOSE/ORAL	1 DAY

Date:05/16/02ISR Number: 3918254-4Report Type:Expedited (15-DaCompany Report #D0038405A
Age:49 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Asthenia Blood Creatinine Increased Blood Potassium Decreased Clonic Convulsion	Foreign Health Professional	Eskalith Tablet-Controlled Release (Lithium Carbonate)	PS		ORAL		

	Coma					
	Convulsion					
	Drug Toxicity					
	Dysarthria					
	Haemodialysis					
	Renal Impairment					
	Somnolence					
	Tremor					

Date:05/16/02ISR Number: 3918305-7Report Type:Expedited (15-DaCompany Report #D0038348A
Age:39 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Diarrhoea	Foreign	Lithium Carbonate					
Hospitalization - Initial or Prolonged	Dizziness	Health Professional	Tablet (Non-Us Product)	PS		ORAL	22500 MG / SINGLE DOSE/	
	Drug Level Above Therapeutic							
	Intentional Misuse							
	Nausea							
	Suicide Attempt							
	Vomiting							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/21/02ISR Number: 3920411-8Report Type:Direct Company Report #CTU 168559
Age:27 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required	Iritis		Topiramate	PS	Ortho-Mcneil	ORAL	100MG PO BID	
Intervention to							BID	
Prevent Permanent			Citalopram	SS			10 MG/D	
Impairment/Damage			Lithium	SS				
			Gabapentin	SS			400 MG/D	

Date:05/22/02ISR Number: 3919892-5Report Type:Expedited (15-DaCompany Report #WAES 0205USA01719
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Coma	Consumer	Vioxx	PS	Merck & Co., Inc	ORAL		
Initial or Prolonged	Medication Error		Lithium Carbonate	SS				
	Oedema Peripheral		Paxil	SS				
	Speech Disorder		Glucophage	C				
			Glucotrol	C				
			Prilosec	C				
			Lipitor	C				
			Metamucil	C				
			[Therapy Unspecified]	C				

Date:05/22/02ISR Number: 3920930-4Report Type:Expedited (15-DaCompany Report #A211114
Age:24 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Renal Failure	Health	Lithane Tablets	PS				
Hospitalization -		Professional	Prinivil	SS				
Initial or Prolonged			Olanzapine	C				

Date:05/22/02ISR Number: 3922163-4Report Type:Expedited (15-DaCompany Report #A210947
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Akathisia	Health Professional	Ziprasidone Po	PS		ORAL	40.00 MG	TOTAL: BID:
	Depression							
	Parkinsonian Gait							
	Tremor		Lithium	SS		ORAL	300.00 MG	TOTAL
			Haldol	SS		ORAL	3.00 MG	TOTAL: ORAL
			Effexor	SS				

Date:05/23/02ISR Number: 3921617-4Report Type:Direct Company Report #CTU 168819
Age:47 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Alcohol Withdrawal Syndrome		Lithium Carbonate 300 Mg Generic	PS	Generic	ORAL	300 MG QID	Required
Intervention to Prevent Permanent Impairment/Damage			Androderm	C				
			Zantac	C				
			Lopid	C				
			Levoxyl	C				
			Tenormin	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Navane C

Date:05/24/02ISR Number: 3923172-1Report Type:Expedited (15-DaCompany Report #D0038507A
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	Agitation Intentional Misuse Suicide Attempt	Foreign Health Professional	Eskalith Tablet-Controlled Release (Lithium Carbonate)	PS		ORAL	10 TABLET /SINGLE DOSE/ ORAL	
			Perphenazine (Formulation Unknown) (Perphenazine)	SS		ORAL	SINGLE DOSE/ ORAL	
			Promethazine Hcl(Formulation Unknown) (Promethazine Hcl)	SS		ORAL	SINGLE DOSE/ORAL	
			Zopiclone Tablet (Zopiclone)	SS		ORAL	SINGLE DOSE/ORAL	
			Ethanol (Formulation Unknown) (Alcohol)	SS		ORAL	1 BOTTLE/SINGLE DOSE /ORAL	

Date:05/24/02ISR Number: 3926845-XReport Type:Periodic Company Report #310506
Age:46 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Confusional State	Consumer	Tamiflu					
	Drug Effect Decreased		(Oseltamivir) 75 Mg	PS		ORAL	75 MG 2 PER	
	Headache						ORAL	
			Klonopin					
			(Clonazepam(	SS		ORAL	ORAL	
			Keflex (Cephalexin)	SS		ORAL	ORAL	
			Serzone (Nefazodone					
			Hydrochloride)	SS		ORAL	ORAL	
			Lithobid (Lithium					
			Carbonate)	SS		ORAL	ORAL	

Date:05/28/02ISR Number: 3924327-2Report Type:Expedited (15-DaCompany Report #A211178
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Delusion	Consumer	Zoloft Tablets	PS				
	Disease Recurrence		Lithium					
	Mental Disorder		(Manufacturer					
	Refusal Of Treatment By		Unknown)	SS				
	Patient		Unspecified					
			Psychiatric					
			Medication	SS				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/28/02ISR Number: 3925881-7Report Type:Periodic Company Report #A116511
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Tremor	Health Professional	Lithane Tablets	PS				
			Ziprasidone	SS				
			Ativan (Lorazepam)	C				
			Luvox (Fluvoxamine Maleate)	C				
			Depakote (Valproate)	C				

Date:05/29/02ISR Number: 3926094-5Report Type:Expedited (15-DaCompany Report #D0038587A
Age:50 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other Required Intervention to Prevent Permanent Impairment/Damage	Coma Intentional Misuse Suicide Attempt	Foreign Health Professional	Eskalith Tablet-Controlled Release (Lithium Carbonate)	PS		ORAL	60 TABLET/ SINGLE DOSE/ ORAL	
			Olanzapine Tablet (Olanzapine)	SS		ORAL	27 TABLET/ SINGLE DOSE/ ORAL	

Date:05/29/02ISR Number: 3926096-9Report Type:Expedited (15-DaCompany Report #B0268009A
Age:51 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Required	Drug Level Increased Headache Intentional Misuse	Foreign Literature Health	Lithium Carbonate Tablet (Non-Us Product)	PS		ORAL	ORAL MONTHS	

Intervention to Prevent Permanent Impairment/Damage	Nausea Suicide Attempt	Professional	Risperidone Fluoxetine	C C			

Date:05/29/02ISR Number: 3926134-3Report Type:Expedited (15-DaCompany Report #D0038278A
Age:28 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Bowel Sounds Abnormal Intentional Misuse Somnolence Suicide Attempt Vomiting	Foreign Health Professional	Lithium Carbonate Tablet (Non-Us Product)	PS		ORAL	8 TABLET / SINGLE DOSE / ORAL
			Flunitrazepam Promethazine Carbamazepine	C C C			

Date:05/29/02ISR Number: 3926649-8Report Type:Expedited (15-DaCompany Report #WAES 0205USA01719
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Coma Medication Error Mutism Oedema Peripheral	Consumer	Vioxx 25 Mg Lithiumco3 Paxil Glucophage	PS SS SS C		ORAL	PO

				Glucotrol	C		
				Lipitor	C		
				Metamucil	C		
				Prilosec	C		
				[Therapy Unspecified]	C		

Date:06/03/02ISR Number: 3926864-3Report Type:Direct Company Report #CTU 169359
Age:50 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Face Oedema		Lithium Carbonate Caps 300mg Able	PS	Able	ORAL	2 CAPSU TWICE DAILY ORAL	
	Pharmaceutical Product							
	Complaint							

Date:06/04/02ISR Number: 3929100-7Report Type:Expedited (15-DaCompany Report #A209649
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Balance Disorder	Consumer	Lithane Tablets	PS		ORAL	TID: ORAL	
	Bone Disorder	Health Professional	Gabapentin	SS		ORAL	300.00 MG TOTAL: DAILY: ORAL	
	Confusional State							
	Dizziness							
	Fatigue		Prevacid	C				
	Nausea		Unknown Stool Softener	C				
	Osteoporosis		Welbutrin Sr	C				
	Parkinson'S Disease							
	Tremor							

Date:06/04/02ISR Number: 3929250-5Report Type:Expedited (15-DaCompany Report #D0038002A
Age:58 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Required Intervention to Prevent Permanent Impairment/Damage	Chills Dyspnoea Euphoric Mood Hyperhidrosis Hypertension Serotonin Syndrome Tremor Vertigo Weight Decreased	Foreign Health Professional	Lithium Carbonate Tablet 450mg (Non-Us Product)	PS		ORAL	
			Sibutramine Hydrochloride Capsule (Sibutramine Hydrochloride)	SS		ORAL	PER DAY /
			Paxil (Formulation Unknown) (Paroxetine Hydrochloride)	SS		ORAL	ORAL
			Tibolone	C			
			Thyroxine Sodium	C			
			Lorazepam	C			
			Norethis.Acet+Oestradiol	C			
			Irbesartan	C			

Date:06/05/02ISR Number: 3928318-7Report Type:Direct Company Report #CTU 169532
Age:39 YR Gender:Female I/FU:I

Outcome
Hospitalization -
Initial or Prolonged

Other

	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Confusional State		Lithium 300mg Tid	PS				
	Depressed Level Of Consciousness		Lisinopril 5mg Qd	SS				
	Dialysis							
	Diarrhoea							
	Drug Interaction							
	Drug Level Increased							
	Lethargy							
	Staring							
	Urinary Incontinence							
	Vomiting							

Date:06/05/02ISR Number: 3928370-9Report Type:Direct Company Report #CTU 169549
Age:44 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Diabetes Insipidus		Lithium	PS				
Other								

Date:06/05/02ISR Number: 3928436-3Report Type:Direct Company Report #CTU 169517
Age:57 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dizziness		Lithium Carbonate (Lithobid)	PS				
	Drug Level Increased							
	Dysarthria							
	Fall							
	Medication Error							

Date:06/05/02ISR Number: 3928469-7Report Type:Direct Company Report #CTU 169569
Age:67 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Hospitalization -	Diarrhoea		Lithium Carbonate	PS		ORAL
450MG BID PO						
Initial or Prolonged	Drug Toxicity		Latanoprost Opth	C		
	Haemodialysis		Tamsulosin	C		
	Mental Status Changes		Timolol Opth	C		
	Oedema Peripheral		Aspirin	C		
	Oral Intake Reduced		Naproxen	C		
	Renal Failure Acute		Ranitidine	C		
	Sinus Bradycardia		Trazodone	C		
	Tremor		Metoprolol	C		

Date:06/05/02ISR Number: 3929533-9Report Type:Expedited (15-DaCompany Report #A211751
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Required	Anxiety	Consumer	Lithane Tablets	PS		
Intervention to	Renal Cell Carcinoma					
Prevent Permanent	Stage Unspecified					
Impairment/Damage						

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/05/02ISR Number: 3930705-8Report Type:Expedited (15-DaCompany Report #001-0981-M0202875
Age:59 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Crying	Consumer	Atorvastatin					
	Drug Interaction		(Atorvastatin)	PS		ORAL	10 MG	
	Feeling Abnormal						(DAILY), PER	
	Suicidal Ideation						ORAL	
	Tremor		Gabapentin	SS				
			Lithium	SS				
			Paroxetine Hydrochloride	SS				
			Trazadone	SS				
			Buspirone	SS				
			Enalapril	C				

Date:06/06/02ISR Number: 3929788-0Report Type:Expedited (15-DaCompany Report #044-0945-M0200083
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Neuroleptic Malignant Syndrome	Foreign Health Professional	Neurontin (Gabapentin)	PS			1200 MG (DAILY),	
			Lithium	SS			1200 MG (DAILY),	
			...	SS				

Date:06/07/02ISR Number: 3929441-3Report Type:Direct Company Report #CTU 169676
Age:47 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Intentional Misuse		Depakote	PS			1000 MG BID	

Initial or Prolonged	Lethargy		Risperidone	SS		ORAL
1 MG PO BID						
	Stupor		Lithium	SS		
450 MG BID						
	Vision Blurred		Quetiapine	SS		
200 MG BID						
			Hydroxyzine	C		
			Naproxen	C		
			Citalopram	C		
			Lorazepam	C		

Date:06/07/02ISR Number: 3930987-2Report Type:Expedited (15-DaCompany Report #B0269250A
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Required Intervention to Prevent Permanent Impairment/Damage	Serotonin Syndrome Tinnitus	Foreign Health Professional	Lithium Carbonate Tablet (Non-Us Product)	PS		ORAL	250 MG TWICE PER DAY ORAL
			Paxil Tablet (Paroxetine Hydrochloride)	SS		ORAL	20 MG PER DAY ORAL

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/07/02ISR Number: 3934080-4Report Type:Expedited (15-DaCompany Report #D0038633A
Age:35 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agitation Bowel Sounds Abnormal Dysarthria Enuresis Faecal Incontinence Haemodialysis Intentional Misuse Suicide Attempt	Foreign Health Professional	Eskalith Tablet - Controlled Release (Lithium Carbonate)	PS		ORAL	90 TABLET/ SINGLE DOSE/ ORAL	
			Olanzapine Tablet (Olanzapine)	SS		ORAL	20 TABLET/ SINGLE DOSE/ ORAL	
			Citalopram Tablet (Citalopram)	SS		ORAL	20 TABLET/ SINGLE DOSE/ ORAL	
			Thyroxine Sodium Tablet (Levothyroxine Sodium)	SS		ORAL	50 TABLET/ SINGLE DOSE/ ORAL	
			Prothipendyl Hcl Tablet (Prothipendyl Hcl)	SS		ORAL	10 TABLET/ SINGLE DOSE/ ORAL	

Date:06/10/02ISR Number: 3930915-XReport Type:Direct Company Report #CTU 169794
Age:60 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	Polydipsia		Lithium	PS				

Date:06/10/02ISR Number: 3931377-9Report Type:Expedited (15-DaCompany Report #2002101362US
Age: Gender: I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Interaction Grand Mal Convulsion	Health Professional	Medrol(Methylprednisolone)Tablet	PS		ORAL	ORAL	1 DAY
			Zyprexa (Olanzapine)	SS				
			Lithium (Lithium)	SS				
			Propranolol(Propranolol)	SS				
			Levothyroxine(Levothyroxine)	SS				

Date:06/12/02ISR Number: 3936716-0Report Type:Expedited (15-DaCompany Report #D0038482A
Age:53 YR Gender:Female I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Convulsion Disorientation

		Hypertension Intentional Misuse Somnolence Suicide Attempt Urinary Incontinence	Report Source Foreign Health Professional	Product	Role	Manufacturer	Route
Dose	Duration						
				Eskalith Tablet-Controlled Release (Lithium Carbonate)	PS		ORAL
3 TABLET / SINGLE DOSE/ ORAL							
				Galantamine Hydrobromide Tablet (Galantamine Hydrobromide)	SS		ORAL
3 TABLET/ SINGLE DOSE/ ORAL							
				Olanzapine Tablet (Olanzapine)	SS		ORAL
3 TABLET/ SINGLE DOSE/ ORAL							
				Venlafaxine Hydrochloride Tablet (Venlafaxine Hydrochloride)	SS		ORAL
4 TABLET/ SINGLE DOSE/ ORAL							
				Unknown Tablet (Unknown)	SS		ORAL
SINGLE DOSE/ ORAL							
				Amitriptyline Hcl Tablet (Amitriptyline Hcl)	SS		ORAL
SINGLE DOSE/							

ORAL

Date:06/13/02ISR Number: 3934077-4Report Type:Expedited (15-DaCompany Report #D0038001A
Age:63 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Constipation Pain Serotonin Syndrome	Foreign Health Professional	Eskalith Tablet-Controlled Release (Lithium Carbonate)	PS		ORAL	450 MG /ORAL	
			Mirtazapine (Formulation Unknown) (Mirtazapine)	SS		ORAL	ORAL	
			Tramadol Hydrochloride (Formulation Unknown)	SS		ORAL	ORAL	
			Celecoxib	C				
			Piretanide	C				
			Valerian	C				
			Tizanidine Hydrochloride	C				

Date:06/13/02ISR Number: 3934078-6Report Type:Expedited (15-DaCompany Report #B0269250A
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Diarrhoea Serotonin Syndrome	Foreign Health Professional	Lithium Carbonate Tablet	PS		ORAL	250 MG/TWICE PER DAY/ORAL	
			Paxil Tablet (Paroxetine Hydrochloride)	SS		ORAL	20 MG PER DAY/ORAL	

Date:06/14/02ISR Number: 3934539-XReport Type:Expedited (15-DaCompany Report #A213023
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Unevaluable Event	Consumer	Lithane	PS			900.00 MG TOTAL	
Other			Gabapentin	SS			600.00 MG TOTAL:DAILY	

Date:06/19/02ISR Number: 3940307-5Report Type:Expedited (15-DaCompany Report #D0038737A
Age:20 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Required Intervention to Prevent Permanent	Intentional Misuse Suicidal Ideation	Foreign Health Professional	Lithium Carbonate Tablet (Non-Us Product)	PS		ORAL	11 TABLET / SINGLE DOSE /	

Impairment/Damage
ORAL

Date:06/19/02ISR Number: 3940436-6Report Type:Expedited (15-DaCompany Report #D0038507A
Age:47 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Agitation Alanine Aminotransferase Increased Blood Creatine Phosphokinase Increased Diarrhoea Gamma-Glutamyltransferase Increased Overdose Somnolence Suicide Attempt Tachycardia White Blood Cell Count Increased	Foreign Health Professional	Eskalith Tablet-Controlled Release (Lithium Carbonate)	PS		ORAL	SINGLE	DOSE/ORAL
			Perphenazine (Formulation Unknown) (Perphenazine)	SS		ORAL	SINGLE	DOSE/ORAL
			Promethazine Hcl (Formulation Unknown) (Promethazine Hcl)	SS		ORAL	SINGLE	DOSE/ORAL
			Zopiclone Tablet (Zopiclone)	SS		ORAL	SINGLE	DOSE/ORAL
			Ethanol (Formulation Unknown) (Alochol)	SS		ORAL	1	BOTTLE/SINGLE

DOSE/ORAL

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/20/02ISR Number: 3937915-4Report Type:Expedited (15-DaCompany Report #LBID00202000638
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Asthma	Study Health Professional	Lithobid (Lithium Carbonate)	PS		ORAL	DAILY PO	

Date:06/20/02ISR Number: 3940466-4Report Type:Expedited (15-DaCompany Report #D0035086A 1999031048-1
Age:65 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Delirium Disorientation Disturbance In Attention Fall	Foreign Health Professional	Eskalith Tablet-Controlled Release (Lithium Carbonate)	PS			450 MG/PER DAY	
	Hallucinations, Mixed							
	Head Injury Laceration Restlessness		Valproate Sodium Aspirin Doxepin Hydrochloride	C C C				

Date:06/20/02ISR Number: 3940470-6Report Type:Expedited (15-DaCompany Report #D0034945A
Age:65 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Agitation Delirium Disorientation Disturbance In Attention	Foreign Health Professional	Eskalith Tablet-Controlled Release (Lithium Carbonate)	PS		ORAL	450 MG/PER DAY/ORAL	
	Electroencephalogram							
	Abnormal Fall Fumbling Hallucinations, Mixed		Valproate Sodium Doxepin Hydrochloride Aspirin	C C C				

Head Injury
Laceration
Lethargy
Nervous System Disorder
Restlessness

Date:06/21/02ISR Number: 3937971-3Report Type:Expedited (15-DaCompany Report #001-0945-M0200710
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Unevaluable Event	Consumer	Neurontin (Gabapentin)	PS			600 MG	(DAILY)
			Lithium	SS			900 MG	

Date:06/24/02ISR Number: 3937895-1Report Type:Direct Company Report #CTU 170792
Age:8 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Thyroid Stimulating Hormone Increased		Lithium Carbonate 300mg Roxane Labs	PS	Roxane Labs	ORAL	300MGS TWICE DAILY ORAL; 600MGS TWICE	

DAILY ORAL

Date:06/24/02ISR Number: 3941740-8Report Type:Expedited (15-DaCompany Report #NSADSS2002009867
Age:73 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Acute Myocardial Infarction	Foreign Study	Remicade (5 Mg/Ml Lyophilized Powder)(Infliximab, Recombinant)	PS		INTRAVENOUS	300 MG, 1 IN	Required
Hospitalization - Initial or Prolonged	Blood Glucose Increased	Health Professional						
Other	Bronchospasm							
	Bundle Branch Block Left							
	Cardiac Failure		Vioxx (Rofecoxib)	SS			1 TIME(S), IV	
Intervention to Prevent Permanent Impairment/Damage	Congestive Cardiotoxicity		Methotrexate (Methotrexate)	SS			25, DAILY	
	Dehydration						7.5 MG, 1 IN	
	Duodenal Ulcer		Lithium (Lithium)	SS			1 WEEK(S)	
	Haemorrhage		Mellaril(Thioridazine Hydrochloride)	SS				
	General Physical Health Deterioration		Feldene(Piroxicam)	C				
	Haemoptysis		Enconcor	C				
	Heart Rate Increased		Dilutol(Torsemide)	C				
	Hyperhidrosis		Karvia	C				
	Hypoventilation		Isocover	C				
	Intercostal Retraction		Pulmicort(Budesonide)	C				
	Lung Crepitation		Atrovent(Ipratropium Bromide)	C				
	Oxygen Saturation Decreased		Nitroderm(Glyceryl Trinitrate)	C				
	Pallor		Oxis (Formoterol)	C				
	Pulmonary Fibrosis							
	Rales							
	White Blood Cell Count Increased							

Date:06/25/02ISR Number: 3940024-1Report Type:Expedited (15-DaCompany Report #HQ294424JUN2002
Age:40 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Liver Function Test Abnormal	Health Professional	Temesta (Lorazepam, Unspec)	PS		ORAL	SEE IMAGE	65 DAY
	Weight Increased		Quilonorm Retard (Lithium Carbonate,)	SS			SEE IMAGE	10 DAY
			Zyprexa (Olanzapine,)	SS			SEE IMAGE	5 DAY

Date:06/27/02ISR Number: 3940464-0Report Type:Expedited (15-DaCompany Report #D0038479A
Age:53 YR Gender:Male I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Blood Creatine Phosphokinase Increased
	Diarrhoea
	Drug Level Above Therapeutic
	Drug Toxicity
	Fall
	Head Injury
	Intentional Misuse
	Muscle Spasms

		Somnolence Staring					
			Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
			Foreign Health Professional	Eskalith Tablet-Controlled Release (Lithium Carbonate)	PS		ORAL
50 TABLET/ SINGLE DOSE/							
ORAL	1 DAY						
				Carbamazepine Tablet (Carbamazepine)	SS		ORAL
100 TABLET/SINGLE							
DOSE/ORAL	1 DAY						
				Prothipendyl Hcl Tabelt (Prothipendyl Hcl)	SS		ORAL
20 TABLET/SINGLE							
DOSE/ORAL	1 DAY						

Date:06/27/02ISR Number: 3940828-5Report Type:Direct Company Report #CTU 171059
Age:53 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization - Initial or Prolonged	Diarrhoea Drug Toxicity Vomiting		Lithium Estrogen Clonazepam Paxil Quetiapine Risperidol	PS C C C C C		

Date:06/28/02ISR Number: 3941243-0Report Type:Direct Company Report #CTU 171228
Age:45 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Disturbance In Attention Fatigue Hypothyroidism Lethargy		Lithium Sr 450mg	PS		ORAL	450MG BID	ORAL

Date:07/03/02ISR Number: 3945029-2Report Type:Expedited (15-DaCompany Report #A211178
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Bipolar Disorder Fear Thinking Abnormal	Consumer	Zoloft Tablets Lithium (Manufacturer Unknown) Unspecified Psychiatric Medication	PS SS SS				

Date:07/03/02ISR Number: 3945705-1Report Type:Expedited (15-DaCompany Report #D0038775A
Age:29 YR Gender:Male I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Coordination Abnormal Drug Effect Decreased

		Drug Interaction Speech Disorder Tongue Disorder	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
			Foreign Health Professional	Lithium Carbonate Tablet (Non-Us Product)	PS		ORAL
ORAL							
				Quetiapine Fumarate Tablet (Quetiapine Fumarate)	SS		ORAL
ORAL							
				Imipramine Hydrochloride	C		
				Lorazepam	C		
				Ranitidine Hydrochloride	C		
				Olanzapine	C		

Date:07/05/02ISR Number: 3945761-0Report Type:Expedited (15-DaCompany Report #EMADSS2001005486
Age:48 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Life-Threatening	Catatonia Dysphagia Neuroleptic Malignant	Foreign Study Health	Risperidone (Unspecified) (Risperidone)	PS		
PATIENT HAD	Syndrome	Professional				
PREVIOUSLY	Respiratory Failure					
RECEIVED						
RISPERIDONE						
FROM						
			Topiramate (Capsule) (Topiramate)	SS		ORAL
3 CAP, DAILY,						
ORAL						
			Placebo (Placebo)	SS		ORAL
3 CAP, DAILY,						
ORAL						

Lithium (Lithium)	SS

DAATE

UNSPECIFIED

Lorazepam (Lorazepam)	C
Chloral Hydrate (Chloral Hydrate)	C
Diazepam (Diazepam)	C
Olanzapine (Olanzapine)	C
Senna (Senna)	C
Lactulose (Lactulose)	C
Haloperidol (Haloperidol)	C
Lithium Carbonate (Lithium Carbonate)	C

Date:07/05/02ISR Number: 3946334-6Report Type:Expedited (15-DaCompany Report #A214139
Age: Gender:Female I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Blood Creatine Phosphokinase Increased
	Blood Creatinine Increased
	Blood Glucose Increased
	Encephalopathy

	Hallucination, Auditory Hallucination, Visual Paranoia	Report Source	Product	Role	Manufacturer	Route	Dose Duration
		Foreign	Zoloft Tablets	PS		ORAL	100.00 MG
		Health					TOTAL:DAILY:O
		Professional					RAL
			Lithium	SS			
			Valproic Acid	C			
			Lasix	C			
			Magnesium	C			
			Allopurinol	C			
			Tafil	C			
			Stilnox	C			

Date:07/10/02ISR Number: 3946490-XReport Type:Direct Company Report #CTU 171982
Age:60 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Abnormal Behaviour Speech Disorder		Lithium	PS			600 MG BID

Date:07/10/02ISR Number: 3947937-5Report Type:Expedited (15-DaCompany Report #2002000750
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Agitation Akinesia Anxiety	Foreign Health Professional	Atarax (Tablet) (Hydroxyzine Hydrochloride)	PS		ORAL	25 MG
	Caesarean Section						(DAILY), ORAL
	Foetal Heart Rate Abnormal		Lithium (Lithium) Chlorpromazine	SS			
	Maternal Drugs Affecting		(Chlorpromazine)	SS		ORAL	(DAILY), ORAL
	Foetus		Clomipramine				

	Neonatal Apnoeic Attack		(Clomipramine)	SS		ORAL (DAILY), ORAL
	Pregnancy		Clonazepam			
	Psychomotor Hyperactivity		(Clonazepam)	C		
	Tachypnoea					
	Tremor Neonatal					

Date:07/10/02ISR Number: 3947994-6Report Type:Expedited (15-DaCompany Report #2002000749
Age:40 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Hospitalization - Initial or Prolonged	Caesarean Section	Foreign	Atarax (Tablet)			
Other	Complications Of Maternal	Health	(Hydroxyzine			
Required	Exposure To Therapeutic	Professional	Hydrochloride)	PS		ORAL 25 MG (DAILY), ORAL
Intervention to Prevent Permanent Impairment/Damage	Drugs					
	Foetal Arrhythmia		Lithium (Lithium)	SS		
	Induced Labour		Chlorpromazine			
	Maternal Drugs Affecting		(Chlorpromazine)	SS		ORAL (DAILY), ORAL
	Foetus		Clomipramine			
	Pregnancy		(Clomipramine)	SS		ORAL (DAILY), ORAL
	Prolonged Labour		Clonazepam			
			(Clonazepam)	C		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/10/02ISR Number: 3949723-9Report Type:Expedited (15-DaCompany Report #D0038587A
Age:50 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged Other Required	Coma Haemodialysis Intentional Misuse Polyuria	Foreign Health Professional	Eskalith Tablet-Controlled Release	PS		ORAL	60 TABLET/ SINGLE DOSE/ ORAL
Intervention to Prevent Permanent Impairment/Damage	Somnolence Suicide Attempt		Olanzapine Tablet (Olanzapine)	SS		ORAL	27 TABLET / SINGLE DOSE/ ORAL

Date:07/12/02ISR Number: 3948423-9Report Type:Expedited (15-DaCompany Report #A212025
Age:12 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged Other	Aggression Condition Aggravated Drug Ineffective	Health Professional	Ziprasidone Eskalith (Lithium Carbonate)	PS SS		ORAL	ORAL
	Excoriation Heart Rate Increased Heart Rate Irregular Irritability		Clonidine (Clonidine)	C			

Date:07/12/02ISR Number: 3950426-5Report Type:Expedited (15-DaCompany Report #D0038633A
Age:35 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Agitation Dysarthria Enuresis	Foreign Health Professional	Eskalith Tablet-Controlled Release (Lithium				

	Faecal Incontinence	Carbonate)	PS	ORAL
90 TABLET/				
SINGLE DOSE/	Haemodialysis			
ORAL	Intentional Misuse			
	Somnolence	Olanzapine Tablet		
	Suicide Attempt	(Olanzapine)	SS	ORAL
20 TABLET/				
SINGLE DOSE/	Vomiting			
ORAL				
		Citalopram Tablet		
		(Citalopram)	SS	ORAL
20 TABLET/				
SINGLE DOSE/				
ORAL				
		Thyroxine Sodium Tablet (Levothyroxine Sodium)	SS	ORAL
50 TABLET/				
SINGLE DOSE/				
ORAL				
		Prothipendyl Hcl Tablet (Prothipendyl Hcl)	SS	ORAL
10 TABLET/				
SINGLE DOSE/				
ORAL				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/18/02ISR Number: 3951104-9Report Type:Expedited (15-DaCompany Report #001-0945-M0200710
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Bipolar Disorder	Consumer	Neurontin (Gabapentin)	PS			600 MG (DAILY)	
			Lithium (Lithium)	SS			900 MG	

Date:07/23/02ISR Number: 3953553-1Report Type:Expedited (15-DaCompany Report #2002IC000229
Age:42 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Convulsion Dehydration Migraine Sleep Disorder Vomiting	Study Consumer	Librium 10mg Peg-Intron (Peginterferon Alfa-2b)	PS SS		ORAL SUBCUTANEOUS	10mg 120 MCG; WEEKLY; SUBCUTANEOUS	ORAL
			Rebetol	SS		ORAL	1000 MG; DAILY;ORAL	
			Lithium	SS		ORAL	ORAL	
			Klonopin	C				

Date:07/24/02ISR Number: 3953634-2Report Type:Expedited (15-DaCompany Report #2002000750
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agitation Neonatal Akinesia	Foreign Health	Atarax (Tablet) (Hydroxyzine					

	Anxiety	Professional	Hydrochloride)	PS		ORAL
25 MG						
	Apgar Score Low					
(DAILY),						
	Caesarean Section					
ORAL						
	Foetal Cardiac Disorder		Lithium (Lithium)	SS		
	Maternal Drugs Affecting		Chlorpromazine			
	Foetus		(Chlorpromazine)	SS		ORAL
(DAILY), ORAL						
	Neonatal Apnoeic Attack		Clomipramine			
	Pregnancy		(Clomipramine)	SS		ORAL
(DAILY), ORAL						
	Prolonged Labour		Clonazepam			
	Psychomotor Hyperactivity		(Clonazepam)	C		
	Somnolence Neonatal		Heptaminol			
	Transient Tachypnoea Of		Hydrochloride	C		
	The Newborn					
	Tremor Neonatal					

Date:07/24/02ISR Number: 3955108-1Report Type:Expedited (15-DaCompany Report #2002-BP-03433RO (0)
Age:42 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Convulsion	Study	Lithium Carbonate			
Initial or Prolonged	Dehydration	Consumer	Usp, 300 Mg (Lithium			
	Migraine	Health	Carbonate)	PS	Usp	ORAL
PO						
	Nausea	Professional	Librium			
	Sleep Disorder	Other	(Chlordiazepoxide			
	Tremor		Hydrochloride)	SS		ORAL
PO						
	Vomiting		Peg-Intron			
			(Peginterferon			
			Alfa-2b)	SS		
SUBCUTANEOUS 120 MCG,						
WEEKLY,						

SUBCUTANEOUSL

Y (1 IN 1

WK), SC

			Rebetol (Ribavirin)	SS		ORAL

1000 MG (1 IN

1 D), PO

			Klonopin (Clonazepam)	C		

Date:07/24/02ISR Number: 3955959-3Report Type:Expedited (15-DaCompany Report #A0374148A
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Mania	Health	Eskalith			
	Overdose	Professional	Tablet-Controlled Release (Lithium Carbonate)	PS		

TWICE PER DAY

Date:07/25/02ISR Number: 3954071-7Report Type:Expedited (15-DaCompany Report #A211114
Age:24 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Life-Threatening	Blood Sodium Decreased	Consumer	Lithium (Lithium)	PS		ORAL
ORAL						
Hospitalization - Initial or Prolonged	Drug Level Increased	Health Professional	Prinivil (Lisinopril)	SS		ORAL
ORAL	Renal Failure					
			Verapamil	C		
			Prinzide (Prinzide)	C		
			Zyprexa (Olanzapine)	C		

Date:07/30/02ISR Number: 3956550-5Report Type:Expedited (15-DaCompany Report #LBID00202001804
Age:13 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Haematemesis	Health Professional	Lithobid (Lithium Carbonate)	PS		ORAL	600 MG BID PO	

Date:07/31/02ISR Number: 3957252-1Report Type:Expedited (15-DaCompany Report #2002-BP-03500RO (0)
Age:79 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Atherosclerosis	Study	Lithium Carbonate	PS		ORAL	800 MG, QD, PO	
	Mental Status Changes	Health Professional	Cgp 57148b (St1571/Cgp57148b T35717+Caps) Capsule	SS		ORAL	800 MG, QD, PO	
	Triple Vessel Bypass Graft	Other						

Date:08/01/02ISR Number: 3957958-4Report Type:Expedited (15-DaCompany Report #2002-DE-01604GD (0)
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	Dialysis	Foreign Study Literature	Lithium Carbonate (Lithium Carbonate)	PS				
	Renal Failure Chronic							

Date:08/01/02ISR Number: 3957960-2Report Type:Expedited (15-DaCompany Report #2002-DE-01603GD (0)
Age:66 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other Required Intervention to Prevent Permanent Impairment/Damage	Dialysis Renal Failure Chronic	Foreign Study Literature	Lithium Carbonate (Lithium Carbonate)	PS				

Date:08/01/02ISR Number: 3957961-4Report Type:Expedited (15-DaCompany Report #2002-DE-01601GD (0)
Age:66 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other Required Intervention to Prevent Permanent Impairment/Damage	Dialysis Renal Failure Chronic	Foreign Study Literature	Lithium Carbonate (Lithium Carbonate)	PS			19	YR

Date:08/01/02ISR Number: 3957962-6Report Type:Expedited (15-DaCompany Report #2002-DE-01600GD (0)
Age:76 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other Required Intervention to Prevent Permanent Impairment/Damage	Dialysis Renal Failure Chronic	Foreign Study Literature	Lithium Carbonate (Lithium Carbonate)	PS			32	YR

Date:08/01/02ISR Number: 3957966-3Report Type:Expedited (15-DaCompany Report #2002-DE-01597GD (0)
Age:57 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dialysis	Foreign	Lithium Carbonate					

Required Intervention to Prevent Permanent Impairment/Damage	Renal Failure Chronic	Study Literature	(Lithium Carbonate)	PS	

Date:08/01/02ISR Number: 3958073-6Report Type:Expedited (15-DaCompany Report #2002-DE-01596GD (0)
Age:71 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dialysis	Foreign	Lithium Carbonate					
Required Intervention to Prevent Permanent Impairment/Damage	Renal Failure Chronic	Study Literature	(Lithium Carbonate)	PS				

Date:08/01/02ISR Number: 3958075-XReport Type:Expedited (15-DaCompany Report #2002-DE-01595GD (0)
Age:78 YR Gender:Female I/FU:I

Outcome
Other
Required Intervention to

Prevent Permanent
Impairment/Damage

	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Dialysis Renal Failure Chronic	Foreign Study Literature	Lithium Carbonate (Lithium Carbonate)	PS				

Date:08/01/02ISR Number: 3958565-XReport Type:Expedited (15-DaCompany Report #B0274494A
Age:42 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Anorexia Bradycardia Bradyphrenia Depression	Literature Health Professional	Eskalith (Formulation Unknown) (Lithium Carbonate)	PS			1500 MG / PER	
	Disturbance In Attention						DAY	
	Drug Ineffective Drug Interaction Drug Level Increased Fatigue Lethargy Medication Error Memory Impairment Nausea Neurotoxicity Nystagmus Tremor Weight Increased		Topiramate (Formulation Unknown) (Topiramate) Wellbutrin (Formulation Unknown) (Bupropion Hydrochloride) Semisodium Valproate (Formulation Unknown) (Divalproex Sodium) Citalopram	SS SS SS C				

Date:08/01/02ISR Number: 3958690-3Report Type:Expedited (15-DaCompany Report #D0038687A
Age:70 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Encephalopathy Hypercalcaemia Hypernatraemia	Foreign Health Professional	Eskalith Tablet-Controlled Release (Lithium					

	Hyperthyroidism		Carbonate)	PS		ORAL
TWICE PER						
	Pneumonia					
DAY/ ORAL						
	Tremor		Acetylcysteine	C		
			Tramadol Hydrochloride	C		
			Esomeprazole	C		
			Moduretic	C		

Date:08/02/02ISR Number: 3956996-5Report Type:Expedited (15-DaCompany Report #WAES 0207USA01759
Age:53 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Asthenia	Health	Vioxx	PS	Merck & Co., Inc	ORAL
	Difficulty In Walking	Professional	Lithium Citrate	SS		
	Drug Interaction		Allegra	C		
	Gastrointestinal Disorder		Atenolol	C		
	Mania		Klonopin	C		
			Oxycontin	C		
			Paxil	C		
			Trazodone	C		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/02/02ISR Number: 3957718-4Report Type:Direct Company Report #CTU 173441
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Congenital Anomaly	Craniosynostosis Maternal Drugs Affecting Foetus Neonatal Disorder Spinal Disorder		Lithium	PS				

Date:08/02/02ISR Number: 3961178-7Report Type:Periodic Company Report #NSADSS2002003734
Age:49 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Amnesia Convulsion Personality Disorder Purpura	Consumer	Risperdal (4 Mg Tablet) (Risperidone)	PS		ORAL	4 MG, 2 IN 1	DAY(S), ORAL
			Lithium (Lithium)	SS		ORAL	300 MG, 3 IN	1 DAY(S), ORAL
			Prolixin (Fluphenazine Hydrochloride)	C				
			Lopid (Gemfibrozil)	C				
			Cogentin (Benzatropine Mesilate)	C				

Date:08/05/02ISR Number: 3959038-0Report Type:Expedited (15-DaCompany Report #EPOS00302001860
Age:53 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Bipolar Disorder	Foreign	Teveten (Eprosartan)	PS		ORAL	400 MG DAILY	

Initial or Prolonged	Diabetes Mellitus	Study					
PO							
	Drug Level Above	Health	Hypnorex Retard				
	Therapeutic	Professional	(Lithium Carbonate)	SS			ORAL
0.5 DF BID							
	Dyskinesia	Other					
PO, DAILY PO							
			Ass (Acetylsalicylic Acid)	C			
			Sortis (Atorvastatin Calcium)	C			

Date:08/06/02ISR Number: 3959154-3Report Type:Expedited (15-DaCompany Report #EMADSS2001005486
Age:48 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Life-Threatening	Catatonia	Foreign	Risperidone			
	Dysphagia	Study	(Risperidone)	PS		
PATIENT HAD						
	Headache	Health				
PREVIOUSLY						
	Muscle Rigidity	Professional				
RECEIVED						
	Neuroleptic Malignant					
RISPERIDONE						
	Syndrome					
FROM						
	Respiratory Failure		Topiramate (Capsule) (Topiramate)	SS		ORAL
3 CAP, DAILY,						
ORAL						
			Placebo (Placebo)	SS		ORAL
3 CAP, DAILY,						
ORAL						
			Lithium (Lithium)	SS		

			Lorazepam (Lorazepam)	C			
			Chloral Hydrate (Chloral Hydrate)	C			
			Diazepam (Diazepam)	C			
			Olanzapine (Olanzapine)	C			
			Senna (Senna)	C			
			Lactulose (Lactulose)	C			
			Haloperidol (Haloperidol)	C			
			Lithium Carbonate (Lithium Carbonate)	C			

Date:08/06/02ISR Number: 3959625-XReport Type:Expedited (15-DaCompany Report #A211114
Age:24 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Drug Toxicity	Consumer	Lithium (Lithium)	PS		ORAL		
Hospitalization - Initial or Prolonged	Haemodialysis	Health Professional	Prinivil (Lisinopril)	SS		ORAL		
	Renal Failure Acute							
	Urinary Tract Infection		Verapamil	C				
			Prinzide (Prinzide)	C				
			Zyprexa (Olanzapine)	C				

Date:08/06/02ISR Number: 3960209-8Report Type:Expedited (15-DaCompany Report #A209649
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Confusional State	Consumer	Lithium (Lithium)	PS		ORAL	(TID), ORAL	
	Depression	Health Professional	Gabapentin (Gabapentin)	SS		ORAL	300 MG	
	Dizziness						(DAILY), ORAL	
	Fatigue							
	Nausea		Prevacid (Lansoprazole)	C				
	Osteoporosis							

	Parkinson'S Disease		Unknown Stool Softener (Laxative-S)	C		
			Welbutrin Sr (Bupropion Hydrochloride)	C		
			Propanolol	C		

Date:08/07/02ISR Number: 3959393-1Report Type:Expedited (15-DaCompany Report #C2002-2188.01
Age:16 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Arrhythmia	Health Professional	Pindolol Tablets	PS		
	Drowning		Imipramine Tablets	SS		
	Drug Level Above Therapeutic		Chlorpromazine	SS		
	Drug Toxicity		Lithium	SS		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/07/02ISR Number: 3960398-5Report Type:Expedited (15-DaCompany Report #B0274494A
Age:42 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Anorexia	Literature	Eskalith (Lithium					
	Bradycardia	Health	Carbonate)	PS			1500 MG / PER	
	Bradyphrenia	Professional					DAY	
	Depression		Topiramate					
	Disturbance In Attention		(Topiramate)	SS				
	Drug Interaction		Wellbutrin					
	Drug Level Increased		(Bupropion					
	Fatigue		Hydrochloride)	SS				
	Lethargy		Semisodium Valproate					
	Medication Error		(Divalproex Sodium)	SS				
	Memory Impairment		Citalopram	C				
	Nausea							
	Neurotoxicity							
	Nystagmus							
	Tremor							
	Weight Decreased							
	Weight Increased							

Date:08/08/02ISR Number: 3960886-1Report Type:Expedited (15-DaCompany Report #200216336GDDC
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Diarrhoea	Foreign	Metronidazole	PS		ORAL	PO	
Initial or Prolonged	Drug Interaction	Other	Lithium	SS		ORAL	PO	
Disability	Hyperhidrosis		Amlodipine Besilate					
	Hypertension		(Istin)	C				
	Somnolence		Bismuth	C				
	Vomiting		Amoxicillin	C				
			Omeprazole	C				

Date:08/08/02ISR Number: 3960925-8Report Type:Expedited (15-DaCompany Report #HQ3226315JUL2002
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Leukocytosis Lower Respiratory Tract Infection	Health Professional	Efexor Xr (Venlafaxine Hydrochloride, Capsule, Extended Release)	PS		ORAL	75 MG 1X PER	1 DAY ORAL
			Lithium (Lithium,)	SS		ORAL		

Date:08/09/02ISR Number: 3962020-0Report Type:Expedited (15-DaCompany Report #A211114
Age:24 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Blood Sodium Decreased	Consumer	Lithium (Lithium)	PS		ORAL	ORAL	
Hospitalization - Initial or Prolonged	Haemodialysis Renal Failure Acute	Health Professional	Prinivil (Lisinopril)	SS		ORAL	ORAL	
	Therapeutic Agent Toxicity Urinary Tract Infection		Verapamil Prinzide (Prinzide) Zyprexa (Olanzapine)	C C C				

Date:08/12/02ISR Number: 3961544-XReport Type:Expedited (15-DaCompany Report #2002002891
Age:42 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Convulsion	Consumer	Lithium	PS			UNKNOWN	
	Dehydration						(UNKNOWN),	
	Migraine						UNKNOWN	
	Nausea		Librium					
	Sleep Disorder		(Chlordiazeoxide)	SS			UNKNOWN	
	Tremor						(UNKNOWN),	
	Vomiting						UNKNOWN	
			Rebetol (Rivavirin)	SS			UNKNOWN	
							(UNKNOWN),	
							UNKNOWN	
			Peg-Intron (Peginterferon Alfa-2b)	SS			UNKNOWN	
							(UNKNOWN),	
							UNKNOWN	

Date:08/15/02ISR Number: 3963683-6Report Type:Expedited (15-DaCompany Report #D0039066A
Age:71 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Diarrhoea	Foreign	Eskalith					
	Haemodialysis	Health	Tablet-Controlled					
Other	Intentional Misuse	Professional	Release (Lithium					
	Suicide Attempt		Carbonate)	PS		ORAL	10	
	Vomiting						TABLET/SINGLE	

DOSE/ORAL

Date:08/16/02ISR Number: 3964263-9Report Type:Expedited (15-DaCompany Report #A0367112A
Age:36 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Distension Abdominal Pain Upper Asthenia Fatigue Gastrointestinal Disorder Gastrointestinal Ulcer Inflammation Muscle Disorder Myalgia Nausea Overdose	Health Professional	Lithium Salt (Formulation Unknown) (Generic) (Lithium Salt) Multiple Medication (Formulation Unknown) (Multiple Medication)	PS SS		ORAL	UNK / DAY	PER

Date:08/17/02ISR Number: 3963348-0Report Type:Direct Company Report #CTU 174404
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	Drug Toxicity Fall Hypoglycaemia		Lithium Zoloft Artane Benedryl Trifluoperazine Insalen	PS C C C C C		ORAL	600 MG PO TID	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/19/02ISR Number: 3964179-8Report Type:Direct Company Report #CTU 174515
Age:37 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Muscle Rigidity		Geodon Pfizer , Inc	PS	Pfizer, Inc	ORAL	80MG BID	
			Lithium	SS		ORAL	600MG BID	
			Depakote	C			ORAL	
			Klonopin	C				
			Cogentin	C				
			Propranolol	C				
			Amaryl	C				
			Levoxyl	C				
			Copaxone	C				
			Gluophage	C				

Date:08/19/02ISR Number: 3964796-5Report Type:Expedited (15-DaCompany Report #B0275800A
Age:49 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Diarrhoea Drug Interaction Hyperhidrosis Hypertension	Foreign	Lithium Salt (Formulation Unknown) (Lithium Salt)	PS		ORAL	ORAL	
	Somnolence Vomiting		Metronidazole (Formulation Unknown) (Metronidazole)	SS		ORAL	ORAL	
			Amlodipine Besylate	C				
			Bismuth Salt	C				
			Amoxicillin Trihydrate	C				
			Omeprazole	C				
			Statins	C				

Date:08/19/02ISR Number: 3964922-8Report Type:Expedited (15-DaCompany Report #D0038687A
Age:70 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Cholelithiasis Condition Aggravated Encephalopathy Hypercalcaemia Hypernatraemia Hyperparathyroidism Hyperthyroidism Nephrogenic Diabetes Insipidus Pneumonia Pseudomonas Infection Psoriasis Sepsis Tremor	Foreign Health Professional	Eskalith Tablet-Controlled Release (Lithium Carbonate) Acetylcysteine Tramadol Hydrochloride Esomeprazole Moduretic	PS C C C C		ORAL	TWICE PER DAY / ORAL ; SEE TEXT	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/20/02ISR Number: 3965141-1Report Type:Expedited (15-DaCompany Report #001-0981-M0200681
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Bipolar I Disorder	Consumer	Atorvastatin					
Required	Bladder Disorder	Health	(Atorvastatin)	PS		ORAL	10 MG	
Intervention to	Cataract	Professional					(DAILY), ORAL	
Prevent Permanent	Oedema Peripheral		Gabapentin	SS				
Impairment/Damage	Pollakiuria		Lithium Carbonate	SS				
	Renal Disorder							
	Sepsis							
	Weight Increased							

Date:08/20/02ISR Number: 3965632-3Report Type:Expedited (15-DaCompany Report #EMADSS2001005486
Age:48 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Drug Ineffective	Foreign	Risperidone					
	Neuroleptic Malignant	Study	(Unspecified)					
	Syndrome	Health	(Risperidone)	PS			PATIENT HAD	
	Respiratory Failure	Professional					PREVIOUSLY	
							RECEIVED	
							RISPERIDONE	
							FROM	
			Topiramate (Capsule)					
			(Topiramate)	SS		ORAL	3 CAP DAILY,	
							ORAL	
			Placebo (Placebo)	SS		ORAL	3 CAP, DAILY,	
							ORAL	
			Lithium (Lithium)	SS				
			Lorazepam					
			(Lorazepam)	C				

			Chloral Hydrate (Chloral Hydrate)	C			
			Diazepam (Diazepam)	C			
			Olanzapine (Olanzapine)	C			
			Senna (Senna)	C			
			Lactulose (Lactulose)	C			
			Haloperidol (Haloperidol)	C			
			Lithium Carbonate (Lithium Carbonate)	C			

Date:08/23/02ISR Number: 3967179-7Report Type:Expedited (15-DaCompany Report #2002003870
Age:44 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Akathisia	Health	Lithium	PS		ORAL	ORAL	
		Professional	Ziprasidone	SS		ORAL	40 MG (BID),	ORAL
			Verapamil	C				
			Synthroid (Levothyroxine Sodium)	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/26/02ISR Number: 3967487-XReport Type:Direct Company Report #CTU 175056
Age:39 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Coma		Lithium 300mg	PS		ORAL	300MG PO BID	
			Phenelzine 45mg	SS			45MG QD	
			Olanzapine	C				
			Trazadone	C				

Date:08/27/02ISR Number: 3968292-0Report Type:Expedited (15-DaCompany Report #B0277136A
Age:59 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Asthenia Cerebral Atrophy Drug Interaction Electroencephalogram	Foreign Literature Health Professional	Eskalith (Formulation Unknown) (Lithium Carbonate)	PS			UNKNOWN	UNKNOWN
	Abnormal Fall Muscle Twitching Tremor		Carbamazepine (Formulation Unknown) (Carbamazepine)	SS			UNKNOWN	UNKNOWN 10 DAY
			Clozapine (Formulation Unknown) (Clozapine)	SS			UNKNOWN	UNKNOWN

Date:08/27/02ISR Number: 3968293-2Report Type:Expedited (15-DaCompany Report #B0276937A
Age:21 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Aggression Alanine Aminotransferase Increased Drug Interaction Red Blood Cell Count Increased	Foreign Literature Health Professional	Eskalith (Formulation Unknown) (Lithium Carbonate)	PS				
			Carbamazepine (Formulation					

	Tremor			Unknown) (Carbamazepine)	SS			
UNKNOWN	UNKNOWN	13	DAY	Clozapine (Formulation Unknown) (Clozapine)	SS			
UNKNOWN								

Date:08/27/02ISR Number: 3968313-5Report Type:Expedited (15-DaCompany Report #EMADSS2002004997
Age:46 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Agitation	Foreign	Haldol (Unspecified) (Haloperidol)	PS			5 MG,	
	Blood Creatine Phosphokinase Increased	Health Professional	Lithium Carbonate (Lithium Carbonate)	SS				
	Dystonia		Risperidone (Risperidone)	C				
	Overdose		Fluoxetine (Fluoxetine)	C				
			Depot Provera (Medroxyprogesterone Acetate)	C				
			Clonazepam (Clonazepam)	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/27/02ISR Number: 3968326-3Report Type:Expedited (15-DaCompany Report #EPOS00302001860
Age:53 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Bipolar Disorder Cerebellar Syndrome Diabetes Mellitus Drug Level Above Therapeutic Dyskinesia Extensor Plantar Response Hemiparesis Hypertension Movement Disorder Neurological Examination Abnormal	Foreign Study Health Professional Other	Teveten (Eprosartan) Hypnorex Retard (Lithium Carabonate) Ass (Acetylsalicylic Acid) Sortis (Atorvastatin Calcium)	PS SS C C		ORAL ORAL	400 MG DAILY PO 0.5 DF BID PO, DAILY PO

Date:08/27/02ISR Number: 3969192-2Report Type:Expedited (15-DaCompany Report #A0377880A
Age:41 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	Disturbance In Attention Drug Level Increased Dyspepsia Muscle Rigidity Overdose Psychomotor Hyperactivity Restlessness Somnolence Speech Disorder Staring Vomiting	Health Professional	Eskalith Tablet -Controlled Release (Lithium Carbonate) Buspirone Hydrochloride (Formulation Unknown) Buspirone Hydrochloride) Olanzapine (Formulation Unknown)Olanzapine)	PS SS SS		ORAL ORAL ORAL	UNK / SEE DOSAGE TEXT / ORAL ORAL

	Risperidone (Formulation Unknown)Risperidone)	SS	ORAL
ORAL			
	Benztropine Mesylate (Formulation Unknown)(Benztropine Mesylate)	SS	ORAL
ORAL			
	Thyroxine Sodium (Formulation Unknown) Levothyroxine Sodium)	SS	ORAL
ORAL			

Date:08/27/02ISR Number: 3969232-0Report Type:Expedited (15-DaCompany Report #B0277028A
Age:52 YR Gender:Male I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Anxiety
	Bipolar Disorder
	Blood Creatinine Increased
	Blood Urea Increased
	Condition Aggravated
	Nervousness
	Sinus Tachycardia
	Thyroiditis

	Upper Respiratory Tract Infection Weight Decreased	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
		Literature Health	Lithium Salt (Lithium Salt)	PS		
15 YR						
		Professional	Olanzapine	C		
			Simvastatin	C		
			Valproic Acid	C		
			Aspirin	C		

Date:08/27/02ISR Number: 3969234-4Report Type:Expedited (15-DaCompany Report #B0258321A
Age:45 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Anxiety	Literature	Lithium Salt			
	Convulsion	Health	(Lithium Salt)	PS		ORAL
300 MG /						
	Depression	Professional				
TWICE PER DAY						
	Drug Ineffective					
/ ORAL 1 DAY						
	Insomnia		Lithium Salt			
			(Lithium Salt)	SS		ORAL
ORAL 3 DAY						
			Lithium Salt			
			(Lithium Salt)	SS		ORAL
ORAL						
			Bupropion Hydrochloride	C		
			Venlafaxine Hydrochloride	C		
			Gabapentin	C		
			Clonazepam	C		
			Glycopyrronium Bromide	C		
			Methohexitone	C		
			Suxamethonium	C		

Date:08/29/02ISR Number: 3969294-0Report Type:Expedited (15-DaCompany Report #2002004395
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Serotonin Syndrome	Literature Consumer	Lithium (Lithium) Fluoxetine (Fluoxetine)	PS SS				

Date:08/30/02ISR Number: 3969440-9Report Type:Expedited (15-DaCompany Report #2002003870
Age:44 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Akathisia	Health	Lithium	PS		ORAL		
	Drug Interaction	Professional	Ziprasidone	SS		ORAL	60 MG	(DAILY), ORAL
	Dyskinesia							
			Verapamil	C				
			Synthroid (Levothyroxine Sodium)	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/30/02ISR Number: 3970209-XReport Type:Expedited (15-DaCompany Report #2002004291
Age:49 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Bipolar Disorder	Foreign Health Professional	Cetirizine (Tablets) (Cetirizine)	PS		ORAL	10 MG, ORAL	
Disability			Lithium (Lithium)	SS			800 MG	

Date:09/03/02ISR Number: 3972923-9Report Type:Expedited (15-DaCompany Report #B0277651A
Age:53 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Coma Haemodialysis Pancreatitis Acute	Foreign	Augmentin Tablet (Amox.Trihyd+Pot.Cla vulan.)	PS		ORAL	ORAL	
	Suicide Attempt		Lithium Carbonate Tablet (Non-Us Product)	SS		ORAL	ORAL	
			Bromazepam Tablet (Bromazepam)	SS		ORAL	ORAL	
			Paxil Tablet (Paroxetine Hydrochloride)	SS		ORAL	ORAL	

Date:09/04/02ISR Number: 3970456-7Report Type:Direct Company Report #CTU 175626
Age:62 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	Laboratory Test Abnormal Lethargy Mental Status Changes		Lithium	PS			300MG TI	
			Benztropine	C				
			Diphenhydramine	C				
			Fluphenazine	C				
			Thiamine	C				

Impairment/Damage			Folic Acid	C		

Date:09/04/02ISR Number: 3971562-3Report Type:Expedited (15-DaCompany Report #2002-BP-04158RO(0)
Age:79 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Atherosclerosis Confusional State Drug Toxicity	Study Health Professional	Lithium Carbonate Capsules Usp, 300 Mg (Lithium Carbonate)	PS		ORAL	PO	
	Enterococcal Infection Lung Disorder Urinary Tract Infection	Other	Gleevec (Code Not Broken)	SS				

Date:09/04/02ISR Number: 3971566-0Report Type:Expedited (15-DaCompany Report #9409995
Age:16 YR Gender:Female I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged Other	Anorexia Bipolar Disorder Depression Hallucination Heart Rate Increased Overdose Psychotic Disorder Respiratory Rate

		Increased Suicide Attempt					
			Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
			Health	Zoloft (Sertraline)	PS		ORAL
200 MG (DAILY), ORAL			Professional				
				Lithium	SS		
				Depakote (Valproate Semisodium)	SS		
				Remeron (Mirtazapine)	SS		
				Tylenol (Paracetamol)	C		
				Advil (Ibuprofen)	C		
				All Other Therapeutic Products	C		

Date:09/05/02ISR Number: 3970853-XReport Type:Direct Company Report #CTU 175744
Age:49 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Required	Blood Thyroid Stimulating		Lithium 300mg	PS		ORAL
300MG TID Intervention to	Hormone Increased					
ORAL Prevent Permanent	Chronic Obstructive		Levothroxine .125mg	SS		ORAL
0.375MG QD Impairment/Damage	Airways Disease					
ORAL						
	Exacerbated					
	Drug Level Above Therapeutic					
	Tremor					

Date:09/05/02ISR Number: 3972744-7Report Type:Expedited (15-DaCompany Report #2002003870
Age:44 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					

Other	Akathisia	Health	Lithium	PS		ORAL	ORAL
	Formication	Professional	Ziprasidone	SS		ORAL	120 MG (BID),
	Insomnia						ORAL
	Lethargy		Mellaril (Thioridazine Hydrochloride)	SS			
			Zyprexa (Olanzapine)	SS			
			Verapamil	C			
			Synthroid (Levothyroxine Sodium)	C			

Date:09/05/02ISR Number: 3972802-7Report Type:Expedited (15-DaCompany Report #2002002891
Age:42 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Convulsion	Consumer	Lithium	PS		ORAL	ORAL
Initial or Prolonged	Dehydration		Librium				
	Migraine		(Chlordiazepoxide)	SS		ORAL	ORAL
	Nausea		Rebetol (Ribabirin)	SS		ORAL	1000
	Sleep Disorder						MG(DAILY),
	Tremor						ORAL
	Vomiting		Peg-Introl (Peginterferon				

				Alfa-2b)	SS		
SUBCUTANEOUS	120 MCG(WEEKLY), SUBCUTANEOUS						
				Clonazepam	C		

Date:09/06/02ISR Number: 3972655-7Report Type:Expedited (15-DaCompany Report #B0277530A
Age:47 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Pressure Increased Coordination Abnormal Depression Drug Toxicity Dysarthria Hyperthyroidism Polyuria Sinus Tachycardia Therapeutic Agent Toxicity Thyroiditis Tremor	Literature Health Professional	Eskalith (Formulation Unknown) (Lithium Carbonate)	PS			600 MG/TWICE PER DAY	

Date:09/06/02ISR Number: 3972661-2Report Type:Expedited (15-DaCompany Report #A0374148A
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Mania Overdose	Health Professional	Eskalith Tablet-Controlled Release (Lithium Carbonate)	PS			TWICE PER DAY	

Date:09/09/02ISR Number: 3973797-2Report Type:Expedited (15-DaCompany Report #HQ3226315JUL2002
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Leukocytosis Pneumonia	Health Professional	Efexor Xr (Venlafaxine Hydrochloride, Capsule, Extended Release)	PS		ORAL	75 MG 1X PER	1 DAY
			Lithium (Lithium,)	SS		ORAL		

Date:09/09/02ISR Number: 3974518-XReport Type:Direct Company Report #CTU 175987
Age:73 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Toxicity Dysarthria Mental Status Changes		Lithium	PS				

Date:09/10/02ISR Number: 3973846-1Report Type:Expedited (15-DaCompany Report #B0277878A
Age:26 YR Gender:Female I/FU:I

Outcome	PT	Report Source
Other	Hyperthyroidism	Foreign Literature

			Health Professional				
				Product	Role	Manufacturer	Route
Dose	Duration						
				Eskalith (Formulation Unknown) (Lithium Carbonate)	PS		
PER DAY							

Date:09/10/02ISR Number: 4000916-4Report Type:Periodic Company Report #2002114176US
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
	Delirium	Consumer	Bextra (Valdecoxib)			
	Drug Interaction		Tablet	PS		ORAL
20 MG QD,						
ORAL	10 DAY					
			Lithium (Lithium)	SS		
			Itraconazole (Itraconazole)	SS		

Date:09/12/02ISR Number: 3975243-1Report Type:Expedited (15-DaCompany Report #2002003870
Age:44 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Other	Akathisia	Health	Lithium	PS		ORAL
900 MG						
	Drug Interaction	Professional				
(DAILY), ORAL						
	Feeling Abnormal		Geodon (Ziprasidone)	SS		ORAL
1`20 MG						
	Insomnia					
(BID), ORAL						
	Lethargy		Mellaril (Thiridazine Hydrochloride)	SS		
			Zyprexa (Olanzapine)	SS		
			Verapamil	C		
			Synthroid			

			(Levothyroxine Sodium)	C		

Date:09/13/02ISR Number: 3975712-4Report Type:Direct Company Report #CTU 176374
Age:72 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Asthenia Confusional State Drug Level Increased Renal Failure Acute		Lithium Carbonate	PS			300MG Q8	

Date:09/13/02ISR Number: 3976218-9Report Type:Expedited (15-DaCompany Report #D0039220A
Age:27 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Intentional Misuse Somnolence Suicide Attempt	Foreign Health Professional	Lithium Carbonate Tablet (Non-Us Product)	PS		ORAL	450 MG/ SINGLE DOSE / ORAL	
			Gelonida Tablet (Gelonida)	SS		ORAL	500 MG/ SINGLE DOSE /	

ORAL

Date:09/16/02ISR Number: 3977258-6Report Type:Direct Company Report #CTU 176527
Age:53 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Renal Failure Acute		Lithium	PS			300MG BID	
			Cipro	C				
			Ferrous Sulfate	C				
			Multivitamins	C				
			Temazepam	C				

Date:09/16/02ISR Number: 3977288-4Report Type:Direct Company Report #CTU 176563
Age:53 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Mental Status Changes		Lithium	PS			300MG TID	
			Temazepam	C				
			Risperidone	C				
			Terazosin	C				
			Hctz	C				

Date:09/18/02ISR Number: 3977596-7Report Type:Direct Company Report #CTU 176804
Age:36 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Renal Impairment		Lithium Carbonate 300mg	PS		ORAL	600MG PO BID	
			Haloperidol	C				
			Divalproex	C				
			Propranolol	C				

Date:09/18/02ISR Number: 3980009-2Report Type:Expedited (15-DaCompany Report #2002-BP-04158BRO
Age:79 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Confusional State Coronary Artery Surgery Enterococcal Infection Lung Disorder Mental Status Changes Urinary Tract Infection	Study Health Professional Other	Lithium Carbonate Gleevec (Code Not Broken)	PS SS	Usp	ORAL	PO	

Date:09/19/02ISR Number: 3977726-7Report Type:Expedited (15-DaCompany Report #B0279406A
Age:39 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Drug Level Increased Medication Error	Literature Health Professional	Lithium Salt (Lithium Salt) Paracetamol (Acetaminophen)	 PS SS				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/19/02ISR Number: 3977778-4Report Type:Expedited (15-DaCompany Report #B0279405A
Age:44 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Alcohol Poisoning	Literature	Ethanol (Formulation Unknown) (Alcohol)	PS		ORAL		
	Completed Suicide	Health						
	Intentional Misuse	Professional	Trazodone (Formulation Unknown) (Trazodone)	SS		ORAL		
			Lithium Salt (Formulation Unknown) (Lithium Salt)	SS		ORAL		

Date:09/19/02ISR Number: 3978187-4Report Type:Expedited (15-DaCompany Report #B0279388A
Age:45 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Drug Level Increased	Literature	Lithium Salt (Formulation Unknown) (Lithium Salt)	PS		ORAL		
	Medication Error	Health						
		Professional						

Date:09/19/02ISR Number: 3978189-8Report Type:Expedited (15-DaCompany Report #B0279389A
Age:50 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Drug Level Above Therapeutic	Literature	Lithium Salt (Formulation Unknown) (Lithium Salt)	PS		ORAL		
	Medication Error	Health						
		Professional						

Date:09/19/02ISR Number: 3978192-8Report Type:Expedited (15-DaCompany Report #B0279390A
Age:41 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide Intentional Misuse	Literature Health Professional	Lithium Salt (Formulation Unknown) (Lithium Salt)	PS		ORAL		
			Haloperidol (Formulation Unknown) (Haloperidol)	SS		ORAL		

Date:09/19/02ISR Number: 3978196-5Report Type:Expedited (15-DaCompany Report #B0279432A
Age:40 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide Intentional Misuse	Literature Health Professional	Lithium Salt (Formulation Unknown) (Lithium Salt)	PS				
			Thyroxine Sodium	C				
			Frusemide	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/19/02ISR Number: 3978200-4Report Type:Expedited (15-DaCompany Report #B0279433A
Age:34 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardio-Respiratory Arrest	Literature	Lithium Salt (Formulation Unknown) (Lithium Salt)	PS				
	Completed Suicide	Health	Opiate	C				
	Intentional Misuse	Professional	Benzodiazepines	C				

Date:09/19/02ISR Number: 3978203-XReport Type:Expedited (15-DaCompany Report #B0279434A
Age:80 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Literature	Lithium Salt (Formulation Unknown) (Lithium Salt)	PS				
	Intentional Misuse	Health	Temazepam	C				
		Professional						

Date:09/19/02ISR Number: 3978205-3Report Type:Expedited (15-DaCompany Report #B0279666A
Age:26 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Unevaluable Event	Literature	Lithium Salt (Formulation Unknown)	PS		ORAL	ORAL	
		Health	Olanzapine (Formulation Unknown) (Olanzapine)	SS				
		Professional						

Date:09/19/02ISR Number: 3978207-7Report Type:Expedited (15-DaCompany Report #B0279407A
Age:44 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Drug Level Increased	Literature Health Professional	Paracetamol (Formulation Unknown) (Acetaminophen)	PS				
			Lithium Salt (Formulation Unknown) (Lithium Salt)	SS				

Date:09/19/02ISR Number: 3978269-7Report Type:Expedited (15-DaCompany Report #A0380038A
Age:16 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Interaction Drug Toxicity Pharyngitis Streptococcal	Health Professional	Eskalith (Formulation Unknown) (Lithium Carbonate)	PS		ORAL		
			Phenoxymethylpenicillin Potassium (Penicillin V Potassium)	SS		ORAL		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/19/02ISR Number: 3978323-XReport Type:Expedited (15-DaCompany Report #B0279371A
Age:55 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Literature	Lithium Salt					
	Intentional Misuse	Health	(Lithium Salt)	PS		ORAL	ORAL	
		Professional	Fluphenazine					
			(Fluphenazine)	SS		ORAL	ORAL	
			Quetiapine					
			(Quetiapine)	SS		ORAL	ORAL	

Date:09/20/02ISR Number: 3979523-5Report Type:Expedited (15-DaCompany Report #2002057061
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Confusional State	Consumer	Dilantin (Phenytoin					
	Difficulty In Walking		Sodium)	PS		ORAL	400 MG	
	Drug Interaction						(DAILY), ORAL	
	Drug Toxicity		Lithium	SS		ORAL	ORAL	
	Dyskinesia		Valproate Semisodium	SS		ORAL	ORAL	
	Insomnia							
	Mood Altered							
	Speech Disorder							
	Tremor							
	Weight Decreased							

Date:09/23/02ISR Number: 3979591-0Report Type:Expedited (15-DaCompany Report #LBID00202002284
Age:32 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Balance Disorder	Consumer	Lithobid (Lithium					
	Confusional State		Carbonate)	PS		ORAL	DAILY PO	

	Disturbance In Attention
	Muscle Twitching
	Suicide Attempt
	Vomiting

Date:09/24/02ISR Number: 3980954-8Report Type:Expedited (15-DaCompany Report #D0039220A
Age:27 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Intentional Misuse Somnolence Suicide Attempt	Foreign Health Professional	Lithium Carbonate Tablet (Non-Us Product)	PS		ORAL	450 MG, SINGLE DOSE; ORAL	
			Gelonida Tablet (Gelonida)	SS		ORAL	500 MG, SINGLE DOSE; ORAL	

Date:09/25/02ISR Number: 3982309-9Report Type:Expedited (15-DaCompany Report #B0279668A
Age: Gender:Female I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Drug Level Decreased Haemodialysis Neuroleptic Malignant

		Syndrome Pancreatitis					
			Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
			Literature Health Professional	Ziprasidone Hcl (Ziprasidone Hcl) (Formulation Unknown)	PS		
2	WK						
				Lithium Salt (Lithium Salt) (Formulation Unknown)	SS		
YR							
				Clozapine (Clozapine) (Formulation Unknown)	SS		
YR							

Date:09/27/02ISR Number: 3981743-0Report Type:Expedited (15-DaCompany Report #D0039066A
Age:71 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged Other	Diarrhoea Haemodialysis Intentional Misuse Nausea	Foreign Health Professional	Eskalith Tablet-Controlled Release (Lithium Carbonate)	PS		ORAL
10	Suicide Attempt					
TABLET/SINGLE	Vomiting					
DOSE/ORAL						

Date:09/27/02ISR Number: 3982696-1Report Type:Direct Company Report #CTU 177460
Age:54 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged Required	Nephrogenic Diabetes Insipidus		Lithium Carbonate Tablets Quetapine Fumarate	PS C		

Intervention to Prevent Permanent Impairment/Damage

Etodolac	C
Sildenapril Citrate	C
Aspirin	C
Multivitamin/Minerals	C
Metformin Hcl	C
Furosemide	C
Felodipine	C
Cyclobenzaprine Hcl	C
Minocycline Hcl	C
Glipizide	C
Rantidine Hcl	C
Clotrimazole	C
Guaifensin	C
Albuterol 90/Ipratrop	C
Oxycodone 5mg/Acetaminophen	C

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/27/02ISR Number: 3982878-9Report Type:Expedited (15-DaCompany Report #NSADSS2002033048
Age:9 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Diabetes Insipidus	Consumer	Topamax (Tablet) (Topiramate)	PS				
SEE IMAGE			Lithobid (Lithium Carbonate)	SS				
			Zyprexa (Olanzapine)	C				
			..	C				

Date:10/01/02ISR Number: 3986093-4Report Type:Expedited (15-DaCompany Report #2001AP05204
Age:55 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Literature	Quetiapine	PS				
	Drug Toxicity	Health	Fluphenazine	SS				
		Professional	Lithium	SS				

Date:10/01/02ISR Number: 4027317-7Report Type:Periodic Company Report #2001UW07551
Age:24 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required	Drooling	Health	Seroquel "Zeneca"	PS		ORAL	400 MG QAM PO	
Intervention to	Neuroleptic Malignant	Professional	Seroquel "Zeneca"	SS		ORAL	1600 MG HS PO	
Prevent Permanent	Syndrome		Haldol	SS		ORAL	5 MG BID PO	
Impairment/Damage			Lithium	SS		ORAL	600 MG QAM PO	
			Lithium	SS		ORAL	300 MG HS PO	
			Propranolol	C				

Date:10/02/02ISR Number: 3983158-8Report Type:Expedited (15-DaCompany Report #WAES 0205USA01719
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Coma Dysarthria Oedema Peripheral Paraesthesia	Health Professional	Vioxx Lithium Carbonate Paxil Glucophage Glucotrol Prilosec Lipitor Metamucil [Therapy Unspecified]	PS SS SS C C C C C C	Merck & Co., Inc	ORAL		

Date:10/02/02ISR Number: 3983231-4Report Type:Expedited (15-DaCompany Report #WAES 0204SWE00002
Age:81 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Creatinine Increased Depressed Level Of Consciousness Drug Level Increased Extrapyramidal Disorder	Health Professional	Vioxx Lithium Sulfate Levothyroxine Sodium Dipyridamole Lofepramine Hydrochloride Zolpidem Tartrate Calcium Carbonate And Cholecalciferol	PS SS C C C C C	Merck & Co., Inc	ORAL ORAL	25	DAY

			Tramadol Hydrochloride	C		

Date:10/02/02ISR Number: 3983817-7Report Type:Direct Company Report #CTU 177820
Age:56 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Other	Nephrogenic Diabetes Insipidus Post Procedural Complication		Lithium	PS		500 MG QD

Date:10/02/02ISR Number: 3985468-7Report Type:Direct Company Report #CTU 177745
Age:44 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Hospitalization - Initial or Prolonged	Drug Level Above Therapeutic		Lithium	PS		ORAL 1200MG, 600MG BI ORAL
Required Intervention to Prevent Permanent Impairment/Damage			Lithium	C		
			Carbonate	C		
			Quetiapine Fumarate	C		
			Clonazepam	C		
			Glyburide 2.5mg/Metformin Hcl	C		
			Ibuprofen	C		
			Hydroxyzine Pamoate	C		

Date:10/03/02ISR Number: 3986956-XReport Type:Expedited (15-DaCompany Report #2002058798
Age:55 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Hospitalization - Initial or Prolonged	Coordination Abnormal	Health Professional	Lithane (Lithium)	PS		ORAL ORAL
	Dysarthria Motor Dysfunction		Risperidone Trifluoperazine	SS		

	Overdose		Hydrochloride	C			
	Somnolence		Carbamazepine	C			
			Olanzapine	C			

Date:10/03/02ISR Number: 3987084-XReport Type:Expedited (15-DaCompany Report #2002125973AU
Age:64 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Blood Creatinine Increased	Foreign Literature	Celebrex (Celecoxib) Capsule	PS		ORAL	200 MG, BID,
	Confusional State	Health Professional				ORAL	
	Dehydration		Lithium (Lithium)	SS			250 MG MANE,
	Drug Interaction	Other					500 MG NOCTE,
	Drug Level Above Therapeutic		Risperidone	C			
	Gait Disturbance		Venlafaxine	C			
	Nystagmus						
	Thirst						
	Tremor						

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/07/02ISR Number: 3986901-7Report Type:Expedited (15-DaCompany Report #LBID00202002402
Age:32 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Blindness Transient Deafness Unilateral Diarrhoea Ear Pain Migraine Tinnitus Vision Blurred	Consumer	Lithobid (Lithium Carbonate) Risperdal (Risperidone)	PS C		ORAL	300 & 600 MG DAILY PO,	

Date:10/08/02ISR Number: 3989985-5Report Type:Expedited (15-DaCompany Report #EPOS00302001860
Age:53 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Level Increased Dyskinesia Hemiparesis Hypertension	Foreign Study Health Professional Other	Teveten (Eprosartan) Hypnorex Retard (Lithium Carbonate) Ass (Acetylsalicylic Acid) Sortis (Atorvastatin Calcium) Glucobay 50 Metfogamma 850 (Metformin)	PS SS C C C C		ORAL ORAL	400 MG DAILY PO 1 DF BID PO, UNK DAILY PO	

Date:10/08/02ISR Number: 3990112-9Report Type:Expedited (15-DaCompany Report #B0280507A
Age:29 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Mouth Ulceration	Foreign	Lithium Acetate					

Initial or Prolonged		Health Professional	Tablet (Lithium Acetate)	PS	ORAL
ORAL					
			Lamictal Unspecified Tablet (Lamotrigine)	SS	ORAL
SEE DOSAGE TEXT / ORAL					
			Risperidone	C	
			Reboxetine	C	
			Diane-35	C	

Date:10/09/02ISR Number: 3987182-0Report Type:Direct Company Report #CTU 178381
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Blood Creatinine Increased Blood Urea Increased Confusional State Dysarthria Lethargy Sedation		Lithium Carbonate	PS		ORAL	600MG PO BID	
			Lisinopril	SS				
			Rispeeridone	C				
			Niccoderm Patch	C				
			Insulin	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/09/02ISR Number: 3987558-1Report Type:Direct Company Report #CTU 178368
Age:51 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Toxicity		Lithium	PS		ORAL	1200MG,600 MG BID	
			Spironolactone	C				
			Furosemide	C				

Date:10/09/02ISR Number: 3988241-9Report Type:Direct Company Report #CTU 178292
Age:69 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	Drug Level Above Therapeutic		Lithium	PS				

Date:10/09/02ISR Number: 3990829-6Report Type:Expedited (15-DaCompany Report #02P-163-0201728-00
Age:42 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Chest Pain Dizziness Drug Interaction Extrapyramidal Disorder	Health Professional	Meridia 10 Mg (Meridia) (Sibutramine) (Sibutramine)	PS		ORAL	10 MG, 1 IN 1 D, PER ORAL	
	Hyperglycaemia Hypotension Serotonin Syndrome		Lithium (Lithium)	SS				
			Citalopram Hydrobromide	C				
			Aspirin	C				
			Buspirone Hydrochloride	C				
			Trazodone	C				

			Lisinopril	C			
			Naproxen	C			
			Glucophage	C			
			Clozapine	C			
			Risperidone	C			
			Insulin	C			
			Fluticasone	C			

Date:10/11/02ISR Number: 3992715-4Report Type:Expedited (15-DaCompany Report #2002059783
Age:64 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Confusional State	Foreign	Lithane (Lithium)	PS		ORAL	750 MG (BID) 400 MG (BID), ORAL	
	Dehydration	Literature	Celebrex (Celecoxib)	SS				
	Gait Disturbance	Health						
	Nystagmus	Professional	Risperidone	C				
	Thirst		Venlafaxine	C				
	Tremor							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/12/02ISR Number: 3988688-0Report Type:Expedited (15-DaCompany Report #WAES 0205USA01719
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Coma		Vioxx	PS	Merck & Co., Inc	ORAL		
	Drug Interaction		Lithium Carbonate	SS				
	Dysarthria		Paxil	SS				
	Oedema Peripheral		Glucophage	C				
	Paraesthesia		Glucotrol	C				
			Prilosec	C				
			Lipitor	C				
			Metamucil	C				
			[Therapy Unspecified]	C				

Date:10/15/02ISR Number: 3992665-3Report Type:Expedited (15-DaCompany Report #2002059783
Age:64 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Confusional State	Foreign	Lithane (Lithium)	PS			750 MG (BID)	
	Dehydration	Literature	Celebrex (Celecoxib)	SS		ORAL	400 MG (BID), ORAL	
	Drug Interaction	Consumer						
	Drug Toxicity	Health	Risperidone	C				
	Gait Disturbance	Professional	Venlafaxine	C				
	Nystagmus							
	Thirst							
	Tremor							

Date:10/15/02ISR Number: 3993510-2Report Type:Expedited (15-DaCompany Report #2002057061
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Back Pain	Consumer	Dilantin (Phenytoin Sodium)	PS		ORAL	400 MG DAILY, ORAL	
Other	Confusional State	Health						
	Convulsion	Professional						

	Depressed Level Of	Lithium	SS	ORAL
ORAL				
	Consciousness	Valproate Semisodium	SS	ORAL
ORAL				
	Difficulty In Walking			
	Discomfort			
	Drug Interaction			
	Drug Level Decreased			
	Drug Level Increased			
	Drug Toxicity			
	Dyskinesia			
	Ecchymosis			
	Fall			
	Fear			
	Inappropriate Affect			
	Insomnia			
	Mental Impairment			
	Mental Status Changes			
	Mood Altered			
	Nervous System Disorder			
	Rib Fracture			
	Speech Disorder			
	Tremor			
	Weight Decreased			

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/16/02ISR Number: 3992987-6Report Type:Direct Company Report #CTU 178838
Age:60 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	Polydipsia		Lithium	PS				

Date:10/16/02ISR Number: 3993210-9Report Type:Expedited (15-DaCompany Report #A0367112A
Age:36 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Distension Abdominal Pain Upper Asthenia Attention Deficit/Hyperactivity Disorder Fatigue Gastrointestinal Ulcer Inflammation Myalgia Nausea Overdose Suicide Attempt	Health Professional	Lithium Salt (Formulation Unknown) (Generic) (Lithium Salt)	PS		ORAL	PER DAY/ ORAL	

Date:10/16/02ISR Number: 3999469-6Report Type:Expedited (15-DaCompany Report #B0282184A
Age:47 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Confusional State Coordination Abnormal Drug Level Increased Hypotension Mental Status Changes Renal Failure	Literature Health Professional	Lithium Salt (Formulation Unknown) (Lithium Salt)	PS				

	Tachycardia					

Date:10/17/02ISR Number: 3996735-5Report Type:Expedited (15-DaCompany Report #B0281079A
Age:59 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Haematemesis	Foreign	Lithium Salt (Lithium Salt)	PS		ORAL		
	Haemoglobin Abnormal							
ORAL								
			Co-Amilofruse	C				
			Norethisterone	C				
			Quinine Sulphate	C				

Date:10/18/02ISR Number: 3992061-9Report Type:Expedited (15-DaCompany Report #B0281040A
Age:24 YR Gender:Female I/FU:F

Outcome	PT
Other	Blister
	Depressed Mood
	Drug Withdrawal Syndrome

		Feeling Abnormal					
		Headache					
		Impulsive Behaviour	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
		Nausea		Paxil	PS	Glaxo Wellcome	ORAL
		Restlessness		Milnacipran			
		Suicidal Ideation		Hydrochloride	SS		ORAL
15MG Per day	10 DAY						
				Lithium Carbonate	SS	Glaxo Wellcome	ORAL
600MG Twice							
per day							
				Sodium Valproate	SS		ORAL
400MG Twice							
per day							

Date:10/18/02ISR Number: 3997450-4Report Type:Expedited (15-DaCompany Report #2002058798
Age:55 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization -	Coordination Abnormal	Health	Lithane (Lithium)	PS		ORAL
ORAL						
Initial or Prolonged	Dysarthria	Professional	Risperidone	SS		
	Pneumonia		Trifluoperazine			
	Somnolence		Hydrochloride	C		
			Carbamazepine	C		
			Olanzapine	C		

Date:10/18/02ISR Number: 3997463-2Report Type:Expedited (15-DaCompany Report #200220323US
Age:54 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Disability	Agitation	Consumer	Fexofenadine			
Other	Difficulty In Walking		Hydrochloride			
	Drug Interaction		(Allegra)	PS		
60 MG BID	6 MON					
	Fluid Retention		Lithium Carbonate	SS		
600 MG BID						
	Oliguria		Alprazolam (Xanax)	C		
			Glyburide	C		

			Celecoxib (Celebrex)	C		
			Nefazodone	C		

Date:10/21/02ISR Number: 3998254-9Report Type:Expedited (15-DaCompany Report #2002058798
Age:55 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Coordination Abnormal	Health	Lithane (Lithium)	PS		ORAL	ORAL
	Drug Level Increased	Professional	Risperidone	SS			
	Dysarthria		Trifluoperazine Hydrochloride	C			
	Nervous System Disorder		Carbamazepine	C			
	Pneumonia		Olanzapine	C			
	Pyrexia		Hydrocortisone	C			
	Somnolence		Neomycin	C			

Date:10/23/02ISR Number: 3999416-7Report Type:Expedited (15-DaCompany Report #B0282448A
Age:54 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Death	Completed Suicide	Literature	Lithium Salt (Formulation Unknown) (Lithium Salt)	PS		ORAL	ORAL
	Intentional Misuse	Health Professional	Avandia (Formulation				

			Unknown) (Rosiglitazone Maleate)	SS			ORAL
ORAL							
			Fluvastatin Sodium (Formulation Unknown) (Fluvastatin Sodium)	SS			

Date:10/23/02ISR Number: 3999468-4Report Type:Expedited (15-DaCompany Report #B0282449A
Age:38 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide Intentional Misuse	Literature Health Professional	Lithium Salt (Formulation Unknown) (Lithium Salt)	PS		ORAL		
ORAL								
			Venlafaxine Hydrochloride (Formulation Unknown) (Venlafaxine	SS		ORAL		
ORAL								
			Benzodiazepines (Formulation Unknown) (Benzodiazepines)	SS				

Date:10/23/02ISR Number: 3999557-4Report Type:Expedited (15-DaCompany Report #B0282404A
Age:53 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide Drug Level Above Therapeutic Intentional Misuse	Literature Health Professional	Lithium Salt (Formulation Unknown) (Lithium Salt)	PS		ORAL		
ORAL								

Date:10/23/02ISR Number: 3999558-6Report Type:Expedited (15-DaCompany Report #B0282419A
Age:51 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Literature	Lithium Salt (Formulation Unknown) (Lithium Salt)	PS				
	Intentional Misuse	Health Professional	Salicylate (Formulation Unknown) (Salicylate)	SS				
			Mirtazapine (Formulation Unknown) (Mirtazapine)	SS				

Date:10/23/02ISR Number: 3999559-8Report Type:Expedited (15-DaCompany Report #B0282392A
Age:27 YR Gender:Not SpecifiI/FU:I

Outcome	PT
Death	Completed Suicide
	Drug Level Above

		Therapeutic Intentional Misuse						
			Report Source	Product	Role	Manufacturer	Route	Dose Duration
			Literature Health Professional	Lithium Salt (Formulation Unknown)(Lithium Salt)	PS		ORAL	ORAL
				Clonazepam (Formulation Unknown) (Clonazepam)	SS		ORAL	ORAL
				Metformin Hydrochloride (Formulation Unknown) (Metformin Hydrochloride)	SS		ORAL	ORAL

Date:10/23/02ISR Number: 3999581-1Report Type:Expedited (15-DaCompany Report #B0282426A
Age:57 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Death	Drug Level Above Therapeutic Medication Error	Literature Health Professional	Lithium Salt (Formulation Unknown) (Lithium Salt)	PS		ORAL	ORAL

Date:10/23/02ISR Number: 3999583-5Report Type:Expedited (15-DaCompany Report #B0282428A
Age:46 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Death	Completed Suicide Intentional Misuse	Literature Health Professional	Ltihium Salt (Formulation Unknown) (Lithium Salt)	PS		ORAL	ORAL
			Hydrocodone +				

			Paracetamol (Formulation Unknown)				
			(Hydrocodone + Sertraline (Formulation Unknown)	SS			
			(Sertraline)	SS			

Date:10/24/02ISR Number: 3995631-7Report Type:Expedited (15-DaCompany Report #D0039574A
Age:62 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Intentional Misuse	Health	Quilonum Retard	PS	Glaxo Wellcome	ORAL	1	DAY
	Somnolence	Professional	Remergil	SS		ORAL	7TAB	Single
	Suicide Attempt						dose	1 DAY

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/24/02ISR Number: 4000424-0Report Type:Expedited (15-DaCompany Report #PHRM2002FR02543
Age:23 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Drug Level Above Therapeutic	Foreign Health	Leponex (Clozapine) Tablet	PS		ORAL	ORAL	
	Overdose Suicide Attempt	Professional Other	Teralhite (Lithium Carbonate)	SS		ORAL	ORAL	
	Toxicologic Test Abnormal		Amoxapine (Amoxapine)	C				
			Diazepam	C				

Date:10/28/02ISR Number: 3997625-4Report Type:Expedited (15-DaCompany Report #A0383289A
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Level Increased Overdose		Eskalith	PS	Glaxo Wellcome			

Date:10/28/02ISR Number: 3997633-3Report Type:Expedited (15-DaCompany Report #B0281040A
Age:24 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blister Drug Withdrawal Syndrome Suicidal Ideation	Health Professional	Paxil Milnacipran Hydrochloride	PS	Glaxo Wellcome	ORAL	15MG Per day	10 DAY
			Lithium Carbonate	SS	Glaxo Wellcome	ORAL	600MG Twice per day	
			Sodium Valproate	SS		ORAL	400MG Twice per day	

Date:10/28/02ISR Number: 4001575-7Report Type:Expedited (15-DaCompany Report #LBID00202002570
Age:9 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Coordination Abnormal Cough Dehydration Drug Level Above Therapeutic Influenza Mental Status Changes Nodal Arrhythmia Oral Intake Reduced Pyrexia Sinus Bradycardia Vomiting	Literature Health Professional	Lithium (Lithium) Clozapine (Clozapine)	PS C		ORAL	1200 MG DAILY PO	

Date:10/28/02ISR Number: 4002629-1Report Type:Expedited (15-DaCompany Report #021022-PM0004-00
Age:61 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Confusional State Fall	Foreign Health Professional Other	Tranxene (Clorazepate Dipotassium) Zolpidem	PS SS		ORAL	10 MG, P.O. BID 10 MG, P.O. QD	

			Lithium Carbonate	SS		ORAL P.O.
			Amitriptyline Hydrochloride	SS		ORAL 25 MG, P.O. QD
			Risperidone	SS		ORAL 1 MG, P.O. QD

Date:10/29/02ISR Number: 4001223-6Report Type:Direct Company Report #CTU 179818
Age:51 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Blood Creatinine		Lithium	PS		ORAL	900 MG PO QD	12 YR
	Increased Confusional State		Celexa	C				
	Parkinsonism		Mirapex	C				
			Sinemet	C				
			Sinemet Cr	C				
			Clonazepam	C				
			Ambien	C				
			Lipitor	C				
			Lisinopril	C				

Date:10/31/02ISR Number: 4003059-9Report Type:Direct Company Report #CTU 180100
Age:68 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	Coordination Abnormal		Lithium - Various	PS		ORAL	PO, 150 -> 450 MG	
	Difficulty In Walking							
	Drooling		Ec Aspirin	C				
	Drug Toxicity		Levothyroxin	C				
	Dysphagia		Multivitamins	C				
	Neurotoxicity		Calc W/ Vit D	C				
	Tremor		Lithium	C				
			Pericolace	C				
			Pbn Oint	C				
			Prevacid	C				

			Tylenol	I		

Date:10/31/02ISR Number: 4003639-0Report Type:Expedited (15-DaCompany Report #DE9213421OCT2002
Age:57 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Arteriosclerosis	Study	Tavor (Lorazepam)	PS		ORAL	VARIABLE	
Initial or Prolonged	Cerebellar Atrophy						BETWEEN 2-4MG	
Other	Delirium		Antra (Omeprazole)	SS		ORAL	41	DAY
	Nervous System Disorder		Aponal (Doxepin Hydrochloride)	SS		ORAL		
			Augmentan I.V. (Amoxicillin Sodium/Clavulanate Potassium)	SS				
INTRAVENOUS							12	DAY
			Augmentan Oral (Amoxicillin Trihydrate/Clavulanate Potassium)	SS		ORAL	7	DAY
			Jatrosom N (Tranylcypromine Sulfate)	SS		ORAL		
			Quilonum - Slow Release (Lithium					

			Carbonate)	SS		ORAL

Date:10/31/02ISR Number: 4004612-9Report Type:Expedited (15-DaCompany Report #DE9213421OCT2002
Age:57 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - VARIABLE Initial or Prolonged BETWEEN 2-4 Other MG ORAL	Cerebellar Atrophy Cerebral Atherosclerosis Confusional State Delirium	Foreign Health Professional Other	Tavor (Lorazepam) Antra (Omeprazole, , 0) Aponal (Doxepin Hydrochloride, , 0)	PS SS SS		ORAL ORAL ORAL	ORAL INTRAVENOUS	41 DAY 12 DAY
FOR A LONG TIME			Augmentan I.V. (Amoxicillin Sodium/Clavulanate Potassium, ,)	SS			INTRAVENOUS	12 DAY
			Augmentan Oral (Amoxicillin Trihydrate/Clavulanate Potassium)	SS		ORAL	ORAL	7 DAY
			Jatrosom N (Tranylcypromine Sulfate,)	SS		ORAL	ORAL	44 DAY
			Quilonum - Slow Release (Lithium Carbonate, , 0)	SS		ORAL	ORAL	7 DAY

Date:11/01/02ISR Number: 4001433-8Report Type:Expedited (15-DaCompany Report #A0383937A
Age:39 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Nephritis Interstitial		Eskalith	PS	Glaxo Wellcome	ORAL		
Other			Acyclovir	C	Glaxo Wellcome			

Date:11/04/02ISR Number: 4028890-5Report Type:Periodic Company Report #CNL-127992-NL
Age:70 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Pollakiuria	Consumer	Remeron Soltab	PS			67.5 DF	DAILY
			Lithium	SS			DF	DAILY

Date:11/05/02ISR Number: 4005814-8Report Type:Expedited (15-DaCompany Report #2002-175
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Creatinine Increased	Health Professional	Lithium 600 Mg	PS		ORAL	600 MG, ORAL	20 YR
Disability	Dialysis		Pyridium Plus (Warner Chilcott)	SS	Warner Chilcott	ORAL	ORAL	(FEW
Required Intervention to Prevent Permanent Impairment/Damage	Hepatic Failure							DAYS)
	Nephropathy Toxic							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/05/02ISR Number: 4006946-0Report Type:Expedited (15-DaCompany Report #2002-DE-02568GD(0)
Age:77 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Atrial Fibrillation Bundle Branch Block Right	Literature	Lithium Carbonate (Lithium Carbonate)	PS			100 MG	
	Conduction Disorder Drug Ineffective		Desipramine (Desipramine)	SS			450 MG	
	Electrocardiogram Abnormal		Enalapri (Enalapril Maleate)	C				
			Atenolol(Atenolol)	C				
			Furosemide(Furosemide)	C				
			Warfarin (Warfarin)	C				
			Levothydroxine(Levothyroxine)	C				
			Rosiglitazone (Drug Used In Diabetes)	C				
			Metformin(Metformin)	C				

Date:11/06/02ISR Number: 4007369-0Report Type:Expedited (15-DaCompany Report #2002063980
Age:62 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Asthenia Blood Creatine Increased	Health Professional	Nardil (Phenelzine Sulfate)	PS		ORAL	90 MG	
Other	Confusional State						(DAILY), ORAL	
	Dehydration		Lithium (Lithium)	SS		ORAL	ORAL	
	Haematocrit Abnormal Hyperpyrexia		Valproate Semisodium	SS				
	Pneumonia Aspiration		Butalbital W/Aspirin, Caffeine	SS		ORAL	ORAL	
	Pollakiuria Pyrexia Tremor							

Date:11/06/02ISR Number: 4007786-9Report Type:Expedited (15-DaCompany Report #2002058798
Age:55 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Coordination Abnormal	Health	Lithane (Lithium)	PS		ORAL		
	Csf Lymphocyte Count Abnormal	Professional	Risperidone	SS				
			Trifluoperazine Hydrochloride	C				
	Csf White Blood Cell Count Positive		Carbamazepine	C				
	Dysarthria		Olanzapine	C				
	Medication Error		Neomycin	C				
	Nervous System Disorder							
	Overdose							
	Pneumonia							
	Pneumonia Aspiration							
	Pyrexia							
	Somnolence							

Date:11/06/02ISR Number: 4008508-8Report Type:Expedited (15-DaCompany Report #2002063479
Age:78 YR Gender:Female I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Atrioventricular Block
	Blood Creatinine

	Increased Sinus Arrhythmia						
		Report Source	Product	Role	Manufacturer	Route	Dose Duration
		Foreign Health Professional	Amlodipine (Amlodipine)	PS		ORAL	5 MG (DAILY), ORAL
			Eupressyl (Urapidil)	SS		ORAL	60 MG (DAILY), ORAL
			Aspirin Upsa (Acetylsalicylic Acid)	SS		ORAL	325 MG (DAILY), ORAL
			Depamide (Valpromide)	SS		ORAL	600 MG (DAILY), ORAL
			Teralithe (Lithium Carbonate)	SS		ORAL	ORAL

Date:11/07/02ISR Number: 4008902-5Report Type:Expedited (15-DaCompany Report #A214139
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Bipolar Disorder Blood Creatine Increased	Foreign Health Professional	Zoloft (Sertraline)	PS		ORAL	100 MG (DAILY), ORAL
	Blood Creatine Phosphokinase Increased Blood Glucose Increased C-Reactive Protein Increased Encephalopathy Hallucinations, Mixed Nephropathy		Lithium Valproic Acid Lasix (Furosemide) Magnesium Allopurinol Tafil (Alprazolam) Stilnox (Zolpidem)	SS C C C C C C			

	Paranoia					

Date:11/07/02ISR Number: 4009343-7Report Type:Expedited (15-DaCompany Report #2002064377
Age:50 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Blood Cholesterol	Consumer	Lithane (Lithium)	PS		ORAL	1200 MG	
Hospitalization -	Increased						(BID), ORAL	
Initial or Prolonged	Cardiac Disorder		Zoloft (Sertraline)	SS		ORAL	(DAILY), ORAL	
Other	Conduction Disorder		Lipitor					
	Depression		(Atorvastatin)	SS		ORAL	(DAILY), ORAL	
	Drug Ineffective		Potassium	C				
	Eye Disorder		Diltiazem					
	Mental Disorder		Hydrochloride	C				
	Ovarian Rupture		Estrogens Conjugated	C				
	Scar		Warfarin	C				
	Surgical Procedure		Lansoprazole	C				
	Repeated							
	Thyroid Disorder							
	Vision Blurred							
	Weight Increased							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/07/02ISR Number: 4011841-7Report Type:Expedited (15-DaCompany Report #B0283458A
Age:47 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Depression Drug Effect Decreased Hypomania Irritability Persecutory Delusion Serotonin Syndrome Urinary Incontinence White Blood Cell Count Increased	Foreign Literature Health Professional	Lithium Salt (Lithium Salt) Citalopram Olanzapine	PS C C				

Date:11/08/02ISR Number: 4009145-1Report Type:Expedited (15-DaCompany Report #LBID00202002798
Age:46 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide Drug Level Increased Intentional Misuse	Literature Health Professional	Lithium Carbonate [Manufacturer Unknown] (Lithium Carbonate Manufacturer	PS		ORAL	DAILY PO	
			Acetaminophen W/Hydrocodone Bitartrate (Acetaminophen W/Hydrocodone	SS		ORAL	DAILY PO	
			Sertraline (Sertraline)	SS		ORAL	DAILY PO	

Date:11/08/02ISR Number: 4009149-9Report Type:Expedited (15-DaCompany Report #LBID00202002796
Age:57 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Drug Level Increased Medication Error	Literature Health	Lithium Carbonate [Manufacturer					

	Overdose	Professional	Unknown] (Lithium Carboate [Manufacturer	PS		ORAL DAILY PO

Date:11/08/02ISR Number: 4009153-0Report Type:Expedited (15-DaCompany Report #LBID00202002786
Age:54 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Death	Completed Suicide Drug Level Increased Intentional Misuse	Literature Health Professional	Lithium Carbonate (Manufacture Unknown) (Lithium Carbonate (Manufacture	PS		DAILY PO
			Fluvastatin (Fluvastatin)	SS		ORAL DAILY PO
			Rosiglitazone (Rosiglitazone)	SS		ORAL PO

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/08/02ISR Number: 4009155-4Report Type:Expedited (15-DaCompany Report #LBID00202002787
Age:53 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Drug Level Increased Overdose	Literature Health Professional	Lithium Carbonate (Manufacturer Unknown) (Lithium Carbonate (Manufacturer	PS		ORAL	DAILY PO	

Date:11/08/02ISR Number: 4009161-XReport Type:Expedited (15-DaCompany Report #LBID00202002788
Age:38 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardio-Respiratory Arrest	Literature	Lithium Carbonate	PS		ORAL	DAILY PO	
	Completed Suicide	Health Professional	Venlafaxine (Venlafaxine)	SS		ORAL	DAILY PO	
			Benzodiazepine (Benzodiazepine)	SS		ORAL	DAILY PO	

Date:11/08/02ISR Number: 4009166-9Report Type:Expedited (15-DaCompany Report #LBID00202002785
Age:47 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Confusional State	Literature	Lithium Carbonate	PS		ORAL	DAILY PO	
Hospitalization - Initial or Prolonged	Coordination Abnormal Drug Level Increased Hypotension Mental Status Changes Overdose Renal Failure Tachycardia	Health Professional						

Date:11/08/02ISR Number: 4009746-0Report Type:Expedited (15-DaCompany Report #2002UW14815
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required	Diabetes Insipidus	Health	Seroquel	PS		ORAL	300 MG PO	
Intervention to		Professional	Effexor-Xr	SS			225 MG	
Prevent Permanent			Eskalith	SS			450 MG	
Impairment/Damage								

Date:11/12/02ISR Number: 4008381-8Report Type:Direct Company Report #CTU 180779
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardiac Disorder		Lithium	PS				
	Cardio-Respiratory Arrest							
	Dysarthria							
	Mental Status Changes							
	Syncope							

Date:11/13/02ISR Number: 4011507-3Report Type:Expedited (15-DaCompany Report #LBID00202001237
Age:43 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Dental Caries Dialysis Drug Level Above Therapeutic Drug Toxicity Foot Fracture Nail Disorder Tooth Disorder Tooth Loss Toothache	Consumer	Lithobid (Lithium Carbonate) Premarin (Estrogens Conjugated) Allegra (Fexofenadine Hydrochloride) Prilosec (Omeprazole) Lorazepam (Lorazepam) Ambien (Zolpidem Tartrate)	PS C C C C		ORAL PO	1800 MG DAILY

Date:11/13/02ISR Number: 4011968-XReport Type:Expedited (15-DaCompany Report #PHNU2002DE03696
Age:21 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Other	Convulsion Drug Interaction Drug Level Increased	Foreign Health Professional Other	Leponex Clozaril (Clozapine) (Clozapine) Tablet Hypnorex - Slow Release (Lithium Carbonate) Slow Release Tablet	PS SS		ORAL ORAL	300 MG/DAY,

Date:11/14/02ISR Number: 4009185-2Report Type:Expedited (15-DaCompany Report #D0039742A
Age:55 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Road Traffic Accident		Quilonum Retard	PS	Glaxo Wellcome	ORAL	2TAB Per day	
	Somnolence							

Date:11/14/02ISR Number: 4010018-9Report Type:Direct Company Report #CTU 180895
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardio-Respiratory Arrest		Lithium	PS				
	Drug Level Above Therapeutic							
	Dysarthria							
	Mental Status Changes							
	Syncope							

Date:11/15/02ISR Number: 4010466-7Report Type:Expedited (15-DaCompany Report #WAES 0204SWE00002
Age:81 YR Gender:Female I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Depressed Level Of Consciousness
	Drug Level Increased
	Extrapyramidal Disorder

	Fatigue Medication Error Renal Failure	Report Source	Product	Role	Manufacturer	Route	Dose Duration
			Vioxx	PS	Merck & Co., Inc	ORAL	25 DAY
			Lithium Sulfate	SS		ORAL	
			Levothyroxine Sodium	C			
			Dipyridamole	C			
			Lofepramine Hydrochloride	C			
			Zolpidem Tartrate	C			
			Calcium Carbonate And Cholecalciferol	C			
			Tramadol Hydrochloride	C			

Date:11/18/02ISR Number: 4011531-0Report Type:Direct Company Report #CTU 181147
Age:47 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Life-Threatening Hospitalization - Initial or Prolonged	Drug Toxicity Hypercalcaemia Nephrogenic Diabetes Insipidus Renal Failure Acute		Eskalith Cipro	PS SS		ORAL	450MG PO BID [LONG STANDING] DOSE NOT DOCUMENTED [FOR 1 MONTH PRIOR TO EVENT]

Date:11/20/02ISR Number: 4012204-0Report Type:Expedited (15-DaCompany Report #B0284518A
Age:51 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Life-Threatening	Condition Aggravated		Lithium	PS	Glaxo Wellcome	ORAL	
Hospitalization -	Nephrogenic Diabetes		Atorvastatin	C		ORAL	
10MG Per day							
Initial or Prolonged	Insipidus		Metformin	C		ORAL	
500MG Three							
Disability	Pneumonia						
times per day							
	Pulmonary Embolism		Sodium Valproate	C		ORAL	
300MG Twice							
	Renal Tubular Necrosis						
per day							
	Shock		Fenofibrate	C		ORAL	
	Urinary Incontinence						

Date:11/22/02ISR Number: 4016133-8Report Type:Expedited (15-DaCompany Report #12109385
Age:27 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Death	Completed Suicide	Literature	Metformin Hcl	PS		ORAL	
ORAL							
Other	Overdose	Health	Clonazepam	SS		ORAL	
ORAL							
		Professional	Lithium (Lithium Salts)	SS		ORAL	
ORAL							

Date:11/25/02ISR Number: 4016215-0Report Type:Expedited (15-DaCompany Report #MK200211-0206-1
Age:46 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Death	Completed Suicide	Literature	Hydrocodone/Apap	PS			
	Overdose	Health	Lithium Carbonate	SS			
		Professional	Sertraline	SS			

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/26/02ISR Number: 4015899-0Report Type:Direct Company Report #CTU 181692
Age:55 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	Confusional State		Lithium 450 Cr	PS		ORAL	TID PO	
	Drug Level Increased		Maxzide 75/50	SS		ORAL	PO QD	
	Tremor							
	Visual Disturbance							

Date:11/26/02ISR Number: 4015959-4Report Type:Direct Company Report #CTU 181776
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Asthenia		Lithium	PS		ORAL	600 MG BID PO	
	Constipation		Benztropine	C				
	Drug Level Increased		Olanzapine	C				
	Somnolence		Risperidone	C				
	Tremor		Ranitidine	C				
			Loperamide	C				
			Macrodantin	C				

Date:11/26/02ISR Number: 4018015-4Report Type:Expedited (15-DaCompany Report #2002066670
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Overdose	Health Professional	Lithane (Lithium)	PS				
			Ziprasidone	C				

Date:11/26/02ISR Number: 4018019-1Report Type:Expedited (15-DaCompany Report #2002058798
Age:55 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Hospitalization - Initial or Prolonged	Coordination Abnormal	Health Professional	Lithane (Lithium)	PS	ORAL
	Csf Test Abnormal		Risperidone	SS	
	Dysarthria		Trifluoperazine Hydrochloride	C	
	Mental Status Changes		Carbamazepine	C	
	Motor Dysfunction		Olanzapine	C	
	Nervous System Disorder		Hydrocortisone	C	
	Overdose		Neomycin	C	
	Pneumonia Aspiration				
	Pyrexia				
	Somnolence				

Date:11/27/02ISR Number: 4019037-XReport Type:Expedited (15-DaCompany Report #2002067242
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Hepatic Failure	Health Professional	Geodon (Ziprasidone)	PS				
Hospitalization - Initial or Prolonged	Sepsis		Metformin	SS				
Other			Ramipril	SS				
			Quetiapine Fumarate	SS				
			Lithium Carbonate	SS				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/27/02ISR Number: 4019313-0Report Type:Expedited (15-DaCompany Report #2002-BP-05509RO (0)
Age:28 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Disability	Dialysis Hypertension Renal Failure Chronic Renal Transplant Thyroid Disorder Weight Increased	Consumer Health Professional	Lithium Carbonate Capsules Usp, 300 Mg (Lithium Carbonate)	PS	Usp	ORAL PO		

Date:12/02/02ISR Number: 4017521-6Report Type:Expedited (15-DaCompany Report #D0039829A
Age:44 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Delirium	Health	Quilonum Retard	PS	Glaxo Wellcome	ORAL	450MG	Unknown 3 DAY
	Drug Interaction	Professional	Zyprexa	SS		ORAL	2	DAY
	Drug Level Increased		Laubeel	C		ORAL	30	DAY

Date:12/02/02ISR Number: 4017522-8Report Type:Expedited (15-DaCompany Report #D0039832A
Age:68 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Mental Impairment	Health	Quilonum Retard	PS	Glaxo Wellcome	ORAL	450MG per day	
	Serotonin Syndrome	Professional	Stangyl	SS		ORAL	75MG per day	
			Trevilor	SS		ORAL		
			Ass	C		ORAL	100MG per day	
			Beloc Zok	C		ORAL	100MG per day	
			Kalium Duriles	C		ORAL	1TAB per day	
			Vitamins	C		ORAL	60DROP per	

day						
			Diazepam	C		ORAL
15 DAY						

Date:12/03/02ISR Number: 4018206-2Report Type:Expedited (15-DaCompany Report #B0286643A
Age:9 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Agitation	Consumer	Paxil	PS	Glaxo Wellcome			
	Anger		Lithium	SS	Glaxo Wellcome			
	Anxiety		Risperidone	SS				
	Depression		Gabapentin	SS				
	Drug Ineffective							
	Insomnia							
	Suicidal Ideation							

Date:12/03/02ISR Number: 4018207-4Report Type:Expedited (15-DaCompany Report #D0039828A
Age:64 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Myocardial Infarction	Health	Quilonorm Retard	PS	Glaxo Wellcome	ORAL	2.5TAB per	
Hospitalization -	Suicide Attempt	Professional						day
Initial or Prolonged			Remeron	SS		ORAL	120MG per day	
			Imovane	SS		ORAL	15MG per day	
			Extract Of Valerian	C		ORAL	1TAB per day	
			Aspirin	C		ORAL	300MG per day	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/03/02ISR Number: 4018222-0Report Type:Expedited (15-DaCompany Report #A0386369A
Age:19 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Drug Interaction	Consumer	Albuterol	PS	Glaxo Wellcome			
RESPIRATORY								
Initial or Prolonged	Gait Disturbance							
(INHALATION)							2PUFF	Four
	Grand Mal Convulsion							
times per day								
	Road Traffic Accident		Salmeterol	SS	Glaxo Wellcome			
RESPIRATORY								
	Serotonin Syndrome							
(INHALATION)							2PUFF	Twice
	Speech Disorder							
per day								
			Montelukast	SS				
UNKNOWN							20MG	per day
			Budesonide	SS				
RESPIRATORY								
(INHALATION)							2PUFF	Twice
per day								
			Phenobarbital	SS				
INTRAVENOUS								
			Diazepam	SS				
INTRAVENOUS								
			Lithium Carbonate	SS	Glaxo Wellcome	ORAL		
			Paroxetine	SS	Glaxo Wellcome	ORAL		
			Cromoglycate	C				
			Omeprazole	C				
20MG At night								
			Lansoprazole	C				
20MG At night								
			Venlafaxine	C				
75MG In the								
morning								

Date:12/03/02ISR Number: 4018266-9Report Type:Expedited (15-DaCompany Report #B0286643A
Age:9 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Agitation		Paxil	PS	Glaxo Wellcome	
	Anger		Lithium	SS	Glaxo Wellcome	
	Anxiety		Risperidone	SS		
	Bipolar Disorder		Gabapentin	SS		
	Drug Ineffective					
	Insomnia					
	Malaise					
	Suicidal Ideation					

Date:12/03/02ISR Number: 4021016-3Report Type:Expedited (15-DaCompany Report #2002068179
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Cardio-Respiratory Arrest		Neurontin			
Initial or Prolonged	Delirium		(Gabapentin)	PS		
Other			Geodon (Ziprasidone)	SS		
120 MG BID						
			Clozappine	SS		
			Lithium	SS		

Date:12/05/02ISR Number: 4024431-7Report Type:Periodic Company Report #HQ9377811DEC2001
Age:32 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Disability	Priapism	Health	Effexor Xr			
Other		Professional	(Venlafaxine Hydrochloride, Capsule, Extended Release)	PS		ORAL
300 MG 1 X						
PER 1 DAY,						
ORAL						
			Clozaril (Clozapine,			

			)	SS		ORAL
50 MG 1X PER						
1 DAY, ORAL						
			Klonopin (Clonazepam,)	SS		ORAL
2 MG 1X PER 1						
DAY, ORAL						
			Lithium (Lithium,)	SS		ORAL
300 MG TO						
1500 MG DAILY						
AT BEDTIME,						
ORAL						

Date:12/09/02ISR Number: 4023123-8Report Type:Expedited (15-DaCompany Report #2002069558
Age:46 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Completed Suicide	Literature	Sertraline			
	Intentional Misuse	Health	(Sertraline)	PS		
(DAILY)						
		Professional	Lithane (Lithium)	SS		
(DAILY)						
			Vicodin	SS		
(DAILY)						

Date:12/09/02ISR Number: 4031076-1Report Type:Periodic Company Report #2002114176US
Age:69 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
	Delirium	Consumer	Bextra(Valdecoxib)			
	Drug Interaction	Health	(Continued)	PS		ORAL
20 MG, QD,						
		Professional				
ORAL						
			Lithium(Lithium)	SS		
UNK, UNK, UNK						
			Itraconazole(Itracon			

			azole)	SS		
UNK, UNK, UNK						
			Wellbutrin (Amfebutamone Hydrochloride)	C		
			Prilosec	C		
			Atenolol	C		
			Vitamin E	C		
			Aspirin "Bayer"	C		

Date:12/10/02ISR Number: 4025124-2Report Type:Expedited (15-DaCompany Report #HQ5609604DEC2002
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Complications Of Maternal Exposure To Therapeutic Drugs	Literature	Effexor (Venlafaxine Hydrochloride, Unspec)	PS		ORAL		
	Drug Level Increased		Lithium (Lithium,)	SS		ORAL		
	Goitre Congenital		Cyamemazine (Cyamemazine)	C				
	Maternal Drugs Affecting Foetus		Olanzapine (Olanzapine)	C				

Date:12/10/02ISR Number: 4025132-1Report Type:Expedited (15-DaCompany Report #B0285794A
Age:84 YR Gender:Female I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Accidental Exposure
	Clonic Convulsion
	Confusional State
	Hypertension

	Lack Of Spontaneous Speech Mental Status Changes	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
	Status Epilepticus Tremor	Foreign Literature Health Professional	Eskalith (Formulation Unknown) (Lithium Carbonate) Lisinopril	PS C		

Date:12/10/02ISR Number: 4025553-7Report Type:Expedited (15-DaCompany Report #PHBS2002JP14775
Age:69 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged 75 MG/DAY	Arthralgia Clonic Convulsion	Foreign Literature	Diclofenac(Diclofenac)	PS		
	Depressed Level Of Consciousness	Health Professional	Lithium Carbonate (Lithium Carbonate) 600 MG/DAY	SS		
	Diabetes Mellitus Non-Insulin-Dependent Drug Interaction Drug Toxicity Dyskinesia Electrocardiogram Delta Waves Abnormal Mania Tremor	Other	Haloperidol	C		

Date:12/11/02ISR Number: 4022261-3Report Type:Direct Company Report #CTU 182514
Age:53 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged 300MG PO TID	Anaemia Drug Toxicity		Lithium CHRONIC	PS		ORAL
	Hyponatraemia		Chlorpromazine 100 MG Q AM	SS		

	Nephrogenic Diabetes			
200 MG Q PM				
	Insipidus			
CHRONIC				
	Renal Impairment		Amitriptyline	C
	Urinary Tract Infection		Vit E	C
			Synthroid	C
			Lorazepam	C
			Avandia	C
			Premphase	C
			Docusate	C
			Bethanecol	C
			Aspirin	C
			Iron	C

Date:12/11/02ISR Number: 4024892-3Report Type:Expedited (15-DaCompany Report #2002-11-2655
Age:13 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Interaction	Consumer	Clarinex					
	Heart Rate Decreased	Company	(Desloratadine)					
		Representative	Tablets	PS		ORAL	5MG PRN ORAL	
			Risperdal Tablets	SS			0.75 QD	
			Eskalith Capsules	SS			450MG BID	2 YR

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/11/02ISR Number: 4025277-6Report Type:Expedited (15-DaCompany Report #02P-163-0205275-00
Age:46 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Literature	Hydrocodone/Acetamin					
		Health	ophen (Vicodin)					
		Professional	(Hydrocodone/Acetami					
			nophen)(Hydrocodone					
			Acetaminophen)	PS				
			Lithium	SS				
			Sertraline	SS				

Date:12/16/02ISR Number: 4023975-1Report Type:Expedited (15-DaCompany Report #D0039742A
Age:53 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Depression	Health	Quilonum Retard	PS	Glaxo Wellcome	ORAL	1TAB Twice	
	Road Traffic Accident	Professional					per day	

Date:12/16/02ISR Number: 4027608-XReport Type:Expedited (15-DaCompany Report #PHFR2002GB02068
Age:29 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Nephropathy Toxic	Foreign	Clozaril (Clozapine)					
Initial or Prolonged	Renal Failure	Health	Tablet	PS		ORAL	500 MG/DAY,	
		Professional					ORAL	
		Other	Lithium(Lithium)	SS				

Date:12/18/02ISR Number: 4025779-2Report Type:Direct Company Report #CTU 182905
Age:58 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Dehydration		Lithium Carbonate					

Hospitalization - Initial or Prolonged	Diabetes Insipidus	300mg Capsules	PS	ORAL 2 CAPSULES, BID PO
	Diabetes Mellitus			
	Drug Toxicity			
	Hypernatraemia			
	Mental Status Changes			
	Oxygen Saturation Decreased			
	Renal Failure Acute			

Date:12/19/02ISR Number: 4030184-9Report Type:Expedited (15-DaCompany Report #2002-BP-05509RO
Age:28 YR Gender:Female I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Anaemia
	Arthralgia
Disability	Basal Cell Carcinoma
	Blood Calcium Increased
	Dialysis
	Drug Level Increased
	Fibrocystic Breast Disease
	Haematocrit Decreased
	Hyperreflexia
	Hypertension
	Nocturia

	Pollakiuria Renal Failure Chronic Renal Transplant	Report Source	Product	Role	Manufacturer	Route Dose Duration
	Speech Disorder Thyroid Disorder Tremor	Consumer Health Professional	Lithium Carbonate Capsules Usp, 300 Mg (Lithium Carbonate)	PS		FROM HIGH OF
	Urinary Tract Infection					900 MG/DAY TO
	Weight Increased					LOW OF
	White Blood Cell Count Decreased		Ismelin (Guanethidine Sulfate)	C		
			Minipress (Prazosin Hydrochloride)	C		
			Prinivil (Lisinopril)	C		
			Prolixin (Fluphenazine Hydrochloride)	C		
			Theragran (Theragran)	C		
			Vitamin E (Tocopherol)	C		
			Metamucil (Psyllium Hydrophilic Mucilloid)	C		

Date:12/23/02ISR Number: 4029184-4Report Type:Direct Company Report #CTU 183289
Age:82 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Hospitalization - Initial or Prolonged	Dehydration Delirium		Lithium 300mg Qam, 450mg Q Pm	PS		

Date:12/26/02ISR Number: 4038223-6Report Type:Periodic Company Report #02-05-0521
Age:29 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration

Hospitalization - Initial or Prolonged	Convulsion	Other	Clozapine - Ivax Pharmaceuticals, Inc. Tablets	PS	Ivax Pharmaceuticals, Inc.	ORAL	25-150 MG QD
Other							ORAL
			Lithium Unknown	SS			

Date:12/30/02ISR Number: 4036153-7Report Type:Expedited (15-DaCompany Report #B0288424A
Age:63 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Ascites	Foreign	Eskalith Tablet	PS		ORAL	ORAL	
	Essential Tremor	Health Professional						
	Pleural Effusion							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/03/03ISR Number: 4035108-6Report Type:Direct Company Report #CTU 183745
Age:30 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Cognitive Disorder Memory Impairment Thought Blocking		Priadel -Lithium-400mg/200mg	PS		ORAL	1000MG ONCE AT ORAL	
			Thirodizine-Mellirel - 100mg/50mg	SS		ORAL	1000MG/X 4 PER ORAL	

Date:01/03/03ISR Number: 4035385-1Report Type:Direct Company Report #CTU 183811
Age:70 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blood Creatinine Increased		Lithium	PS				
			Simvastatin	C				
			Ibuprofen	C				
			Bupropion Hcl	C				
			Hydrocortisone Acetate	C				
			Paroxetine Hcl	C				
			Clonazepam	C				
			Olanzapine	C				
			Sertraline Hcl	C				
			Trazodone Hcl	C				
			Ipratropium Bromide	C				

Date:01/03/03ISR Number: 4035408-XReport Type:Direct Company Report #CTU 183809
Age:29 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blood Creatinine Increased		Lithium	PS				
			Felodipine	C				
			Fluticas 500/Salmeterol 50					

Inhl Disk 60	C
Buspirone Hcl	C
Lithium Carbonate	C
Olanzapine	C
Paroxetine Hcl	C
Sertraline Hcl	C
Trazodone Hcl	C
Ipratropium Bromide	C

Date:01/06/03ISR Number: 4036011-8Report Type:Expedited (15-DaCompany Report #B0288724A
Age:29 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Nephropathy Toxic	Consumer	Lithium	PS	Glaxo Wellcome			UNKNOWN
Initial or Prolonged	Renal Failure		Clozaril	SS		ORAL	500MG per day	Other

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/06/03ISR Number: 4036012-XReport Type:Expedited (15-DaCompany Report #D0040113A
Age:38 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dry Mouth Gastrointestinal Disorder Hypotonia Intentional Misuse Suicide Attempt	Health Professional	Quilonum Retard Zopiclone Trimipramine Ergenyl Chrono	PS SS SS SS	Glaxo Wellcome	ORAL ORAL ORAL ORAL	450MG See dosage text 7.5MG See dosage text 100MG See dosage text 300MG See dosage text	1 DAY 1 DAY 1 DAY 1 DAY

Date:01/06/03ISR Number: 4036984-3Report Type:Direct Company Report #CTU 183931
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dizziness Medication Error Overdose		Lithium (Liquid-Unit Dose Padeaging)	PS		ORAL	2700MG PO QD	2 DAY

Date:01/06/03ISR Number: 4036985-5Report Type:Direct Company Report #CTU 183932
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Toxicity		Lithium 450mg	PS		ORAL	PO ALT BID /TID QOD	

CHRONIC

Date:01/10/03ISR Number: 4040145-1Report Type:Direct Company Report #CTU 184198
Age:55 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Tremor		Lithium	PS		ORAL	900 MG	300 MG
							PO ORAL	

Date:01/10/03ISR Number: 4041165-3Report Type:Expedited (15-DaCompany Report #03P-056-0207494-00
Age:69 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Loss Of Consciousness	Foreign	Depakote (Divalproex Sodium) (Divalproex Sodium)	PS		ORAL	500 MG, ORAL	
	Prostatic Pain	Health						
	Urinary Retention	Professional						
			Mirtazapine	SS		ORAL	5 MG, 3 IN 1	
							D, ORAL	
			Zopiclone	SS		ORAL	15 MG, 1 IN 1	
							D, ORAL	
			Propranolol	SS				
RECTAL							60 MG, 1 IN 1	
							D, RECTAL	
			Lithium Carbonate	SS		ORAL	200 MG, 2 IN	
							1 D, ORAL	
			Cisapride	SS		ORAL	ORAL	
			Alfuzosin	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/10/03ISR Number: 4041506-7Report Type:Expedited (15-DaCompany Report #2002066670
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Overdose Treatment Noncompliance	Health Professional	Lithane (Lithium)	PS				

Date:01/13/03ISR Number: 4041984-3Report Type:Expedited (15-DaCompany Report #030109-PM0019-00
Age:55 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Bradycardia	Foreign Health Professional	Tranxene (Clorazepate Dipotassium)	PS		ORAL	5 MG, P.O. QD	
		Other	Lithium Carbonate	SS		ORAL	250 MG, P.O.	BID
			Olanzapine	SS		ORAL	10 MG, P.O.	QD
			Zopiclone	SS		ORAL	7.5 MG, P.O.	QD YR

Date:01/14/03ISR Number: 4041954-5Report Type:Direct Company Report #CTU 184468
Age:53 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Confusional State Dizziness		Lithium	PS				

Date:01/14/03ISR Number: 4041977-6Report Type:Direct Company Report #CTU 184478
Age:68 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Confusional State Diarrhoea Difficulty In Walking Nausea Vomiting		Lithium	PS				

Date:01/15/03ISR Number: 4042601-9Report Type:Direct Company Report #CTU 184591
Age:39 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Depressed Level Of Consciousness Difficulty In Walking Drug Level Increased Drug Screen Positive Lethargy Respiratory Depression Somnolence		Lithium Buspar Valproic Acid	PS C C		ORAL PO		

Date:01/15/03ISR Number: 4043779-3Report Type:Expedited (15-DaCompany Report #2003-DE-00019YA (0)
Age:65 YR Gender:Male I/FU:I

Outcome	PT
Disability	Cholelithiasis Nephrolithiasis

	Renal Cyst Renal Failure					
		Report Source	Product	Role	Manufacturer	Route
Dose Duration						
		Foreign	Flomax	PS		ORAL
0.4 MG PO 365 DAY						
		Other	Depamide (Valpromide) (Nr)	SS		ORAL
300 MG PO						
			Teralithe (Lithium Carbonate) (Nr)	SS		ORAL
1500 MG PO						
			Tadenan (Pygeum Africanum) (Nr)	SS		ORAL
100 MG PO						

Date:01/16/03ISR Number: 4044082-8Report Type:Expedited (15-DaCompany Report #PHBS2002JP14758
Age:69 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Akathisia Blood Creatine Phosphokinase Increased	Foreign Health Professional	Parlodel (Bromcriptine Mesilate) Unknown	PS		ORAL
7.5 MG/DAY, ORAL2.5 MG/DAY, ORAL	Blood Creatinine Increased Hyperhidrosis Hypertension Parkinsonism	Other	Barnetil (Sultopride)	SS		ORAL
800 MG/DAY, ORAL			Limas (Lithium Carbonate)	SS		ORAL
400 MG/DAY, ORAL			Lodopin (Zotepine)	SS		ORAL
400 MG/DAY, ORAL			Coniel (Benidipine Hydrochloride)	SS		

			Inhibace (Cilazapril)	Roche SS	Roche	
			Amoban	C		
			Benzalin	C		
			Hirnamin	C		
			Pyrethia	C		

Date:01/20/03ISR Number: 4043547-2Report Type:Expedited (15-DaCompany Report #D0040150A
Age:72 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Renal Impairment		Quilonum	PS	Glaxo Wellcome	ORAL		
			Cipramil	C		ORAL	20MG In the morning	
			Trimipramine	C		ORAL	100MG Per day	
			Zopiclone	C		ORAL		
			Fosinorm	C		ORAL	10MG In the morning	
			Dociton	C	Glaxo Wellcome	ORAL	20MG Twice per day	
			Unat	C		ORAL	5MG Per day	

Date:01/21/03ISR Number: 4043970-6Report Type:Direct Company Report #CTU 184834
Age:9 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Mania		Geodon	PS		ORAL	60MG DAILY ORAL	

			Lithobid	SS		ORAL
DAILY ORAL						

Date:01/21/03ISR Number: 4044696-5Report Type:Expedited (15-DaCompany Report #2003-DE-00014GD
Age:20 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Akathisia	Literature	Lithium Carbonate			
Initial or Prolonged	Bipolar Disorder		(Lithium Carbonate)	PS		
SEE IMAGE 3 MON						
	Body Temperature		Risperidone			
	Increased		(Risperidone)	SS		
3 MG NR						
	Cognitive Disorder		Paroxetine			
	Constipation		(Paroxetine)	SS		
20 MG NR						
	Drug Interaction		Olanzapine			
	Drug Level Below		(Antipsychotics)	SS		
SEE IMAGE						
	Therapeutic		Benztropine			
	Dry Mouth		(Benzatropine			
	Parkinsonian Crisis		Mesilate)	SS		
2 MG						
	Vision Blurred		Nortriptyline			
			(Nortriptyline)	SS		
50 MG						

Date:01/21/03ISR Number: 4044717-XReport Type:Expedited (15-DaCompany Report #2003UW00549
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Ammonia Increased	Health	Seroquel	PS		ORAL
600 MG PO						
Initial or Prolonged		Professional	Lithium	SS		

Date:01/21/03ISR Number: 4045925-4Report Type:Expedited (15-DaCompany Report #2003-DE-00095GD
Age:1 DY Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Apgar Score Low	Foreign	Lithium Carbonate					
Required	Goitre	Literature	(Lithium Carbonate)	PS				
INTRA-UTERINE							IU	
Intervention to	Hypothyroidism		Cyamemazine	C				
Prevent Permanent	Maternal Drugs Affecting		Venlafaxine					
Impairment/Damage	Foetus		(Antidepressants)	C				
	Neonatal Disorder		Olanzapine					
	Pregnancy		(Antipsychotics)	C				
	Small For Dates Baby							

Date:01/23/03ISR Number: 4047068-2Report Type:Expedited (15-DaCompany Report #2002067242
Age:58 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Autoimmune Hepatitis	Health	Geodon (Ziprasidone)	PS		ORAL		
Hospitalization -	Cholelithiasis	Professional	Metformin	SS		ORAL	500 MG	
Initial or Prolonged	General Physical Health						(DAILY), ORAL	
Other	Deterioration		Ramipril	SS				
	Hepatic Failure		Quetiapine Fumarate	SS			100 MG	
	Ischaemia						(DAILY)	
	Pancreatitis		Lithium Carbonate	SS				
	Sepsis		Vitamins	C				
			Docusate Sodium	C				
			Psyllium	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/28/03ISR Number: 4049015-6Report Type:Expedited (15-DaCompany Report #B0289517A
Age:48 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Hyperthyroidism Thyroiditis	Foreign Literature Health Professional	Lithium Carbonate (Formulation Unknown) (Generic) (Lithium Carbonate)	PS			

Date:01/29/03ISR Number: 4050057-5Report Type:Expedited (15-DaCompany Report #LBID00203000023
Age:48 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Diabetes Insipidus Lethargy	Health Professional	Lithobid (Lithium Carbonate)	PS		ORAL	300 MG BID PO
	Mood Altered Oedema Peripheral Pneumonia		Depakote (Valproate Semisodium)	C			
			Risperdal (Risperidone)	C			
			Vitamin D (Vitamin D)	C			
			Multivitamins (Multivitamins)	C			
			Actonel (Actonel)	C			
			Warfarin (Warfarin)	C			

Date:01/30/03ISR Number: 4049392-6Report Type:Expedited (15-DaCompany Report #B0290594A
Age:42 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Abdominal Pain Coordination Abnormal	Consumer	Lithium	PS	Glaxo Wellcome		
			Clozaril	SS		ORAL	284 DAY
Other	Dehydration Diabetes Insipidus Grand Mal Convulsion						

Date:01/30/03ISR Number: 4050493-7Report Type:Expedited (15-DaCompany Report #PHBS2003JP00627
Age:40 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Depressed Level Of Consciousness	Foreign Literature	Voltaren(Diclofenac Sodium) Tablet	PS		ORAL	25 MG/DAY,	
	Drug Interaction	Health					ORAL	
	Drug Toxicity	Professional	Lithium Carbonate(Lithium Carbonate)	SS			400 MG/DAY	
	Mouth Breathing	Other						

Date:01/30/03ISR Number: 4050883-2Report Type:Expedited (15-DaCompany Report #HQ6252120JAN2003
Age:69 YR Gender:Male I/FU:I

Outcome	PT
Death	Bladder Dilatation
	Drug Level Below Therapeutic
	Drug Toxicity
	Hydronephrosis
	Inflammation
	Loss Of Consciousness

		Renal Cyst Sudden Death Urinary Retention	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
			Health Professional Other	Avlocardyl (Propranolol Hydrochloride, Tablet)	PS		ORAL
60 MG 1 X PER 1 DAY,	ORAL						
				Depakote (Valproate Semisodium)	SS		ORAL
1500 MG 1X PER 1 DAY,	ORAL						
				Imovane (Zopiclone)	SS		ORAL
15 MG 1X PER 1 DAY,	ORAL						
				Monuril (Fosfomycin Trometamol)	SS		ORAL
ORAL							
				Teralithe (Lithium Carbonate)	SS		ORAL
800 MG 1X PER 1 DAY,	ORAL						
				Xatral (Alfuzosin)	SS		ORAL
5 MG 1X PER 1 DAY,	ORAL						
				Spasfon (Phloroglucinol/Trimethylphloroglucinol)	SS		ORAL
ORAL							
				Mirtazapine	SS		ORAL
3 "DF" DAILY,	ORAL						
				Prepulsid (Cisapride)	C		

Date:01/31/03ISR Number: 4051233-8Report Type:Expedited (15-DaCompany Report #2003003013
Age:59 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Amnesia	Foreign Health Professional	Lithium (Lithium)	PS				
	Coordination Abnormal		Atorvastatin	C				
	Dehydration		Mianserin	C				
	Dizziness		Cimetidine	C				
	Drug Toxicity		Atenolol	C				
	Dysgeusia		Isosorbide Mononitrate	C				
	Gastroenteritis		Acetylsalicylic Acid	C				
	Nausea		Enalapril	C				
	Tinnitus		Omeprazole	C				
	Tremor							

Date:02/03/03ISR Number: 4051537-9Report Type:Expedited (15-DaCompany Report #2003-BP-00500RO
Age:73 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Vision Blurred	Foreign Health Professional	Lithium Carbonate Capsules Usp, 300 Mg (Lithium Carbonate)	PS		ORAL	SEE IMAGE	
		Other	Tranxene (Clorazepate Dipotassium)	SS		ORAL	10 MG, PO	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/03/03ISR Number: 4051539-2Report Type:Expedited (15-DaCompany Report #2003-BP-00499RO
Age:61 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Confusional State Fall	Foreign Health Professional	Lithium Carbonate Capsules Usp, 300 Mg (Lithium Carbonate)	PS		ORAL	PO	
		Other	Tranxene (Clorazepate Dipotassium)	SS		ORAL	20 MG (10 MG, 2 IN 1 D), PO	
			Zolpidem (Zolpidem)	SS		ORAL	10 MG (10 MG, 1 IN 1 D), PO	
			Amitriptyline Hydrochloride (Amitriptyline Hydrochloride)	SS		ORAL	25 MG (25 MG, 1 IN 1 D), PO	
			Risperidone (Risperidone)	SS		ORAL	1 MG (1 MG, 1 IN 1 D), PO	

Date:02/04/03ISR Number: 4052313-3Report Type:Expedited (15-DaCompany Report #2003UW01191
Age:61 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Confusional State Fall	Foreign Consumer	Elavil Tranxene	PS SS		ORAL ORAL	25 MG QD PO 10 MG BID PO	
		Other	Lithium Carbonate	SS				

			Risperidone	SS		ORAL
1 MG QD PO						
			Zoldipem	SS		ORAL
10 MG QD PO						

Date:02/04/03ISR Number: 4052330-3Report Type:Expedited (15-DaCompany Report #2003003832
Age:48 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Agitation	Health	Lithium (Lithium)	PS		ORAL
ORAL						
Initial or Prolonged	Anxiety	Professional	Olanzapine	C		
	Confusional State		Atenolol	C		
	Drug Toxicity		Lorazepam	C		
	Dysarthria					
	Gait Disturbance					
	Renal Failure Acute					
	Schizophrenia					

Date:02/05/03ISR Number: 4052100-6Report Type:Direct Company Report #CTU 185997
Age:77 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Life-Threatening	Drug Level Above		Lithium Citrate	PS		ORAL
400 MG PO						
	Therapeutic					

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Freedom Of Information (FOI) Report

Date:02/07/03ISR Number: 4053901-0Report Type:Expedited (15-DaCompany Report #2003002586
Age:51 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Literature	Lithane (Lithium)	PS				
		Health Professional	Salicylates	SS				
			Mirtazapine	SS				

Date:02/07/03ISR Number: 4053968-XReport Type:Expedited (15-DaCompany Report #2003003729
Age:61 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Confusional State	Foreign	Lithane (Lithium)	PS		ORAL	25 MG	(DAILY), ORAL
	Fall	Health Professional	Amitriptyline Hydrochloride	SS		ORAL	10 MG (BID),	ORAL
			Clorazepate Dipotassium	SS		ORAL	10 MG	(DAILY), ORAL
			Risperidone	SS		ORAL	1 MG (DAILY),	ORAL

Date:02/07/03ISR Number: 4054205-2Report Type:Expedited (15-DaCompany Report #2003004340
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Diarrhoea	Foreign	Neurontin(Gabapentin)	PS		ORAL	600 MG	
	Therapeutic Response	Health						

	Increased	Professional					
(DAILY), ORAL							
	Tremor		Lithium	SS			
			Lithium Carbonate	C			

Date:02/10/03ISR Number: 4054442-7Report Type:Direct Company Report #CTU 186302
Age:19 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Life-Threatening	Emotional Disorder		Haldol Decanoate	PS			MONTHLY SHOTS
Hospitalization -	Grand Mal Convulsion		Lithium	SS		ORAL	DAILY ORALLY
Initial or Prolonged	Malaise						
Disability	Mental Disorder						
Required	Nervous System Disorder						
Intervention to							
Prevent Permanent							
Impairment/Damage							

Date:02/10/03ISR Number: 4054620-7Report Type:Expedited (15-DaCompany Report #PHNU2002DE03696
Age:21 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Other	Convulsion	Foreign	Leponex/Clozaril				
	Drug Interaction	Health	(Clozapine/Clozapine				
	Drug Level Increased	Professional	) Tablet	PS		ORAL	300MG/DAY,
	Grand Mal Convulsion	Other					ORAL
	Petit Mal Epilepsy		Hypnorex - Slow				
			Release (Lithium				
			Carbonate) Slow				

			Release Tablet	SS		ORAL 150MG/DAY, ORAL

Date:02/10/03ISR Number: 4054639-6Report Type:Direct Company Report #CTU 186314
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Required Intervention to Prevent Permanent Impairment/Damage	Vein Disorder		Clozaril 500ml Daily Eskalith 900 Ml Daily	PS SS		

Date:02/10/03ISR Number: 4055075-9Report Type:Expedited (15-DaCompany Report #2003004062
Age:55 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Hospitalization - Initial or Prolonged	Bradycardia	Consumer	Lithane (Lithium)	PS		ORAL 250 MG (BID), ORAL
			Clorazepate Dipotassium	SS		ORAL 5 MG (DAILY), ORAL
			Olanzapine	SS		ORAL 10 MG (DAILY), ORAL
			Zopiclone	SS		ORAL 7.5 MG (DAILY), ORAL

Date:02/11/03ISR Number: 4054204-0Report Type:Expedited (15-DaCompany Report #DE-GLAXOSMITHKLINE-D0040372A
Age:52 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Bradycardia	Health	Quilonum	PS	Glaxosmithkline	ORAL	36000MG	
	Intentional Misuse	Professional					Single dose	
	Somnolence							
	Suicide Attempt							

Date:02/11/03ISR Number: 4055752-XReport Type:Direct Company Report #CTU 186453
Age:50 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Coordination Abnormal		Lithium Carbonate	PS		ORAL	300MG PO TID	
Initial or Prolonged	Diarrhoea		Quinapril	C				
	Mental Status Changes		Quetiapine	C				
	Nausea		Mirtazapine	C				
	Vomiting		Gabapentin	C				
			Atorvastatin	C				
			Gemfibrozil	C				
			Omeprazole	C				
			Tramadol	C				
			Levothyroxine	C				
			Amantadine	C				
			Bupropion	C				
			Thiothixine	C				
			Metformin	C				
			Novolin 70/30	C				
			Combivent	C				
			B-12	C				

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Date:02/11/03ISR Number: 4056197-9Report Type:Expedited (15-DaCompany Report #2003004700
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Confusional State Drug Level Decreased	Consumer	Lithium (Lithium)	PS				

Date:02/11/03ISR Number: 4056523-0Report Type:Expedited (15-DaCompany Report #PHBS2003JP01119
Age:72 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Fall Forearm Fracture	Foreign Literature Health Professional	Melleril (Thioridazine Hydrochloride) Tablet	PS		ORAL	30 MG/D, ORAL	
		Other	Levomepromazine Hydrochloride (Levomepromazine Hydrochloride)	SS			5 MG/D	
			Lithium Carbonate (Lithium Carbonate)	SS			600 MG/D	
			Prothiaden (Dosulepin)	SS			75 MG/D	
			Zopiclone (Zopiclone)	SS			30 MG/D	
			Tiapride Hydrochloride (Tiapride Hydrochloride)	SS			25 MG/D	
			Biperiden Hydrochloride (Biperiden Hydrochloride)	SS			3 MG/D	

Date:02/12/03ISR Number: 4057228-2Report Type:Expedited (15-DaCompany Report #030130-PM0024-00
Age:48 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Intentional Misuse Rhabdomyolysis Suicide Attempt	Foreign Health Professional Other	Tranxene (Clorazepate Dipotassium) Tablets	PS		ORAL	5 MG, P.O QD	
			Risperedone Tablets	SS		ORAL	P.O.	
			Olanzapine Tablets	SS		ORAL	P.O.	
			Lithium Carbonate Tablets	SS		ORAL	P.O.	
			Levomepromazine Tablets	SS		ORAL	P.O.	

Date:02/12/03ISR Number: 4057235-XReport Type:Expedited (15-DaCompany Report #030109-PM0019-01
Age:55 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Bradycardia	Foreign Health Professional Other	Tranxene (Clorazepate Dipotassium)	PS		ORAL	5 MG, P.O. QD	YR
			Lithium Carbonate	SS		ORAL	250 MG, P.O., BID	YR
			Olanzapine	SS		ORAL	10 MG, P.O., QD	

			Zopiclone	SS		ORAL	7.5 MG, P.O.,
QD	YR						

Date:02/13/03ISR Number: 4057377-9Report Type:Expedited (15-DaCompany Report #PHBS2003JP01358
Age:70 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Condition Aggravated Drug Interaction	Foreign Health	Voltaren (Diclofenac Sodium) Suppository	PS		RECTAL		RECTAL
	Gait Disturbance Major Depression	Professional	Limas (Lithium Carbonate)	SS				
			Hypnotics And Sedatives	C				
			Antianxietics	C				

Date:02/13/03ISR Number: 4057982-XReport Type:Expedited (15-DaCompany Report #PHBS2003JP01119
Age:72 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Fall Forearm Fracture	Foreign Literature Health Professional	Melleril (Thioridazine Hydrochloride) Tablet	PS		ORAL	30 MG/D,	ORAL
		Other	Levomepromazine Hydrochloride (Levomepromazine Hydrochloride)	SS			5 MG/D,	
			Lithium Carbonate (Lithium Carbonate)	SS			600 MG/D,	
			Prothiaden (Dosulepin)	SS			75 MG/D,	
			Zopiclone (Zopiclone)	SS			30 MG/D,	

				Tiapride Hydrochloride (Tiapride Hydrochloride)	SS		25 MG/D,
				Biperiden Hydrochloride (Diperiden Hydrochloride)	SS		3 MG/D,

Date:02/14/03ISR Number: 4056116-5Report Type:Expedited (15-DaCompany Report #DE-GLAXOSMITHKLINE-D0038001A
Age:63 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Akathisia	Health	Quilonum Retard	PS	Glaxosmithkline	ORAL	450MG	Unknown 93 DAY
	Constipation	Professional	Remeron	SS		ORAL	60MG per day	138 DAY
	Oedema Peripheral		Tramal	SS		ORAL	250MG per day	3 DAY
	Pain		Celebrex	C		ORAL	400MG per day	60 DAY
	Serotonin Syndrome		Arelix	C		ORAL	6MG per day	
	Suicide Attempt		Baldrian	C		ORAL	30DROP per	
							day	24 DAY
			Sirdalud	C		ORAL	6MG per day	82 DAY
			Dipiperon	C		ORAL	22 DAY	

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Date:02/14/03ISR Number: 4056806-4Report Type:Direct Company Report #CTU 186706
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Psoriasis		Lithium	PS				

Date:02/19/03ISR Number: 4057489-XReport Type:Direct Company Report #CTU 186825
Age:41 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Affective Disorder		Lithium	PS				
Hospitalization - Initial or Prolonged	Blood Creatinine Increased							
Disability	Brain Damage							
Required Intervention to Prevent Permanent Impairment/Damage	Clonic Convulsion							
	Condition Aggravated							
	Convulsion							
	Coordination Abnormal							
	Dialysis							
	Difficulty In Walking							
	Drug Level Increased							
	Loss Of Consciousness							
	Mental Status Changes							
	Oral Intake Reduced							
	Tremor							
	Urinary Tract Infection							

Date:02/19/03ISR Number: 4059118-8Report Type:Expedited (15-DaCompany Report #LBID00203000023
Age:48 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Depressed Mood	Health Professional	Lithobid (Lithium Carbonate)	PS		ORAL	300 MG BID PO	
Hospitalization - Initial or Prolonged	Diabetes Insipidus							
	Lethargy		Depakote (Valproate Semisodium)	C				
	Oedema Peripheral		Risperdal (Risperidone)	C				
	Pneumonia		Vitamin D (Vitamin					

D)	C
Multivitamins (Multivitamins)	C
Actonel (Actonel)	C
Warfarin (Warfarin)	C

Date:02/19/03ISR Number: 4059120-6Report Type:Expedited (15-DaCompany Report #LBID00203000351
Age:18 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Nausea Suicide Attempt Vomiting	Health Professional	Lithobid (Lithium Carbonate)	PS		ORAL	DAILY PO	

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Freedom Of Information (FOI) Report

Date:02/19/03ISR Number: 4060308-9Report Type:Expedited (15-DaCompany Report #2003001969
Age:62 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Blood Calcium Abnormal Circulatory Collapse Epilepsy Postictal State	Foreign Health Professional Company Representative	Geodon (Ziprasidone) Lithium	PS SS		ORAL ORAL	80 MG (BID), ORAL 600 MG (DAILY), ORAL
Other							

Date:02/21/03ISR Number: 4058419-7Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0397122A
Age:42 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Aphasia Hypersomnia Incoherent Lethargy Medication Error Pneumonia Speech Disorder	Consumer	Lithium	PS	Glaxosmithkline	ORAL	3TAB See dosage text

Date:02/21/03ISR Number: 4059140-1Report Type:Direct Company Report #CTU 187077
Age:67 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Decreased Activity Drug Level Increased Mental Status Changes		Lithium Carbonate 300mg	PS		ORAL	300MG BID ORAL

Date:02/21/03ISR Number: 4062129-XReport Type:Expedited (15-DaCompany Report #EMADSS2001005486
Age:48 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Blood Creatine Phosphokinase Increased	Foreign Study	Risperidone (Unspecified)					
	Dysphagia	Health	(Risperidone)	PS			SEE IMAGE	
	Headache	Professional	Topiramate (Capsule)					
	Neuroleptic Malignant Syndrome		(Topiramate)	SS		ORAL	3 CAP, DAILY,	ORAL
	Respiratory Failure		Placebo (Placebo)	SS			3 CAP, DAILY,	ORAL
	Speech Disorder		Lithium (Lithium)	SS			DATA	
			Lorazepam	C			UNSPECIFIED	
			Chloral Hydrate (Chloral Hydrate)	C				
			Diazepam (Diazepam)	C				
			Olanzapine (Olanzapine)	C				
			Senna (Senna)	C				
			Lactulose (Lactulose)	C				
			Haloperidol (Haloperidol)	C				
			Lithium Carbonate (Lithium Carbonate)	C				

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Date:02/21/03ISR Number: 4064815-4Report Type:Expedited (15-DaCompany Report #PHBS2002JP14758
Age:69 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abnormal Behaviour	Foreign	Parlodel					
	Akathisia	Health	(Bromocriptine					
	Blood Creatine	Professional	Mesilate)	PS		ORAL	SEE IMAGE	
	Phosphokinase Increased	Other	Limas(Lithium					
	Hyperhidrosis		Carbonate)	SS		ORAL	400 MG/DAY,	
	Hypertension						ORAL	
	Parkinsonism		Lodopin(Zotepine)	SS		ORAL	50 MG/DAY,	
							ORAL	
			Inhibace					
			(Cilazapril)	SS	Roche			
			Coniel (Benidipine					
			Hydrochloride)	SS				
			Barnetil(Sultopride)	C		ORAL	800 MG/DAY,	
							ORAL	
			Amoban	C				
			Benzalin	C				
			Hirnamin	C				
			Pyrethia	C				

Date:02/25/03ISR Number: 4059971-8Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0383288A
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Cholesterol Increased	Consumer	Eskalith	PS	Glaxosmithkline		300MG See dosage text	
	Diarrhoea		Lithium	SS	Glaxosmithkline			
	Drug Level Increased		Estrogen	C				
	Drug Toxicity							
	Initial Insomnia							
	Middle Insomnia							

	Parathyroid Disorder					
	Renal Impairment					
	Seasonal Affective					
	Disorder					
	Surgery					
	Weight Decreased					

Date:02/25/03ISR Number: 4062004-0Report Type:Direct Company Report #CTU 187383
Age:47 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Blood Creatinine		Irbesartan	PS		ORAL	300 MG PO QD	
Initial or Prolonged	Increased		Lithium	SS		ORAL	300 MG PO QD	
	Blood Urea Increased		Irbesartan	C				
	Confusional State		Hydrochlorothiazide	C				
	Coordination Abnormal		Tegretol	C				
	Drug Toxicity		Lithium	C				
	Lethargy		Olanzapine	C				
	Tremor		Albuterol	C				
			Advair	C				
			Mvi	C				

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Date:02/26/03ISR Number: 4060817-2Report Type:Expedited (15-DaCompany Report #WAES 0302CHE00024
Age:52 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Brain Oedema		Moduretic	PS	Merck & Co., Inc	ORAL		
	Drug Interaction		Lithium Carbonate	SS		ORAL		
	Drug Level Increased		Valproate Sodium	C		ORAL		
	Nephrogenic Diabetes Insipidus		Haloperidol	C		ORAL		
			Amoxicillin Trihydrate And Clavulanate Potassium	C		ORAL	4	DAY
			Methotrimeprazine	C		ORAL		
			Risperidone	C		ORAL		
			Tizanidine	C		ORAL		
			Flavoxate Hydrochloride	C		ORAL		
			Oxerutins	C		ORAL		

Date:02/26/03ISR Number: 4061851-9Report Type:Direct Company Report #CTU 187493
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Confusional State		Lithium	PS				
	Drug Toxicity		Benztropine	C				
	Tremor		Fluphenazine	C				
			Glipizide	C				
			Paroxetine	C				
			Trazodone	C				

Date:02/26/03ISR Number: 4066629-8Report Type:Expedited (15-DaCompany Report #2003004062
Age:55 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Bradycardia	Consumer	Lithane (Lithium)	PS		ORAL	250 MG (BID), ORAL	
		Health Professional	Clorazepate					

			Dipotassium	SS		ORAL
5 MG (DAILY),						
ORAL						
			Olanzapine	SS		ORAL
10 MG						
(DAILY), ORAL						
			Zopiclone	SS		ORAL
7.5 MG						
(DAILY), ORAL						

Date:02/26/03ISR Number: 4066877-7Report Type:Expedited (15-DaCompany Report #030130-PM0024-01
Age:48 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Intentional Misuse	Foreign	Tranxene (Clorazepate			
	Rhabdomyolysis	Health				
	Suicide Attempt	Professional	Dipotassium) Tablets	PS		ORAL
5 MG, P.O. QD						
		Other	Risperedone Tablets	SS		ORAL
P.O.						
			Olanzapine Tablets	SS		ORAL
P.O.						
			Lithium Carbonate Tablets	SS		ORAL
P.O.						
			Levomepromazine Tablets	SS		ORAL
P.O.						

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Date:02/28/03ISR Number: 4062477-3Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0398148A
Age:13 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Myositis	Health Professional	Lithium	PS	Glaxosmithkline	ORAL	1200MG Per day	YR
			Risperdal	C				
			Cogentin	C				

Date:02/28/03ISR Number: 4067555-0Report Type:Expedited (15-DaCompany Report #EMADSS2003001581
Age:52 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agitation Brain Oedema Dehydration	Foreign Health Professional	Haldol (10 Mg Tablet) (Haloperidol)	PS		ORAL	10 MG, DAILY,	ORAL
	Depressed Level Of Consciousness Drug Interaction		Priadel (Lithium Carbonate)	SS		ORAL	800 MG,	DAILY, ORAL
	Miosis Nephrogenic Diabetes Insipidus		Depakine Chrono (Ergenyl Chrono)	SS		ORAL	SEE IMAGE	
	Oedema Peripheral Pitting Oedema		Moduretic (Moduretic)	SS		ORAL	2 TABLE, WEEK	(S), ORAL
	Pneumonia Somnolence		Augmentin (Clavulin)	SS		ORAL	ORAL	
	Therapeutic Agent Toxicity		Risperdal (Risperidone)	C				
			Nozinan (Levomepromazine)	C				
			Sirdalud (Tizanidine Hydrochloride)	C				
			Venoruton					

			(Troxerutin)	C		
			Urispas(Flavoxate Hydrochloride)	C		

Date:02/28/03ISR Number: 4067961-4Report Type:Expedited (15-DaCompany Report #2003002655
Age:27 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Literature	Lithium(Lithium)	PS		ORAL	ORAL	
	Intentional Misuse	Health	Clonazepam	SS		ORAL	ORAL	
		Professional	Metformin	SS		ORAL		

Date:02/28/03ISR Number: 4067962-6Report Type:Expedited (15-DaCompany Report #2003002625
Age:47 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Confusional State	Literature	Lithium (Lithium)	PS		ORAL	ORAL	
Hospitalization - Initial or Prolonged	Coordination Abnormal	Health Professional						
Other	General Physical Health Deterioration							
	Hypotension							
	Mental Status Changes							
	Renal Failure							
	Tachycardia							

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Date:02/28/03ISR Number: 4067963-8Report Type:Expedited (15-DaCompany Report #2003002630
Age:38 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardio-Respiratory Arrest	Literature	Lithium(Lithium)	PS		ORAL	ORAL	
	Completed Suicide	Health Professional	Venlafaxine(Venlafaxine)	SS		ORAL	ORAL	
	Intentional Misuse		Benzodiazepine(Benzodiazepine Derivatives)	SS		ORAL	ORAL	

Date:02/28/03ISR Number: 4067964-XReport Type:Expedited (15-DaCompany Report #2003002629
Age:54 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Literature	Lithium(Lithium)	PS		ORAL	ORAL	
	Drug Level Increased	Health Professional	Fluvastatin (Fluvastatin)	SS		ORAL	ORAL	
			Rosiglitazone (Rosiglitazone)	SS		ORAL	ORAL	

Date:03/03/03ISR Number: 4064797-5Report Type:Expedited (15-DaCompany Report #DE-GLAXOSMITHKLINE-D0040372A
Age:52 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Ankle Fracture		Quilonum	PS	Glaxosmithkline	ORAL	36000MG	Single dose
	Bradycardia							
	Circulatory Collapse							
	Fall							
	Hyporeflexia							
	Hypotension							
	Intentional Misuse							

	Somnolence					
	Suicide Attempt					

Date:03/03/03ISR Number: 4069172-5Report Type:Expedited (15-DaCompany Report #2003002626
Age:53 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Drug Level Above Therapeutic	Literature Health Professional	Lithane (Lithium)	PS		

Date:03/03/03ISR Number: 4069215-9Report Type:Expedited (15-DaCompany Report #2003002628
Age:46 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Completed Suicide	Literature Health Professional	Lithane (Lithium)	PS		
			Sertraline (Sertraline)	SS		
			Vicodin	SS		

Date:03/03/03ISR Number: 4069819-3Report Type:Expedited (15-DaCompany Report #B0292616A
Age:11 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blood Cholesterol Increased Blood Ph Decreased Blood Pressure Diastolic Decreased Glomerulonephritis Focal Haematuria Nephrotic Syndrome Proteinuria White Blood Cell Count Decreased	Literature Health Professional	Eskalith (Formulation Unknown)(Lithium Carbonate) Topiramate Risperidone	PS C C			300 MG / TWICE PER DAY /	

Date:03/03/03ISR Number: 4069824-7Report Type:Expedited (15-DaCompany Report #2003003832
Age:48 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anion Gap Increased Anxiety Blood Alkaline Phosphatase Increased Blood Bicarbonate Decreased Blood Glucose Increased Blood Thyroid Stimulating Hormone Increased Depression Dysarthria Gait Disturbance Haematocrit Decreased Lymphocyte Count Decreased Neutrophil Count Increased	Health Professional	Lithium (Lithium) Olanzapine Atenolol Lorazepam	PS SS C C		ORAL ORAL	600 MG(BID), ORAL 20 MG, ORAL	

	Platelet Disorder
	Red Blood Cell Count Decreased
	Renal Failure Acute
	Schizophrenia
	Therapeutic Agent Toxicity

Date:03/03/03ISR Number: 4069825-9Report Type:Expedited (15-DaCompany Report #2003002627
Age:57 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Drug Interaction Medication Error	Literature Health Professional	Lithane (Lithium)	PS				

Date:03/04/03ISR Number: 4065482-6Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0293775A
Age:48 YR Gender:Female I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Intentional Misuse Rhabdomyolysis

	Suicide Attempt						
		Report Source	Product	Role	Manufacturer	Route	Dose Duration
		Health Professional	Lithium Carbonate	PS	Glaxosmithkline		
			Tranxene	SS		ORAL	5MG Four times per day
			Risperidone	SS		ORAL	
			Olanzapine	SS			
			Levomepromazine	SS			

Date:03/04/03ISR Number: 4067148-5Report Type:Direct Company Report #CTU 187911
Age:54 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Mental Status Changes		Lithium	PS		ORAL	BY MOUTH PHYSICIAN

Date:03/05/03ISR Number: 4066297-5Report Type:Expedited (15-DaCompany Report #DE-GLAXOSMITHKLINE-D0040521A
Age:62 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Other	Drug Level Increased	Health Professional	Quilonum Retard	PS	Glaxosmithkline	ORAL	900MG per day
	Personality Change						
	Renal Failure						
	Tremor						

Date:03/05/03ISR Number: 4071231-8Report Type:Expedited (15-DaCompany Report #LBID00202002402
Age:32 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Disability	Blindness Transient	Consumer	Lithobid (Lithium				

	Deafness		Carbonate)	PS		ORAL
SEE IMAGE						
	Diarrhoea		Risperdal			
	Ear Pain		(Risperidone)	C		
	Migraine					
	Tinnitus					
	Vision Blurred					

Date:03/06/03ISR Number: 4066845-5Report Type:Expedited (15-DaCompany Report #DE-GLAXOSMITHKLINE-D0040372A
Age:52 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Ankle Fracture	Health	Quilonum	PS	Glaxosmithkline	ORAL	36000MG	
Initial or Prolonged	Bradycardia	Professional						
Single dose								
	Circulatory Collapse							
	Fall							
	Hyporeflexia							
	Hypotension							
	Intentional Misuse							
	Somnolence							
	Suicide Attempt							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/06/03ISR Number: 4072062-5Report Type:Expedited (15-DaCompany Report #2003008811
Age:55 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Bradycardia	Consumer	Lithane (Lithium)	PS		ORAL	250 MG (BID),	ORAL
			Zopiclone	SS		ORAL	7.5 MG (QD),	ORAL
			Clorazepate Dipotassium	SS		ORAL	5 MG (QD),	ORAL
			Olanzapine	SS		ORAL	10 MG (QD),	ORAL

Date:03/07/03ISR Number: 4069512-7Report Type:Direct Company Report #CTU 188183
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Aphasia		Lithium 300 Mg	PS		ORAL	300 MG TID	ORAL
	Dysarthria							
	Insomnia		Micardis Hct 80 /12.5 Mg	SS		ORAL	80/12.5 MG QD	ORAL
	Lethargy							
	Mental Impairment							
	Oral Intake Reduced		Synthroid	C				
	Somnolence		Norvasc	C				
	Tremor		Calcium	C				
			Allegra Prn	C				

Date:03/10/03ISR Number: 4068765-9Report Type:Expedited (15-DaCompany Report #DE-GLAXOSMITHKLINE-D0040581A
Age:51 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Alopecia Nail Disorder Therapeutic Agent Toxicity		Quilonum Retard	PS	Glaxosmithkline	ORAL		

Date:03/11/03ISR Number: 4072835-9Report Type:Direct Company Report #CTU 188501
Age:48 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Flushing		Lithium Carbonate Elavil	PS C				

Date:03/11/03ISR Number: 4074694-7Report Type:Expedited (15-DaCompany Report #03P-151-0212144-00
Age:52 YR Gender:Female I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Agitation Brain Oedema Dehydration Depressed Level Of Consciousness Drug Interaction Drug Level Increased Miosis Nephrogenic Diabetes Insipidus

		Pneumonia Renal Failure Acute Schizophrenia	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
		Somnolence Tachypnoea	Foreign Health Professional Other	Depakine Chrono Tablets (Depakene) (Sodium Valproate/Valproic Acid) (Sodium	PS		ORAL
SEE IMAGE							
				Lithium Carbonate	SS		ORAL
400 MG, 2 IN 1 D, ORAL							
				Haloperidol	SS		ORAL
5 MG, 2 IN 1 D, PER ORAL							
				Moduretic	SS		ORAL
1 TABLET, 2 IN 1 WK, ORAL							
				Clavulin	SS		ORAL
ORAL							
				Levomepromazine	C		
				Risperidone	C		
				Tizanidine Hydrochloride	C		
				Flavoxate Hydrochloride	C		
				Troxerutin	C		

Date:03/12/03ISR Number: 4075266-0Report Type:Expedited (15-DaCompany Report #B0294000A
Age:69 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization - Initial or Prolonged	Arthralgia Clonic Convulsion Depressed Level Of Consciousness Diabetes Mellitus Non-Insulin-Dependent Drug Interaction Drug Toxicity	Foreign Literature Health Professional	Eskalith (Lithium Carbonate) Diclofenac (Diclofenac) Haloperidol	PS SS C		

Dyskinesia
Electroencephalogram
Abnormal
Insomnia
Psychomotor Retardation
Tremor

Date:03/12/03ISR Number: 4075280-5Report Type:Expedited (15-DaCompany Report #B0292874A
Age: Gender:Female I/FU:I

Outcome	PT
Other	Apgar Score Low
	Cardiomegaly
	Complications Of Maternal
	Exposure To Therapeutic
	Drugs
	Drug Level Increased
	Hyperbilirubinaemia
	Neonatal
	Hypoglycaemia Neonatal
	Maternal Drugs Affecting
	Foetus
	Nephrogenic Diabetes
	Insipidus

	Oliguria					
	Patent Ductus Arteriosus					
	Polyuria	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
	Pregnancy	Foreign	Lithium Salt			
	Pregnancy Induced	Literature	(Lithium Salt)	PS		
TRANSPLACENTAL	TRANSPLACENTA					
	Hypertension	Health				
RY						
	Premature Baby	Professional	Labetalol			
	Premature Rupture Of		Hydrochloride	C		
	Membranes		Betamethasone	C		
	Prolonged Labour					
	Respiratory Disorder					
	Neonatal					
	Urine Osmolarity					
	Decreased					
	Weight Decrease Neonatal					

Date:03/12/03ISR Number: 4075294-5Report Type:Expedited (15-DaCompany Report #B0293592A
Age:78 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization -	Aortic Valve Stenosis	Foreign	Lithium Salt			
Initial or Prolonged	Bundle Branch Block Left	Literature	(Formulation			
Other	Cardiac Failure	Health	Unknown)	PS		
	Cardiac Murmur	Professional	Imipramine			
	Cardiomyopathy		(Formulation			
	Drug Interaction		Unknown)			
	Drug Toxicity		(Imipramine)	SS		
	Electrocardiogram Qrs		Amineptine			
	Complex Shortened		Hydrochloride			
	Hypertension		(Formulation			
	Prescribed Overdose		Unknown) (Amineptine			
	Pulmonary Hypertension		Hydrochloride)	SS		
	Renal Impairment		Methotrimeprazine			
	Ventricular Extrasystoles		(Formulation			
			Unknown)			
			(Methotrimeprazine)	SS		
			Lorazepam			
			(Formulation			
			Unknown) (Lorazepam)	SS		

Date:03/13/03ISR Number: 4071168-4Report Type:Expedited (15-DaCompany Report #DE-GLAXOSMITHKLINE-D0040613A
Age:64 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dyskinesia		Quilonum Retard	PS	Glaxosmithkline	ORAL		
	Glossitis		Trevilor	SS		ORAL		33 DAY
	Glossodynia		Taxilan	SS		ORAL		26 DAY
	Trismus		Tafil	C		ORAL		
			Isoptin	C			UNKNOWN	240MG per day
			Liviella	C		ORAL		1TAB Per day
			L -Thyroxine	C	Glaxosmithkline		UNKNOWN	.075MG per day
			Noctamid	C		ORAL		1MG per day

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/13/03ISR Number: 4071169-6Report Type:Expedited (15-DaCompany Report #DE-GLAXOSMITHKLINE-D0040615A
Age:49 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Creatinine Increased		Quilonum Retard	PS	Glaxosmithkline	ORAL	1350MG per day	4 YR
	Confusional State		Tegretal	C		ORAL	400MG per day	
	Convulsion							
	Drug Level Increased							
	Meningioma							
	Nervous System Disorder							
	Restlessness							
	Sleep Disorder							
	Therapeutic Agent Toxicity							

Date:03/13/03ISR Number: 4076132-7Report Type:Expedited (15-DaCompany Report #PHBS2003JP01358
Age:70 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Depression	Foreign	Voltaren(Diclofenac Sodium) Suppository	PS		RECTAL	RECTAL	
	Drug Interaction	Health Professional	Limas(Lithium Carbonate)	SS				
	Gait Disturbance	Other	Hypnotics And Sedatives	C				
	Major Depression		Anxiolytics	C				

Date:03/14/03ISR Number: 4076972-4Report Type:Expedited (15-DaCompany Report #2003-DE-00746GD
Age:72 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Diarrhoea Gaze Palsy	Foreign Literature	Lithium Carbonate (Lithium Carbonate)	PS			600 MG	
	Mental Disorder							

Parkinsonism
Pyrexia
Therapeutic Agent
Toxicity

Date:03/17/03ISR Number: 4077741-1Report Type:Expedited (15-DaCompany Report #200310852EU
Age:68 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Death	Foreign	Metronidazole					
Other	Drug Toxicity		(Flagyl "Aventis"	PS		ORAL	1.2 G/DAY PO	3 WK
	Hypernatraemia		Lithium Sulfate (Lithionit)	SS		ORAL	166 MG/DAY PO	
			Venlafaxine Hydrochloride (Efexor Depot)	C				
			Pivampicillin Hydrochloride (Pondocillin)	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/18/03ISR Number: 4077845-3Report Type:Expedited (15-DaCompany Report #LBID00203000351
Age:15 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Level Increased Nausea Suicide Attempt Vomiting	Health Professional	Lithobid (Lithium Carbonate)	PS		ORAL	DAILY PO	

Date:03/19/03ISR Number: 4074238-XReport Type:Expedited (15-DaCompany Report #AT-GLAXOSMITHKLINE-B0295035A
Age:37 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Apnoea	Health Professional	Quilonorm	PS	Glaxosmithkline	ORAL	450MG Twice per day	13 DAY
Hospitalization - Initial or Prolonged	Blood Potassium Decreased							
	Cardiac Arrest		Zyprexa	C		ORAL	30MG per day	13 DAY
	Self-Medication		Rivotril	C		ORAL	13 DAY	
	Shock		Augmentin	C	Glaxosmithkline	ORAL		
			Pantoloc	C		ORAL	40MG per day	
			Akineton	C		ORAL	2MG per day	2 DAY
			Depakine	C		ORAL		
			Nubain	C			SUBCUTANEOUS	20MG per day 1 DAY
			Tricyclic Antidepressant	C				
			Scopolamin	C			SUBCUTANEOUS	.5ML per day 1 DAY

Date:03/19/03ISR Number: 4074255-XReport Type:Expedited (15-DaCompany Report #GB-GLAXOSMITHKLINE-B0294710A
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Other	Akathisia	Health	Seroxat	PS	Glaxosmithkline	ORAL 40MG per day
	Drug Interaction	Professional	Lithium	SS	Glaxosmithkline	ORAL 1.2G per day
	Dysphasia		Thyroxine	C	Glaxosmithkline	ORAL
			Risperidone	C		

Date:03/19/03ISR Number: 4076524-6Report Type:Direct Company Report #CTU 189074
Age:10 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Hospitalization - Initial or Prolonged	Aphasia Blood Pressure Increased		Lithium 300mg And 150mg	PS		ORAL 450MG TWO DAY
Required Intervention to Prevent Permanent Impairment/Damage	Dizziness Dyskinesia Dyspnoea Fatigue Headache Memory Impairment Productive Cough Speech Disorder Tremor		Resperdal 1mg And .5mg	SS		ORAL 1.5MG THREE TIMES DAY ORAL

Date:03/19/03ISR Number: 4078502-XReport Type:Expedited (15-DaCompany Report #LBID00203000674
Age:51 YR Gender:Female I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Abdominal Adhesions Abdominal Pain Anaemia

		Diarrhoea Drug Toxicity Extramedullary Haemopoiesis Kidney Enlargement Renal Cell Carcinoma Stage Unspecified Renal Failure Acute Thrombocythaemia	Report Source Literature Health Professional	Product Lithium Carbonate (Lithium Carbonate)	Role PS	Manufacturer	Route ORAL	Dose DAILY PO

Date:03/19/03ISR Number: 4078517-1Report Type:Expedited (15-DaCompany Report #200300783S
Age:46 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Sudden Death	Health Professional	(Myslee) Zolpidem Tablet 10 Mg	PS		ORAL	10 MG	18 MON
			(Dogmatyl) Sulpiride Tablet 100 Mg	SS			200 MG	88 MON
			(Limas) Lithium Carbonate Tablet 200 Mg	SS		ORAL	800MG	2 YR
			(Artane) Trihexyphenidyl Hydrochloride Tablet 2mg	SS		ORAL	4MG	21 MON
			(Toledomin) Milnacipran Hydrochloride Tablet	SS		ORAL	100MG	7 MON
			(Tetramide) Mianserin Hydrochloride Tablet	SS			20MG	88 MON
			(Contmin) Chlorpromazine Tablet 25mg	SS			25MG	21 MON
			(Silece)					

					Flunitrazepam Tablet 2mg	SS		
2MG	61	MON						
					(Seroquel) Quetiapine Fumarate Tablet	SS		
150MG	11	MON						

Date:03/19/03ISR Number: 4078927-2Report Type:Expedited (15-DaCompany Report #PHBS2003FI02658
Age:45 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anorexia Difficulty In Walking	Foreign Health	Lamisil(Terbinafine Hydrochloride)	PS		ORAL	250 MG/D, ORAL	
	Drug Interaction	Professional						
	Drug Level Increased Muscle Twitching Tremor Weight Decreased	Other	Lito(Lithium Carbonate) Truxal (Chlorprothixene Hydrochloride)	SS C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/19/03ISR Number: 4078933-8Report Type:Expedited (15-DaCompany Report #B0294723A
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Goitre Congenital Maternal Drugs Affecting Foetus	Foreign Literature Health Professional	Lithium Salt (Formulation Unknown) (Lithium Salt)	PS				

TRANSPLACENTAL TRANSPLACENTA

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Date:03/21/03ISR Number: 4082179-7Report Type:Expedited (15-DaCompany Report #L03-NLD-01012-01
Age:49 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Cerebellar Syndrome	Foreign	Carbamazepine	PS			1200 MG QD	
Initial or Prolonged	Drug Level Above Therapeutic	Literature Other	Lithium	SS				
			Trifluperidol	SS			1.5 MG QD	
	Lobar Pneumonia							
	Pneumonia Streptococcal							
	Therapeutic Agent Toxicity							

Date:03/24/03ISR Number: 4076710-5Report Type:Expedited (15-DaCompany Report #CH-GLAXOSMITHKLINE-B0294907A
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Tremor		Deroxat	PS	Glaxosmithkline	ORAL	20MG Per day	56 DAY
Initial or Prolonged			Lithium Sulphate	SS		ORAL	330MG Per day	12 DAY
			Zyprexa	SS		ORAL	5MG Per day	50 DAY
			Temesta	C		ORAL	3MG Per day	

Date:03/25/03ISR Number: 4077593-XReport Type:Expedited (15-DaCompany Report #DE-GLAXOSMITHKLINE-D0040688A
Age:27 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Intentional Misuse		Quilonum	PS	Glaxosmithkline	ORAL		
	Suicide Attempt		Trevilor	SS		ORAL		
			Zyprexa	SS		ORAL	400MG per day	

Date:03/25/03ISR Number: 4082240-7Report Type:Direct Company Report #CTU 189077
Age:52 YR Gender:Male I/FU:I

Outcome	PT
	Cardiac Disorder
	Chills
	Coronary Artery Occlusion
	Diabetes Mellitus
	Discomfort
	Dyspnoea
	Eye Pain
	General Physical Health Deterioration
	Headache
	Malaise
	Muscular Weakness
	Palpitations
	Therapeutic Agent Toxicity

	Treatment Noncompliance Tremor						
		Report Source	Product	Role	Manufacturer	Route	Dose Duration
			Eskalith 450 Cr	PS			5 YR

Date:03/26/03ISR Number: 4083862-XReport Type:Expedited (15-DaCompany Report #2003011623
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Anger	Consumer	Navane (Capsule)				6 MG (TID)
	Anorexia		(Tiotixene)	PS			
Other	Arthritis		Geodon (Ziprasidone)	SS			20 MG
	Asthenia						(WEEKLY)
	Bladder Disorder		Lithane (Lithium)	SS			
	Blood Cholesterol		Valdecoxib	SS			
	Blood Pressure		Celecoxib	SS			
	Blood Pressure Systolic		Haloperidol	SS			
	Cough		Calcium Ascorbate	C			
	Dizziness		Cyanocobalamin	C			
	Dyspepsia		Pyridoxine				
	Fatigue		Hydrochloride	C			
	Feeling Abnormal		Zinc Picolinate	C			
	Frequent Bowel Movements		Fluphenazine				
	Gait Disturbance		Hydrochloride	C			
	Headache		Methylphenidate				
	Heart Rate Increased		Hydrochloride	C			
	Incontinence		Ketoconazole	C			
	Increased Appetite		Levothyroxine Sodium	C			
	Mental Disorder		Estrogens Conjugated	C			
	Muscle Spasms		Clobetasol				
	Pain In Extremity		Propionate	C			
	Paranasal Sinus		Rofecoxib	C			
	Hypersecretion		Tocopherol	C			
	Physical Examination		Clarithromycin	C			
	Abnormal		Entex	C			
	Pollakiuria		Mesoridazine	C			
	Pyrexia		Risperidone	C			
	Schizoaffective Disorder		Olanzapine	C			
	Screaming		Valproate Semisodium	C			

Sleep Disorder	Omeprazole	C	
Stress	Nizatidine	C	
Suicidal Ideation	Thiamine Hydrochloride	C	
Urinary Retention			
Weight Fluctuation			

Date:03/26/03ISR Number: 4083975-2Report Type:Expedited (15-DaCompany Report #2003AP01246
Age:46 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardiovascular Disorder	Foreign	Seroquel	PS		ORAL	50 MG TID, PO	
	Sudden Death	Health Professional	Limas	SS		ORAL	200 MG QID PO	
			Artane	SS		ORAL	2 MG BID PO	
		Other	Dogmatyl	SS		ORAL	100 MG BID PO	
			Toledomin	SS		ORAL	50 MG PO	
			Tetramide	SS		ORAL	20 MG QD PO	
			Contomin	SS		ORAL	25 MG QD PO	
			Silece	SS		ORAL	2 MG QD PO	
			Zolpidem	SS		ORAL	10 MG QD PO	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/26/03ISR Number: 4084136-3Report Type:Expedited (15-DaCompany Report #NALB20030001
Age:42 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Bipolar Disorder	Foreign	Nalbuphine	PS		SUBCUTANEOUS	20 MG	ONCE
Hospitalization -	Bradycardia	Health				SUBCU		
Initial or Prolonged	Cardiac Arrest	Professional	Scopolamine	SS		SUBCUTANEOUS	0.5 ML	ONCE
Required	Condition Aggravated					SUBCU		
Intervention to	Drug Interaction		Olanzapine	SS		ORAL	30 MG	PO
Prevent Permanent	Infection		Lithium Carbonat	SS		ORAL	900 MG	PO
Impairment/Damage	Inflammation		Clonazepam	SS		ORAL	10 MG	PO
	Mania		Pantoprazol	SS			40 MG	
			Biperidine	SS			2 MG	
			Valproinat	SS			3000 MG	
			Olanzapine	C				
			Lithium Carbonat	C				
			Clonazepam	C				
			Amoxicillin/Clavulanat	C				
			Valproinat	C				
			Amoxicillin/Clavulanat	C				
			Valproinat	C				

Date:03/28/03ISR Number: 4080305-7Report Type:Expedited (15-DaCompany Report #JP-GLAXOSMITHKLINE-B0296034A
Age:61 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Drug Eruption		Lithium Carbonate	PS	Glaxosmithkline			
600MG per day	42	DAY						
Initial or Prolonged	Erythema		Chlorpromazine	C	Glaxosmithkline			
	Haemodialysis		Levomepromazine	C				
	Skin Test Positive		Risperidone	C				

	Swelling		Zonisamide	C		
			Biperiden Hydrochloride	C		
			Pollen Extract	C		
			Vegetamin A	C		
			Amobarbital	C		
			Bromovalerylurea	C		
			Sairei-To	C		

Date:03/28/03ISR Number: 4080306-9Report Type:Expedited (15-DaCompany Report #DE-GLAXOSMITHKLINE-D0040521A
Age:62 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Drug Level Increased Personality Change Renal Failure Tremor		Quilonum Retard	PS	Glaxosmithkline	ORAL	900MG per day

Date:03/31/03ISR Number: 4080840-1Report Type:Expedited (15-DaCompany Report #JP-GLAXOSMITHKLINE-B0295537A
Age:60 YR Gender:Male I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Bipolar I Disorder Cerebral Ventricle Dilatation Delirium Depressed Level Of

	Consciousness					
	Disorientation					
	Disturbance In Attention					
	Drug Interaction	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
	Dysarthria		Lithium Carbonate	PS	Glaxosmithkline	
41	DAY					
	Grandiosity		Haloperidol	C		
	Hallucination, Visual					
	Insomnia					
	Irritability					
	Logorrhoea					
	Psychomotor Hyperactivity					
	Speech Disorder					
	Therapeutic Agent					
	Toxicity					

Date:03/31/03ISR Number: 4087386-5Report Type:Expedited (15-DaCompany Report #2003-DE-01061GD (0)
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Death	Therapeutic Agent	Literature	Lithium Carbonate			
	Toxicity		(Lithium Carbonate)	PS		

Date:04/01/03ISR Number: 4082336-XReport Type:Expedited (15-DaCompany Report #US-BRISTOL-MYERS SQUIBB COMPANY-12216925
Age:62 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization -	Hyponatraemia		Trazodone Hcl Tabs	PS	Apothecon	ORAL
Initial or Prolonged	Polydipsia		Lithium	SS		ORAL
			Aminophylline	C		
			Benzhexol Hcl	C		
			Haloperidol	C		
			Acetaminophen	C		

Date:04/01/03ISR Number: 4084982-6Report Type:Direct Company Report #CTU 189959
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					

Hospitalization - 2 TABS TID	Dysarthria		Lithium 300mg	PS			
Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Mental Status Changes		Lorazepam	C			
			Clonazepam	C			
			Divalproex	C			
			Benzotropine	C			

Date:04/01/03ISR Number: 4085017-1Report Type:Direct Company Report #CTU 189952
Age:85 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - 300MG PO QHS	Aggression		Lithium Carbonate	PS		ORAL		
Initial or Prolonged	Confusional State Fatigue							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/01/03ISR Number: 4085925-1Report Type:Direct Company Report #CTU 189934
Age:77 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dehydration Sinus Bradycardia		Lithium Carbonate	PS		ORAL	300MG PO QAM AND 600MG PO QHS	

Date:04/01/03ISR Number: 4085931-7Report Type:Direct Company Report #CTU 189941
Age:65 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Asthenia Blood Urea Drug Level Increased Lethargy		Lithium Carbonate 450mg Lithium Carbonate 300mg Lisinopril Spironolactone	 PS SS C C			450MG PO QHS 300MG PO QD	

Date:04/03/03ISR Number: 4084101-6Report Type:Expedited (15-DaCompany Report #DE-GLAXOSMITHKLINE-D0040582A
Age:62 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Coordination Abnormal Movement Disorder Restlessness Therapeutic Agent Toxicity Tremor	Health Professional	Quilonum Retard	PS	Glaxosmithkline	ORAL	450MG See dosage text	

Date:04/03/03ISR Number: 4084102-8Report Type:Expedited (15-DaCompany Report #DE-GLAXOSMITHKLINE-D0040603A
Age:44 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Asthenia	Health Professional	Quilonum Retard	PS	Glaxosmithkline	ORAL	150MG per day	142 DAY
	Back Pain		Clozapine	C		ORAL	400MG per day	39 DAY
	Diarrhoea		Nefadar	C		ORAL	7.5MG Per day	39 DAY
	Drug Toxicity		Zolpidem	C		ORAL		
	Nausea		Blopress	C		ORAL		
	Pyrexia		Nebilet	C		ORAL		
	Vomiting		Zopiclon	C		ORAL		

Date:04/04/03ISR Number: 4085044-4Report Type:Expedited (15-DaCompany Report #DE-GLAXOSMITHKLINE-D0040372A
Age:52 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Ankle Fracture		Quilonum	PS	Glaxosmithkline	ORAL	36000MG Single dose	
	Bradycardia							
	Circulatory Collapse							
	Fall							
	Hyporeflexia							
	Hypotension							
	Somnolence							
	Suicide Attempt							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/04/03ISR Number: 4085128-0Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0350706A
Age:41 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Hallucination, Visual		Eskalith	PS	Glaxosmithkline	ORAL	6	YR
Initial or Prolonged	Medication Error		Risperdal	C				
Other	Nocturia							
	Psychotic Disorder							
	Schizophrenia							
	Somnolence							

Date:04/04/03ISR Number: 4085215-7Report Type:Expedited (15-DaCompany Report #AT-ROCHE-335077
Age:42 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Cardiac Arrest		Rivotril	PS	Roche	ORAL	2	DAY
	Cardiac Failure Acute		Rivotril	SS	Roche	ORAL	4	DAY
	Mania		Zyprexa	SS		ORAL	13	DAY
			Quilonorm Retard	SS		ORAL	13	DAY
			Augmentin	SS		ORAL	3	DAY
			Augmentin	SS		ORAL		
			Augmentin	SS		ORAL	7	DAY
			Depakine	SS		ORAL		
			Depakine	SS		ORAL		
			Depakine	SS		ORAL	26	DAY
			Depakine	SS		ORAL	2	DAY
			Nubain	SS				

SUBCUTANEOUS STRENGTH 20

MG/2ML.

GIVEN IN THE

EVENING.

				Scopolamine	SS	Roche	

SUBCUTANEOUS GIVEN IN THE

EVENING.

				Pantoloc	C		ORAL
				Akineton	C		ORAL

2 DAY

Date:04/04/03ISR Number: 4090055-9Report Type:Expedited (15-DaCompany Report #200300783S
Age:46 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Death	Sudden Death	Foreign	...Yslee Zolpidem			
		Health	Tablet 10mg	PS		ORAL
10MG, PO	18 MON					
		Professional	Dogmatyl Sulpiride			
			Tablet 100mg	SS		
4 MG	94 MON					
			...Imas Lithium Carbonate Tablet			
			200mg	SS		
80MG,	2 YR					
			Artane Trihexyphonidyl Hydrochloride Tablet			
			2mg	SS		
4MG	21 MON					
			Toledomin Milnacipran Hydrochloride Tablet	SS		
100MG	7 MON					
			Tetramide Mianserin Hydrochloride Tablet	SS		
20MG	88 MON					
			Contmin Chlorpromazine Tablet 25mg	SS		
25MG	21 MON					
			Silece Flunitrazepam Tablet			

			2mg	SS	
2MG	61	MON			
			Seroquel Quetiapine Fumarate Tablet	SS	
150MG	11	MON			

Date:04/04/03ISR Number: 4090195-4Report Type:Expedited (15-DaCompany Report #2003GB00695
Age:66 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Drug Interaction	Foreign Health Professional Other	Atenolol	PS				
	Drug Level Increased		Lithium	SS			800 MG DAILY	
			Bendrofluazide	SS			2.5 MG DAILY	
			Venlafaxine	C				
			Sulpiride	C				
			Detrusitol	C				

Date:04/04/03ISR Number: 4090617-9Report Type:Expedited (15-DaCompany Report #B0294723A
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Blood Thyroid Stimulating Hormone Increased	Foreign Literature Health Professional	Eskalith (Formulation Unknown) (Lithium Carbonate)	PS			TRANSPLACENTAL	TRANSPLACENTARY
	Congenital Hypothyroidism							
	Drug Exposure During Pregnancy							
	Goitre Congenital		Cyamemazine	C				
	Pregnancy		Venlafaxine Hydrochloride	C				
			Olanzapine	C				

Date:04/07/03ISR Number: 4085581-2Report Type:Expedited (15-DaCompany Report #US-BRISTOL-MYERS SQUIBB COMPANY-12227005
Age:50 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Life-Threatening	Haemodynamic Instability		Glucophage Tabs 850			
Hospitalization -	Intentional Misuse		Mg	PS	Bristol-Myers Squibb	
Initial or Prolonged	Lactic Acidosis				Company	ORAL
Other	Nausea		Lithium	SS		
	Renal Failure Acute		Tricyclic			
	Suicide Attempt		Antidepressants	SS		
	Tachypnoea					
	Vomiting					

Date:04/07/03ISR Number: 4088123-0Report Type:Direct Company Report #CTU 190326
Age:59 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Attention		Lithium Carbonate	PS		ORAL	1200MG QHS	
Initial or Prolonged	Deficit/Hyperactivity							
ORAL								
	Disorder		Hctz 25mg	SS		ORAL	25MG QD ORAL	
	Coordination Abnormal							
	Delirium							
	Leukocytosis							
	Sluggishness							
	Therapeutic Agent							
	Toxicity							
	Tremor							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/08/03ISR Number: 4086291-8Report Type:Expedited (15-DaCompany Report #GB-GLAXOSMITHKLINE-B0296292A
Age:42 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Abdominal Pain		Lithium Carbonate	PS	Glaxosmithkline			
UNKNOWN							800MG Per day	
Initial or Prolonged	Blood Creatinine		Clozapine	SS		ORAL	300MG Twice	
	Increased							
per day								296 DAY
	Blood Sodium Increased		Ranitidine	C	Glaxosmithkline	ORAL	150MG Twice	
	Blood Urea Increased							
per day								
	Coordination Abnormal		Sodium Phosphate	C				
	Dehydration							
	Diabetes Insipidus							
	Grand Mal Convulsion							

Date:04/08/03ISR Number: 4091123-8Report Type:Expedited (15-DaCompany Report #2003013100
Age:42 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Blood Cholesterol	Health	Geodon (Ziprasidone)	PS		ORAL	40 MG (BID),	
Initial or Prolonged	Increased	Professional					ORAL	
Other	Diabetes Mellitus		Lithane (Lithium)	SS		ORAL	1500 MG	
	Nocturia							
(DAILY), ORAL								
			Valproate Semisodium (Valproate Semisodium)	C				

Date:04/08/03ISR Number: 4091440-1Report Type:Expedited (15-DaCompany Report #2003-BP-02012RO (0)
Age:36 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Psychotic Disorder	Other	Lithium Carbonate					

			Capsules Usp, 300 Mg (Lithium Carbonate)	PS		ORAL
PO YEARS						

Date:04/08/03ISR Number: 4091879-4Report Type:Expedited (15-DaCompany Report #03P-009-0214904-00
Age:42 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Life-Threatening Hospitalization - Initial or Prolonged	Bradycardia Cardiac Arrest Drug Level Above Therapeutic Inflammation	Foreign Health Professional	Depakine (Depakene)(Sodium Valproate/Valproic Acid) (Sodium Valproate/Valproic	PS		ORAL	SEE IMAGE
	Oxygen Saturation Decreased		Olanzapine	SS		ORAL	30 MG, 1 IN 1 D, PER ORAL
	Pyrexia		Lithium Carbonate	SS		ORAL	PER ORAL
	Self-Medication Shock Toxicologic Test Abnormal		Nalbuphine Hydrochloride	SS			20 MG, 1 IN 1 D, SUBCUTANEOUS
			Hyoscine	SS			0.5 ML, 1 IN 1 D, SUBCUTANEOUS
			Clonazepam	SS		ORAL	16 MG, 1 IN 1 D, PER ORAL
			....	C			
			Amoxicillin Trihydrate	C			
			Pantoprazole	C			

			Biperiden	C		

Date:04/09/03ISR Number: 4087784-XReport Type:Expedited (15-DaCompany Report #DE-GLAXOSMITHKLINE-D0040772A
Age:22 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Intentional Misuse		Quilonum Retard	PS	Glaxosmithkline	ORAL	900MG per day	HR
	Suicide Attempt		Atarax	SS		ORAL	50MG per day	HR
			Dipiperon	SS		ORAL	320MG per day	HR
			Fluoxetin	SS		ORAL	60MG per day	HR
			Risperdal	SS		ORAL	6MG per day	HR

Date:04/09/03ISR Number: 4087785-1Report Type:Expedited (15-DaCompany Report #DE-GLAXOSMITHKLINE-D0040777A
Age:61 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Creatinine		Quilonorm Retard	PS	Glaxosmithkline	ORAL	450MG Twice per day	
	Blood Potassium							
	Blood Sodium							
	Depression							
	Dizziness							
	Tremor							
	White Blood Cell Count							

Date:04/09/03ISR Number: 4090309-6Report Type:Direct Company Report #CTU 190558
Age:18 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Micturition Disorder		Eskalith Cr 450 Mg Bid	PS		ORAL	450 MG PO BID	
	Micturition Urgency							

Pollakiuria
Specific Gravity Urine
Urine Osmolarity

Date:04/09/03ISR Number: 4092783-8Report Type:Expedited (15-DaCompany Report #PHBS2003JP01119
Age:72 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Fall Forearm Fracture	Foreign Literature Health Professional Other	Melleril (Thioridazine Hydrochloride) Tablet	PS		ORAL	30 MG/DAY, ORAL	
			Levomepromazine Hydrochloride (Levomeprazine Hydrochloride)	SS			5 MG/D	
			Lithium Carbonate (Lithium Carbonate)	SS			600 MG/D	
			Prothiaden (Dosulepin)	SS			75 MG/D	
			Zopiclone (Zopiclone)	SS			30 MG/D	
			Tiapride Hydrochloride (Tiapride Hydrochloride)	SS			25 MG/D	

			Biperiden Hydrochloride (Biperiden Hydrochloride)	SS			3 MG/D

Date:04/09/03ISR Number: 4093279-XReport Type:Expedited (15-DaCompany Report #LBID00203000872
Age:21 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agitation Back Pain Blindness Hysterical Blood Urea Decreased Central Pontine Myelinolysis Coordination Abnormal Crying Diarrhoea Disturbance In Attention Drug Level Above Therapeutic Eye Movement Disorder Facial Paresis Fatigue Gait Disturbance Hallucination, Visual Headache Hypoaesthesia Intracranial Pressure Increased Mood Swings Mydriasis Nausea Papilloedema Photosensitivity Reaction Pollakiuria Screaming Thirst Visual Disturbance Vomiting White Blood Cell Count	Literature Health Professional	Lithobid (Lithium Carbonate)	PS		ORAL	1050 MG DAILY	PO 2 YR

Increased

Date:04/10/03ISR Number: 4088151-5Report Type:Expedited (15-DaCompany Report #CH-GLAXOSMITHKLINE-B0296700A
Age:64 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Renal Interstitial Fibrosis Tubulointerstitial Nephritis		Quilonorm	PS	Glaxosmithkline	ORAL	13 YR	
			Leponex	SS		ORAL	YR	

Date:04/10/03ISR Number: 4088387-3Report Type:Expedited (15-DaCompany Report #US-BRISTOL-MYERS SQUIBB COMPANY-12227005
Age:50 YR Gender:Female I/FU:F

Outcome
Life-Threatening
Hospitalization -

Initial or Prolonged
Other

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Cardiac Failure		Glucophage Tabs 850					
	Drug Toxicity		Mg	PS	Bristol-Myers Squibb			
	Haemodynamic Instability				Company	ORAL		
	Intentional Misuse		Lithium	SS				
	Lactic Acidosis		Tricyclic					
	Lung Disorder		Antidepressants	C				
	Renal Failure Acute							
	Suicide Attempt							

Date:04/10/03ISR Number: 4088640-3Report Type:Direct Company Report #CTU 190592
Age:47 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Neurological Examination		Lithium Carbonate Sa					
Initial or Prolonged	Abnormal		450 Mg Eskalith	PS	Eskalith	ORAL	900MG QHS	
Required	Renal Impairment							
ORAL								
Intervention to	Therapeutic Agent		Levothryroxine					
Prevent Permanent	Toxicity		Synthroid	C				
Impairment/Damage			Pindolol	C				
			Calcium Carbonate	C				
			Hydroxyzine	C				
			Vit E	C				
			Nortriptyline	C				
			Risperidone	C				
			Estrogen	C				
			Cyproheptadine	C				
			Diazepam	C				
			Alprazolam	C				
			Sulfamethoxazole	C				
			Trimeth	C				
			Lithium Carb	C				
			Eskalith	C				
			Candesartan	C				

Date:04/10/03ISR Number: 4091385-7Report Type:Direct Company Report #CTU 190632
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Clonic Convulsion		Lithium	PS		ORAL	300MG PO BID	
	Coma		Theophylline	C				
	Lethargy		Risperdal	C				
	Tremor		Trazodone	C				

Date:04/10/03ISR Number: 4093563-XReport Type:Expedited (15-DaCompany Report #B0295537A
Age:60 YR Gender:Male I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Cerebral Atrophy
	Cerebral Ventricle Dilatation
	Delirium
	Depressed Level Of Consciousness
	Disorientation
	Drug Interaction

		Dysarthria Electroencephalogram Abnormal	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
		Extrapyramidal Disorder Hallucination, Visual Psychomotor Hyperactivity Speech Disorder Therapeutic Agent Toxicity	Foreign Literature Health Professional	Lithium Carbonate (Formulation Unknown) (Lithium Carbonate) Haloperidol	PS C		

Date:04/10/03ISR Number: 4093587-2Report Type:Expedited (15-DaCompany Report #2003-DE-00019YA(1)
Age:65 YR Gender:Male I/FU:F

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Disability		Blood Fibrinogen Calcinosis Cholelithiasis	Foreign Other	Omix (Tamsulosin) (Nr) (Tamsulosin Hydrochloride)	PS		ORAL
0.4 MG	365 DAY						
		Hyperparathyroidism Nephrolithiasis		Depamide (Valproate) (Nr)	SS		ORAL
PO							
		Renal Cyst Renal Failure		Teralithe (Lithium Carbonate) (Nr)	SS		ORAL
1500 MG, PO							
		Therapeutic Agent Toxicity		Tadenan (Pygeum Africanum) (Nr)	SS		ORAL
100 MG, PO							

Date:04/11/03ISR Number: 4088884-0Report Type:Expedited (15-DaCompany Report #DE-GLAXOSMITHKLINE-D0040830A
Age:81 YR Gender:Female I/FU:I

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Other		Suicide Attempt Vomiting	Health Professional	Quilonum Retard	PS	Glaxosmithkline	ORAL
9000MG per day							

Date:04/11/03ISR Number: 4091133-0Report Type:Direct Company Report #CTU 190717
Age:64 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	Therapeutic Agent Toxicity		Lithium Carbonate 300mg	PS		ORAL	1200MG QHS ORAL	

Date:04/14/03ISR Number: 4095238-XReport Type:Expedited (15-DaCompany Report #2003014034
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Back Injury Back Pain Dysgraphia Eating Disorder Fall Intentional Misuse Migraine Suicide Attempt Tremor Weight Fluctuation	Consumer	Lithane (Lithium) Nardil (Phenelzine Sulfate) Paracetamol (Paracetamol) All Other Therapeutic Products All Other Therapeutic Products	PS SS SS SS C		ORAL ORAL ORAL	(BID),ORAL 45 MG, ORAL ORAL	

Date:04/15/03ISR Number: 4095501-2Report Type:Expedited (15-DaCompany Report #PHNR2003AU00641
Age:41 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Blood Alkaline Phosphatase Increased	Foreign	Clozaril					
Hospitalization - Initial or Prolonged		Other	(Clozapine)(Clozapine) Tablet	PS		ORAL	250, 300 MG/	ONCE/DAY,
	C-Reactive Protein Increased							
	Dialysis							
	Haematocrit Decreased		Lithium (Lithium)	SS			625 MG, BID	
	Neutrophil Count Increased		Ranitidin "Aliud Pharma"	C				
	Platelet Count Increased		Valproate Sodium	C				
	Red Blood Cell Count Decreased		Alanzapine	C				
	Renal Failure		Diazepam	C				
	Therapeutic Agent Toxicity		Ceclor	C				
	White Blood Cell Count Increased							

Date:04/15/03ISR Number: 4095597-8Report Type:Expedited (15-DaCompany Report #2003AP01246
Age:46 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardiovascular Disorder	Foreign	Seroquel	PS		ORAL	50 MG TID PO	
	Sudden Death	Health Professional	Limas	SS		ORAL	200 MG QID PO	
			Artane	SS		ORAL	2 MG BID PO	
		Other	Dogmatyl	SS		ORAL	100 MG BID PO	
			Toledomin	SS		ORAL	50 MG PO	
			Tetramide	SS		ORAL	20 MG QD PO	
			Contomin	SS		ORAL	25 MG QD PO	

			Silece	SS		ORAL
2 MG QD PO						
			Zolpidem	SS		ORAL
10 MG QD PO						

Date:04/16/03ISR Number: 4094682-4Report Type:Direct Company Report #CTU 191046
Age:45 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Asthenia Confusional State Haemodialysis Somnolence		Lithium	PS		

Date:04/16/03ISR Number: 4096124-1Report Type:Direct Company Report #CTU 191113
Age:38 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Drug Interaction Laboratory Test Abnormal Renal Failure Acute		Lithium Carbonate 300mg Cap	PS		ORAL
900MG QAM, 1200MG QHS BY MOUTH						
			Lisinopril 40mg Tab	SS		ORAL
40MG QDBY						
MOUTH (PO)						
			Topiramate	C		
			Quetiapine Fumarate	C		
			Diltiazem	C		
			Lorazepam Tab	C		
			Lorazepam (Ativan)			

			Inj	C			

Date:04/17/03ISR Number: 4098291-2Report Type:Expedited (15-DaCompany Report #EMADSS2003002526
Age:76 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Bronchopneumonia Depression Dysphagia Fatigue Gait Disturbance Muscle Spasms Salivary Hypersecretion Tremor	Foreign Study Health Professional Other	Galantamine (Tablet) (Galantamine) Lithionit (Lithium Sulfate) Enalapril Maleate (Enalapril Maleate) Mirtazapine (Mirtazapine) Risperidone (Unspecified) (Risperidone) Oxazepam (Oxazepam) Calcium Carbonate (Calcium Carbonate) Lactulose (Lactulose) Paracetamol (Paracetamol) Zopiclone (Zopiclone) Paracetamol With Codeine (Acetaminophen/Codeine)	PS SS C C C C C C C C C		ORAL ORAL	SEE IMAGE, 41.5 MG, 2 IN 1 DAY (S),

Date:04/21/03ISR Number: 4093933-XReport Type:Expedited (15-DaCompany Report #AU-GLAXOSMITHKLINE-B0297551A
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Renal Failure Chronic		Lithium Carbonate	PS	Glaxosmithkline			YR

Date:04/21/03ISR Number: 4093955-9Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0350706A
Age:41 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dysgeusia	Consumer	Eskalith	PS	Glaxosmithkline	ORAL	7	YR
Other	Hallucination, Visual		Risperdal	C			UNKNOWN	
	Libido Decreased		Navane	C			UNKNOWN	
	Mania		Cogentin	C				
	Medication Error							
	Pollakiuria							
	Psychotic Disorder							
	Schizophrenia							
	Somnolence							
	Therapeutic Agent							
	Toxicity							
	Vomiting							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/21/03ISR Number: 4094104-3Report Type:Expedited (15-DaCompany Report #US-BRISTOL-MYERS SQUIBB COMPANY-12227005
Age:53 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Blood Pressure	Health	Glucophage Tabs 850					
Hospitalization - Initial or Prolonged	Cardiac Failure	Professional	Mg	PS	Bristol-Myers Squibb Company	ORAL		
	Cardiogenic Shock							
	Dehydration		Laroxyl	SS				
	Depressed Level Of Consciousness		Teralithe	SS				
			Cotareg	SS				
	Drug Toxicity		Motilium	C				
	Electrolyte Imbalance							
	Gastroenteritis							
	Haemodialysis							
	Hypoglycaemia							
	Intentional Misuse							
	Lactic Acidosis							
	Pneumonia Haemophilus							
	Renal Failure Acute							
	Suicide Attempt							
	Tachypnoea							

Date:04/21/03ISR Number: 4098436-4Report Type:Expedited (15-DaCompany Report #C2003-0743.01
Age:30 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Insomnia	Health	Clozapine Tablets					
	Restlessness	Professional	100 Mg Mylan	PS	Mylan	ORAL	300 MG QD,	
Other	Speech Disorder						ORAL ;	
	Weight Decreased						SEVERAL	MONTHS
			Lithium	SS			SEVERAL	MONTHS

Date:04/21/03ISR Number: 4099271-3Report Type:Expedited (15-DaCompany Report #03P-009-0214904-00
Age:42 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Cardiac Arrest	Foreign	Depakine (Depakene)					
Hospitalization - Initial or Prolonged	Drug Level Increased	Health Professional	(Sodium Valproate/Valproic Acid) (Sodium					
	Inflammation							
	Mania							
	Oxygen Saturation Decreased		Depakine (Depakene)	PS		ORAL	SEE IMAGE	
	Pneumonia		Olanzapine	SS		ORAL	30 MG, 1 IN 1 D, PER ORAL	
	Self-Medication		Lithium Carbonate	SS		ORAL	PER ORAL	
	Shock		Clonazepam	SS		ORAL	16 MG, 1 IN 1 D, PER ORAL	
			Nalbuphine Hydrochloride	SS		SUBCUTANEOUS	20 MG, 1 IN 1 D,	SUBCUTANEOUS
			Hyoscine	SS		SUBCUTANEOUS	0.5 ML, 1 IN 1 D,	SUBCUTANEOUS

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/21/03ISR Number: 4099562-6Report Type:Expedited (15-DaCompany Report #2003-DE-00014GD
Age:20 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Akathisia Anxiety Bipolar Disorder Body Temperature Increased Catatonia Cognitive Disorder Constipation Drug Interaction Drug Level Below Therapeutic Drug Level Increased Dry Mouth Insomnia Parkinsonism Tremor Vision Blurred	Literature	Lithium Carbonate (Lithium Carbonate) Risperidone (Risperidone) Paroxetine (Paroxetine) Olanzapine (Antipsychotics) Benztropine (Benzatropine Mesilate) Nortriptyline (Nortriptyline)	PS SS SS SS SS SS			600 MG 3 MG 20 MG 5 MG 2 MG 50 MG	> 3 MONTHS

Date:04/22/03ISR Number: 4097297-7Report Type:Direct Company Report #CTU 191401
Age:49 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Confusional State Delirium		Lithium	PS				

Date:04/23/03ISR Number: 4101134-1Report Type:Expedited (15-DaCompany Report #LBID00203000872
Age:21 YR Gender:Female I/FU:F

Outcome	PT
Hospitalization -	Agitation

Initial or Prolonged	Back Pain
	Blindness Hysterical
	Blood Urea Decreased
	Central Pontine
	Myelinolysis
	Confusional State
	Conversion Disorder
	Coordination Abnormal
	Crying
	Delirium
	Demyelination
	Diarrhoea
	Disturbance In Attention
	Fatigue
	Gait Disturbance
	Hallucination, Visual
	Headache
	Hypoaesthesia
	Intracranial Pressure
	Increased
	Mood Swings
	Mydriasis
	Nausea
	Papilloedema
	Photosensitivity Reaction
	Pollakiuria

	Screaming						
	Thirst						
	Visual Disturbance	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Vomiting	Literature	Lithobid (Lithium				
	White Blood Cell Count	Health	Carbonate)	PS		ORAL	1050 MG
	Increased	Professional					DAILY, PO 2 YR

Date:04/23/03ISR Number: 4101711-8Report Type:Expedited (15-DaCompany Report #2003016166
Age:58 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Blood Creatinine	Foreign	Lithane (Lithium)	PS			210 MG (BID)
Initial or Prolonged	Increased	Literature	Celecoxib	SS			800 MG (BID)
Other	Bradycardia	Health	Sertraline				
	Drug Level Above	Professional	(Sertraline)	C			
	Therapeutic		Levomepromazine				
	Haemodialysis		(Levomepromazine)	C			
	Hypotension		Esomeprazole				
	Malaise		(Esomeprazole)	C			
	Sinoatrial Block		Tibolone (Tibolone)	C			
	Somnolence		Ibuprofen				
			(Ibuprofen)	C			

Date:04/23/03ISR Number: 4102211-1Report Type:Expedited (15-DaCompany Report #2003-BP-02209RO
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Akathisia	Health	Lithium Carbonate				
Initial or Prolonged	Aphasia	Professional	Capsules Usp, 300 Mg				
	Blood Pressure Increased	Other	(Lithium Carbonate)	PS		ORAL	PO
	Drug Interaction		Clozapine				
	Insomnia		(Clozapine)	SS		ORAL	300 MG QD
	Restlessness						(100 MG), PO;

Weight Decreased
SEVERAL

MONTHS

Date:04/23/03ISR Number: 4112456-2Report Type:Periodic Company Report #A0380041A
Age:22 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged Disability Required Intervention to Prevent Permanent Impairment/Damage	Alanine Aminotransferase Aspartate Aminotransferase Csf White Blood Cell Count Increased Neuroleptic Malignant Syndrome	Health Professional	Eskalith Tablet-Controlled Release (Lithium Carbonate)	PS		ORAL	450 MG / TWICE PER DAY / ORAL
			Risperidone (Risperidone)	SS		ORAL	3 MG / AT NIGHT / ORAL

Date:04/23/03ISR Number: 4112457-4Report Type:Periodic Company Report #A0373625A
Age:73 YR Gender:Female I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Dehydration
	Pyrexia
Other	Therapeutic Agent

		Toxicity Tremor					
			Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
			Health Professional	Eskalith Tablet-Controlled Release (Lithium Carbonate)	PS		ORAL
450 MG / PER DAY / ORAL							
				Ceftriaxone Sodium	C		
				Lorazepam	C		
				Insulin	C		

Date:04/23/03ISR Number: 4112458-6Report Type:Periodic Company Report #A0368269A
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Bladder Disorder Drug Interaction Somnolence Therapeutic Agent	Consumer	Esaklith Tablet-Controlled Tablet (Lithium Carbonate)	PS		ORAL
ORAL						
	Toxicity Urine Abnormality Urine Odour Abnormal Vision Blurred		Metformin Hydrochloride (Metformin Hydrochloride)	SS		
			Liotrix	C		
			Clonazepam	C		

Date:04/23/03ISR Number: 4112459-8Report Type:Periodic Company Report #A0372683A
Age:29 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Epilepsy Therapeutic Agent Toxicity	Health Professional	Lithium Carbonate (Lithium Carbonate) (Generic)	PS		
			Clozapine Tablet	SS		ORAL
PER DAY /						

ORAL

Date:04/24/03ISR Number: 4096612-8Report Type:Expedited (15-DaCompany Report #GB-GLAXOSMITHKLINE-B0297755A
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Abnormal Behaviour		Paxil	PS	Glaxosmithkline	ORAL		
Hospitalization -	Psychotic Disorder		Lithium	SS	Glaxosmithkline			UNKNOWN
Initial or Prolonged	Suicide Attempt							
Other	Therapeutic Agent							
	Toxicity							

Date:04/24/03ISR Number: 4096648-7Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0405145A
Age:52 YR Gender:Male I/FU:F

Outcome	PT
Hospitalization -	Blood Glucose Increased
Initial or Prolonged	Chest Pain
	Chills
	Coordination Abnormal
	Coronary Artery Occlusion

		Drug Level Above Therapeutic					
		Dyspnoea	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
		Eye Pain	Consumer	Eskalith	PS	Glaxosmithkline	
UNKNOWN	1350MG	See General Physical Health					
dosage text	13 YR						
		Deterioration		Vasotec	SS		
UNKNOWN	5MG Per day	3 MON					
		Headache		Verapamil	SS		
UNKNOWN	180MG Per day						
		Lethargy		Zocor	C		
UNKNOWN							
		Malaise		Metformin	C		
UNKNOWN							
		Muscular Weakness		Glyburide	C		
UNKNOWN							
		Myalgia		Zestril	C		
UNKNOWN	5MG Per day	1 MON					
		Nausea					
		Palpitations					
		Tremor					
		Vomiting					

Date:04/25/03ISR Number: 4097997-9Report Type:Direct Company Report #USP 51454
Age: Gender: I/FU:I

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Other		Laboratory Test Abnormal		Maxzide(Hydrochlorot			
Required		Medication Error		hiazide,			
Intervention to				Triamterene)	PS	Bertek	
Prevent Permanent				Lithium Carbonate	SS		
Impairment/Damage							

Date:04/25/03ISR Number: 4101213-9Report Type:Direct Company Report #USP 55806
Age: Gender:Female I/FU:I

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Death		Medication Error		Lithium Carbonate	PS	Roxanne	
Hospitalization -				Lithium Carbonate	SS	Roxanne	

Initial or Prolonged

Date:04/25/03ISR Number: 4103036-3Report Type:Expedited (15-DaCompany Report #2003-BP-02317RO
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death Hospitalization - Initial or Prolonged	Medication Error Overdose	Health Professional Other	Lithium Carbonate Capsules Usp, 150 Mg (Lithium Carbonate)	PS		ORAL	150MG; DISPENSED 300MG (150 MG), PO	PRESCRIBED

Date:04/25/03ISR Number: 4103171-XReport Type:Expedited (15-DaCompany Report #2003016563
Age:55 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Consumer	Lithane (Lithium)	PS		ORAL	ORAL	
		Health Professional	Quetiapine (Quetiapine)	SS		ORAL	ORAL	
			Fluphenazine (Fluphenazine)	SS		ORAL	ORAL	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/25/03ISR Number: 4103172-1Report Type:Expedited (15-DaCompany Report #2003016464
Age:44 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardiac Arrest	Literature	Lithane (Lithium)	PS		ORAL	ORAL	
	Completed Suicide	Health	Ethanol (Ethanol)	SS		ORAL	ORAL	
	Respiratory Arrest	Professional	Trazodone (Trazodone)	SS		ORAL	ORAL	
			All Other Therapeutic Products	SS		ORAL	ORAL	

Date:04/25/03ISR Number: 4103177-0Report Type:Expedited (15-DaCompany Report #2003016549
Age:80 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Literature	Lithane (Lithium)	PS				
	Drug Toxicity	Health	Temazepam					
		Professional	(Temazepam)	SS				

Date:04/25/03ISR Number: 4103212-XReport Type:Expedited (15-DaCompany Report #2003016566
Age:26 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Unevaluable Event	Literature	Lithane (Lithium)	PS		ORAL	ORAL	
		Health	Olanzapine					
		Professional	(Olanzapine)	SS		ORAL	ORAL	

Date:04/28/03ISR Number: 4098572-2Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0405516A
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Other	Overdose		Eskalith	PS	Glaxosmithkline	ORAL
1 DAY						

Date:04/28/03ISR Number: 4103380-XReport Type:Expedited (15-DaCompany Report #LBID00203001025
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Myoclonus	Literature Health Professional	Lithium Carbonate (Lithium Carbonate)	PS		ORAL	300 MG BID PO	

Date:04/28/03ISR Number: 4103408-7Report Type:Expedited (15-DaCompany Report #2003016466
Age:39 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Drug Toxicity	Literature	Lithane (Lithium)	PS		ORAL	ORAL	
	Medication Error	Health Professional	Paracetamol (Paracetamol)	SS		ORAL	ORAL	

Date:04/28/03ISR Number: 4103696-7Report Type:Expedited (15-DaCompany Report #2003016544
Age:45 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Drug Level Increased Medication Error	Literature Health Professional	Lithane (Lithium)	PS				

Date:04/28/03ISR Number: 4104080-2Report Type:Expedited (15-DaCompany Report #2003016467
Age:44 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Death	Literature	Lithane (Lithium)	PS		ORAL	ORAL	
	Drug Toxicity	Health Professional	Paracetamol (Paracetamol)	SS		ORAL	ORAL	
			Venlafaxine (Venlafaxine)	SS		ORAL	ORAL	

Date:04/28/03ISR Number: 4104087-5Report Type:Expedited (15-DaCompany Report #2003157053NO
Age:58 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain Arrhythmia Blood Creatinine Increased Bradycardia Drug Interaction Drug Level Above Therapeutic Haemodialysis Hypotension Malaise Nausea Sedation Sinoatrial Block Somnolence	Foreign Literature Health Professional Other	Celebrex (Celecoxib) Capsule Lithium (Lithium) Sertraline (Sertraline) Levomepromazine Esomeprazole Tibolone (Tibolone) Ibuprofen	PS SS C C C C C		ORAL ORAL	400 MG, BID, 84 MG/MORNING, 126MG/NIGHT,	ORAL 5 DAY

Date:04/28/03ISR Number: 4104101-7Report Type:Expedited (15-DaCompany Report #2003016548
Age:34 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Death	Cardio-Respiratory Arrest	Literature	Lithane (Lithium)	PS		
Other	Completed Suicide	Health Professional	Opioids	SS		
			Benzodiazepine Derivatives	SS		

Date:04/28/03ISR Number: 4104109-1Report Type:Expedited (15-DaCompany Report #2003016546
Age:41 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Death	Completed Suicide	Literature	Lithane (Lithium)	PS		
		Health Professional	Haloperidol (Haloperidol)	SS		

Date:04/28/03ISR Number: 4104122-4Report Type:Expedited (15-DaCompany Report #2003016545
Age:50 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Death	Death	Literature	Lithane (Lithium)	PS		
	Medication Error	Health Professional				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/28/03ISR Number: 4104123-6Report Type:Expedited (15-DaCompany Report #2002-10-2453
Age:44 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Abdominal Pain Upper	Other	Trilafon					
Other	Bronchitis		(Perphenazine)					
	Chest Pain		Tablets	PS		ORAL	2 MG HS	ORAL
	Conversion Disorder		Zyprexa (Olanzapine)					
	Convulsion		Tablets	SS		ORAL	ORAL	
	Disturbance In Attention		Trazodone	SS			50 MG HS	
	Drug Interaction		Prozac	SS			30-10 MG QD	
	Dyskinesia		Caffeine	SS				
	Dysphagia		Lithium	SS				
	Dysphonia		...	C				
	Fatigue		Indocin	C				
	Head Discomfort		Ativan	C				
	Headache		Multivitamins	C				
	Mastitis		Flexeril	C				
	Muscle Spasms		...	C				
	Nausea		...	C				
	Neck Pain		Vicodin	C				
	Neuralgia		...	C				
	Reading Disorder		...	C				
	Respiratory Disorder							
	Speech Disorder							
	Tardive Dyskinesia							
	Throat Tightness							
	Vomiting							
	Weight Decreased							

Date:04/28/03ISR Number: 4104126-1Report Type:Expedited (15-DaCompany Report #2003016547
Age:40 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Literature	Lithane (Lithium)	PS				
		Health Professional	Levothyroxine (Levothyroxine)	SS				
			Furosemide (Furosemide)	SS				

Date:04/28/03ISR Number: 4104147-9Report Type:Expedited (15-DaCompany Report #LBID00203001035
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Myoclonus	Literature	Lithobid	PS		ORAL	DAILY PO	
		Health Professional	Propranolol (Propranolol)	C				

Date:04/28/03ISR Number: 4104148-0Report Type:Expedited (15-DaCompany Report #LBID00203001037
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Myoclonus	Literature	Lithobid	PS		ORAL	300 MG BID PO	
		Health Professional						

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/28/03ISR Number: 4104151-0Report Type:Expedited (15-DaCompany Report #LBID00203001033
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Myoclonus	Literature	Lithobid	PS		ORAL	600 MG BID PO	
		Health Professional						

Date:04/28/03ISR Number: 4104155-8Report Type:Expedited (15-DaCompany Report #LBID00203001038
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Clonic Convulsion	Literature	Lithobid	PS		ORAL	300 MG BID PO	
		Health Professional	Nefazodone (Nefazodone)	SS		ORAL	200 MG BID PO	
			Sertraline (Sertraline)	SS		ORAL	100 MG DAILY	
							PO	

Date:04/29/03ISR Number: 4103675-XReport Type:Direct Company Report #CTU 191888
Age:45 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dermatitis		Lithium (Eskalith)	PS	Eskalith		600MG AM, 300MG PM	

Date:04/30/03ISR Number: 4104576-3Report Type:Expedited (15-DaCompany Report #03P-163-0216644-00
Age:16 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Death Required Intervention to Prevent Permanent Impairment/Damage	Arrhythmia Drowning Drug Interaction Drug Level Increased Drug Toxicity Overdose	Health Professional Other	Janimine (Imipramine Hcl) (Imipramine Hcl) Pindolol Chlorpromazine Lithium	PS SS SS SS

Date:04/30/03ISR Number: 4105843-XReport Type:Expedited (15-DaCompany Report #2003-BP-02517RO
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Interaction	Consumer Health Professional	Lithium Carbonate Capsules Usp, 300 Mg (Lithium Carbonate) Tylenol # 3 (Panadeine Co) Tylenol # 4 (Panadeine Co)	PS SS SS				

Date:05/01/03ISR Number: 4106332-9Report Type:Expedited (15-DaCompany Report #S03-FRA-01838-01
Age:40 YR Gender:Male I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Agitation Confusional State Depressed Level Of Consciousness

	Drug Interaction Drug Level Below Therapeutic Dyskinesia Hyperhidrosis Major Depression Pyrexia Serotonin Syndrome	Report Source Foreign Health Professional Other	Product Seropram (Citalopram Hydrobromide) Levothyrox (Levothyroxine Sodium) Teralithe (Lithium Carbonate) Hydrocortisone	Role PS SS SS C	Manufacturer	Route ORAL ORAL ORAL
Dose 1 UNK QD PO 25 MCG QD PO 400 MG QD PO	Duration					

Date:05/02/03ISR Number: 4106658-9Report Type:Expedited (15-DaCompany Report #B0298122A
Age:31 YR Gender:Female I/FU:I

Outcome Life-Threatening Hospitalization - Initial or Prolonged	PT Coordination Abnormal Dysarthria Extensor Plantar Response Haemoglobin Decreased Haemolysis Hepatocellular Damage Hyperpyrexia Mydriasis Nervous System Disorder Pancreatitis Platelet Count Decreased Rhabdomyolysis Shock Therapeutic Agent Toxicity Tremor	Report Source Foreign Literature Health Professional	Product Parnate (Formulation Unknown) (Tranylcypromine Sulphate) Lithium Salt (Formulation Unknown) (Lithium Salt)	Role PS SS	Manufacturer	Route
Dose	Duration					

Date:05/02/03ISR Number: 4107197-1Report Type:Expedited (15-DaCompany Report #B0297691A
Age:61 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					

Disability	Nystagmus	Literature	Lithium Salt	
		Health	(Lithium Salt)	PS
16 YR				
		Professional	Thyroxine Sodium	C
			Fluoxetine	C

Date:05/05/03ISR Number: 4108424-7Report Type:Expedited (15-DaCompany Report #2003014034
Age: Gender:Female I/FU:F

Outcome	PT
Hospitalization -	Amnesia
Initial or Prolonged	Back Injury
Other	Back Pain
	Condition Aggravated
	Depression
	Drug Level Increased
	Dysgraphia
	Eating Disorder
	Fall
	Intentional Misuse
	Stress
	Suicide Attempt

	Treatment Noncompliance Tremor						
		Report Source	Product	Role	Manufacturer	Route	Dose Duration
		Consumer	Lithane (Lithium)	PS		ORAL	(BID), ORAL
			Nardil (Phenelzine Sulfate)	SS		ORAL	45 MG, ORAL
			Paracetamol (Paracetamol)	SS			

Date:05/06/03ISR Number: 4108572-1Report Type:Expedited (15-DaCompany Report #6003416
Age:40 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Agitation Confusional State Drug Interaction Hyperhidrosis	Foreign Health Professional Other	Levothyrox 25 (Tablets) (Levothyroxine Sodium)	PS		ORAL	25 MCG (1 IN 1 D) ORAL 12 DAY
	Pyrexia Serotonin Syndrome		Seropram (Citalopram Hydrobromide)	SS		ORAL	(1 IN 1 D) ORAL 183 DAY
			Teralithe (400 Mg, Tablets) (Lithium Carbonate)	SS			400 MG (1 IN 1 D) 3 YR
			Hydrocortisone (Hydrocortisone)	C			

Date:05/08/03ISR Number: 4110060-3Report Type:Direct Company Report #USP 081041
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration

Other	Medication Error		Lithonate 300mg	PS	Solvay	
			Lithium Carbonate	SS	Roxane	

Date:05/08/03ISR Number: 4110115-3Report Type:Expedited (15-DaCompany Report #2003UW05734
Age:73 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Required	Retinal Haemorrhage	Health	Seroquel	PS		ORAL	25 MG DAILY
Intervention to		Professional					PO
Prevent Permanent			Eskalith	SS			300 MG
Impairment/Damage			Xanax	SS			0.25 MG PRN
			Wellbutrin	SS			150 MG BID

Date:05/09/03ISR Number: 4106576-6Report Type:Expedited (15-DaCompany Report #DE-GLAXOSMITHKLINE-D0040967A
Age:76 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Hallucination	Health	Quilonum Retard	PS	Glaxosmithkline	ORAL	675MG Per day
Initial or Prolonged	Muscle Contractions Involuntary	Professional					
	Nephritis						

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/09/03ISR Number: 4108300-XReport Type:Direct Company Report #CTU 192592
Age:48 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Toxicity		Lithium	PS		ORAL	600 MG	
Required Intervention to Prevent Permanent Impairment/Damage	Nausea						BEDTIME ORAL	
	Renal Failure		Fosinopril Na	C				
	Tremor		Furosemide	C				
	Vomiting							

Date:05/09/03ISR Number: 4110545-XReport Type:Expedited (15-DaCompany Report #2002-10-2453
Age:42 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Bronchitis	Other	Trilafon (Perphenazine)					
Disability	Chest Pain		Tablets	PS		ORAL	2 MG HS ORAL	
Other	Conversion Disorder		Zyprexa (Olanzapine)					
	Convulsion		Tablets	SS		ORAL	ORAL	
	Disturbance In Attention		Trazodone	SS			50 MG HS	
	Drug Interaction		Prozac	SS			30-10 MG QD	
	Dyskinesia		Caffeine	SS				
	Dysphagia		Lithium	SS				
	Dystonia		Vicodin	C				
	Fatigue		Flexeril	C				
	Head Discomfort		Indocin	C				
	Headache		Multivitamins	C				
	Mastitis		Ativan	C				
	Menopausal Symptoms		Thyroid	C				
	Muscle Spasms							
	Musculoskeletal Discomfort							
	Nausea							
	Neuralgia							
	Somatisation Disorder							
	Speech Disorder							
	Tardive Dyskinesia							

	Vomiting
	Weight Decreased

Date:05/09/03ISR Number: 4110549-7Report Type:Expedited (15-DaCompany Report #A210937
Age:73 YR Gender:Female I/FU:I

Outcome	PT
Other	Arachnoid Cyst
	Chest Pain
	Constipation
	Convulsion
	Drug Withdrawal Syndrome
	Dry Mouth
	Electroencephalogram
	Abnormal
	Heart Rate Irregular
	Impaired Driving Ability
	Insomnia
	Major Depression
	Malaise
	Parkinson'S Disease
	Tachycardia
	Tardive Dyskinesia

Tongue Disorder

Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Consumer	Geodon (Ziprasidone)	PS		ORAL	40 MG (BID),	ORAL
Health Professional	Lithane (Lithium) (Lithium)	SS		ORAL		ORAL
	Levoxyl (Levothyroxine) (Levothyroxine Sodium)	C				
	Lipitor (Atorvastatin) (Atorvastatin)	C				
	Triamterene/Hydrochlorothiazide (Hydrochlorothiazide, Triamterene)	C				
	Conjugated Estrogens (Estrogens Conjugated)	C				
	Multivitamin (Ergocalciferol, Ascorbic Acid, Folic Acid, Thiamine Hydrochloride,	C				
	Vitamin E (Tocopherol)	C				
	Glucosamine (Glucosamine)	C				
	Calcium (Calcium)	C				
	Aspirin (Acetylsalicylic Acid) (Acetylsalicylic Acid)	C				
	Cenestin (Estrogens Conjugated)	C				

Date:05/09/03ISR Number: 4110660-0Report Type:Expedited (15-DaCompany Report #LBID00203001122
Age:58 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Diarrhoea Drug Withdrawal Syndrome Dysarthria Electroencephalogram Abnormal Flat Affect Hyponatraemia Mental Status Changes Somnolence	Literature Health Professional	Lithium Carbonate (Manufacturer Unknown) (Lithium Carbonate (Manufacturer Risperdal (Risperidone) Benazepril (Benazepril) Lasix (Furosemide) Theophylline (Theophylline) Glucophage (Metformin Hydrochloride) Serevent (Salmeterol Xinafoate)	PS C C C C C C		ORAL	DAILY PO	

			Ativan (Lorazepam)	C			
			Cisplatin (Cisplatin)	C			

Date:05/12/03ISR Number: 4111285-3Report Type:Expedited (15-DaCompany Report #HQWYE051005MAY03
Age:45 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Arrhythmia Depressed Level Of Consciousness Hyperventilation Overdose Somnolence Transient Ischaemic Attack	Health Professional	Temesta (Lorazepam, Tablet) Clozapine (Clozapine,) Leponex "Novartis" (Clozapine,) Lithium (Lithium,) Valproate Sodium (Valproate Sodium,)	PS SS SS SS SS		ORAL	2.5 MG 1X PER 1 DAY ORAL 200MG AT 7:30 AM, 100MG AT 10:05, AND 200MG AT 11: AM	1 DAY

Date:05/12/03ISR Number: 4111375-5Report Type:Expedited (15-DaCompany Report #B0298122A
Age:31 YR Gender:Female I/FU:F

Outcome	PT
Life-Threatening Hospitalization - Initial or Prolonged	Agitation Alanine Aminotransferase Increased Aspartate Aminotransferase Increased Blood Creatinine Increased

Blood Lactate
Dehydrogenase Increased
Blood Pressure Decreased
Blood Pressure Increased
Body Temperature
Increased
Cardiovascular Disorder
Central Nervous System
Stimulation
Convulsion
Drug Level Above
Therapeutic
Dry Skin
Electroencephalogram
Abnormal
Epinephrine Increased
Extensor Plantar Response
Glasgow Coma Scale
Abnormal
Haemoglobin Decreased
Haemolysis
Haptoglobin Decreased
Hyperreflexia
Hypertonia

	Loss Of Consciousness Motor Dysfunction Muscle Contractions Involuntary Mydriasis Nervous System Disorder Neuromyopathy Norepinephrine Increased Overdose Pallor Pancreatitis Peripheral Coldness Platelet Count Decreased Prothrombin Time Shortened Rhabdomyolysis Shock Sinus Tachycardia Supraventricular Tachycardia Therapeutic Agent Toxicity	Report Source Foreign Literature Health Professional	Product Parnate (Formulation Unknown) (Tranylcypromine Sulphate) Lithium Salt (Formulation Unknown) (Lithium Salt) Amphetamine Benzodiazepines	Role PS SS C C	Manufacturer	Route

Date:05/13/03ISR Number: 4108389-8Report Type:Expedited (15-DaCompany Report #DE-GLAXOSMITHKLINE-D0040613A
Age:64 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Dyskinesia Glossitis	Health Professional	Quilonum Retard Trevilor	PS SS	Glaxosmithkline	ORAL ORAL
33 DAY						
	Glossodynia		Taxilan	SS		ORAL
26 DAY						
	Mastication Disorder		Tafil Isoptin	C C		ORAL
UNKNOWN 240MG per day						
			Liviella	C		ORAL
1TAB Per day						
			L -Thyroxine	C	Glaxosmithkline	
UNKNOWN .075MG per						
day						
			Noctamid	C		ORAL
1MG per day						

Date:05/13/03ISR Number: 4112256-3Report Type:Expedited (15-DaCompany Report #2003018940
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Congenital Anomaly	Blood Thyroid Stimulating	Foreign	Lithane (Lithium)	PS				
Other	Hormone Increased	Literature	Cyamemazine					
	Free Thyroxine Index	Health	(Cyamemazine)	C				
	Decreased	Professional	Venlafaxine					
	Goitre Congenital		(Venlafaxine)	C				
	Maternal Drugs Affecting		Olanzapine					
	Foetus		(Olanzapine)	C				
	Neonatal Disorder							
	Pregnancy							

Date:05/13/03ISR Number: 4112951-6Report Type:Direct Company Report #CTU 192881
Age:55 YR Gender:Female I/FU:I

Outcome	PT
Disability	Bipolar Disorder
	Blindness
	Condition Aggravated

	Loss Of Consciousness Visual Disturbance					
		Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
			Depakote	PS		
500 MG 2X/DAY						
			Lithium	SS		
UNK AT THIS						
TIME						
			Seroquel	C		
			Geodon	C		

Date:05/14/03ISR Number: 4113061-4Report Type:Direct Company Report #CTU 192899
Age:45 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization -	Asthenia		Lithium Carbonate			
Initial or Prolonged	Dizziness		300mg	PS		ORAL
600MG QPM						
	Dysarthria					
ORAL						
	Hallucination, Visual					
	Headache					

Date:05/14/03ISR Number: 4113192-9Report Type:Direct Company Report #CTU 192916
Age:49 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization -	Coordination Abnormal		Lithium Carbonate			
Initial or Prolonged	Diarrhoea		300mg	PS		ORAL
300MG BID						
	Drug Interaction					
ORAL						
	Drug Level Increased					
	Dysarthria					
	Myalgia					
	Tremor					
	Urinary Incontinence					
	Visual Disturbance					

Date:05/14/03ISR Number: 4113502-2Report Type:Expedited (15-DaCompany Report #B0297755A
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Hospitalization - Initial or Prolonged	Abnormal Behaviour Psychotic Disorder Suicide Attempt Therapeutic Agent Toxicity	Foreign Consumer	Paroxetine Hydrochloride Tablet (Paroxetine Hydrochloride) Lithium Salt (Formulation Unknown) (Lithium Salt)	PS SS		ORAL ORAL		

Date:05/15/03ISR Number: 4109982-9Report Type:Expedited (15-DaCompany Report #DE-GLAXOSMITHKLINE-D0040772A
Age:22 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Atrioventricular Block Intentional Misuse Somnolence Suicide Attempt		Quilonum Retard Atarax Dipiperon Fluoxetin Risperdal	PS SS SS SS SS	Glaxosmithkline	ORAL ORAL ORAL ORAL ORAL	900MG per day 50MG per day 320MG per day 60MG per day 6MG per day	HR HR HR HR HR

Date:05/15/03ISR Number: 4112706-2Report Type:Expedited (15-DaCompany Report #2003014034
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Accident At Work	Consumer	Lithane (Lithium)	PS		ORAL	(BID), ORAL	
Initial or Prolonged	Analgesic Drug Level	Health	Nardil (Phenelzine					
Other	Increased	Professional	Sulfate)	SS		ORAL	45 MG, ORAL	
	Back Injury		Paracetamol					
	Condition Aggravated		(Paracetamol)	SS				
	Depression		All Other					
	Dysgraphia		Therapeutic Products	SS		ORAL	ORAL	
	Eating Disorder		All Other					
	Fall		Therapeutic Products	C				
	Intentional Misuse							
	Memory Impairment							
	Stress							
	Suicide Attempt							
	Treatment Noncompliance							
	Tremor							
	Weight Fluctuation							

Date:05/15/03ISR Number: 4113086-9Report Type:Expedited (15-DaCompany Report #2002-10-2453
Age:42 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Abdominal Pain Upper	Other	Trilafon					
Initial or Prolonged	Bronchitis		(Perphenazine)					
Disability	Chest Pain		Tablets	PS		ORAL	2 -6 MG QD	
Other	Convulsion						ORAL	
	Disturbance In Attention		Zyprexa (Olanzapine)					
	Drug Interaction		Tablets	SS		ORAL	ORAL	
	Dysphagia		Trazodone	SS			50 MG HS	
	Dysphonia		Prozac	SS			30-10 MG QD	
	Dyspnoea		Caffeine	SS				
	Eye Movement Disorder		Lithium	SS				

Fatigue	Vicodin	C	
Headache	Flexeril	C	
Mastitis	Indocin	C	
Menopausal Symptoms	Multivitamins	C	
Muscle Spasms	Ativan	C	
Musculoskeletal	Thyroid	C	
Discomfort	Wellbutrin		
Nausea	(Bupropion)	C	
Neck Pain	Zoloft	C	
Reading Disorder	Desipramine	C	
Speech Disorder	Effexor	C	
Tardive Dyskinesia	Depakote	C	
Throat Tightness	Nortriptyline	C	
Vomiting	Doxepin	C	
Weight Decreased			

Date:05/15/03ISR Number: 4113165-6Report Type:Expedited (15-DaCompany Report #DEWYE127512MAY03
Age:64 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Dyskinesia Glossitis Glossodynia Trismus	Study	Trevilor (Venlafaxine Hydrochloride, Tablet, 0)	PS		ORAL	37.5 -112.5MG	1X PER 1 DAY 21 DAY

				Quilonum - Slow Release (Lithium Carbonate, , 0)	SS		ORAL 225,450 MG 1X PER 1 DAY
				Taxilan (Perazine, , 0)	SS		ORAL 50,100,50,25 MG 1X PER 1 DAY
				Alprazolam(Alprazolam)	C		
				Isoptin (Verapamil Hydrochloride)	C		
				L-Thyroxin (Levothyroxine Sodium)	C		
				Noctamid (Lormetazepam)	C		

Date:05/16/03ISR Number: 4110559-XReport Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0383288A
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Amyotrophic Lateral Sclerosis	Health Professional	Eskalith	PS	Glaxosmithkline		300MG See dosage text	
	Blood Cholesterol Increased		Lithium	SS	Glaxosmithkline			
			Estrogen	C				
	Blood Creatine Increased							
	Blood Urea Increased							
	Diarrhoea							
	Drug Ineffective							
	Drug Level Increased							
	Hypersomnia							
	Initial Insomnia							
	Memory Impairment							
	Middle Insomnia							
	Pharmaceutical Product Complaint							

Psychomotor Hyperactivity
Renal Impairment
Seasonal Affective
Disorder
Sleep Disorder
Therapeutic Agent
Toxicity
Treatment Noncompliance
Unevaluable Event
Weight Decreased

Date:05/16/03ISR Number: 4113668-4Report Type:Expedited (15-DaCompany Report #6003463
Age:46 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Hepatic Enzyme Increased	Health Professional Other	Levothyrox (Tablets) (Levothyroxine Sodium)	PS		ORAL	ORAL	
			Teralithe (Lithium Carbonate)	SS				
			Brexin (Piroxicam Betadex)	SS				

			Depakote (500 Mg, Tablets) (Valproate Semisodium)	SS		ORAL	2 DOSAGE FORMS (2 DOSAGE FORMS, 1 IN 1 D)
ORAL	78 DAY						

Date:05/19/03ISR Number: 4115122-2Report Type:Expedited (15-DaCompany Report #B0298962A
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Required Intervention to Prevent Permanent Impairment/Damage	Renal Failure	Foreign Study Literature Health Professional	Lithium Salt (Formulation Unknown) (Lithium Salt)	PS			

Date:05/19/03ISR Number: 4115198-2Report Type:Expedited (15-DaCompany Report #DEWYE123308MAY03
Age:50 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Intentional Misuse Somnolence Vomiting	Health Professional	Tavor (Lorazepam, Tablet, 0)	PS		ORAL	MAXIMALLY 18 TBL. AT 2.5MG EACH AND MAXIMALLY 50 TBL. AT 0.5MG 1 DAY
			Atenolol (Atenolol, ,0)	SS		ORAL	MAXIMALLY 100

TBL. AT 50MG

EACH ORAL 1 DAY

Hoggar N (Doxylamine Succinate, ,0) SS ORAL

MAXIMALLY 20

TBL. AT 25MG

EACH ORAL 1 DAY

Hypnorex - Slow Release (Lithium Carbonate, ,0) SS ORAL

MAXIMALLY 50

TBL. AT 400MG

EACH ORAL 1 DAY

Hytacand (Candesartan Cilexetil/Hydrochlorothiazide, ,0) SS ORAL

MAXIMALLY 14

TBL. AT

8MG/12.5MG

EACH ORAL 1 DAY

Ibuprofen (Ibuprofen, ,0) SS ORAL

MAXIMALLY 40

TBL. AT 400MG

EACH ORAL 1 DAY

Insidon (Opipramol Hydrochloride, ,0) SS ORAL

MAXIMALLY 20

TBL. AT 50MG

EACH ORAL 1 DAY

Opipramol (Opipramol, ,0) SS ORAL

MAXIMALLY 4

TBL. AT 100MG

EACH ORAL 1 DAY

Date:05/19/03ISR Number: 4115201-XReport Type:Expedited (15-DaCompany Report #DEWYE123408MAY03
Age:43 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Intentional Misuse Somnolence Vomiting	Foreign Health Professional	Tavor (Lorazepam, Tablet, 0)	PS		ORAL	MAXIMALLY 18 TBL. AT 2.5MG EACH AND MAXIMALLY 50 TBL. AT 0.5MG	1 DAY
			Atenolol (Atenolol, ,0)	SS		ORAL	MAXIMALLY 100 TBL. AT 50MG EACH ORAL	1 DAY
			Hoggar N (Doxylamine Succinate, ,0)	SS		ORAL	MAXIMALLY 20 TBL. AT 25 MG EACH ORAL	1 DAY
			Hypnorex - Slow Release (Lithium Carbonate, ,0)	SS		ORAL	MAXIMALLY 50 TBL. AT 400MG EACH ORAL	1 DAY
			Hytacand (Candesartan Cilexetil/Hydrochlorothiazide, ,0)	SS		ORAL	MAXIMALLY 14	

TBL. AT

8MG/12.5MG

EACH ORAL 1 DAY

Ibuprofen (Ibuprofen, ,0) SS ORAL

MAXIMALLY 40

TBL. AT 400MG

EACH ORAL 1 DAY

Insidon (Opipramol Hydrochloride, ,0) SS ORAL

MAXIMALLY 20

TBL. AT 50MG

EACH ORAL 1 DAY

Opipramol (Opipramol, ,0) SS ORAL

MAXIMALLY 4

TBL. AT 100MG

EACH ORAL 1 DAY

Date:05/19/03ISR Number: 4115315-4Report Type:Expedited (15-DaCompany Report #B0299184A
Age:42 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Disability	Necrosis Oedema Pain Rash Erythematous Skin Exfoliation Skin Ulcer Vasculitic Rash	Foreign Literature Health Professional	Lithium Salt (Lithium Salt)	PS				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/20/03ISR Number: 4114595-9Report Type:Direct Company Report #CTU 193439
Age:51 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Glucose		Lithium Carbonate	PS		ORAL	900MG PO BID	
	Depressed Level Of Consciousness		Glucovance 5/500mg	SS		ORAL	5/500MG PO BID	SINCE 1991
	Dysphagia							
	Lethargy		Lisinopril	C				
	Oral Intake Reduced		Olanzapine	C				
	Pneumonia Aspiration		Quetiapine	C				
	Productive Cough		Divalproex	C				
	Therapeutic Agent Toxicity							
	Urine Output Decreased							
	White Blood Cell Count							

Date:05/20/03ISR Number: 4114830-7Report Type:Direct Company Report #CTU 193502
Age:44 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abnormal Behaviour		Lithium	PS				
	Delirium		Combivent	C				
			Prevacid	C				
			Effexor	C				
			Klonopin	C				
			Zyprexa	C				
			Haldol	C				
			Desyrel	C				
			Synthroid	C				

Date:05/21/03ISR Number: 4113017-1Report Type:Expedited (15-DaCompany Report #DE-GLAXOSMITHKLINE-D0040830A
Age:81 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Hospitalization - Initial or Prolonged	Flatulence Suicide Attempt Vomiting		Quilonum Retard	PS	Glaxosmithkline	ORAL 9000MG per day

Date:05/21/03ISR Number: 4115573-6Report Type:Expedited (15-DaCompany Report #B0298117A
Age:25 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Hospitalization - Initial or Prolonged	Lymph Node Pain Lymphoedema Pharyngolaryngeal Pain Pyrexia White Blood Cell Count Decreased	Foreign Health Professional	Eskalith (Lithium Carbonate) Paxil Tablet (Paroxetine Hydrochloride) Bromazepam Clonazepam Teprenone Zopiclone Flunitrazepam Nitrazepam Chlorpromazine/Promethazi Valproate Sodium	PS SS C C C C C C C C		ORAL ORAL ORAL

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/21/03ISR Number: 4116036-4Report Type:Direct Company Report #CTU 193702
Age:43 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hyperpyrexia		Risperidone	PS			4 MG QHS	1 DAY
	Pyrexia		Lithium	SS			900 MG/DAY	1 DAY
			Albuterol/Atrovent Inhaler	C				
			Enalapril	C				
			Kcl	C				

Date:05/22/03ISR Number: 4113926-3Report Type:Expedited (15-DaCompany Report #US-BRISTOL-MYERS SQUIBB COMPANY-12227005
Age:53 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Cardiac Failure	Health	Glucophage Tabs 850					
Hospitalization - Initial or Prolonged	Cardiogenic Shock	Professional	Mg	PS	Bristol-Myers Squibb Company	ORAL		
	Dyslipidaemia							
	Gastrointestinal Disorder		Laroxyl	SS				
	Hypoglycaemia		Teralithe	SS				
	Lactic Acidosis		Cotareg	SS				
	Liver Function Test Abnormal		Motilium	C				
	Loss Of Consciousness							
	Lung Disorder							
	Renal Failure Acute							

Date:05/22/03ISR Number: 4116112-6Report Type:Expedited (15-DaCompany Report #2002-10-2453
Age:42 YR Gender:Female I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Abdominal Pain Upper
	Bronchitis
Disability	Chest Pain
Other	Cognitive Disorder
	Conversion Disorder
	Convulsion
	Disturbance In Attention
	Drug Interaction

Drug Withdrawal Syndrome
Dyskinesia
Dysphagia
Dysphonia
Emotional Disorder
Fatigue
Head Discomfort
Headache
Mastitis
Memory Impairment
Menopausal Symptoms
Muscle Spasms
Musculoskeletal
Discomfort
Nausea
Neck Pain
Neuralgia
Performance Status
Decreased
Reading Disorder
Respiratory Disorder

Somatisation Disorder Speech Disorder Tardive Dyskinesia	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Throat Tightness Vomiting Weight Decreased	Other	Trilafon (Perphenazine) Tablets	PS		ORAL	2 -6 MG QD ORAL
		Zyprexa (Olanzapine) Tablets	SS		ORAL	 ORAL
		Trazodone	SS			50 MG HS
		Prozac	SS			30-10 MG QD
		Caffeine	SS			
		Lithium	SS			
		Vicodin	C			
		Flexeril	C			
		Indocin	C			
		Multivitamins	C			
		Ativan	C			
		Thyroid Unknown	C			
		Wellbutrin (Bupropion)	C			
		Zoloft	C			
		Desipramine	C			
		Effexor	C			
		Depakote	C			
		Nortriptyline	C			
		Doxepin	C			
		Dicloxacillin	C			
		Clonazepam	C			
		Beclomethasone	C			
		Ibuprofen	C			
		Alprazolam	C			
		Cephalexin	C			
		Septran Ds (Trimethoprim/Sulfamethoxazole)	C			

Date:05/22/03ISR Number: 4117433-3Report Type:Direct Company Report #USP 51031
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Medication Error		Lithium 300mg	PS		ORAL	PO	TABLET
			Cogentin	SS	Merck		PO	TABLET
			Solu Medrol	SS			INTRAVENOUS	IV

Date:05/23/03ISR Number: 4116029-7Report Type:Expedited (15-DaCompany Report #C2003-0743.01
Age:29 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agitation Catatonia	Health Professional	Clozapine Tablets 100 Mg Mylan	PS	Mylan	ORAL	300 MG, QD,	
Other	Insomnia						ORAL	
	Neuroleptic Malignant Syndrome		Lithium 300 Mg	SS		ORAL	600 MG Q AM	
	Restlessness						AND 900 MG Q	
	Serotonin Syndrome Speech Disorder Weight Decreased						HS, ORAL	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/29/03ISR Number: 4118519-XReport Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0350706A
Age:41 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Depression		Eskalith	PS	Glaxosmithkline	ORAL	7	YR
Initial or Prolonged	Dysgeusia		Risperdal	C				
Other	Hallucination		Navane	C				
UNKNOWN							15MG	At night
	Hallucination, Auditory		Cogentin	C				
UNKNOWN								
	Libido Decreased							
	Mania							
	Pollakiuria							
	Psychotic Disorder							
	Schizophrenia							
	Somnolence							
	Therapeutic Agent							
	Toxicity							
	Thirst							
	Vomiting							

Date:05/30/03ISR Number: 4119377-XReport Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0409227A
Age:64 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Death		Lamictal	PS	Glaxosmithkline	ORAL	5	WK
			Eskalith	SS	Glaxosmithkline	ORAL		
			No Concurrent Medication	C				

Date:05/30/03ISR Number: 4120102-7Report Type:Expedited (15-DaCompany Report #B0299984A
Age:42 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Literature	Lithium Salt					
	Intentional Misuse	Health Professional	(Formulation Unknown) (Lithium					

			Salt)	PS		ORAL	ORAL
			Olanzapine (Formulation Unknown) (Olanzapine)	SS		ORAL	ORAL

Date:05/30/03ISR Number: 4120104-0Report Type:Expedited (15-DaCompany Report #B0299983A
Age:74 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Drug Interaction Medication Error Overdose	Literature Health Professional	Lithium Salt (Formulation Unknown) (Lithium Salt)	PS		ORAL	ORAL	
			Amitriptyline (Formulation Unknown) (Amitriptyline)	SS		ORAL	ORAL	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/30/03ISR Number: 4120112-XReport Type:Expedited (15-DaCompany Report #B0299896A
Age:61 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide Overdose	Literature Health Professional	Lithium Salt (Formulation Unknown) (Lithium Salt)	PS		ORAL	ORAL	

Date:05/30/03ISR Number: 4120114-3Report Type:Expedited (15-DaCompany Report #B0299981A
Age:79 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Literature Health Professional	Lithium Salt (Formulation Unknown) (Lithium Salt)	PS			ORAL	

Date:05/30/03ISR Number: 4120115-5Report Type:Expedited (15-DaCompany Report #B0299982A
Age:33 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide Overdose	Literature Health Professional	Lithium Salt (Formulation Unknown) (Lithium Salt)	PS		ORAL	ORAL	
			Hydrocodone + Paracetamol (Formulation Unknown) (Hydrocodone +	SS		ORAL	ORAL	
			Olanzapine (Formulation Unknown) (Olanzapine)	SS		ORAL	ORAL	

Date:05/30/03ISR Number: 4120117-9Report Type:Expedited (15-DaCompany Report #B0299895A
Age:58 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Medication Error	Literature Health Professional	Lithium Salt (Formulation Unknown) (Lithium Salt)	PS		ORAL	ORAL	

Date:05/30/03ISR Number: 4120679-1Report Type:Expedited (15-DaCompany Report #2003013100
Age:42 YR Gender:Female I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Asthenia
Other	Blood Cholesterol Increased
	Blood Glucose Increased
	Blood Sodium Decreased
	Formication
	Irritability
	Mood Altered
	Nocturia

Palpitations

Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Health Professional	Geodon (Ziprasidone)	PS		ORAL	40 MG (BID), ORAL	
	Lithane (Lithium)	SS		ORAL	900 MG (DAILY), ORAL	
	Valproae Semisodium (Valproate Semisodium)	C				
	Lithium Carbonate (Lithium Carbonate)	C				
	Clonazepam (Clonazepam)	C				
	Levetiracetam (Levetiracetam)	C				

Date:05/30/03ISR Number: 4121197-7Report Type:Expedited (15-DaCompany Report #EMADSS2003002526
Age:76 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Alanine Aminotransferase Aspartate Aminotransferase	Foreign Study Health Professional	Galantamine (Galantamine)	PS		ORAL	ORAL; 8 MG, 2 IN 1 DAILY	
	Atrial Fibrillation							
	Blood Alkaline Phosphatase		Lithionit (Lithium Sulfate)	SS		ORAL	83 MG, 2 IN 1 DAY(S), ORAL	
	Bronchopneumonia							
	Cerebrovascular Accident		Enalapril Maleate (Enalapril Maleate)	C				
	Communication Disorder							
	Condition Aggravated		Mirtazapine (Mirtazapine)	C				
	Confusional State							
	Depression		Risperidone (Risperidone)	C				
	Disease Recurrence							
	Drug Level Increased		Oxazepam (Oxazepam)	C				

Electroencephalogram		Calcium Carbonate	
Abnormal		(Calcium Carbonate)	C
Fatigue		Lactulose	
Gamma-Glutamyltransferase		(Lactulose)	C
Haemoglobin		Paracetamol	
Medication Error		(Paracetamol)	C
Metabolic Disorder		Zopiclone	
Neurologic Neglect		(Zopiclone)	C
Syndrome		Paracetamol With	
Somnolence		Codeine	
White Blood Cell Count		(Acetaminophen/Codei	
		ne)	C

Date:05/30/03ISR Number: 4121245-4Report Type:Expedited (15-DaCompany Report #2003-BP-02012RO
Age:36 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Carbon Monoxide Poisoning	Other	Lithium Carbonate					
	Pharmaceutical Product		Capsules Usp, 300 Mg					
	Complaint		(Lithium Carbonate)	PS		ORAL	PO	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/30/03ISR Number: 4121246-6Report Type:Expedited (15-DaCompany Report #2003-BP-02209RO
Age:29 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Akathisia	Health Professional Other	Lithium Carbonate Capsules Usp, 300 Mg (Lithium Carbonate)	PS		ORAL	PO	
	Aphasia							
	Blood Pressure Increased							
	Catatonia		Clozapine (Clozapine)	SS		ORAL	300 MG QD	
	Diabetic Ketoacidosis							
	Drug Interaction						(100 MG), PO	
	Heart Rate Increased							
	Insomnia							
	Neuroleptic Malignant Syndrome							
	Pharmaceutical Product Complaint							
	Psychomotor Hyperactivity							
	Restlessness							
	Rhabdomyolysis							
	Serotonin Syndrome							
	Urinary Tract Infection							
	Weight Decreased							

Date:05/30/03ISR Number: 4121564-1Report Type:Expedited (15-DaCompany Report #2003-DE-01906GD
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Atherosclerosis	Foreign Literature Health Professional	Lithium Carbonate (Lithium Carbonate)	PS		ORAL	PO	
	Drug Toxicity							
	General Physical Health Deterioration		Valproate (Valproic Acid)	SS		ORAL	4 G, PO	
	Haemorrhage		Diazepam	SS		ORAL	PO	
	Myocardial Ischaemia		Glibenclamide	SS		ORAL	PO	
	Sudden Death							

Date:05/30/03ISR Number: 4121566-5Report Type:Expedited (15-DaCompany Report #2003-DE-01909GD
Age:58 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Abdominal Pain	Foreign	Lithium Carbonate					
Hospitalization - Initial or Prolonged	Blood Creatinine Increased	Literature	(Lithium Carbonate)	PS			210 MG (IN THE MORNING AND AT NIGHT)	
	Bradycardia							
	Drug Interaction		Celecoxib (Antiinflammatory/Antirheumatic Products)	SS			800 MG (TWICE DAILY)	
	Drug Toxicity							
	Haemodialysis							
	Heart Rate Irregular							
	Hypotension							
	Malaise		Sertraline (Sertraline)					
	Nausea		(Sertraline-Hcl)	C				
	Renal Impairment		Ibuprofen (Ibuprofen)					
	Sinoatrial Block		(Ibuprofen)	C				
	Somnolence		Levomeprazine (Levomepromazine)	C				
			Esomeprazole (Drugs For Treatment Of Peptic Ulcer)	C				
			Tibolone (Tibolone)	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/02/03ISR Number: 4120348-8Report Type:Expedited (15-DaCompany Report #DE-GLAXOSMITHKLINE-D0041080A
Age:50 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Fatigue	Health	Quilonum Retard	PS	Glaxosmithkline	ORAL	4500MG Single	
	Intentional Misuse	Professional						
dose							1	DAY
	Suicide Attempt		Mianserin	SS		ORAL	600MG Single	
dose								

Date:06/02/03ISR Number: 4121822-0Report Type:Direct Company Report #CTU 194513
Age:71 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Toxicity		Lithium	PS				
	Mental Status Changes							
Other Required Intervention to Prevent Permanent Impairment/Damage								

Date:06/02/03ISR Number: 4121827-XReport Type:Direct Company Report #CTU 194515
Age:61 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Toxicity		Lithium Carbonate 600mg Po Tid	PS		ORAL	600 MG PO TID	
	Dysarthria							
Other	Malaise		Atenolol	C				
	Muscle Twitching		Terazosin	C				
	Nystagmus		Rabeprazole	C				

Date:06/02/03ISR Number: 4125978-5Report Type:Periodic Company Report #2002069461
Age:59 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Social Problem	Health Professional	Lithane (Lithium)	PS		ORAL	15 MG (QD)	ORAL
Other			Olanzapine	C				

Date:06/02/03ISR Number: 4125984-0Report Type:Periodic Company Report #2002063425
Age:51 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Confusional State Coordination Abnormal Dizziness Memory Impairment Onychomycosis Therapeutic Agent Toxicity Tremor	Health Professional	Lithium Ziprasidone Depakote (Valproate Semisodium) Wellbutrin (Bupropion Hydrochloride) Norflex (Orphenadrine Citrate) Anafranil (Clomipramine Hydrochloride)	PS C C C C C		ORAL		ORAL

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/02/03ISR Number: 4125986-4Report Type:Periodic Company Report #2003002462
Age:66 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Therapeutic Agent Toxicity	Health Professional	Lithane (Lithium)	PS				
			Amitriptyline Hydrochloride	C				
			Lamotrigine	C				
			Benzatropine Mesilate	C				

Date:06/02/03ISR Number: 4125988-8Report Type:Periodic Company Report #2003004063
Age:73 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Vision Blurred	Health Professional	Lithium	PS		ORAL	250 MG (TID), ORAL	
			Clorazepate Dipotassium	SS		ORAL	10 MG, ORAL	

Date:06/03/03ISR Number: 4121754-8Report Type:Direct Company Report #CTU 194600
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Asthenia Bradycardia Coma Dizziness Drug Toxicity Dysarthria Hypotension Vomiting		Lithium	PS		ORAL	600 MG PO BID	3 MON
			Lorazepam	C				

Date:06/03/03ISR Number: 4121756-1Report Type:Direct Company Report #CTU 194601
Age:55 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product		Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Drug Toxicity		Lithium	300mg	PS		ORAL	600 MG PO BID	
Initial or Prolonged	Haemodialysis								
	Mental Status Changes								
	Pyrexia								

Date:06/03/03ISR Number: 4121786-XReport Type:Direct Company Report #CTU 194584
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Anorexia		Lisinopril	PS		ORAL	10MG PO QD	
Initial or Prolonged	Coordination Abnormal		Lithium	SS		ORAL	300 MG PO TID	
Other	Drug Toxicity							
	Dysarthria							
	Gait Disturbance							
	Mental Status Changes							
	Renal Failure Acute							
	Tremor							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/03/03ISR Number: 4122049-9Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0410367A
Age:16 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Arrhythmia		Eskalith	PS	Glaxosmithkline			
	Drowning		Thorazine	SS	Glaxosmithkline			
	Drug Interaction		Pindolol	SS				
	Drug Toxicity		Imipramine	SS				

Date:06/03/03ISR Number: 4122273-5Report Type:Direct Company Report #CTU 194693
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Difficulty In Walking		Lithium Carbonate 300 Mg	PS		ORAL	600 MG	BID
	Incoherent							
	Lethargy							
	Tremor		Nortriptyline	C				
			Quetiapine	C				
			Trihexyphenidyl	C				

Date:06/03/03ISR Number: 4122414-XReport Type:Direct Company Report #CTU 194753
Age:66 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Confusional State		Lithium 300 Mg					
	Gait Disturbance		Roxane	PS	Roxane	ORAL	600 MG PO	BID
Required Intervention to Prevent Permanent Impairment/Damage	Hallucination, Visual							
	Tremor							

Date:06/04/03ISR Number: 4122380-7Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0410574A
Age:27 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - 2 DAY	Ketoacidosis		Eskalith	PS	Glaxosmithkline	
Initial or Prolonged 206 DAY	Mania		Seroquel	SS		
Other	Mydriasis Swelling Face		Prolixin	SS		

Date:06/04/03ISR Number: 4122390-XReport Type:Expedited (15-DaCompany Report #DE-GLAXOSMITHKLINE-D0041103A
Age:61 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Hypotension	Health	Quilonum	PS	Glaxosmithkline	ORAL
Initial or Prolonged	Renal Failure	Professional				

Date:06/04/03ISR Number: 4123304-9Report Type:Direct Company Report #CTU 194848
Age:57 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - FROM NON VA	Mental Status Changes		Lithium	PS		
Initial or Prolonged GIVEN						
			Lisinopril	SS		
40MG QD						
			Risperidone	C		
			Lovastatin	C		
			Glyburide	C		

			Hctz	C		
			Adalat Cc	C		

Date:06/04/03ISR Number: 4123346-3Report Type:Direct Company Report #CTU 194872
Age:58 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Mental Status Changes		Lithium	PS				

Date:06/04/03ISR Number: 4123544-9Report Type:Direct Company Report #CTU 195010
Age:28 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dysarthria		Depakote	PS			1000MG BID	
	Medication Error		Lithium	SS		ORAL	600MG PO BID	
	Tremor		Seroquel	C				
	Vision Blurred							
	Vomiting							

Date:06/04/03ISR Number: 4123654-6Report Type:Direct Company Report #CTU 195027
Age:63 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Extrapyramidal Disorder		Lithium Carbonate 300mg Cap	PS			600MG BID BY MOUTH	
			Risperidone	SS		ORAL	1.5MG BID BY MOUTH (PO)	
			Lovastatin	C				
			Irbesartan	C				
			Benztropine Mesylate	C				

			Vitamin E	C		
			Perphenazine	C		
			Psyllium Sf	C		
			Amoxicillin 875/Clavulanate K	C		
			Docusate Sodium (Colace)	C		
			Lorazepam (Ativan)	C		

Date:06/04/03ISR Number: 4124211-8Report Type:Expedited (15-DaCompany Report #B0300213A
Age:35 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Death	Literature Health Professional	Lithium Salt (Formulation Unknown) (Lithium Salt)	PS		
			Fluphenazine (Formulation Unknown) (Fluphenazine)	SS		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/04/03ISR Number: 4124218-0Report Type:Expedited (15-DaCompany Report #B0300208A
Age:42 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide Overdose	Literature Health Professional	Lithium Salt (Formulation Unknown) (Lithium Salt)	PS				

Date:06/04/03ISR Number: 4124220-9Report Type:Expedited (15-DaCompany Report #B0300207A
Age:40 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide Overdose	Literature Health Professional	Lithium Salt (Formulation Unknown) (Lithium Salt)	PS				

Date:06/04/03ISR Number: 4124306-9Report Type:Expedited (15-DaCompany Report #A02200301243
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Creatinine Increased	Health Professional	Stilnox - (Zolpidem) - Tablet - 10 Mg	PS		ORAL	10 MG	
	Confusional State Dehydration Hypernatraemia Nephrogenic Diabetes Insipidus		Teralithe - (Lithium Carbonate) - Tablet - 400 Mg / Tablet - 400 Mg	SS		ORAL	600 MG QD / 200 MG	
	Nervous System Disorder		Athymil(Mianserin Hydrochloride)	C				

Date:06/04/03ISR Number: 4124660-8Report Type:Expedited (15-DaCompany Report #B0300206A
Age:58 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Cardio-Respiratory Arrest Overdose	Literature Health Professional	Parnate (Tranylcypromine Sulphate) Lithium Salt (Lithium Salt) Pemoline (Formulation Unknown) (Pemoline)	PS SS SS		

Date:06/04/03ISR Number: 4124672-4Report Type:Expedited (15-DaCompany Report #B0300209A
Age:70 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Medication Error	Literature Health Professional	Lithium Salt (Lithium Salt) Fluoxetine (Formulation Unknown) (Fluoxetine) Trazodone (Formulation	PS SS		

Unknown) (Trazodone) SS

Date:06/04/03ISR Number: 4124674-8Report Type:Expedited (15-DaCompany Report #B0300211A
Age:30 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Adverse Drug Reaction	Literature	Lithium Salt			
		Health	(Lithium Salt)	PS		
		Professional	Fluoxetine (Formulation Unknown)			
			(Fluoxetine)	SS		
			Haloperidol (Formulation Unknown)			
			(Haloperidol)	SS		

Date:06/05/03ISR Number: 4123067-7Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-B0301439A
Age:53 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Completed Suicide		Lithium	PS	Glaxosmithkline	
			Amlodipine	SS		
			Nifedipine	SS	Glaxosmithkline	

Date:06/05/03ISR Number: 4123795-3Report Type:Direct Company Report #CTU 195088
Age:71 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Drug Level Above Therapeutic		Lithium 600 MG, 300 MG BI ORAL	PS		ORAL
Required Intervention to Prevent Permanent Impairment/Damage			Terazosin Hcl	C		
			Lithium Carbonate	C		
			Acetaminophen	C		
			Oxybutynin Chloride	C		
			Nutrition Supl Ensure/Vanilla	C		

Sodium Chloride	C
Aspirin	C
Vitamin E	C
Primidone	C
Betaxolol Hcl	C
Albuterol/Ipratrop	C
Beclomethasone	C
Guaifenisin	C
Sildenafil Citrate	C
Multivitamin/Mineral s	C
Trazodone Hcl	C
Levothyroxine Na	C
Atenolol	C
Finasteride	C
Fexofenadine Hcl	C

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/05/03ISR Number: 4125430-7Report Type:Expedited (15-DaCompany Report #200310440BCA
Age:77 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Anorexia	Foreign	Aspirin					
	Apathy	Health	(Acetylsalicylic					
	Confusional State	Professional	Acid)	PS		ORAL	80 MG, TOTAL	
	Depressed Level Of	Other					DAILY, ORAL	6 DAY
	Consciousness		Codeine	SS				
	Drug Level Increased		Duralith (Lithium					
	Mental Disorder		Carbonate)	SS		ORAL	600 MG, TOTAL	
	Renal Failure Acute						DAILY, ORAL	6 DAY
	Tachypnoea		Glucophage					
	Urinary Incontinence		(Metformin					
			Hydrochloride)	SS		ORAL	1500 MG,	
							TOTAL DAILY,	
							ORAL	6 DAY
			Lasix (Furosemide)	SS		ORAL	120 MG, TOTAL	
							DAILY, ORAL	6 DAY
			Prinivil					
			(Lisinopril)	SS		ORAL	30 MG, TOTAL	
							DAILY, ORAL	

Date:06/05/03ISR Number: 4125580-5Report Type:Expedited (15-DaCompany Report #200310852EU
Age:68 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Hypernatraemia	Foreign	Metronidazole					
Other	Therapeutic Agent	Other	(Flagyl "Aventis")	PS				
INTRAVENOUS	1.5 G/DAY IV	4 DAY						
	Toxicity		Metronidazole					

			(Flagyl "Aventis")	SS		ORAL	1.2 G/DAY PO 3 WK
			Lithium Sulfate (Lithionit)	SS		ORAL	166 MG/DAY PO
			Venlafaxine Hydrochloride (Efexor Depot)	C			
			Pivampicillin Hydrochloride (Pondocillin)	C			

Date:06/06/03ISR Number: 4124808-5Report Type:Direct Company Report #CTU 195226
Age:56 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Drug Toxicity		Lithium 300 Mg	PS		ORAL	300 MG TID
			Clonazepam	C			
			Albuterol/Ipratrop	C			
			Aspirin	C			
			Fluoxetine Hcl	C			
			Fluticas/Salmeterol	C			
			Gemfibrozil	C			
			Hydroxyzine Pamoate	C			
			Isosorbide Mononitrate	C			
			Levothyroxine Na	C			
			Metformin Hcl	C			
			Metoprolol Succinate	C			
			Ranitidine Hcl	C			
			Risperidone	C			

			Insulin Nph	C		

Date:06/06/03ISR Number: 4126221-3Report Type:Expedited (15-DaCompany Report #2003-DE-01981GD
Age:19 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Abuser Drug Interaction Gait Disturbance Grand Mal Convulsion Serotonin Syndrome Speech Disorder	Literature	Budesonide (Budesonide)	PS		IH	4 PUF (BID), RESPIRATORY (INHALATION)	
			Lithium Carbonate (Lithium Carbonate)	SS			300 MG	
			Paroxetine (Paroxetine)	SS			20 MG	
			Salmeterol (Salmeterol)	SS			4 PUF (BID), RESPIRATORY (INHALATION)	
			Albuterol (Salbutamol)	SS			8 PUF (QID), RESPIRATORY (INHALATION)	
			Montelukast (Anti-Asthmatics)	SS			20 MG	
			Disodium Cromoglycate (Cromoglicate Sodium)	SS			20 MG	
			Lansoprazole	SS			20 MG (QHS)	

Date:06/09/03ISR Number: 4124969-8Report Type:Expedited (15-DaCompany Report #WAES 0204SWE00002
Age:81 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Creatinine	Health	Vioxx	PS	Merck & Co., Inc	ORAL	25	DAY
	Increased	Professional	Lithium Sulfate	SS		ORAL		
	Depressed Level Of Consciousness		Levothyroxine Sodium	C				
			Dipyridamole	C				
	Drug Level Increased		Lofepramine Hydrochloride	C				
	Extrapyramidal Disorder		Zolpidem Tartrate	C				
	General Physical Health Deterioration		Calcium Carbonate And Cholecalciferol	C				
	Renal Failure		Tramadol Hydrochloride	C				

Date:06/09/03ISR Number: 4126506-0Report Type:Expedited (15-DaCompany Report #EMADSS2003002526
Age:76 YR Gender:Female I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Alanine Aminotransferase
	Aspartate Aminotransferase
	Atrial Fibrillation
	Blood Alkaline Phosphatase
	Bronchopneumonia
	Cerebral Disorder

	Confusional State Depression Drug Level Increased Epilepsy Gamma-Glutamyltransferase Haemoglobin Hypomania Medication Error Metabolic Disorder Neurologic Neglect Syndrome Somnolence White Blood Cell Count	Report Source Foreign Study Health Professional	Product Galantamine (Tablet) (Galantamine) Lithionit (Lithium Sulfate) Enalapril Maleate Mirtazapine Risperidone Oxazepam Calcium Carbonate Lactulose Paracetamol Zopiclone Paracetamol With Codeine (Acetaminophen/Codei ne)	Role PS SS C C C C C C C C	Manufacturer	Route ORAL

Dose Duration

ORAL ; 8 MG,

2 IN 1 DAILY

83 MG, 2 IN 1

DAY(S), ORAL

Date:06/10/03ISR Number: 4126631-4Report Type:Expedited (15-DaCompany Report #2003AP02134
Age:56 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Life-Threatening	Platelet Count Decreased	Foreign Health Professional Other	Iressa Takepron Depakene Limas	PS SS SS SS		ORAL

Dose Duration

250 MG DAILY

PO

Date:06/10/03ISR Number: 4127142-2Report Type:Direct Company Report #CTU 195517
Age:55 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	Drug Toxicity		Lihium	PS		ORAL	300MG QI, ORAL	

Date:06/10/03ISR Number: 4127152-5Report Type:Direct Company Report #CTU 195525
Age:52 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	Antidepressant Drug Level Above Therapeutic Drug Toxicity		Lithium	PS		ORAL	1800MG, 900MG, BI ORAL	
			Benztropine Mesylate	C				
			Ziprasidone Hcl	C				
			Rabeprazole Na	C				
			Thiamine Hcl	C				
			Trazodone Hcl	C				
			Vitamin B Complex/ Vitamin C	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/11/03ISR Number: 4127057-XReport Type:Direct Company Report #CTU 195587
Age:57 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Headache		Lithium	PS				26 YR
	Tremor		Doxycycline	C				
			Hydroxyzine	C				
			Clonazepam	C				
			Glyburide	C				
			Simvastatin	C				
			Lisinopril	C				

Date:06/12/03ISR Number: 4128711-6Report Type:Expedited (15-DaCompany Report #2003-BP-01817BP
Age:64 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Autonomic Nervous System Imbalance	Study Health	Micardis Tablets (Bibr 277) (Ta)					
	Haemodialysis	Professional	(Telmisartan)	PS		ORAL	80 MG (80 MG)	37 DAY
	Therapeutic Agent Toxicity		Ramipril Capsules (Micardis Reference) (Bibr 277 (Reference)) (Ka)	SS		ORAL	10 MG (10 MG)	37 DAY
			Lithium	SS				

Date:06/12/03ISR Number: 4128963-2Report Type:Expedited (15-DaCompany Report #A02200301243
Age:91 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Confusional State Dehydration	Health Professional	Stilnox - (Zolpidem) - Tablet - 10 Mg	PS		ORAL	10 MG	
	Diverticulum Intestinal Nephrogenic Diabetes Insipidus Vesical Fistula		Teralithe - (Lithium Carbonate) - Tablet - 400 Mg/ Tablet - 400 Mg	SS		ORAL	600 MG QD/	

200 MG

				Athymil (Miasenrin Hydrochlioride)	C		

Date:06/13/03ISR Number: 4127921-1Report Type:Expedited (15-DaCompany Report #AU-GLAXOSMITHKLINE-B0301770A
Age:40 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blood Pressure Increased		Lithium Carbonate	PS	Glaxosmithkline	ORAL	1300MG per day	
	Dyspnoea							
	Generalised Oedema							
	Thrombosis							

Date:06/13/03ISR Number: 4127925-9Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0350706A
Age:41 YR Gender:Male I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Depression
	Drug Toxicity
Other	Dysgeusia
	Hallucination
	Hallucination, Auditory
	Libido Decreased

	Mania					
	Nocturia					
	Pollakiuria	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
	Psychotic Disorder		Eskalith	PS	Glaxosmithkline	ORAL
7 YR						
	Schizophrenia		Risperdal	C		
	Somnolence		Navane	C		
UNKNOWN	15MG At night					
	Thirst		Cogentin	C		
UNKNOWN						
	Vomiting					

Date:06/17/03ISR Number: 4129956-1Report Type:Expedited (15-DaCompany Report #DE-GLAXOSMITHKLINE-D0041168A
Age:31 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Other	Bundle Branch Block Right	Health	Quilonum Retard	PS	Glaxosmithkline	ORAL
1125MG per						
	Hyperthyroidism	Professional				
day						
	Hypothyroidism		Truxal	C		ORAL
50DROP Three						
times per day						
			Tavor	C		ORAL
.5MG Twice						
per day						
			Haldol	C		ORAL
5DROP Twice						
per day						
			Atosil	C	Glaxosmithkline	ORAL
25DROP Three						
times per day						
			Dociton	C		ORAL
60MG per day						
			Fluctin	C		ORAL

Date:06/17/03ISR Number: 4130744-0Report Type:Direct Company Report #CTU 195958
Age:63 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Level Above Therapeutic Medication Error Mental Status Changes		Lithium 300 Mg	PS		ORAL	300 MG B.I.D. ORAL	

Date:06/17/03ISR Number: 4131707-1Report Type:Expedited (15-DaCompany Report #B0301439A
Age:53 YR Gender:Unknown I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Literature Health Professional	Lithium Salt (Formulation Unknown) (Generic) (Lithium Salt) Amlodipine (Formulation Unknown) (Amlodipine) Nifedipine (Formulation Unknown) (Nifedipine)	PS SS SS				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/18/03ISR Number: 4130721-XReport Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0368269A
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Balance Disorder		Eskalith Cr	PS	Glaxosmithkline	ORAL		
	Bladder Disorder		Glucophage Xr	SS				
	Diabetes Mellitus		Lasix	SS	Glaxosmithkline			3 DAY
	Inadequate Control		Euthroid	C				
	Disorientation		Klonopin	C			.5MG As required	
	Drug Ineffective							
	Drug Interaction							
	Hypersomnia							
	Somnolence							
	Therapeutic Agent Toxicity							
	Thyroidectomy							
	Urine Abnormality							
	Urine Odour Abnormal							
	Vision Blurred							

Date:06/18/03ISR Number: 4131095-0Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0412629A
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Cardiac Failure		Eskalith Cr	PS	Glaxosmithkline	ORAL		
	Depression		Lasix	SS	Glaxosmithkline			
	Drug Toxicity		Ace Inhibitor	C				
	Hypoglycaemia							
	Medication Error							
	Oedema							
	Red Blood Cell Count Decreased							
	Refusal Of Treatment By Patient							
	Renal Failure							
	Weight Increased							

Date:06/18/03ISR Number: 4132525-0Report Type:Expedited (15-DaCompany Report #2003002462
Age:66 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Asthenia Bipolar Disorder Depression Drug Hypersensitivity Drug Interaction Drug Toxicity Suicidal Ideation	Health Professional	Lithane (Lithium) Antiinflammatory/Antirheumatic Non-Steroids Amitriptyline Hydrochloride (Amitriptyline Hydrochloride) Lamotrigine 9lamotrigine) Benzatropine Mesilate (Benzatropine Mesilate) Os-Cal (Ergocalciferol, Calcium) Multivitamins (Ergocalciferol,	PS SS C C C C				

Ascorbic Acid, Folic Acid, Thiamine Hydrochloride,	C
Acetylsalicylic Acid (Acetylsalicylic Acid)	C
Amlodipine Besilate (Amlodipine Besilate)	C
Levothyroxine Sodium (Levothyroxine Sodium)	C
Salbutamol (Salbutamol)	C

Date:06/19/03ISR Number: 4131497-2Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0412673A
Age:89 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Fall Haemorrhage Head Injury Hypothyroidism		Eskalith	PS	Glaxosmithkline	ORAL	35 YR	

Date:06/19/03ISR Number: 4131502-3Report Type:Expedited (15-DaCompany Report #JP-GLAXOSMITHKLINE-B0298117A
Age:25 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	C-Reactive Protein		Paxil	PS	Glaxosmithkline	ORAL	400MG per day	21 DAY
	Lymphadenopathy		Lithium Carbonate	SS	Glaxosmithkline	ORAL		
	Pharyngolaryngeal Pain		Bromazepam	C		ORAL	10MG per day	
	Pyrexia		Clonazepam	C		ORAL	1.5MG per day	29 DAY
	Viral Infection		Teprenone	C		ORAL	150MG per day	
	White Blood Cell Count		Zopiclone	C		ORAL	7.5MG per day	18 DAY
	Decreased		Flunitrazepam	C		ORAL	2MG per day	16 DAY

			Nitrazepam	C		ORAL
10MG per day						
			Vegetamin B	C		ORAL
22 DAY						
			Sodium Valproate	C		ORAL
400MG per day	24 DAY					

Date:06/19/03ISR Number: 4132829-1Report Type:Expedited (15-DaCompany Report #DEWYE171512JUN03
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Abuser	Foreign	Tavor (Lorazepam)	PS		ORAL	UNKNOWN	
	Somnolence	Health					AMOUNT	
		Professional					(THERAPEUTICA	
		Other					L DOSIS) ORAL	1 DAY
			Hypnorex - Slow Release (Lithium Carbonate, 0)	SS		ORAL	1 TABLET	
							(=400 MG)	
							ORAL	1 DAY
			Trevilor (Venlafaxine Hydrochloride, Tablet, 0)	SS		ORAL	2 TABLETS	
							(UNKNOWN	
							STREGTH) ORAL	1 DAY
			Zopiclone					

			(Zopiclone, 0)	SS		ORAL
4 TABLETS (=30 MG) ORAL	1	DAY				
			Zyprexa (Olanzapine. 0)	SS		ORAL
1 TABLET (=10 MG) ORAL	1	DAY				

Date:06/19/03ISR Number: 4188563-5Report Type:Periodic Company Report #325135
Age:27 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Drug Toxicity	Literature	Clonazepam					
Hospitalization - Initial or Prolonged		Health	(Clonazepam)	PS		ORAL		
		Professional	Metformin (Metformin)	SS		ORAL		
			Lithium (Lithium Nos)	SS		ORAL		

Date:06/20/03ISR Number: 4132320-2Report Type:Expedited (15-DaCompany Report #DE-GLAXOSMITHKLINE-D0041207A
Age:57 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Diarrhoea	Health	Quilonum Retard	PS	Glaxosmithkline	ORAL	9000MG Single	
	Restlessness	Professional					dose	
	Suicide Attempt							
	Vomiting							

Date:06/20/03ISR Number: 4133829-8Report Type:Expedited (15-DaCompany Report #2002-10-2453
Age:42 YR Gender:Female I/FU:F

Outcome	PT
Hospitalization -	Abdominal Pain Upper

Initial or Prolonged	Alcohol Interaction
Disability	Blood Caffeine Increased
Other	Bronchitis
	Chest Pain
	Conversion Disorder
	Convulsion
	Disturbance In Attention
	Drug Interaction
	Drug Withdrawal Syndrome
	Dysphagia
	Dysphonia
	Eye Movement Disorder
	Fatigue
	Head Discomfort
	Headache
	Mastitis
	Menopausal Symptoms
	Mental Disorder
	Muscle Spasms
	Musculoskeletal Discomfort
	Nausea
	Neck Pain
	Neuralgia
	Reading Disorder
	Respiratory Disorder
	Speech Disorder
	Tardive Dyskinesia

	Throat Tightness Vomiting Weight Decreased	Report Source	Product	Role	Manufacturer	Route	Dose Duration
		Other	Trilafon (Perphenazine) Tablets	PS		ORAL	2-6 MG QD
			Zyprexa (Olanzapine) Tablets	SS		ORAL	ORAL
			Trazodone	SS			50 MG HS
			Prozac	SS			30-10 MG QE
			Caffeine	SS			
			Lithium	SS			
			Vicodin	C			
			Flexeril	C			
			Indocin	C			
			Multivitamins	C			
			Ativan	C			
			Thyroid	C			
			Clonazepam	C			
			Beclomethasone Nasal Solution	C			
			Ibuprofen	C			
			Alaprazolam	C			
			Cephalexin	C			
			Septran Ds (Trimethoprim/Sulfamethoxazole)	C			

Date:06/24/03ISR Number: 4134107-3Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0405145A
Age:52 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Blood Glucose Increased See dosage text Chest Pain	Consumer	Eskalith	PS	Glaxosmithkline	UNKNOWN	1350MG 13 YR

	Chills	Vasotec	SS		
UNKNOWN	5MG Per day 3 MON				
	Coordination Abnormal	Verapamil	SS		
UNKNOWN	180MG Per day				
	Coronary Artery Occlusion	Zestril	SS		
UNKNOWN	5MG Per day 1 MON				
	Difficulty In Walking	Metformin	C		
UNKNOWN					
	Dizziness	Glyburide	C		
UNKNOWN					
	Dyskinesia	Aspirin	C	Glaxosmithkline	
	Dyspnoea				
	Eye Pain				
	Gait Disturbance				
	Headache				
	Hypertension				
	Hypoaesthesia				
	Lethargy				
	Malaise				
	Muscle Atrophy				
	Muscle Spasms				
	Muscular Weakness				
	Myalgia				
	Nausea				
	Palpitations				
	Therapeutic Agent				
	Toxicity				
	Tremor				
	Vision Blurred				
	Vomiting				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/24/03ISR Number: 4134108-5Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0410367A
Age:16 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Arrhythmia	Health	Eskalith	PS	Glaxosmithkline			
	Drug Effect Decreased	Professional	Thorazine	SS	Glaxosmithkline			
	Drug Interaction		Pindolol	SS				
	Drug Toxicity		Imipramine	SS				

Date:06/24/03ISR Number: 4134109-7Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0413154A
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Renal Failure		Eskalith	PS	Glaxosmithkline	ORAL		

Date:06/24/03ISR Number: 4135372-9Report Type:Expedited (15-DaCompany Report #B0302157A
Age:66 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abnormal Behaviour	Foreign	Lithium Salt (Formulation Unknown) (Lithium Salt)	PS				
	Amnesia	Literature						
	Depressed Level Of Consciousness	Health Professional						
	Depression		Loxoprofen (Formulation Unknown) (Loxoprofen)	SS				
	Disorientation							
	Drug Interaction							
	Drug Toxicity							
	Hypomania							
	Lethargy							
	Meningioma							
	Parkinsonian Gait							
	Tremor							

Date:06/25/03ISR Number: 4135978-7Report Type:Expedited (15-DaCompany Report #03P-163-0215255-00
Age:46 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Required Intervention to Prevent Permanent Impairment/Damage	Blood Chloride Abnormal Hyperammonaemia Pco2 Abnormal Renal Tubular Acidosis	Health Professional	Depakote (Divalproex Sodium) (Divalproex Sodium)	PS	ORAL
SEE IMAGE, PER ORAL					
			Lithium	SS	ORAL
600 MG, 2 IN 1 D, PER ORAL					
			Celecoxib	C	
			Mirtazapine	C	
			Trihexyphenidyl Hydrochloride	C	
			Risperidone	C	
			Clonazepam	C	
			Salbutamol	C	
			Levothyroxine Sodium	C	
			Sulindac	C	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/26/03ISR Number: 4135954-4Report Type:Direct Company Report #CTU 196656
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Condition Aggravated Depression Difficulty In Walking Drug Level Above Therapeutic Dyspnoea Hallucination, Auditory Insomnia Musculoskeletal Stiffness Tremor		Lithium Carbonate 300 Mg Terazosin Verapamil Clonidine Fosamax And Calcium With Vitamin D Docusate Colchicine Meclizine	PS C C C C C C C		ORAL	300 MG THREE TIMES ORAL	

Date:06/27/03ISR Number: 4138889-6Report Type:Expedited (15-DaCompany Report #2003-BP-04043RO
Age:52 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Accidental Overdose Medication Error Therapeutic Agent Toxicity	Consumer	Lithium Carbonate Capsule Usp, 600 Mg (Lithium Carbonate) Enalapril (Enalapril) Toprol Xl (Metoprolol Succinate) Coumadin (Warfarin Sodium) Ferrous Gluconate (Ferrous Gluconate) Glucosamine (Glucosamine) Chondroitin (Herbal Preparation)	PS C C C C C C		ORAL	SEE IMAGE	

Date:06/27/03ISR Number: 4142624-5Report Type:Periodic Company Report #LBID00202001996
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability Other	Faecal Incontinence	Health Professional	Lithobid (Lithium Carbonate)	PS		ORAL	600 MG DAILY	
							PO, 900 MG	
							DAILY PO	
			Zoloft (Serteraline Hydrochloride)	C				
			Motrin (Ibuprofen)	C				
			Synthroid (Levothyroxine Sodium)	C				

Date:06/27/03ISR Number: 4142625-7Report Type:Periodic Company Report #LBID00203000094
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Toxicity	Consumer	Lithobid (Lithium Carbonate)	PS		ORAL	DAILY PO	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/27/03ISR Number: 4142626-9Report Type:Periodic Company Report #LBID00203000378
Age:16 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Diabetes Insipidus	Health Professional	Lithobid (Lithium Carbonate)	PS		ORAL	600 MG BID PO	11 MON

Date:06/27/03ISR Number: 4142627-0Report Type:Periodic Company Report #LBID00203000553
Age:58 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Blood Creatinine Increased	Health Professional	Lithium (Lithium)	PS		ORAL	600 MG DAILY PO	
	Renal Failure Chronic		Depakote (Valproate Semisodium)	C				
			Lipitor (Atorvastatin)	C				
			Synthroid (Levothyroxine Sodium)	C				

Date:06/30/03ISR Number: 4137206-5Report Type:Expedited (15-DaCompany Report #DE-GLAXOSMITHKLINE-D0041217A
Age:55 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Medication Error	Health Professional	Quilonum	PS	Glaxosmithkline	ORAL	3TAB Single dose	1 DAY
	No Adverse Drug Effect							
	Suicide Attempt		Zyprexa	SS		ORAL	10TAB Single dose	1 DAY

Date:07/02/03ISR Number: 4139570-XReport Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0414191A
Age:60 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Cardiomyopathy		Eskalith Cr	PS	Glaxosmithkline	ORAL		10 YR

Date:07/02/03ISR Number: 4139588-7Report Type:Expedited (15-DaCompany Report #DE-GLAXOSMITHKLINE-D0041168A
Age:31 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Bundle Branch Block Right	Health	Quilonum Retard	PS	Glaxosmithkline	ORAL	450MG Three times per day	
	Drug Level Increased	Professional						
	Hyperthyroidism		Truxal	C		ORAL	50DROP Three times per day	
	Hypothyroidism							
			Tavor	C		ORAL	.5MG Twice per day	
			Haldol	C		ORAL	5DROP Twice per day	
			Atosil	C	Glaxosmithkline	ORAL	25DROP Three times per day	
			Dociton	C		ORAL	60MG per day	
			Fluctin	C		ORAL		92 DAY

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/02/03ISR Number: 4140131-7Report Type:Direct Company Report #CTU 197146
Age:34 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Diarrhoea		Lithium Carbonate Sr 300 Mg Newly-Released Generic	PS		ORAL	600MG QHS	
	Fatigue							
	Headache							
	Nausea							
	Pharmaceutical Product						ORAL	
	Complaint		Lithium Carbonate	C				
			Lamictal	C				
			Zoloft	C				
			Wellbutrin	C				

Date:07/03/03ISR Number: 4140701-6Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0414562A
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Abdominal Pain		Eskalith Cr	PS	Glaxosmithkline	ORAL		
	Diarrhoea							
	Dizziness							
	Fatigue							
	Gastric Disorder							
	Loss Of Consciousness							
	Syncope							
	Temperature Intolerance							
	Vomiting							

Date:07/07/03ISR Number: 4142143-6Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0303163A
Age:65 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Beta Globulin Increased	Consumer	Raniplex	PS	Glaxosmithkline	ORAL	300MG per day	
	Blood Creatinine Increased		Depamide	SS		ORAL	1500MG per	
			Teralithe	SS	Glaxosmithkline	ORAL		

		Blood Parathyroid Hormone						
day	29	YR						
		Increased		Tadenan	SS		ORAL	
100MG per day								
		Cholelithiasis		Omix	SS		ORAL	
.4MG per day	1	YR						
		Creatinine Renal Clearance Decreased Drug Toxicity Hyperparathyroidism Nephrocalcinosis Nephrolithiasis Renal Failure						

Date:07/07/03ISR Number: 4142154-0Report Type:Expedited (15-DaCompany Report #DE-GLAXOSMITHKLINE-D0041254A
Age:56 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Drug Interaction	Health	Quilonum Retard	PS	Glaxosmithkline	ORAL	9	DAY
Initial or Prolonged	Enuresis	Professional	Anafranil	SS		ORAL	44	DAY
	Fall		Haldol	SS		ORAL	63	DAY
	Grand Mal Convulsion		Taxilan	SS		ORAL	50MG per day	5 DAY
	Myoclonus		Leponex	SS		ORAL	2	DAY
	Nervous System Disorder		Akineton	C			UNKNOWN	
	Tongue Biting							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/07/03ISR Number: 4142960-2Report Type:Direct Company Report #CTU 197309
Age:46 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Activities Of Daily		Lithobid	PS		ORAL	300MG BID	
	Living Impaired						ORAL	
	Difficulty In Walking		Fluoxetine	C				
	Therapeutic Agent		Quetiapine	C				
	Toxicity		Naltrexone	C				
	Tremor		Prevacid	C				
			Lamotrigine	C				
			Hydrochlorothiazde	C				
			K-Dur	C				

Date:07/07/03ISR Number: 4144669-8Report Type:Expedited (15-DaCompany Report #2003027467
Age:16 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Alanine Aminotransferase Increased	Foreign	Lithium (Lithium)	PS			900 MG	
	Apathy	Literature Health Professional	Haloperidol (Haloperidol)	SS			4.5 MG	
	Aspartate Aminotransferase Increased		Olanzapine (Olanzapine)	SS				
	Blood Creatine Phosphokinase Increased		Valproate Semisodium (Valproate Semisodium)	C				
	Blood Sodium Decreased		Clonazepam					
	Blood Urea Increased		(Clonazepam)	C				
	Catatonia		Carbamazepine					
	Echolalia		(Carbamazepine)	C				
	Echopraxia		Thioridazine					
	Extensor Plantar Response		(Thioridazine)	C				
	Haemoglobin Decreased							
	Hyperreflexia							
	Monocyte Count Decreased							
	Movement Disorder							
	Muscle Rigidity							
	Myalgia							
	Negativism							

	Neuroleptic Malignant Syndrome
	Neutrophil Count Increased
	Pyrexia
	Red Blood Cell Count Decreased
	Somnolence
	Tachycardia
	Urinary Retention
	White Blood Cell Count Increased

Date:07/08/03ISR Number: 4144054-9Report Type:Expedited (15-DaCompany Report #C2002-2188.01
Age:16 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Arrhythmia	Health	Pindolol Tablets	PS				
	Drowning	Professional	Imipramine Tablets	SS				
		Other	Chlorpromazine	SS				
			Lithium	SS				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/08/03ISR Number: 4145522-6Report Type:Expedited (15-DaCompany Report #A120276
Age:26 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Confusional State Coordination Abnormal Drug Level Increased Gastrointestinal Disorder Lethargy Psychotic Disorder	Health Professional	Geodon (Ziprasidone) Lithium (Lithium) Effexor Xr (Venlafaxine Hydrochloride) Wellbutrin (Bupropion Hydrochloride) Topamax (Topiramate) Parlodel (Bromocriptine Mesilate)	PS SS C C C C		ORAL ORAL	80 MG (BID), ORAL 1200 MG (BID), ORAL

Date:07/09/03ISR Number: 4143795-7Report Type:Expedited (15-DaCompany Report #DE-GLAXOSMITHKLINE-D0041217A
Age:55 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	No Adverse Drug Effect Suicide Attempt	Health Professional	Quilonum Zyprexa	PS SS	Glaxosmithkline	ORAL ORAL	3TAB Single dose 1 DAY 10TAB Single dose 1 DAY

Date:07/10/03ISR Number: 4144486-9Report Type:Expedited (15-DaCompany Report #DE-GLAXOSMITHKLINE-D0041363A
Age:19 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration

Other	Bradyarrhythmia	Health	Quilonum	PS	Glaxosmithkline	ORAL
	Hypothermia	Professional	Taxilan	SS		ORAL
	Loss Of Consciousness		Godamed	SS	Glaxosmithkline	ORAL
			Clozapine	SS		ORAL
			Akineton	SS		ORAL
			Pirenzepin	SS		ORAL
			Dominal Forte	SS		ORAL
			Lorazepam	SS		ORAL
			Chlorprothixen	SS		ORAL
			Rivotril	SS		ORAL
			Orfiril	SS		ORAL
			Zyprexa	SS		ORAL
			Topamax	SS		ORAL
			Seroquel	SS		ORAL

Date:07/10/03ISR Number: 4146699-9Report Type:Expedited (15-DaCompany Report #2002-10-2453
Age:42 YR Gender:Female I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Abdominal Pain Upper
	Alcohol Interaction
Disability	Bronchitis
Other	Chest Pain
	Conversion Disorder
	Convulsion
	Disturbance In Attention
	Drug Interaction

		Dysphagia Dysphonia Dystonia	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
		Eye Movement Disorder	Other	Perphenazine Tablets	PS		ORAL
2-6 MG QD							
		Headache					
ORAL							
		Mastitis		Trilafon			
		Muscle Spasms		(Perphenazine)			
		Musculoskeletal		Tablets	SS		ORAL
2-6 MG QD							
		Discomfort					
ORAL							
		Nausea		Trazodone	SS		
50 MG HS							
		Neck Pain		Prozac	SS		
30-10 MG QD							
		Neuralgia		Caffeine	SS		
		Speech Disorder		Lithium	SS		
		Tardive Dyskinesia		Zyprexa (Olanzapine)			
		Throat Tightness		Tablets	SS		ORAL
ORAL							
		Vomiting		Vicodin	C		
		Weight Decreased		Flexeril	C		
				Indocin	C		
				Multivitamins	C		
				Ativan	C		
				Thyroid	C		
				Wellbutrin (Bupropion)	C		
				Zoloft	C		
				Desipramine	C		
				Effexor	C		
				Depakote	C		
				Nortriptyline	C		
				Doxepin	C		
				Dicloxacillin	C		
				Clonazepam	C		
				Beclomethasone	C		
				Ibuprofen	C		
				Alprazolam	C		
				Cephalexin	C		
				Septran Ds (Trimethoprim/Sulfamethoxazole)	C		

Date:07/11/03ISR Number: 4145230-1Report Type:Expedited (15-DaCompany Report #GB-GLAXOSMITHKLINE-B0303716A
Age:58 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Drug Interaction		Lithium Carbonate	PS	Glaxosmithkline	ORAL	800MG At night	17 MON
	Electrocardiogram Qt Prolonged		Escitalopram	SS		ORAL	20MG Per day	
			Lansoprazole	C		ORAL	30MG per day	
			Thyroxine	C	Glaxosmithkline	ORAL	75UG per day	
			Lamotrigine	C	Glaxosmithkline	ORAL	25MG Twice per day	

Date:07/11/03ISR Number: 4146276-XReport Type:Direct Company Report #CTU 197767
Age:76 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Drug Toxicity		Lithium	PS		ORAL	1200MG , Initial or Prolonged 600MGBID, ORAL	
			Haloperidol	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/11/03ISR Number: 4147949-5Report Type:Expedited (15-DaCompany Report #2003-DE-00019YA
Age:65 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Adenoma Benign Blood Fibrinogen	Foreign Health	Omix (Tamsulosin Hydrochloride)	PS		ORAL	0.4 MG PO	365 DAY
	Cholelithiasis Drug Toxicity	Professional Other	Depamide (Valpromide)	SS		ORAL	300 MG PO	308 DAY
	Electrophoresis Protein Abnormal		Teralithe(Lithium Carbonate)	SS		ORAL	1500 MG PO	29 YR
	Hyperparathyroidism		Raniplex(Ranitidine)	SS		ORAL	1 ANZ (1 IN 1 D) PO	
	Nephrocalcinosis Nephrolithiasis Renal Cyst Renal Failure Ultrasound Kidney Abnormal		Tadenan(Pygeum Africanum)	C				

Date:07/15/03ISR Number: 4147186-4Report Type:Direct Company Report #CTU 197911
Age:71 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Confusional State Coordination Abnormal		Lithium Carbonate 300 Mg	PS		ORAL	300 MG BID	
Required Intervention to Prevent Permanent Impairment/Damage	Delusion Drug Level Increased Treatment Noncompliance		Olanzapine Lisinopril Propanolol Rosiglitazone Digoxin Brimonidine Tartrate	C C C C C C		ORAL		

Date:07/15/03ISR Number: 4149978-4Report Type:Expedited (15-DaCompany Report #2003028611
Age:66 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abnormal Behaviour Amnesia Depressed Level Of Consciousness Disorientation Drug Interaction Drug Level Decreased Lethargy Parkinsonian Gait Tremor	Foreign Literature	Lithium (Lithium) Loxoprofen (Loxoprofen) Maprotiline (Maprotiline)	PS SS C			400 MG 180 MG	(DAILY) (DAILY)

Date:07/15/03ISR Number: 4150166-6Report Type:Expedited (15-DaCompany Report #03P-153-0223589-00
Age:33 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hyperglycaemic Hyperosmolar Nonketotic Syndrome Malaise Polydipsia Polyuria	Foreign Literature Health Professional	Valproic Acid (Depakene) (Valproic Acid) (Valproic Acid) Lithium Olanzapine	PS SS SS			1000 MG, 1 IN 600 MG, 1 IN 5 MG, 1 IN 1	1 D 1 D

D

			Haloperidol	C		

Date:07/16/03ISR Number: 4150677-3Report Type:Expedited (15-DaCompany Report #2003002462
Age:66 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Bipolar Disorder Condition Aggravated Depression Drug Hypersensitivity Drug Interaction Drug Toxicity Immobile Suicidal Ideation Thinking Abnormal	Health Professional	Lithane (Lithium)	PS				
			Antiinflammatory/ Antirheumatic Non-Steroids	SS				
			Amitriptyline Hydrochloride (Amitriptyline Hydrochloride)	C				
			Lamotrigine	C				
			Benzatropine Mesilate (Benzatropine Mesilate)	C				
			Os-Cal (Ergocalciferol, Calcium)	C				
			Multivitamins (Ergocalciferol, Ascorbic Acid, Folic Acid, Thiamine Hydrochloride,	C				
			Acetylsalicylic Acid (Acetylsalicylic Acid)	C				
			Amlodipine Besilate (Amlodipine Besilate)	C				
			Levothyroxine Sodium (Levothyroxine Sodium)	C				
			Salbutamol (Salbutamol)	C				
			Lithium Carbonate (Lithium Carbonate)	C				
			Olanzapine (Olanzapine)	C				
			Estrogens Conjugated					

			(Estrogens Conjugated)	C		

Date:07/17/03ISR Number: 4151136-4Report Type:Expedited (15-DaCompany Report #S03-UKI-02779-01
Age:58 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Drug Interaction	Foreign	Cipralex					
	Electrocardiogram Qt	Health	(Escitalopram)	PS		ORAL	20 MG QD PO	
	Corrected Interval	Professional	Lithium	SS		ORAL	800 MG QD PO	
	Prolonged	Other	Lansoprazole	C				
			Thyroxine(Levothyroxine Sodium)	C				
			Lamotrigine	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/17/03ISR Number: 4151215-1Report Type:Expedited (15-DaCompany Report #03P-062-0223625-00
Age:19 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Bradyarrhythmia	Foreign	Akineton(Biperiden) (Biperiden)	PS		ORAL	PER ORAL	
	Hypothermia	Health						
	Loss Of Consciousness	Professional	Perazine	SS		ORAL	PER ORAL	
	Poisoning		Godamed	SS		ORAL	PER ORAL	
			Clozapine	SS		ORAL	PER ORAL	
			Pirenzepine	SS		ORAL	PER ORAL	
			Prothipendyl Hydrochloride	SS		ORAL	PER ORAL	
			Lorazepam	SS		ORAL	PER ORAL	
			Chlorprothixene	SS		ORAL	PER ORAL	
			Clonazepam	SS		ORAL	PER ORAL	
			Orfiril	SS		ORAL	PER ORAL	
			Olanzapine	SS		ORAL	PER ORAL	
			Topiramate	SS		ORAL	PER ORAL	
			Quetiapine	SS		ORAL	PER ORAL	
			Lithium Carbonate	SS		ORAL	PER ORAL	

Date:07/18/03ISR Number: 4149427-6Report Type:Expedited (15-DaCompany Report #DE-GLAXOSMITHKLINE-D0041207A
Age:57 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Depression	Health	Quilonum Retard	PS	Glaxosmithkline	ORAL	9000MG Single dose	
	Diarrhoea	Professional						

	Myocardial Infarction Restlessness Suicide Attempt Vertigo Vomiting		Marcumar	C		ORAL

Date:07/18/03ISR Number: 4152348-6Report Type:Expedited (15-DaCompany Report #USA-2003-0008591
Age:45 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged SEE IMAGE	Acute Sinusitis Asthenia	Consumer Health	Oxycontin (Oxycodone Hydrochloride) Cr	PS		ORAL		
	Bipolar Disorder Depression Dizziness	Professional Other	Eskalith-Slow Release (Lithium Carbonate)	SS			450 BID	
	Hallucinations, Mixed Hemiparesis		Celestone (Betamethasone)	SS			EPIDURAL	UNK ML,
	Memory Impairment							THRICE,
	Nausea						EPIDURAL	
	Psychotic Disorder Sleep Disorder Somnolence Surgery		Lortab	C				
			Phenergan (Promethazine Hydrochloride)	C				
			Neurontin (Gabapentin)	C				
			Zanaflex (Tizanidine Hydrochloride)	C				
			Zonegran (Zonisamide)	C				
			Prozac (Fluoxetine Hydrochloride)	C				
			Stelazine (Trifluoperazine					

Hydrochloride)	C
Cogentin (Benzatropine Mesilate)	C
Trazodone (Trazodone)	C
Valium (Diazepam)	C
Mobic (Meloxicam)	C

Date:07/21/03ISR Number: 4150366-5Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0405145A
Age:52 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Asthenia See dosage text		Eskalith	PS	Glaxosmithkline		1350MG	13 YR
	Chest Pain		Vasotec	SS			5MG Per day	3 MON
	Chills		Verapamil	SS			180MG Per day	
	Coordination Abnormal		Zestril	SS			5MG Per day	1 MON
	Coronary Artery Occlusion		Metformin	C				
	Difficulty In Walking		Glyburide	C				
	Dizziness		Aspirin	C	Glaxosmithkline			
	Drug Level Increased							
	Drug Toxicity							
	Dyskinesia							
	Dyspnoea							
	Eye Pain							
	Gait Disturbance							
	General Physical Health Deterioration							
	Headache							
	Hypertension							
	Hypoaesthesia							
	Lethargy							
	Malaise							
	Muscle Atrophy							
	Muscle Spasms							
	Muscular Weakness							

	Myalgia					
	Nausea					
	Palpitations					
	Tremor					
	Vision Blurred					
	Vomiting					

Date:07/21/03ISR Number: 4152906-9Report Type:Expedited (15-DaCompany Report #A120276
Age:26 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Condition Aggravated	Health	Geodon (Ziprasidone)	PS		ORAL	80 MG (BID), ORAL
	Confusional State	Professional					
	Coordination Abnormal		Lithium (Lithium)	SS		ORAL	1200 M G (BID), ORAL
	Drug Level Increased						
	Gastrointestinal Disorder		Venlafaxine Hydrochloride (Venlafaxine Hydrochloride)	C			
	Lethargy		Bupropion Hydrochloride (Bupropion				

			Hydrochloride)	C		
			Topiramate (Topiramate)	C		
			Bromocriptine Mesilate (Bromocriptine Mesilate)	C		

Date:07/21/03ISR Number: 4152938-0Report Type:Expedited (15-DaCompany Report #PHFR2003GB02728
Age:36 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Facial Palsy	Foreign Health Professional Other	Clozaril(Clozapine) Tablet	PS		ORAL	SEE IMAGE	
			Venlafaxine(Venlafaxine)	SS		ORAL	75 MG/DAY,	ORAL
			Lithium(Lithium)	SS		ORAL	1200 MG/DAY,	ORAL

Date:07/23/03ISR Number: 4152151-7Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0417468A
Age:51 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Abnormal Behaviour		Paxil	PS	Glaxosmithkline	ORAL	40MG Per day	
Initial or Prolonged	Fatigue		Wellbutrin	SS	Glaxosmithkline	ORAL	200MG Per day	
Other	Mania		Lithium	SS	Glaxosmithkline	ORAL	1200MG Per	day
			Zyprexa	C				

Date:07/24/03ISR Number: 4156462-0Report Type:Expedited (15-DaCompany Report #6004092
Age:63 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Disability	Blood Pressure Decreased Cardiac Failure Congestive Cardiomyopathy Hepatomegaly Hypocapnia Hypoxia Pleural Effusion Respiratory Alkalosis	Health Professional Other	Levothyrox 50 (Tablets) (Levothyroxine Sodium)	PS		ORAL	1,00 DOSAGE	
			Teralithe (400 Mg, Sustained-Release Tablet) (Lithium)Carbonate)	SS		ORAL	800,0000 MG (400 MG, 2 IN 1 D)	
			Noctamid (1 Mg, Tablet) (Lormetazepam)	SS		ORAL	1,00 MG (1 MG, 1 IN 1 D)	
			Anafranil (Tablets) (Clomipramine Hydrochloride)	SS		ORAL	50,000 MG (25 MG, 2 IN 1 D)	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/25/03ISR Number: 4153952-1Report Type:Expedited (15-DaCompany Report #NL-GLAXOSMITHKLINE-B0303827A
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Ineffective		Leukeran	PS	Glaxosmithkline			
UNKNOWN								
	Drug Interaction		Lithium	SS	Glaxosmithkline			
UNKNOWN							800MG per day	YR
	Drug Level Increased		Frusemide	C	Glaxosmithkline			
UNKNOWN							40MG per day	
	Dysstasia		Metoprolol	C				
UNKNOWN							100MG per day	
	Feeling Drunk		Enalapril	C				
20MG per day								
	Lymphadenopathy		Carbasalate	C				
100MG per day								
			Simvastatin	C				
20MG per day								
			Thyrax	C	Glaxosmithkline			
150MCG per								
day								
			Pantozol	C				
			Prednison	C				

Date:07/25/03ISR Number: 4153987-9Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0414562A
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Abdominal Pain		Eskalith Cr	PS	Glaxosmithkline	ORAL		
	Diarrhoea							
	Dizziness							
	Fatigue							
	Gastric Disorder							
	Loss Of Consciousness							
	Syncope							
	Temperature Intolerance							
	Visual Acuity Reduced							
	Vomiting							

Date:07/25/03ISR Number: 4157436-6Report Type:Expedited (15-DaCompany Report #2003-DE-02909GD
Age:45 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Acute Respiratory Distress Syndrome	Literature	Lithium Carbonate (Lithium Carbonate)	PS		ORAL	1350 MG (450 MG, THRICE DAILY), PO; 40500 MG (450 MG), PO	2 YR
Hospitalization - Initial or Prolonged	Blood Pressure Decreased							
	Confusional State							
	Delirium							
	Depressed Level Of Consciousness		Fluoxetine (Fluoxetine Hydrochloride)	C				
	Drug Level Increased							
	Drug Toxicity							
	Electroencephalogram Abnormal							
	Haemodialysis							
	Heart Rate Increased							
	Hyponatraemia							
	Intentional Misuse							
	Lethargy							
	Muscle Rigidity							
	Neuroleptic Malignant Syndrome							
	Pyrexia							
	Renal Failure Acute							
	Rhabdomyolysis							
	Tachypnoea							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/28/03ISR Number: 4159205-XReport Type:Expedited (15-DaCompany Report #M0744-2003
Age:43 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Abdominal Pain	Health	Mirtazapine	PS		OPHTHALMIC	45 MG	
	Gastroenteritis	Professional	Lithium Sulfate	SS		ORAL	1320 MG	
	Nausea							
	Weight Decreased							

Date:07/29/03ISR Number: 4157467-6Report Type:Direct Company Report #CTU 198895
Age:30 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Spinal Fracture		Lithium	PS				
Disability								

Date:07/29/03ISR Number: 4157512-8Report Type:Direct Company Report #CTU 198893
Age:34 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Mental Retardation		Seroquel	PS				
	Severity Unspecified		Lithium	SS				
	Road Traffic Accident							

Date:07/29/03ISR Number: 4157519-0Report Type:Direct Company Report #CTU 198894
Age:30 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Movement Disorder		Lithobid	PS				
Congenital Anomaly								
Other								

Date:07/29/03ISR Number: 4159658-7Report Type:Expedited (15-DaCompany Report #03P-062-0223625-00
Age:19 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Bradyarrhythmia	Foreign	Akineton (Biperiden) (Biperiden)	PS		ORAL	PER ORAL	
	Hypothermia	Health	Perazine	SS		ORAL	PER ORAL	
	Loss Of Consciousness	Professional	Godamed	SS		ORAL	PER ORAL	
	Poisoning		Clozapine	SS		ORAL	PER ORAL	
			Pirenzepine	SS		ORAL	PER ORAL	
			Prothipendyl Hydrochloride	SS		ORAL	PER ORAL	
			Lorazepam	SS		ORAL	PER ORAL	
			Chlorprothixene	SS		ORAL	PER ORAL	
			Clonazepam	SS		ORAL	PER ORAL	
			Orfiril	SS		ORAL	PER ORAL	
			Olanzapine	SS		ORAL	PER ORAL	
			Topiramate	SS		ORAL	PER ORAL	
			Quetiapine	SS		ORAL	PER ORAL	
			Lithium Carbonate	SS		ORAL	PER ORAL	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/29/03ISR Number: 4183781-4Report Type:Periodic Company Report #USA-2002-0002077
Age:46 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Overdose	Consumer Health Professional Other	Morphine Sulfate (Similar To Nda 19-516) (Morphine Sulfate)	PS				
			Haloperidol (Haloperidol)	SS		ORAL	ORAL	
			Ethanol (Ethanol)	SS				
			Alprazolam (Alprazolam)	SS		ORAL	ORAL	
			Lithobid (Lithium Carbonate)	SS				
			Effexor (Venlafaxine Hydrochloride)	SS		ORAL	ORAL	
			Penicillin	C				
			Desyrel	C				

Date:07/30/03ISR Number: 4157466-4Report Type:Expedited (15-DaCompany Report #DE-GLAXOSMITHKLINE-D0041564A
Age:26 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Aggression		Quilonum Retard	PS	Glaxosmithkline	ORAL	50TAB	Single
	Drug Toxicity						dose	
	Intentional Misuse		Chlorprothixene	SS		ORAL	50TAB	Single
	Somnolence						dose	
	Suicide Attempt							
	Vomiting							

Date:07/30/03ISR Number: 4158652-XReport Type:Expedited (15-DaCompany Report #A-US2003-02972
Age:50 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Asthenia	Health	Tracleer(Bosentan)					
Other	Balance Disorder	Professional	Tablet	PS		ORAL	SEE IMAGE	
Required Intervention to Prevent Permanent Impairment/Damage	Drug Interaction Fall Therapeutic Agent Toxicity		Lithium(Lithium)	SS				

Date:07/30/03ISR Number: 4160281-9Report Type:Expedited (15-DaCompany Report #2003-DE-02977GD (0)
Age:33 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Acetonaemia Blood Glucose Increased	Foreign Literature	Lithium Carbonate (Lithium Carbonate)	PS			600 MG	
	Blood Osmolarity Increased		Olanzapine (Antipsychotics)	SS			5 MG	
	Diabetic Hyperosmolar Coma		Valproic Acid (Valproic Acid)	SS			1000 MG	
	Glucose Urine Present Glycosylated Haemoglobin Increased Malaise Polydipsia Polyuria							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/30/03ISR Number: 4161227-XReport Type:Expedited (15-DaCompany Report #A-US2003-02972
Age:50 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Asthenia	Health	Tracleer(Bosentan)					
Other	Balance Disorder	Professional	Tablet	PS		ORAL	SEE IMAGE	
Required Intervention to Prevent Permanent Impairment/Damage	Drug Interaction		Lithium(Lithium)	SS				
	Drug Level Increased							
	Fall							

Date:08/04/03ISR Number: 4160756-2Report Type:Direct Company Report #CTU 199137
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Abnormal Behaviour		Lithium 1200	PS				
	Anxiety		Strattera 40	SS				
	Educational Problem							
	Judgement Impaired							
	Mood Swings							
	Personality Disorder							

Date:08/04/03ISR Number: 4160767-7Report Type:Direct Company Report #CTU 199143
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Abnormal Behaviour		Lithobid 900-900	PS				
	Anger		Risperdal	SS				
	Drug Ineffective		Adderall	SS				
	Dysthymic Disorder		Depakote 1000	SS				
	Emotional Disorder		Strattera 80	SS				
	Negativism							
	Thinking Abnormal							

Date:08/04/03ISR Number: 4161016-6Report Type:Direct Company Report #CTU 199133
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Abnormal Behaviour		Lithium 300-600	PS				
	Affect Lability		Clozaril	SS			50-100	
	Distractibility		Geodon	SS				
	Educational Problem		Ddavp	SS			.6 OR .8	
	Irritability		Strattera	SS			60	
	Obesity		Lithium	C			300-600	
	Weight Increased							

Date:08/04/03ISR Number: 4161018-XReport Type:Direct Company Report #CTU 199134
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Mood Altered		Lithium	PS			300 - 450	
			Nortriptylene	SS			75	
			Temazepam	SS			30	
			Risperdal	SS			2	
			Strattera	SS			40	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/04/03ISR Number: 4161020-8Report Type:Direct Company Report #CTU 199135
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Increased Appetite		Lithium	PS			300-300	
	Obesity		Risperdal	SS			2	
	Speech Disorder		Ddavp	SS			0.8	
	Tongue Disorder		Strattera	SS			40	

Date:08/04/03ISR Number: 4163939-0Report Type:Expedited (15-DaCompany Report #2003-BP-05195RO
Age:47 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death Hospitalization - Initial or Prolonged	Confusional State Coordination Abnormal Hypotension Mental Status Changes Renal Failure Tachycardia	Literature Health Professional Other	Lithium Carbonate Capsules Usp, 300 Mg (Lithium Carbonate)	PS				

Date:08/05/03ISR Number: 4165849-1Report Type:Expedited (15-DaCompany Report #EPOS00303002082
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Interaction Drug Level Increased Epistaxis	Foreign Health Professional Other	Teveten (Eprosartan) Lithium (Lithium) Inderal (Propranolol Hydrochloride) Zocor (Simvastatin) Truxal (Chlorprothixene Hydrochloride)	PS SS C C C		ORAL	600 MG DAILY PO DAILY	

Date:08/06/03ISR Number: 4162567-0Report Type:Expedited (15-DaCompany Report #CH-GLAXOSMITHKLINE-B0305584A
Age:44 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Interaction		Lithium Carbonate	PS	Glaxosmithkline			
	Grand Mal Convulsion		Mefenamic Acid	SS				
	Memory Impairment		Clozapine	SS				9 DAY
	Muscle Twitching		Sodium Valproate	SS				
	Myoclonus		Laxative	C				

Date:08/06/03ISR Number: 4162569-4Report Type:Expedited (15-DaCompany Report #DE-GLAXOSMITHKLINE-D0041363A
Age:19 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Bradyarrhythmia		Quilonum Retard	PS	Glaxosmithkline	ORAL		
	Hypothermia		Taxilan	SS		ORAL		
	Loss Of Consciousness		Godamed	SS	Glaxosmithkline	ORAL		
			Clozapine	SS		ORAL		
			Akineton	SS		ORAL		
			Pirenzepin	SS		ORAL		
			Dominal Forte	SS		ORAL		
			Lorazepam	SS		ORAL		
			Chlorprothixen	SS		ORAL		
			Rivotril	SS		ORAL		

			Orfiril	SS		ORAL
			Zyprexa	SS		ORAL
			Topamax	SS		ORAL
			Seroquel	SS		ORAL

Date:08/07/03ISR Number: 4163350-2Report Type:Expedited (15-DaCompany Report #GB-GLAXOSMITHKLINE-B0305909A
Age:64 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Interaction		Lithium	PS	Glaxosmithkline	ORAL	600MG per day	
	Drug Level Increased		Trimethoprim	SS	Glaxosmithkline		UNKNOWN	
			Metformin	C		ORAL	850MG Three times per day	
			Perindopril	C		ORAL	2MG Per day	
			Repaglinide	C		ORAL	2MG Twice per day	
			Lithium Carbonate	C	Glaxosmithkline	ORAL	600MG Per day	

Date:08/07/03ISR Number: 4166760-2Report Type:Expedited (15-DaCompany Report #GBWYE224521JUL03
Age:53 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability Other	Anxiety Derealisation Drug Interaction Hallucination Insomnia	Health Professional	Efexor Xl (Venlfaxine Hydrochloride, Capsule, Extended Release, 0)	PS		ORAL	75 MG 1X PER	1 DAY 2 DAY
			Lithium Carbonate (Lithium Carbonate,					

			, 0)	SS		ORAL
400 MG 1X PER 1 DAY						

Date:08/09/03ISR Number: 4167355-7Report Type:Expedited (15-DaCompany Report #200316579US
Age:51 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Blood Glucose Fluctuation	Consumer	Furosemide (Lasix)	PS		
40-80 MG BID 3 DAY						
Initial or Prolonged	Coma	Health	Insulin Glargine			
Other	Depression	Professional	(Lantus) Solution			
	Disorientation		For Injection	SS		
SUBCUTANEOUS 1-10 MG HS SC						
	Drug Ineffective		Lithium Carbonate			
	Drug Interaction		(Eskalith - Slow			
	Oedema		Release)	SS		
375-675 MG QD 3 DAY						
	Therapeutic Agent		Glipizide			
	Toxicity		(Glucotrol)	C		
			Other Medications	C		

Date:08/11/03ISR Number: 4165349-9Report Type:Expedited (15-DaCompany Report #PHBS2003IE08267
Age:35 YR Gender:Female I/FU:I

Outcome	PT
Death	Agitation
Hospitalization -	Bacteria Urine Identified
Initial or Prolonged	Blood Creatine
	Phosphokinase Increased
	Blood Creatine

	Phosphokinase Mb						
	Cardiomegaly						
	Confusional State						
	Dyspnoea	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Electrocardiogram T Wave Inversion		Thioridazine	PS	Novartis Sector: Pharma	ORAL	UNKNOWN
	Gastritis Erosive		Lithium	SS			
	Hypertonia						
	Hypotension						
	Liver Function Test Abnormal						
	Neuroleptic Malignant Syndrome						
	Pyrexia						
	Sepsis						
	Tachypnoea						
	Upper Gastrointestinal Haemorrhage						
	Ventricular Hypokinesia						

Date:08/11/03ISR Number: 4168321-8Report Type:Expedited (15-DaCompany Report #2003032460
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Agitation	Health Professional	Geodon (Ziprasidone)	PS		ORAL	80 MG (DAILY), ORAL
Other	Blood Lactate Dehydrogenase Increased		Lithium (Lithium)	SS		ORAL	ORAL
	Dyskinesia						
	Hallucination, Auditory						
	Paranoia						
	Streptococcal Serology Positive						
	Tic						

Date:08/13/03ISR Number: 4166590-1Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0420517A
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Exposure During Pregnancy Polyhydramnios		Eskalith Cr	PS	Glaxosmithkline	ORAL	450MG Twice per day	9 MON

Date:08/13/03ISR Number: 4169666-8Report Type:Expedited (15-DaCompany Report #K200301308
Age:64 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Interaction Drug Level Increased	Foreign Health Professional Other	Proloprim Tablets (Trimethoprim) Tablet, 100mg	PS				
			Lithium (Lithium)	SS		ORAL	QD, ORAL	
			Metformin Hydrochloride (Metformin Hydrochloride)	C				
			Perindopril (Perindopril)	C				
			Repaglinide (Repaglinide)	C				
			Lithium Carbonate					

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

(Lithium Carbonate) C

Date:08/14/03ISR Number: 4167684-7Report Type:Direct Company Report #CTU 199963
Age:73 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Azotaemia		Methotrexate 2.5mg	PS		ORAL	2.5MG Q12H	
	Coma					ORAL		
	Dehydration		Eskalith Cr 450mg	SS		ORAL	450MG QAM	
	Drug Toxicity					ORAL		
	Hypotension		Skelaxin	C				
	Pancytopenia		Fibercon	C				
	Pulse Absent		Volmax	C				
	Respiratory Arrest		Seroquel	C				
			Ditropan	C				
			Zyprexa	C				
			Serax	C				
			Celebrex	C				
			Fosamax	C				
			Celexa	C				
			Mvi	C				
			Synthroid	C				
			Naprosyn	C				
			Oxacillin	C				
			Mycostatin	C				
			Diflucan	C				
			Vicodin	C				
			Tylenol	C				

Date:08/14/03ISR Number: 4167752-XReport Type:Direct Company Report #CTU 199975
Age:53 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Depressed Level Of		Eskalith 450mg	PS		ORAL	450MG TID	
Hospitalization -	Consciousness					ORAL		

Initial or Prolonged	Drug Toxicity		Ibuprofen 800mg	SS		ORAL
800MG TID						
Required	Haemodialysis					
ORAL						
Intervention to Prevent Permanent Impairment/Damage	Renal Failure Acute					

Date:08/14/03ISR Number: 4170758-8Report Type:Expedited (15-DaCompany Report #BR-JNJFOC-20030802325
Age:5 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Accidental Exposure	Foreign Health Professional	Haldol (Haloperidol) Unspecified	PS		ORAL
ORAL						
			Carbolitium (Lithium Carbonate)	SS		ORAL
ORAL						
			Tegretol (Carbamazepine)	SS		ORAL
ORAL						

Date:08/14/03ISR Number: 4170763-1Report Type:Expedited (15-DaCompany Report #BR-JNJFOC-20030802335
Age:25 YR Gender:Female I/FU:I

Outcome	PT	Report Source
Hospitalization - Initial or Prolonged	Suicide Attempt	Foreign Health

Professional

			Product	Role	Manufacturer	Route	Dose Duration
			Haldol (Haloperidol)				
			Unspecified	PS			
			Carbolitium (Lthium Carbonate)	SS			
			Rivotril (Clonazepam)	SS			

Date:08/15/03ISR Number: 4168645-4Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0420979A
Age:61 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Cellulitis		Wellbutrin	PS	Glaxosmithkline	ORAL	1TAB Twice per day 2 MON
	Oedema						
	Pruritus		Lithium	SS	Glaxosmithkline		
	Rash		Diovan	C			
			Armour Thyroid	C			
			Glucophage	C			

Date:08/15/03ISR Number: 4168659-4Report Type:Expedited (15-DaCompany Report #DE-GLAXOSMITHKLINE-D0041664A
Age:45 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Other	Bradycardia		Quilonum Retard	PS	Glaxosmithkline	ORAL	6750MG per day
	Multiple Drug Overdose						
	Somnolence		Meto Isis	SS		ORAL	4000MG per day
	Suicide Attempt						
			Zyprexa	SS		ORAL	175MG per day
			Diazepam	SS		ORAL	350MG per day

Date:08/15/03ISR Number: 4168660-0Report Type:Expedited (15-DaCompany Report #DE-GLAXOSMITHKLINE-D0041665A
Age:80 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dehydration		Quilonum Retard	PS	Glaxosmithkline	ORAL	450MG Per day	
	Miosis							
	Tremor							

Date:08/15/03ISR Number: 4169133-1Report Type:Direct Company Report #CTU 200025
Age:71 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Confusional State		Lithium Carbonate 300 Mg	PS		ORAL	300 MG BID	
Required	Coordination Abnormal							
ORAL	Delusion							
Intervention to Prevent Permanent Impairment/Damage	Drug Level Increased		Olanzapine	C				
			Lisinopril	C				
			Propranolol	C				
			Rosiglitazone	C				
			Digoxin	C				
			Brimodine Tartrate	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/15/03ISR Number: 4171743-2Report Type:Expedited (15-DaCompany Report #2003-BP-05686RO
Age:53 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Drug Level	Literature	Lithium Carbonate Capsules Usp, 300 Mg (Lithium Carbonate)	PS		PO		

Date:08/15/03ISR Number: 4171745-6Report Type:Expedited (15-DaCompany Report #2003-BP-05687RO
Age:57 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Drug Level Medication Error	Literature	Lithium Carbonate Capsules Usp, 300 Mg (Lithium Carbonate)	PS	Usp	PO		

Date:08/15/03ISR Number: 4171746-8Report Type:Expedited (15-DaCompany Report #2003-BP-05688RO
Age:46 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide Drug Level	Literature	Lithium Carbonate Capsules Usp, 300 Mg (Lithium Carbonate)	PS	Usp	ORAL PO		
			Acetaminophen/Hydrocodone (Vicodin)	SS		ORAL PO		
			Sertraline (Sertraline)	SS		ORAL PO		

Date:08/15/03ISR Number: 4171748-1Report Type:Expedited (15-DaCompany Report #2003-BP-05689RO
Age:54 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide Drug Level Overdose	Literature	Lithium Carbonate Capsules Usp, 300 Mg (Lithium Carbonate)	PS	Usp	ORAL	PO	
			Fluvastatin (Fluvastatin)	SS		ORAL	PO	
			Rosiglitazone (Oral Antidiabetics)	SS		ORAL	PO	

Date:08/15/03ISR Number: 4171775-4Report Type:Expedited (15-DaCompany Report #2003-BP-05690RO
Age:38 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide Intentional Misuse	Literature	Lithium Carbonate Capsules Usp, 3000 Mg (Lithium Carbonate)	PS		ORAL	PO	
			Venlafaxine (Antidepressants)	SS		ORAL	PO	
			Benzodiazepine (Benzodiazepine Derivatives)	SS		ORAL	PO	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/18/03ISR Number: 4169272-5Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0405145A
Age:52 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Arthropathy		Eskalith	PS	Glaxosmithkline	UNKNOWN	1350MG See dosage text	13 YR
	Asthenia							
	Blood Glucose Increased		Vasotec	SS		UNKNOWN	5MG Per day	3 MON
	Chest Pain		Verapamil	SS		UNKNOWN	180MG Per day	
	Chills		Zestril	SS		UNKNOWN	5MG Per day	1 MON
	Coordination Abnormal		Metformin	C		UNKNOWN		
	Coronary Artery Occlusion		Glyburide	C		UNKNOWN		
	Diabetes Mellitus		Aspirin	C	Glaxosmithkline			
	Inadequate Control							
	Difficulty In Walking							
	Dizziness							
	Drug Level Increased							
	Drug Toxicity							
	Dyskinesia							
	Dyspnoea							
	Eye Pain							
	Gait Disturbance							
	General Physical Health Deterioration							
	Headache							
	Hypoaesthesia							
	Lethargy							
	Malaise							
	Muscle Atrophy							
	Muscle Spasticity							
	Muscular Weakness							
	Myalgia							
	Nausea							
	Palpitations							
	Tremor							
	Vision Blurred							
	Vomiting							

Date:08/18/03ISR Number: 4169275-0Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0416594A
Age:43 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Bipolar I Disorder		Eskalith Cr	PS	Glaxosmithkline	ORAL	300MG Variable dose	
	Condition Aggravated							
	Depression		Eskalith Cr	SS	Glaxosmithkline	ORAL	450MG See dosage text	8 YR
	Drug Level Increased							
	Drug Toxicity		Eskalith	SS	Glaxosmithkline	ORAL	450MG See dosage text	19 MON
	Dry Mouth							
	Hallucination, Auditory		Navane	C				
	Libido Decreased		Cogentin	C				
	Mania		Dilantin	C				
	Medication Error							
	Periodontal Disease							
	Self-Injurious Ideation							

Date:08/18/03ISR Number: 4170479-1Report Type:Direct Company Report #CTU 200119
Age: Gender:Male I/FU:I

Outcome	PT
Other	Asthenia
	Dry Mouth

	Feeling Abnormal Pollakiuria Polydipsia	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Respiratory Disorder Tremor		Lithium Carbonate Cap 300 Mg Roxane	PS	Roxane	ORAL	1800 MG /DAY TID ORAL
			Abilify 15 Mg Novaritis	SS	Novaritis	ORAL	15 MG QD ORAL

Date:08/18/03ISR Number: 4173207-9Report Type:Expedited (15-DaCompany Report #PHBS2003IE08267
Age:35 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Death Hospitalization - Initial or Prolonged	Agitation Aspartate Aminotransferase Increased	Foreign Literature Health Professional	Thioridazine (Thioridazine Hydrochloride) Tablet	PS		ORAL	ORAL
	Blood Lactate Dehydrogenase Increased Blood Pressure Systolic Increased Cardiomegaly Catheter Related Infection Confusional State Electrocardiogram T Wave Inversion Gastritis Erosive Haemoglobin Decreased Histology Abnormal Hypertonia Hypotension Intentional Misuse Neuroleptic Malignant Syndrome Sepsis Sinus Tachycardia Upper Gastrointestinal Haemorrhage	Other	Lithium	SS			

	Ventricular Hypokinesia					

Date:08/19/03ISR Number: 4170038-0Report Type:Expedited (15-DaCompany Report #GB-GLAXOSMITHKLINE-B0306812A
Age:53 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Anxiety		Lithium Carbonate	PS	Glaxosmithkline	ORAL	400MG Per day	
	Derealisation		Efexor	SS		ORAL	75MG Per day	2 DAY
	Drug Interaction							
	Hallucination							
	Insomnia							

Date:08/19/03ISR Number: 4170043-4Report Type:Expedited (15-DaCompany Report #CA-GLAXOSMITHKLINE-A0420929A
Age:66 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Parkinson'S Disease		Paxil	PS	Glaxosmithkline			
	Tremor		Lithium	SS	Glaxosmithkline			

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/20/03ISR Number: 4170674-1Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0422255A
Age:53 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Difficulty In Walking		Lithium	PS	Glaxosmithkline	ORAL	UNKNOWN
	Dissociation		Clozapine	SS			
	Dysstasia						
	Fall						

Date:08/20/03ISR Number: 4175686-XReport Type:Expedited (15-DaCompany Report #LBID00203002248
Age:43 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Blood Calcium	Health Professional	Lithobid (Lithium Carbonate)	PS		ORAL	DAILY PO
	Confusional State						
	Renal Failure		Paxil (Paroxetine Hydrochloride)	C			
			Klonopin (Clonazepam)	C			
			Donnatal (Donnatal)	C			

Date:08/22/03ISR Number: 4177143-3Report Type:Expedited (15-DaCompany Report #EPOS00303002082
Age:51 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Confusional State	Foreign Health Professional Other	Teveten (Eprosartan)	PS		ORAL	600 MG QD PO, UNK DAILY PO
	Drug Interaction						
	Drug Toxicity		Neurolithium (Lithium Salts)	SS			4 DF DAILY A FEW YEARS
	Epistaxis						
	Hypertension						
	Renal Artery Stenosis		Inderal (Propranolol Hydrochloride)	C			
	Renal Failure Acute		Zocor (Simvastatin)	C			
	Tremor		Truxal				

	(Chlorprothixene Hydrochloride)	C

Date:08/25/03ISR Number: 4172875-5Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0405145A
Age:52 YR Gender:Male I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Blood Glucose Increased
	Chest Pain
	Chills
	Coordination Abnormal
	Coronary Artery Occlusion
	Difficulty In Walking
	Dizziness
	Dyskinesia
	Dyspnoea
	Eye Pain
	Gait Disturbance
	Headache
	Hypertension
	Hypoaesthesia
	Lethargy
	Malaise
	Muscle Atrophy
	Muscle Spasms

		Muscular Weakness					
		Myalgia					
		Nausea	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
		Palpitations		Eskalith	PS	Glaxosmithkline	
UNKNOWN	1350MG	See					
		Therapeutic Agent					
dosage text	13 YR						
		Toxicity		Vasotec	SS		
UNKNOWN	5MG Per day	3 MON					
		Tremor		Verapamil	SS		
UNKNOWN	180MG Per day						
		Vision Blurred		Zestril	SS		
UNKNOWN	5MG Per day	1 MON					
		Vomiting		Metformin	C		
UNKNOWN							
				Glyburide	C		
UNKNOWN							
				Aspirin	C	Glaxosmithkline	

Date:08/26/03ISR Number: 4197294-7Report Type:Periodic Company Report #021031-PM0006-00
Age:73 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization - Initial or Prolonged	Vision Blurred	Foreign Health Professional	Tranxene (Clorazepate Dipottasium)	PS		ORAL
10 MG, P.O.						
		Other	Lithium Carbonate	SS		ORAL
250 MG, P.O., TID						

Date:08/28/03ISR Number: 4175166-1Report Type:Periodic Company Report #US-BRISTOL-MYERS SQUIBB COMPANY-12283115
Age:52 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
	Akinesia		Abilify Tabs	PS	Otsuka Pharmaceutical Company, Ltd.	
	Difficulty In Walking					
	Drug Interaction					ORAL
Started 10 mg						

	Memory Impairment						
daily and							
	Musculoskeletal Stiffness						
increased to							
	Parkinsonism						
30 mg							
	Tremor						
daily,then							
				Lamictal	C		
				Effexor	C		
				Lithium	I		

Date:08/28/03ISR Number: 4181435-1Report Type:Expedited (15-DaCompany Report #2003035153
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Carbon Monoxide Poisoning	Consumer	Geodon (Ziprasidone)	PS		ORAL		
Life-Threatening	Completed Suicide		Lithium (Lithium)	SS				
	Drug Ineffective		Citalopram Hydrobromide (Citalopram Hydrobromide)	SS		ORAL		
	Lethargy		Lorazepam (Lorazepam)	SS		ORAL		
			Olanzapine (Olanzapine)	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/28/03ISR Number: 4181956-1Report Type:Expedited (15-DaCompany Report #PERI00203002445
Age:71 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Anaemia	Foreign	Coversyl					
Hospitalization -	Atrioventricular Block	Health	(Perindopril)	PS		ORAL	2 DF	DAILY PO
Initial or Prolonged	Bradycardia	Professional	Modopar (Modopar)	SS		ORAL	250 MG	DAILY PO
	Circulatory Collapse	Other						
			Teralithe (Lithium Carbonate)	SS		ORAL	2 DF	DAILY PO
			Vercyte (Pipobroman)	SS		ORAL	1 DF	QD PO
			Lexomil (Bromazepam)	SS		ORAL	1 DF	QD PO
			Chronadalate (Nifedipine)	SS		ORAL	DAILY PO	

Date:08/28/03ISR Number: 4187720-1Report Type:Periodic Company Report #US-BRISTOL-MYERS SQUIBB COMPANY-12330098
Age:9 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Dehydration		Abilify Tabs 15 Mg	PS	Otsuka Pharmaceutical Company, Ltd.	ORAL	7.5 mg (1/2 of a 15 mg tablet)	once daily in the morning
	Drug Level Increased							
	Oedema							
			Lithobid	SS				

Date:09/02/03ISR Number: 4178708-5Report Type:Direct Company Report #CTU 201009
Age:56 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Level Increased Drug Toxicity		Lithium	PS		ORAL	1200MG, 600MG	BI, ORAL
Required Intervention to Prevent Permanent Impairment/Damage			Levofloxacin	C				
			Acetaminophen	C				
			Risperidone	C				
			Magnesium Hydroxide	C				
			Haloperidol	C				
			Bisacodyl (Magic Bullet) Supp	C				
			Haloperidol	C				
			Benztropine	C				

Date:09/02/03ISR Number: 4178799-1Report Type:Direct Company Report #CTU 201128
Age:52 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Asthenia Chest Pain		Lithium 600 Mg	PS		ORAL	600 MG DAILY	ORAL
	Confusional State		Sulindac	C				
	Drug Level Above Therapeutic		Amlodipine	C				
			Olanzapine	C				
	Dysarthria		Clonazepam	C				

Date:09/03/03ISR Number: 4178016-2Report Type:Expedited (15-DaCompany Report #SE-ROCHE-345098
Age:40 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Blood Creatine Phosphokinase Increased	Consumer	Iktorivil	PS	Roche	ORAL	REPORTED TO BE A LONG-TERM TREATMENT.
	Depressed Level Of Consciousness						
	Parkinsonism		Mallorol	SS		ORAL	REPORTED TO BE A LONG-TERM TREATMENT.
			Lithionit	SS		ORAL	REPORTED TO BE A CONTINUOUS TREATMENT.
			Lithionit	SS		ORAL	

Date:09/03/03ISR Number: 4178084-8Report Type:Expedited (15-DaCompany Report #DE-GLAXOSMITHKLINE-D0041664A
Age:45 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Acute Respiratory Distress Syndrome		Quilonum Retard	PS	Glaxosmithkline	ORAL	6750MG per day
	Aspiration		Meto Isis	SS		ORAL	4000MG per day
	Bradycardia						

	Intentional Misuse		Zyprexa	SS		ORAL 175MG per day
	Loss Of Consciousness		Diazepam	SS		ORAL 350MG per day
	Pneumonia Somnolence Suicide Attempt					

Date:09/03/03ISR Number: 4184537-9Report Type:Expedited (15-DaCompany Report #2003032460
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Hospitalization -	Aggression	Health	Geodon (Ziprasidone)	PS		ORAL 80 MG
Initial or Prolonged	Agitation	Professional				(DAILY), ORAL
Other	Blood Lactate		Lithium (Lithium)	SS		ORAL ORAL
	Dehydrogenase Increased Dyskinesia Hallucination, Auditory Impulsive Behaviour Paranoia Tic					

Date:09/03/03ISR Number: 4184973-0Report Type:Expedited (15-DaCompany Report #03P-056-0230582-00
Age:71 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Life-Threatening	Anaemia Macrocytic	Foreign	Vercyte (Pipobroman)			
Hospitalization -	Aplastic Anaemia	Health	(Pipobroman)	PS		ORAL 1 DOSAGE
Initial or Prolonged	Atrioventricular Block	Professional				FORMS, PER
	Complete					ORAL
	Circulatory Collapse		Lithium	SS		ORAL 2 DOSAGE
	Dehydration					FORMS, PER
	General Physical					ORAL
	Condition Abnormal		Madopar	SS		ORAL 125 MG, 2 IN
						1 D, PER ORAL

YEARS

			Nifedipine	SS	ORAL

30 MG, PER

ORAL YEARS

			Perindopril	SS	ORAL

2 DOSAGE

FORMS, PER

ORAL YEARS

			Bromazepam	SS	ORAL

1 DOSAGE

FORMS, PER

ORAL YEARS

			Zolpidem	C	

Date:09/05/03ISR Number: 4186426-2Report Type:Expedited (15-DaCompany Report #M0815-2003
Age:45 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Hepatic Steatosis	Health Professional	Mirtazapine	PS		ORAL	30 MG ORAL	1 MON
			Pimozide	SS		ORAL	2 MG ORAL	5 MON
			Valproate Sodium	SS		ORAL	1100 MG ORAL	2 MON
			Lithium	SS			DF	

Date:09/08/03ISR Number: 4185656-3Report Type:Expedited (15-DaCompany Report #LBID00203002548
Age:66 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hyperparathyroidism Primary	Literature Health Professional	Lithobid (Lithium Carbonate)	PS		ORAL	1200 MG DAILY	
	Parathyroid Tumour Benign						PO, 1200 MG	

DAILY PO

Date:09/08/03ISR Number: 4185657-5Report Type:Expedited (15-DaCompany Report #LBID00203002547
Age:58 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blood Calcium Hyperparathyroidism Primary Parathyroid Tumour Benign	Literature Health Professional	Lithobid (Lithium Carbonate)	PS		ORAL	450 MG DAILY PO, 450 MG DAILY PO	

Date:09/08/03ISR Number: 4185658-7Report Type:Expedited (15-DaCompany Report #LBID00203002546
Age:47 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blood Calcium Hyperparathyroidism Primary Parathyroid Tumour Benign	Literature Health Professional	Lithobid (Lithium Carbonte)	PS		ORAL	1600 MG DAILY PO, 1600 MG DAILY PO	

Date:09/08/03ISR Number: 4185739-8Report Type:Expedited (15-DaCompany Report #LBID00203002552
Age:51 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hypercalcaemia Hyperparathyroidism Primary Hyperplasia Parathyroid Disorder Parathyroid Tumour Benign	Literature Health Professional	Lithobid (Lithium Carbonate)	PS		ORAL	600 MG DAILY PO	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/08/03ISR Number: 4185741-6Report Type:Expedited (15-DaCompany Report #LBID00203002551
Age:58 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hypercalcaemia	Literature	Lithobid (Lithium					
	Hyperparathyroidism	Health	Carbonate)	PS		ORAL	300 MG QD PO,	
	Primary	Professional					300 MG QD PO	
	Hyperplasia							
	Parathyroid Disorder							
	Parathyroid Tumour Benign							

Date:09/08/03ISR Number: 4185743-XReport Type:Expedited (15-DaCompany Report #LBID00203002553
Age:63 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hyperparathyroidism	Literature	Lithobid (Lithium					
	Primary	Health	Carbonate)	PS		ORAL	900 MG DAILY	
	Hyperplasia	Professional					PO, 900 MG	
	Parathyroid Disorder						DAILY PO	
	Parathyroid Tumour Benign							

Date:09/08/03ISR Number: 4185768-4Report Type:Expedited (15-DaCompany Report #LBID00203002544
Age:56 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Adenoma Benign	Literature	Lithobid (Lithium					
	Hyperparathyroidism	Health	Carbonate)	PS		ORAL	900 MG DAILY,	
	Primary	Professional					PO	

Date:09/08/03ISR Number: 4185876-8Report Type:Expedited (15-DaCompany Report #LBID00203002542
Age:59 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Goitre Hyperparathyroidism Primary Parathyroid Tumour Benign	Literature Health Professional	Lithobid (Lithium Carbonate)	PS		ORAL	300 MG QD PO, 300 MG QD PO	

Date:09/08/03ISR Number: 4185878-1Report Type:Expedited (15-DaCompany Report #LBID00203002543
Age:61 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hyperparathyroidism Primary Parathyroid Tumour Benign	Literature Health Professional	Lithobid (Lithium Carbonate)	PS		ORAL	600 MG DAILY PO, 600 MG DAILY PO	

Date:09/08/03ISR Number: 4186049-5Report Type:Expedited (15-DaCompany Report #LBID00203002550
Age:61 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hyperparathyroidism Primary Parathyroid Tumour Benign	Literature Health Professional	Lithobid (Lithium Carbonate)	PS		ORAL	900 MG DAILY PO, 900 MG DAILY PO	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/08/03ISR Number: 4186050-1Report Type:Expedited (15-DaCompany Report #LBID00203002539
Age:66 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hyperparathyroidism Primary	Literature Health Professional	Lithobid (Lithium Carbonate)	PS		ORAL	900 MG DAILY PO, 900 MG DAILY PO	

Date:09/08/03ISR Number: 4186051-3Report Type:Expedited (15-DaCompany Report #LBID00203002540
Age:57 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hyperparathyroidism Primary	Literature Health Professional	Lithobid (Lithium Carbonate)	PS		ORAL	600 MG DAILY PO, 600 MG DAILY PO	

Date:09/08/03ISR Number: 4186052-5Report Type:Expedited (15-DaCompany Report #LBID00203002541
Age:74 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hyperparathyroidism Primary	Literature Health Professional	Lithobid (Lithium Carbonate)	PS		ORAL	300 MG QD PO, 300 MG QD PO	

Date:09/08/03ISR Number: 4186062-8Report Type:Expedited (15-DaCompany Report #LBID00203002545
Age:60 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hyperparathyroidism Primary	Literature Health Professional	Lithobid (Lithium Carbonate)	PS		ORAL	600 MG DAILY	PO, 600 MG DAILY PO

Date:09/08/03ISR Number: 4186064-1Report Type:Expedited (15-DaCompany Report #LBID00203002549
Age:34 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Adenoma Benign Hyperparathyroidism	Literature Health Professional	Lithobid (Lithium Carbonate)	PS		ORAL	600 MG DAILY	PO, 600 MG DAILY PO

Date:09/10/03ISR Number: 4185825-2Report Type:Direct Company Report #CTU 201551
Age:39 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Pharmaceutical Product Complaint		Lithium Carbonate Er 300mg Able Labs	PS	Able Labs	ORAL	1 TAB 2 TABS	ORAL

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/11/03ISR Number: 4183377-4Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0405145A
Age:52 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Balance Disorder Blood Glucose Increased	Health Professional	Eskalith	PS	Glaxosmithkline	UNKNOWN	1350MG See dosage text	13 YR
	Chest Pain		Vasotec	SS		UNKNOWN	5MG Per day	3 MON
	Chills		Verapamil	SS		UNKNOWN	180MG Per day	
	Coordination Abnormal		Zestril	SS		UNKNOWN	5MG Per day	1 MON
	Coronary Artery Occlusion		Metformin	C		UNKNOWN		
	Diabetes Mellitus		Glyburide	C		UNKNOWN		
	Inadequate Control		Aspirin	C	Glaxosmithkline			
	Difficulty In Walking		Depakote	C		1000MG Per day		
	Dizziness							
	Dyskinesia							
	Dyspnoea							
	Eye Pain							
	Gait Disturbance							
	Headache							
	Hypoaesthesia							
	Lethargy							
	Malaise							
	Movement Disorder							
	Muscle Atrophy							
	Muscle Spasms							
	Muscular Weakness							
	Myalgia							
	Nausea							
	Palpitations							
	Polyneuropathy							
	Tension							
	Therapeutic Agent							
	Toxicity							
	Tremor							
	Vision Blurred							
	Vomiting							

Date:09/11/03ISR Number: 4183394-4Report Type:Expedited (15-DaCompany Report #JP-GLAXOSMITHKLINE-B0307825A
Age:42 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - 42 DAY	Alanine Aminotransferase		Paxil	PS	Glaxosmithkline	ORAL		
Initial or Prolonged	Increased		Limas	SS	Glaxosmithkline	ORAL	800MG per day	35 DAY
	Aspartate		Ethyl Loflazepate	SS		ORAL		35 DAY
	Aminotransferase		Cefdinir	SS		ORAL	300MG per day	2 DAY
	Increased		Aldioxa	SS		ORAL	3G per day	2 DAY
	Blood Lactate		Acetaminophen	SS	Glaxosmithkline	ORAL	200MG per day	1 DAY
	Dehydrogenase Increased		Kakkon-To	C		ORAL		
	Eosinophil Count Increased							
	Hepatic Function Abnormal							
	Lymphadenopathy							
	Pyrexia							
	Rash Generalised							
	Toxic Skin Eruption							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/11/03ISR Number: 4183395-6Report Type:Expedited (15-DaCompany Report #AU-GLAXOSMITHKLINE-B0308406A
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anaphylactic Reaction Bronchospasm Urticaria		Quilonorm	PS	Glaxosmithkline	ORAL	450MG Twice per day	

Date:09/11/03ISR Number: 4187357-4Report Type:Direct Company Report #CTU 201604
Age:32 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Chest Pain Pericarditis		Clozapine Lithium (Roxane) Lithium (Roxane) Pepcid	PS SS SS SS	 Roxane Roxane		SEE IMAGE SEE IMAGE SEE IMAGE	

Date:09/15/03ISR Number: 4189780-0Report Type:Expedited (15-DaCompany Report #03-09-1062
Age:53 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Condition Aggravated Dehydration Schizophrenia Therapeutic Agent Toxicity Treatment Noncompliance	Health Professional Other	Clozapine Tablets-Ivax Pharmaceuticals, Inc. Lithium	PS SS	Ivax Pharmaceuticals, Inc.	ORAL	900MG QD ORAL	

Date:09/17/03ISR Number: 4188746-4Report Type:Expedited (15-DaCompany Report #AU-GLAXOSMITHKLINE-B0308406A
Age:42 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Hypersensitivity Hypersensitivity Medication Error Pyrexia Rash		Quilonorm	PS	Glaxosmithkline	ORAL	450MG Twice per day	

Date:09/19/03ISR Number: 4189287-0Report Type:Expedited (15-DaCompany Report #DE-GLAXOSMITHKLINE-D0041890A
Age:50 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Fatigue		Quilonum	PS	Glaxosmithkline	ORAL	200MG Per day	
	Intentional Misuse		Amitriptylin	SS		ORAL	5TAB Per day	
	Suicide Attempt		Ass Ratiopharm 500	SS	Glaxosmithkline	ORAL	10000MG Per day	

Date:09/22/03ISR Number: 4190399-6Report Type:Expedited (15-DaCompany Report #JP-GLAXOSMITHKLINE-B0307825A
Age:42 YR Gender:Female I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Alanine Aminotransferase Increased Aspartate Aminotransferase Increased

	Blood Lactate Dehydrogenase Increased						
	Eosinophil Count	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Increased		Paxil	PS	Glaxosmithkline	ORAL	42 DAY
	Hepatic Function Abnormal		Limas	SS	Glaxosmithkline	ORAL	800MG per day 35 DAY
	Lymphadenopathy		Cefdinir	SS		ORAL	300MG per day 2 DAY
	Oral Discomfort		Acetaminophen	SS	Glaxosmithkline	ORAL	200MG per day 1 DAY
	Pruritus		Aldioxa	SS		ORAL	3G per day 2 DAY
	Pyrexia		Ethyl Loflazepate	C		ORAL	35 DAY
	Rash Generalised		Kakkon-To	C		ORAL	
	Toxic Skin Eruption						

Date:09/22/03ISR Number: 4193990-6Report Type:Direct Company Report #CTU 202169
Age:31 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Required	Micturition Urgency		Lithium Carbonate	PS		ORAL	1200 MG ORAL
Intervention to Prevent Permanent Impairment/Damage	Polydipsia		Risperidone	C			
	Polyuria		Trazadone	C			

Date:09/22/03ISR Number: 4195028-3Report Type:Direct Company Report #CTU 202155
Age:54 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Life-Threatening	Confusional State		Lithium Carbonate				
Hospitalization - Initial or Prolonged	Haemodialysis		300 Mg	PS		ORAL	600 MG TWICE
	Lethargy						DAILY ORAL
Required	Mental Status Changes		Piroxicam 20 Mg	SS		ORAL	20 MG ONCE

Intervention to DAILY ORAL Prevent Permanent Impairment/Damage			Lisinopril	C		

Date:09/23/03ISR Number: 4195226-9Report Type:Direct Company Report #USP 080294
Age: Gender:Not SpecifiI/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
	Medication Error		Lithium Carb Lithium Carbonate	PS	Roxane	
300 MG TAB						
			Nortriptyline	SS	Schein	
50 MC GAP						

Date:09/23/03ISR Number: 4195289-0Report Type:Direct Company Report #USP E080031
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Medication Error		Lithium Carb	PS	Various	
300 MG						
			Cogentin	SS	Msd	
2 MG TABLET						

Date:09/23/03ISR Number: 4196931-0Report Type:Expedited (15-DaCompany Report #B0308860A
Age:63 YR Gender:Male I/FU:I

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

		Blood Fibrinogen Increased Blood Pressure Diastolic Increased Body Temperature Decreased Brain Oedema Cerebral Infarction Coma Coordination Abnormal Delirium Depressed Level Of Consciousness Diabetes Insipidus Diet Refusal Drug Level Below Therapeutic Drug Toxicity Dry Skin Electrocardiogram Normal Electrocardiogram Qt Prolonged Electrocardiogram T Wave Inversion Fibrin D Dimer Increased Fibrin Degradation Products Increased Heart Rate Increased Hypovolaemia Nervous System Disorder Nystagmus Psychomotor Agitation Pupils Unequal Respiratory Rate Increased Subarachnoid Haemorrhage Superior Sagittal Sinus Thrombosis Thrombocytopenia Thrombosis Tremor	Report Source Foreign Literature Health Professional	Product Lithium Carbonate (Formulation Unknown) (Generic) (Lithium Carbonate) Olanzapine Risperidone	Role PS C C	Manufacturer	Route	Dose	Duration
10	YR							

Date:09/24/03ISR Number: 4198907-6Report Type:Expedited (15-DaCompany Report #03P-167-0233597-00
Age:49 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Sodium Decreased	Foreign	Epilim (Sodium					
	Drug Toxicity	Health	Valproate) (Sodium					
	Hypomania	Professional	Valproate) (Sodium					
	Nausea		Valproate)	PS			800 MG, 1 IN	1 D, UNKNOWN
	Polydipsia		Lithium Carbonate	SS				
	Vomiting							
			Diazepam	C				
			Olanzapine	C				
			Carbamazepine	C				

Date:09/25/03ISR Number: 4200235-7Report Type:Expedited (15-DaCompany Report #2003033768
Age:80 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Potassium Increased Confusional State Overdose Therapeutic Agent Toxicity	Foreign Health Professional	Lithium (Lithium) Metformin Hydrochloride (Metformin Hydrochloride) Dipyridamole (Dipyridamole) Furosemide (Furosemide) Glibenclamide (Glibenclamide)	PS C C C		ORAL		

Date:09/26/03ISR Number: 4199514-1Report Type:Expedited (15-DaCompany Report #2003038638
Age:30 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Alanine Aminotransferase Increased Aspartate Aminotransferase Increased Blood Albumin Decreased Blood Bilirubin Increased Blood Creatine Phosphokinase Increased Blood Creatinine Increased Blood Urea Increased Cerebral Atrophy Confusional State Consciousness Fluctuating Delirium Delusional Disorder, Unspecified Type Hallucination, Auditory Hyperpyrexia Hypertension	Literature Health Professional	Lithium (Lithium) Risperidone (Risperidone) Olanzapine (Olanzapine) Valproic Acid (Valproic Acid)	PS SS C C			900 MG (BID)	

Insomnia
Lack Of Spontaneous
Speech
Motor Dysfunction
Muscle Rigidity
Neuroleptic Malignant
Syndrome
Tachycardia
Tongue Spasm
Tremor
White Blood Cell Count
Increased

Date:09/29/03ISR Number: 4196813-4Report Type:Expedited (15-DaCompany Report #DE-GLAXOSMITHKLINE-D0041998A
Age:70 YR Gender:Female I/FU:I

Outcome PT
Other Bradycardia
Overdose

		Somnolence Suicide Attempt					
			Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
				Quilonum Retard	PS	Glaxosmithkline	ORAL
20TAB	Single						
dose							
				Zopiclon	SS		ORAL
40TAB	Single						
dose							

Date:09/29/03ISR Number: 4202051-9Report Type:Expedited (15-DaCompany Report #200304797
Age:21 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Death	Alanine Aminotransferase	Literature	Unspecified			
Hospitalization -	Increased	Other	Acetaminophen			
Initial or Prolonged	Aspartate		Product	PS		ORAL
PO						
Required	Aminotransferase		Lithium	SS		ORAL
PO						
Intervention to	Increased		Risperidone	SS		ORAL
PO						
Prevent Permanent	Blood Bilirubin Increased					
Impairment/Damage	Blood Creatine					
	Phosphokinase Increased					
	Blood Creatinine					
	Increased					
	Blood Lactate					
	Dehydrogenase Increased					
	Blood Ph Decreased					
	Coma					
	Completed Suicide					
	International Normalised					
	Ratio Increased					
	Liver Function Test					
	Abnormal					
	Overdose					
	Respiratory Rate					
	Increased					
	Restlessness					
	Tachypnoea					

Urine Output Decreased

Date:09/30/03ISR Number: 4198137-8Report Type:Direct Company Report #USP 080223
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Medication Error		Chlordiazepoxide	PS	Url		CAPSULES	
			Lithium Carbonate	SS	Url		CAPSULES	

Date:09/30/03ISR Number: 4198146-9Report Type:Direct Company Report #USP 080228
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Medication Error		Lithotabs	PS	Salvay		TABLETS	
			Lithobid	SS	Ciba		TABLET	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/30/03ISR Number: 4199138-6Report Type:Direct Company Report #USP 080371
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Medication Error		Lithium Citrate Syrup	PS	Roxane	SYRUP		

Date:09/30/03ISR Number: 4200148-0Report Type:Direct Company Report #CTU 202854
Age:79 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Bradycardia		Lithium	PS			300 MG, TID,	
Hospitalization -	Drug Toxicity						BY MOUTH	
Initial or Prolonged			Cyanocobalamin	C				
			Fluticasone Prop	C				
			Clotrimazole	C				
			Aloh/Mgoh/Simth	C				
			Salicylic Acid	C				
			Polyvinyl Alcohol	C				
			Timolol Maleate	C				
			Lamotrigine (Lamictal)	C				
			..	C				

Date:10/01/03ISR Number: 4204780-XReport Type:Expedited (15-DaCompany Report #LBID00203002827
Age:30 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Alanine Aminotransferase Increased	Literature Health	Lithium Carbonate (Lithium Carbonate)	PS		ORAL	450 MG BID PO	1 WK
	Aspartate Aminotransferase Increased Blood Albumin Decreased Blood Bilirubin Increased	Professional	Risperidone (Risperidone)	SS		ORAL	DAILY PO	1 WK

	Blood Creatine Phosphokinase Increased
	Blood Creatinine Increased
	Blood Urea Increased
	Cerebral Atrophy
	Delirium
	Hallucination, Auditory
	Neuroleptic Malignant Syndrome
	Social Avoidant Behaviour
	White Blood Cell Count Increased

Date:10/02/03ISR Number: 4199742-5Report Type:Expedited (15-DaCompany Report #CH-BRISTOL-MYERS SQUIBB COMPANY-12365722
Age:53 YR Gender:Male I/FU:F

Outcome	PT
Life-Threatening	Asthenia
Hospitalization - Initial or Prolonged	Cerebral Atrophy
	Circulatory Collapse
Disability	Convulsion
	Diarrhoea
	Drug Interaction

	Drug Level Decreased Dysphagia Heart Rate Increased	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Hypoventilation		Trittico	PS	Apothecon	ORAL	Daily dose: "100 mg or more", takes 100mg day in evening.On
	Myoclonus Nervous System Disorder Paraesthesia Pneumonia Aspiration						
	Pyrexia		Anafranil	SS		ORAL	
	Self-Medication		Lithiofor	SS		ORAL	taken for months, 2 x 600 mg daily, stopped on 11-Jul-2003
	Serotonin Syndrome Shock Tremor						
			Effortil	C			5 mg 1-2x daily-taken for months, stopped on 30-Jun-2003

Date:10/03/03ISR Number: 4204078-XReport Type:Direct Company Report #CTU 203157
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - PO PTA Initial or Prolonged	Medication Error		Lithium	PS		ORAL	
	Tremor		Synthroid	C			
			Remeron	C			

			Zyprexa	C		
			Xanax	C		

Date:10/03/03ISR Number: 4204130-9Report Type:Direct Company Report #CTU 203162
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Drug Level Increased		Lithium	PS		ORAL	600 MG PO BID	Initial or Prolonged
PTA								
			Robaxin	C				
			Levoxyl	C				
			Senokot	C				
			Xanax	C				
			Tigan	C				
			Decadron	C				
			Protonix	C				
			Oxycontin	C				
			Vicodin	C				
			Wellbutrin	C				

Date:10/03/03ISR Number: 4204597-6Report Type:Expedited (15-DaCompany Report #2003039811
Age:21 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Literature	Lithium (Lithium)	PS		ORAL	ORAL	
	Drug Level Increased	Health Professional	Paracetamol (Paracetamol)	SS		ORAL	ORAL	
			Risperidone (Risperidone)	SS		ORAL	ORAL	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/03/03ISR Number: 4204601-5Report Type:Expedited (15-DaCompany Report #2003039908
Age:50 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardio-Respiratory Arrest	Literature	Lithium					
Other	Completed Suicide	Health Professional	(Lithium)	PS		ORAL	ORAL	

Date:10/03/03ISR Number: 4204644-1Report Type:Expedited (15-DaCompany Report #2003039841
Age:27 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Literature	Lithium (Lithium)	PS		ORAL	ORAL	
	Drug Level	Health Professional	Valproic Acid (Valproic Acid)	SS		ORAL	ORAL	

Date:10/03/03ISR Number: 4204648-9Report Type:Expedited (15-DaCompany Report #2003039807
Age:53 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Literature	Lithium (Lithium)	PS		ORAL	ORAL	
	Intentional Misuse	Health Professional	Orlistat (Orlistat)	SS		ORAL	ORAL	
	Poisoning Deliberate		All Other Therapeutic Products	SS		ORAL	ORAL	

Date:10/03/03ISR Number: 4205780-6Report Type:Expedited (15-DaCompany Report #2003039911
Age:86 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Death	Literature	Lithium (Lithium)	PS		ORAL	ORAL	

Other	Drug Interaction Medication Error	Health Professional					

Date:10/03/03ISR Number: 4205783-1Report Type:Expedited (15-DaCompany Report #2003039910
Age:74 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Death	Literature Health Professional	Lithium (Lithium)	PS		ORAL	ORAL	

Date:10/03/03ISR Number: 4206007-1Report Type:Expedited (15-DaCompany Report #2003039906
Age:34 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Death Medication Error	Literature Health Professional	Lithium (Lithium)	PS		ORAL	ORAL	

Date:10/03/03ISR Number: 4206010-1Report Type:Expedited (15-DaCompany Report #2003039907
Age:41 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Death	Literature Health Professional	Lithium (Lithium)	PS		ORAL	ORAL	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/03/03ISR Number: 4206016-2Report Type:Expedited (15-DaCompany Report #2003039842
Age:44 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Literature	Sertraline					
		Health Professional	(Sertraline)	PS				
			Lithium (Lithium)	SS				
			Valproic Acid (Valproic Acid)	SS				
			All Other Therapeutic Products	SS				

Date:10/03/03ISR Number: 4206020-4Report Type:Expedited (15-DaCompany Report #2003039913
Age:51 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Literature	Lithium (Lithium)	PS		ORAL	ORAL	
		Health Professional	Venlafaxine (Venlafaxine)	SS		ORAL	ORAL	

Date:10/03/03ISR Number: 4206351-8Report Type:Expedited (15-DaCompany Report #2003039909
Age:51 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Death	Literature	Lithium (Lithium)	PS		ORAL	ORAL	
		Health Professional						

Date:10/03/03ISR Number: 4206352-XReport Type:Expedited (15-DaCompany Report #2003039912
Age:32 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Literature	Lithium (Lithium)	PS		ORAL	ORAL	

	Drug Level Increased	Health Professional	Valproic Acid (Valproic Acid)	SS		ORAL
ORAL						

Date:10/06/03ISR Number: 4201877-5Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0414191A
Age:60 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Disability	Cardiomyopathy		Eskalith Cr	PS	Glaxosmithkline	ORAL	10 YR
Other							

Date:10/06/03ISR Number: 4205475-9Report Type:Expedited (15-DaCompany Report #2003033768
Age:80 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Blood Potassium Increased	Foreign	Lithium (Lithium)	PS		ORAL	ORAL
	Drug Toxicity Hypoglycaemia	Health Professional	Glibenclamide (Glibenclamide)	SS		ORAL	ORAL
	Overdose		Metformin Hydrochloride (Metformin Hydrochloride)	C			
			Dipyridamole (Dipyridamole)	C			
			Furosemide				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

(Furosemide) C

Date:10/07/03ISR Number: 4202506-7Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0427896A
Age:27 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Pulmonary Embolism		Eskalith	PS	Glaxosmithkline	ORAL	900MG Per day	MON
Hospitalization - Initial or Prolonged			Lamivudine	SS	Glaxosmithkline			
			Lithobid	C	Glaxosmithkline			
			Risperdal	C				
			Lexapro	C				

Date:10/07/03ISR Number: 4206807-8Report Type:Expedited (15-DaCompany Report #2003040902
Age:54 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Mania	Health	Lithium (Lithium)	PS		ORAL	ORAL	
	Self-Injurious Ideation	Professional	Ziprasidone Hydrochloride (Ziprasidone Hydrochloride)	C				

Date:10/08/03ISR Number: 4206892-3Report Type:Direct Company Report #USP 080186
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Medication Error		Lithonate	PS	Solvay		CAPSULES	
			Lithobid	SS	Ciba		TABLET, CONTROLLED RELEASE	

Date:10/08/03ISR Number: 4207934-1Report Type:Expedited (15-DaCompany Report #LBID00203002814
Age:35 YR Gender:Female I/FU:I

Outcome	PT
Death	Agitation
	Aspartate
	Aminotransferase
	Increased
	Blood Creatine
	Phosphokinase Increased
	Blood Lactate
	Dehydrogenase Increased
	Cardiac Failure
	Cardiomegaly
	Catheter Sepsis
	Dyspnoea
	Electrocardiogram T Wave
	Inversion
	Gastritis Erosive
	Gastrointestinal
	Haemorrhage
	Haemoglobin Decreased
	Hypertonia
	Hypotension
	Intentional Misuse
	Neuroleptic Malignant
	Syndrome

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Oedema Pyrexia Rhabdomyolysis	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Tachycardia Tachypnoea	Foreign Literature	Lithobid (Lithium Carbonate)	PS		ORAL	DAILY PO	4 DAY
	Ventricular Dysfunction Ventricular Hypokinesia	Health Professional Other	Thioridzine (Thioridazine)	SS		ORAL	DAILY PO	4 DAY

Date:10/08/03ISR Number: 4207959-6Report Type:Expedited (15-DaCompany Report #B0310504A
Age:32 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Alanine Aminotransferase Increased Arthralgia Aspartate Aminotransferase Increased Blood Amylase Increased Blood Calcium Increased Blood Chloride Decreased Blood Creatine Phosphokinase Increased Blood Glucose Increased Blood Potassium Decreased Blood Pressure Systolic Increased Blood Urine Present Cerebellar Ataxia Coma Glomerulosclerosis Haemodialysis Hyperreflexia Lipase Increased Muscle Rigidity Nephritis Interstitial Overdose Parkinsonism Platelet Count Increased Polyuria	Foreign Literature Health Professional	Eskalith (Formulation Unknown) (Lithium Carbonate)	PS					

Rash
Renal Failure
Respiratory Rate
Increased
Sinus Tachycardia
Somnolence
Vomiting
White Blood Cell Count
Increased

Date:10/09/03ISR Number: 4205055-5Report Type:Expedited (15-DaCompany Report #GB-GLAXOSMITHKLINE-B0310598A
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Accidental Overdose		Lithium	PS	Glaxosmithkline		2	WK
	Brain Damage							
	Cognitive Disorder							
	Emotional Disorder							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/09/03ISR Number: 4208745-3Report Type:Expedited (15-DaCompany Report #S03-USA-04093-01
Age:27 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Deep Vein Thrombosis Pulmonary Embolism	Health Professional	Lexapro (Escitalopram)	PS		ORAL	10 MG QD PO	
			Lexapro (Escitalopram)	SS		ORAL	20 MG QD PO	
			Lexapro (Escitalopram)	SS		ORAL	10 MG QD PO	
			Risperdal (Risperidone)	SS			2.5 MG QD	
			Lithium	SS			1500 MG QD	

Date:10/09/03ISR Number: 4208928-2Report Type:Direct Company Report #CTU 203553
Age:38 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Dehydration Large Intestinal Obstruction Shock Vomiting		Lithium Quetiapine Gabapentin Clonazepam	PS SS SS SS				

Date:10/10/03ISR Number: 4208637-XReport Type:Expedited (15-DaCompany Report #B0310184A
Age:45 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death Hospitalization - Initial or Prolonged	Acute Respiratory Distress Syndrome Delirium Drug Level Increased Haemodialysis	Literature Health Professional	Lithium Salt (Formulation Unknown) (Lithium Salt)	PS		ORAL	450 MG / THREE TIMES	

		Hyponatraemia						
PER DAY /								
		Intentional Misuse						
ORAL	3 YR							
		Lethargy			Fluoxetine	C		
		Neuroleptic Malignant Syndrome						
		Renal Failure Acute						
		Rhabdomyolysis						

Date:10/10/03ISR Number: 4208656-3Report Type:Expedited (15-DaCompany Report #03P-056-0230582-00
Age:71 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Life-Threatening	Anaemia Macrocytic	Foreign	Vercyte (Pipobroman)				
Hospitalization -	Atrioventricular Block	Health	(Pipobroman)	PS		ORAL	1 DOSAGE
Initial or Prolonged	Complete	Professional					FORMS, PER
	Circulatory Collapse						ORAL
	Dehydration		Lithium	SS		ORAL	2 DOSAGE
	General Physical						FORMS, PER
	Condition Abnormal						ORAL YR
			Madopar	SS		ORAL	125 MG, 2 IN
							1 D, PER ORAL YR
			Nifedipine	SS		ORAL	30 MG, PER
							ORAL YR
			Perindopril	SS		ORAL	2 DOSAGE
							FORMS, PER
							ORAL YR

			Bromazepam	SS		ORAL
1 DOSAGE FORMS, PER ORAL	YR					
			Zolpidem	C		

Date:10/10/03ISR Number: 4209306-2Report Type:Expedited (15-DaCompany Report #2003-DE-04462GD
Age:30 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Alanine Aminotransferase Increased	Literature	Lithium Carbonate (Lithium Carbonate)	PS			450 MG BID	
	Aspartate Aminotransferase Increased Blood Albumin Decreased Blood Bilirubin Increased Blood Creatinine Increased Blood Pressure Increased Body Temperature Increased Cerebral Atrophy Delirium Depressed Level Of Consciousness Hallucination, Auditory Heart Rate Increased Lack Of Spontaneous Speech Muscle Contractions Involuntary Muscle Rigidity Neuroleptic Malignant Syndrome Tongue Disorder Tremor White Blood Cell Count Increased		Risperidone (Risperidone)	SS				

Date:10/10/03ISR Number: 4209744-8Report Type:Direct Company Report #USP 080778
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Medication Error		Lithium	PS	Roxane	CAP		
			Lithium	SS	Solvay	CAP		

Date:10/10/03ISR Number: 4209856-9Report Type:Direct Company Report #USP 080744
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Medication Error		Lithium 150 Prescribed	PS	Various	150 MG TAB		
			Lithonate 300 Mg	SS	Solvay	TAB		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/14/03ISR Number: 4207815-3Report Type:Expedited (15-DaCompany Report #DE-GLAXOSMITHKLINE-D0042135A
Age:52 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Intentional Misuse Suicide Attempt		Quilonum Retard	PS	Glaxosmithkline	ORAL	50TAB Single dose	1 DAY

Date:10/14/03ISR Number: 4209461-4Report Type:Expedited (15-DaCompany Report #2003034801
Age:52 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Diabetic Hyperglycaemic	Health	Geodon (Ziprasidone)	PS		ORAL	10 MG (DAILY), ORAL	
Hospitalization - Initial or Prolonged	Coma	Professional Company Representative	Lithium (Lithium) (Lithium)	SS		ORAL	900 MG (BID), ORAL	
			Bupropion Hyrochloride (Bupropion Hydrochloride)	C				
			Anti-Diabetics	C				

Date:10/14/03ISR Number: 4210148-2Report Type:Direct Company Report #CTU 203830
Age:56 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	Balance Disorder Drug Toxicity Tremor		Lithium Cap 300 Mg	PS		ORAL	TAKE 2 CAPS PO Q AM 2 CAPS Q PM	

Impairment/Damage

Date:10/14/03ISR Number: 4210149-4Report Type:Direct Company Report #CTU 203831
Age:72 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged AND Required Intervention to Prevent Permanent Impairment/Damage	Blood Creatinine Increased Blood Urea Increased Dehydration Dizziness Postural Impaired Self-Care Oral Intake Reduced Thirst		Lithium	PS			300 MG Q AM 600 MG Q PM	

Date:10/15/03ISR Number: 4211749-8Report Type:Expedited (15-DaCompany Report #2003018220
Age:20 YR Gender:Female I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Blood Creatine Phosphokinase Increased
Other	Convulsion Drug Interaction Potentiation Electrocardiogram Qrs Complex Shortened Hypoxia

		Intentional Misuse Pneumonia Aspiration Ventricular Tachycardia	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
			Health Professional	Geodon (Ziprasidone)	PS		ORAL
3.36 GRAM, ORAL							
				Quetiapine Fumarate (Quetiapine Fumarate)	SS		
12 GRAM							
				Lithium (Lithium)	SS		

Date:10/16/03ISR Number: 4209776-XReport Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0303163A
Age:65 YR Gender:Male I/FU:F

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Hospitalization - Initial or Prolonged		Adenoma Benign		Raniplex	PS	Glaxosmithkline	ORAL
		Beta Globulin Increased		Depamide	SS		ORAL
300MG per day							
		Blood Creatinine Increased		Teralithe	SS	Glaxosmithkline	ORAL
1500MG per day	29 YR						
		Blood Parathyroid Hormone Increased		Tadenan	SS		ORAL
100MG per day							
				Omix	SS		ORAL
.4MG per day	1 YR						
		Cholelithiasis Creatinine Renal Clearance Decreased Drug Toxicity Hyperparathyroidism Nephrocalcinosis Nephrolithiasis Renal Cyst Renal Failure					

Date:10/17/03ISR Number: 4210959-3Report Type:Expedited (15-DaCompany Report #WAES 0310CHE00016
Age:68 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Blood Creatinine	Health	Vioxx	PS		ORAL		
8 DAY								
Initial or Prolonged	Increased	Professional	Carbamazepine	SS	Merck & Co., Inc	ORAL		
	Blood Pressure Decreased		Lithium Carbonate	SS		ORAL		
	Drug Interaction		Mirtazapine	C		ORAL		
	Drug Level Increased		Pipamperone					
	Electrocardiogram		Hydrochloride	C		ORAL		
	Abnormal		Zopiclone	C		ORAL		
	Headache							
	Malaise							
	Sinus Bradycardia							
	Tremor							
	Vomiting							

Date:10/20/03ISR Number: 4212044-3Report Type:Expedited (15-DaCompany Report #PHBS2003CH11264
Age:68 YR Gender:Female I/FU:I

Outcome	PT
Hospitalization -	Blood Creatinine
Initial or Prolonged	Increased
	Drug Interaction
	Drug Level Increased
	Electrocardiogram T Wave
	Inversion
	Headache

	Hypotension Malaise Sinus Bradycardia	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Tremor Vomiting		Tegretol Cr	PS	Novartis Sector: Pharma	ORAL	400 mg/day
			Priadel	SS			UNKNOWN 400 mg/day
			Vioxx	SS			UNKNOWN 50 mg/day 11520MIN
			Dipiperon	SS			UNKNOWN 60 mg/day
			Mirtazapine	C			UNKNOWN
			Imovane	C			UNKNOWN

Date:10/20/03ISR Number: 4214684-4Report Type:Expedited (15-DaCompany Report #2003034756
Age:50 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Condition Aggravated Confusional State Dehydration Drug Toxicity Gait Disturbance Lethargy Schizoaffective Disorder	Health Professional	Lithium (Lithium) Bupropion (Bupropion) Lorazepam (Lorazepam) Olanzapine (Olanzapine)	PS C C C		ORAL ORAL	

Date:10/21/03ISR Number: 4215699-2Report Type:Expedited (15-DaCompany Report #2003111084
Age:54 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Other	Depression Drug Ineffective	Health Professional	Zoloft (Sertraline) Lithium (Lithium) Venlafaxine Hydrochloride Olanzapine	PS SS C C			900 MG (TID

			Clonzepam	C		
			Mirtazapine	C		

Date:10/23/03ISR Number: 4215715-8Report Type:Direct Company Report #CTU 204395
Age:55 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Life-Threatening	Dysarthria		Lithium	PS		300 MG, BID , BY MOUTH
Hospitalization - Initial or Prolonged	Gait Disturbance		Aripiprazole (Abilify)	C		
Required Intervention to Prevent Permanent Impairment/Damage			Therapeutic Multivitamin	C		
			Lisinopril	C		
			Simvastatin	C		
			Clonazepam (Klonopin)	C		
			Metformin Hcl	C		
			Lithium Carbonate	C		
			Ranitidine Hcl	C		
			Insulin , Human Reg, Novolin-R	C		
			Ranitidine	C		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/23/03ISR Number: 4216795-6Report Type:Direct Company Report #CTU 204443
Age:46 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Diarrhoea		Lithium	PS		ORAL	1,200 UG PO	QHS
	Drug Level Above Therapeutic		Hydroxizine	C				
	Fatigue		Sertraline	C				
	Nausea		Quetiapine	C				
	Photopsia		Furosemide	C				
	Treatment Noncompliance		Ranitidine	C				
	Tremor		Clotrimazole	C				
	Vomiting		Nifedipine	C				
			Loperamide	C				
			Bupropion	C				

Date:10/24/03ISR Number: 4219831-6Report Type:Expedited (15-DaCompany Report #2003019160
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain Upper	Consumer	Nardil (Phenelzine Sulfate)	PS			37 MG (DAILY)	
	Anorgasmia							
	Drug Interaction		Quetiapine Fumarate (Quetiapine Fumarate)	SS			50 MG (DAILY)	
	Dry Mouth							
	Headache							
	Hypersomnia		Olanzapine (Olanzapine)	SS			900 MG (BID)	
	Insomnia							
	Mental Disorder		Lithium Carbonate (Lithium Carbonate)	SS				
	Nausea							
	Rapid Eye Movements Sleep Abnormal		Lamotrigine (Lamotrigine)	SS			50 MG	
	Salivary Gland Disorder		Novothyral (Levothyroxine Sodium, Liothyronine Sodium)	C				
	Skin Disorder							
	Weight Increased							

Date:10/24/03ISR Number: 4220040-5Report Type:Expedited (15-DaCompany Report #2003040902
Age:54 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Confusional State Disturbance In Attention Mania Paranoia Self-Injurious Ideation Thinking Abnormal	Health Professional	Lithium (Lithium) Ziprasidone Hydrochloride (Ziprasidone Hydrochloride)	PS C		ORAL ORAL		

Date:10/24/03ISR Number: 4220042-9Report Type:Expedited (15-DaCompany Report #2003111631
Age:21 YR Gender:Female I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged Other	Basedow'S Disease Benign Breast Neoplasm Blood Pressure Decreased Cataract Drug Ineffective Mania Pharmaceutical Product Complaint

	Pharyngeal Operation Tonsillar Disorder						
		Report Source	Product	Role	Manufacturer	Route	Dose Duration
		Consumer	Lithium (Lithium)	PS			
			Nardil (Phenelzine Sulfate)	SS		ORAL	45 MG (TID), ORAL
			Cetirizine Hydrochloride (Cetirizine Hydrochloride)	C			
			Alprazolam (Alprazolam)	C			

Date:10/24/03ISR Number: 4220112-5Report Type:Expedited (15-DaCompany Report #KII-2002-0004115
Age:47 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged Other	Blood Creatinine Increased Blood Pressure Decreased Body Temperature Increased Depressed Level Of Consciousness Disorientation Intentional Misuse Intentional Self-Injury Liver Function Test Abnormal Loss Of Consciousness Mouth Haemorrhage Multiple Drug Overdose Neuroleptic Malignant Syndrome Pain Rales Respiratory Depression Salivary Hypersecretion Sinus Tachycardia Somnolence	Health Professional	Oxycontin Tablets (Oxycodone Hydrochloride) Cr Tablets	PS			
			Seroquel (Quetiapine)	SS			
			Acetaminophen (Paracetamol)	SS			
			Acetylsalicylic Acid (Acetylsalicylic Acid)	SS			
			Lithium (Lithium)	SS			
			Depakote (Valproate Semisodium)	SS			

Suicidal Ideation
White Blood Cell Count
Increased

Date:10/24/03ISR Number: 4220396-3Report Type:Expedited (15-DaCompany Report #2003UW13371
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Drug Interaction Encephalopathy	Health Professional	Seroquel Lithium	PS SS				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/26/03ISR Number: 4218016-7Report Type:Expedited (15-DaCompany Report #WAES 0310CHE00016
Age:68 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Blood Creatinine		Vioxx	PS		ORAL		8 DAY
Initial or Prolonged	Increased		Carbamazepine	SS	Merck & Co., Inc	ORAL		
	Blood Pressure Decreased		Lithium Carbonate	SS		ORAL		
	Creatinine Renal		Mirtazapine	C		ORAL		
	Clearance Decreased		Pipamperone					
	Drug Interaction		Hydrochloride	C		ORAL		
	Drug Level Increased		Zopiclone	C		ORAL		
	Electrocardiogram							
	Abnormal							
	Headache							
	Sinus Bradycardia							
	Tremor							
	Vomiting							

Date:10/27/03ISR Number: 4221114-5Report Type:Expedited (15-DaCompany Report #2003112216
Age:56 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Blood Potassium Decreased	Foreign	Norvasc (Amlodipine)	PS		ORAL		5 MG (DAILY),
Initial or Prolonged	Blood Sodium Decreased	Health						ORAL
	Catatonia	Professional	Lithium Carbonate					
	Drug Interaction		(Lithium Carbonate)	SS		ORAL		900 MG, ORAL
			Citalopram Hydrobromide (Citalopram					
			Hydrobromide)	SS		ORAL		20 MG, ORAL
			Trimipramine (Trimipramine)	SS		ORAL		25 MG, ORAL
			Oxazepam (Oxazepam)	C				
			Salutec (Hydrochlorothiazide , Ramipril)	C				
			Esomeprazole					

			(Esomeprazole)	C		
			Salvia (Salvia)	C		
			Insulin Injection, Isophane (Insulin Injection, Isophane)	C		

Date:10/28/03ISR Number: 4219561-0Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0431419A
Age:53 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Disability	Aphasia		Eskalith	PS	Glaxosmithkline	ORAL	450MG Twice per day	
	Depressed Level Of Consciousness		Seroquel	C				
	Muscle Rigidity		Depakote	C				
	Neuroleptic Malignant Syndrome		Xanax	C				
	Tonic Convulsion		Zoloft	C				
			Paxil	C	Glaxosmithkline			
			Klonopin	C				
			Zestril	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/28/03ISR Number: 4220467-1Report Type:Direct Company Report #CTU 204705
Age:24 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Depression		Prozac	PS		ORAL	1 PILL DAILY	
	Disturbance In Social					ORAL		
	Behaviour		Lithium	SS		ORAL	2 PILLS TWICE	
	Fatigue					DAILY ORAL		
	Feeling Abnormal							
	Hypersomnia							
	Impaired Work Ability							

Date:10/28/03ISR Number: 4222943-4Report Type:Expedited (15-DaCompany Report #2003034756
Age:50 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Confusional State	Health	Lithium (Lithium)	PS		ORAL		
Initial or Prolonged	Dehydration	Professional	Bupropion					
	Drug Toxicity		(Bupropion)	C				
	Gait Disturbance		Lorazepam					
	Lethargy		(Lorazepam)	C				
	Paranoia		Olanzapine					
	Psychomotor Hyperactivity		(Olanzapine)	C				
	Schizoaffective Disorder							

Date:10/31/03ISR Number: 4224938-3Report Type:Expedited (15-DaCompany Report #LBID00203003079
Age:47 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Depression	Literature	Lithium Carbonate	PS		ORAL		
SEE IMAGE	10 YR							
Initial or Prolonged	Drug Toxicity	Health						
	Electrocardiogram St-T	Professional						
	Segment Abnormal							
	Hyperthyroidism							

Scar
Thyroiditis
Treatment Noncompliance

Date:11/03/03ISR Number: 4227000-9Report Type:Expedited (15-DaCompany Report #2003-DE-05474GD
Age:21 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide Multiple Drug Overdose	Literature	Lithium Carbonate (Lithium Carbonate)	PS		ORAL	PO	
			Paracetamol (Paracetamol)	SS		ORAL	PO	
			Risperidone (Risperidone)	SS		ORAL	PO	

Date:11/03/03ISR Number: 4227002-2Report Type:Expedited (15-DaCompany Report #2003-DE-05237GD
Age:51 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Completed Suicide Multiple Drug Overdose	Literature	Lithium Carbonate (Lithium Carbonate)	PS		ORAL	PO	
			Venlafaxine	SS		ORAL	PO	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/03/03ISR Number: 4227004-6Report Type:Expedited (15-DaCompany Report #2003-DE-05234GD
Age:32 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Literature	Lithium Carbonate (Lithium Carbonate)	PS		ORAL	PO	
	Multiple Drug Overdose		Valproic Acid (Valproic Acid)	SS		ORAL	PO	

Date:11/03/03ISR Number: 4227007-1Report Type:Expedited (15-DaCompany Report #2003-DE-05233GD
Age:86 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Medication Error	Literature	Lithium Carbonate (Lithium Carbonate)	PS		ORAL	PO	
	Overdose							

Date:11/03/03ISR Number: 4227010-1Report Type:Expedited (15-DaCompany Report #2003-DE-05231GD
Age:74 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Adverse Drug Reaction	Literature	Lithium Carbonate (Lithium Carbonate)	PS		ORAL	PO	
	Overdose							

Date:11/03/03ISR Number: 4227013-7Report Type:Expedited (15-DaCompany Report #2003-DE-05230GD
Age:51 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Overdose	Literature	Lithium Carbonate (Lithium Carbonate)	PS		ORAL	PO	

Date:11/03/03ISR Number: 4227018-6Report Type:Expedited (15-DaCompany Report #2003-DE-05226GD
Age:50 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardio-Respiratory Arrest	Literature	Lithium Carbonate					
	Completed Suicide		(Lithium Carbonate)	PS		ORAL	PO	
	Overdose							

Date:11/03/03ISR Number: 4227023-XReport Type:Expedited (15-DaCompany Report #2003-DE-05223GD
Age:41 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Overdose	Literature	Lithium Carbonate					
			(Lithium Carbonate)	PS		ORAL	PO	

Date:11/03/03ISR Number: 4227024-1Report Type:Expedited (15-DaCompany Report #2003-DE-05220GD
Age:34 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Medication Error	Literature	Lithium Carbonate					
	Overdose		(Lithium Carbonate)	PS		ORAL	PO	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/04/03ISR Number: 4225478-8Report Type:Expedited (15-DaCompany Report #DE-GLAXOSMITHKLINE-D0042327A
Age:46 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Intentional Misuse		Quilonum Retard	PS	Glaxosmithkline	ORAL	25TAB Single	
	Suicide Attempt						dose	1 DAY
			Cipralex	SS		ORAL	20TAB Single	
							dose	1 DAY
			Wine	SS		ORAL		

Date:11/04/03ISR Number: 4226262-1Report Type:Expedited (15-DaCompany Report #WAES 0310CHE00033
Age:73 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agitation		Vioxx	PS		ORAL	14 DAY	
	Bacteria Urine Identified		Diclofenac Sodium	SS		ORAL		
	Confusional State		Hyzaar	SS		ORAL		
	Disturbance In Attention		Lithium Carbonate	SS		ORAL		
	Drug Interaction		Lithium Carbonate	SS		ORAL	15 YR	
	Drug Level Increased		Amlodipine Besylate	C	Merck & Co., Inc	ORAL		
	Fear		Maprotiline Hydrochloride	C		ORAL		
	Hallucination		Phenprocoumon	C		ORAL		
	Speech Disorder		Nadroparin	C		SUBCUTANEOUS		
	Tremor		Cozaar	C		ORAL		
	Urinary Tract Infection		Bisoprolol Fumarate	C		ORAL		
			Esomeprazole Magnesium	C		ORAL		
			Clomipramine Hydrochloride	C		ORAL		

Date:11/05/03ISR Number: 4237436-8Report Type:Expedited (15-DaCompany Report #B0312661B
Age: Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Electrocardiogram Qrs Complex Shortened	Foreign Literature	Lithium Salt (Lithium Salt)	PS		TRANSPLACENTAL	TRANSPLACENTARY	
Other	Eyelid Ptosis	Health Professional						
Required Intervention to Prevent Permanent Impairment/Damage	Haemangioma Congenital Maternal Drugs Affecting Foetus Motor Dysfunction Neonatal Disorder Neonatal Respiratory Distress Syndrome Nephrogenic Diabetes Insipidus Polyhydramnios Premature Baby Premature Rupture Of Membranes Supraventricular Tachycardia							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/06/03ISR Number: 4227956-4Report Type:Expedited (15-DaCompany Report #WAES 0310FIN00017
Age:70 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Blood Creatinine		Vioxx	PS		ORAL	8	DAY
	Increased		Lithium Carbonate	SS		ORAL		
	General Physical Health		Vioxx	SS		ORAL	28	DAY
	Deterioration		Acetaminophen	C	Merck & Co., Inc	ORAL		
	Therapeutic Agent		Cefuroxime	C		ORAL	19	DAY
	Toxicity		Cefuroxime Sodium	C			INTRAVENOUS	4 DAY
			Chlorpromazine Hydrochloride	C		ORAL		
			Tolterodine Tartrate	C				
			Tramadol Hydrochloride	C		ORAL		
			Zuclopenthixol Hydrochloride	C			INTRAMUSCULAR	
			Vitamins (Unspecified)	C		ORAL		
			Valproate Sodium	C		ORAL		
			Valproate Sodium	C		ORAL		
			Tolterodine Tartrate	C		ORAL	216	DAY
			Olanzapine	C		ORAL		
			Picosulfate Sodium	C		ORAL		
			Lorazepam	C		ORAL		
			Etilefrine Hydrochloride	C		ORAL		
			Levothyroxine Sodium	C		ORAL		
			Levothyroxine Sodium	C		ORAL		

Date:11/06/03ISR Number: 4228504-5Report Type:Expedited (15-DaCompany Report #WAES 0310FIN00018
Age:61 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Blood Creatinine		Vioxx	PS		ORAL	29	DAY
	Increased		Lithium Carbonate	SS		ORAL		

	General Physical Health Deterioration Therapeutic Agent Toxicity		Lithium Carbonate	SS		ORAL
			Moduretic	C	Merck & Co., Inc	ORAL
			Ascorbic Acid And Nitrofurantoin	C		ORAL
10 DAY						
			Picosulfate Sodium	C		ORAL
			Trimethoprim	C		ORAL
			Risperidone	C		
OPHTHALMIC						
			Propoxyphene Hydrochloride	C		
27 DAY						
			Methotrimeprazine	C		ORAL
			Fluoxetine Hydrochloride	C		ORAL
			Levothyroxine Sodium	C		ORAL

Date:11/06/03ISR Number: 4230683-0Report Type:Expedited (15-DaCompany Report #2003114536
Age:55 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Cerebrovascular Accident Drug Ineffective	Consumer	Zoloft (Sertraline)	PS		
			Lithium (Lithium)	SS		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/07/03ISR Number: 4231353-5Report Type:Expedited (15-DaCompany Report #KII-2003-0004681
Age:53 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Anion Gap Abnormal	Health	Morphine Sulfate					
Hospitalization -	Aspartate	Professional	(Similar To Nda					
Initial or Prolonged	Aminotransferase	Other	19-516) (Morphine					
Other	Blood Bicarbonate		Sulfate) Unknown	PS				
	Blood Calcium		Dexedrine "Smith					
	Blood Chloride		Kline					
	Blood Creatine		Beecham"(Dexamfetami					
	Phosphokinase		ne Sulfate)	SS	Smith Kline Beecham			
	Blood Creatinine		Temazepam					
	Blood Glucose Increased		(Temazepam)	SS				
	Blood Ph		Chlorpromazine					
	Blood Potassium		(Chlorpromazine)	SS				
	Blood Pressure Systolic		Levothyroxine					
	Body Temperature		(Levothyroxine)	SS				
	Increased		Chlorpromazine					
	Bundle Branch Block Right		(Chlorpromazine)	SS				
	Chills		Soma(Carisoprodol)	SS				
	Death		Lithium (Lithium)	SS				
	Drug Screen Positive		Metoprolol					
	Eye Rolling		(Metoprolol)	SS				
	Hyperhidrosis		Lovastatin					
	Loss Of Consciousness		(Lovastatin)	SS				
	Road Traffic Accident		Fluoxetine					
	Sinusitis		(Fluoxwtine)	SS				
	Tachycardia							
	Tremor							
	Troponin							
	Vomiting							
	White Blood Cell Count							

Date:11/07/03ISR Number: 4231641-2Report Type:Expedited (15-DaCompany Report #DSA_23528_2003
Age:41 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Aggression	Foreign	Temesta Epidet	PS		ORAL	7.5 MG QD PO/	
Initial or Prolonged	Disorientation	Health						
A FEW YEARS								

Other	Drug Interaction	Professional	Lithiofor	SS
660 MG Q DAY				
	Gait Disturbance	Other	Lithiofor	SS
1320 MG ONCE				
	Sedation		Lithiofor	SS
1320 MG QD				
	Tremor		Seropram	SS
20 MG QD				
	Urinary Incontinence		Seropram	SS
20 MG ONCE				
			Tegretol	SS
200 MG QD				
			Tegretol	SS
200 MG ONCE				
			Akineton	C
			Clopixol (Decanoate)	C
			Ferrum Hausmann	C
			Pantozol	C

Date:11/07/03ISR Number: 4232074-5Report Type:Expedited (15-DaCompany Report #DE-GLAXOSMITHKLINE-D0042135A
Age:52 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Diarrhoea		Quilonum Retard	PS	Glaxosmithkline	ORAL	50TAB Single dose	1 DAY
	Overdose							
	Suicide Attempt							
	Vomiting							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/10/03ISR Number: 4231028-2Report Type:Expedited (15-DaCompany Report #DE-GLAXOSMITHKLINE-D0041998A
Age:70 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Bradycardia	Health	Quilonum Retard	PS	Glaxosmithkline	ORAL	20TAB	Single
	Somnolence	Professional						
	Suicide Attempt		Zopiclon	SS		ORAL	40TAB	Single
			Charcoal	C				
UNKNOWN								

Date:11/10/03ISR Number: 4232356-7Report Type:Direct Company Report #CTU 205594
Age:67 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Blood Sodium Increased		Eskalith R 450 Mg	PS		ORAL	450MG	QD
	Coronary Artery Disease		Zyprexa	C				
	Dehydration		Synthroid	C				
	Diabetes Insipidus		Zantac	C				
	Drug Toxicity		Aspirin	C				
	Mental Status Changes		Artane	C				
	Refusal Of Treatment By Patient		Hydroxyzine	C				
			Wellbutrin Sr	C				
	Ventricular Tachycardia		Enalapril	C				
			Thiamine	C				
			Folic Acid	C				
			Multivitamin	C				
			Oxycontin	C				
			Oxycodone	C				

Date:11/10/03ISR Number: 4232378-6Report Type:Direct Company Report #CTU 205635
Age:58 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Diabetes Insipidus		Lithium	PS				

Initial or Prolonged						
Required						
Intervention to						
Prevent Permanent						
Impairment/Damage						

Date:11/10/03ISR Number: 4232381-6Report Type:Direct Company Report #CTU 205636
Age:51 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Confusional State		Lithium Carbonate	PS				

Date:11/10/03ISR Number: 4234438-2Report Type:Expedited (15-DaCompany Report #03P-167-0238804-00
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required	Diabetes Insipidus	Foreign	Depakote (Divalproex					
Intervention to	Hypoglycaemia	Health	Sodium) (Divalproex					
Prevent Permanent	Lethargy	Professional	Sodium)	PS		ORAL	500 MG, 2 IN	
Impairment/Damage	Somnolence						1 D, ORAL	
			Valproate Sodium (Sodium Valproate)	SS				
			Lithium	SS				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/12/03ISR Number: 4234084-0Report Type:Direct Company Report #CTU 205889
Age:17 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Blood Potassium Increased Drug Toxicity Renal Impairment Thyroid Disorder		Eskalith	PS		ORAL	900 MG QAM ORAL	

Date:11/12/03ISR Number: 4234179-1Report Type:Direct Company Report #CTU 205933
Age:11 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hypomania		Lithobid 300mg, Bid	PS		ORAL	PO 2 BID	
	Pharmaceutical Product Complaint		Resperidol	C				

Date:11/12/03ISR Number: 4235790-4Report Type:Expedited (15-DaCompany Report #2003-UK-00640UK
Age:69 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Hospitalization - Initial or Prolonged	Abdominal Pain Anorexia Blood Urea Increased Chest Pain Confusional State Convulsion Drug Interaction Dysuria	Other	Mobic(14598/-) (Meloxicam) (Nr) (Meloxicam) Priadel (Lithium Carbonate) (Nr)	PS SS		ORAL ORAL	75 MG TWICE DAILY (TWICE DAILY) 400MG NOCTE (NOT	10 DAY

REPORTED)

Nicorandil (Nicorandil)	C
Thyroxine (Thyroxine I 125)	C
Felodipine (Felodipine)	C
Irbesartan	C
Mebeverine (Mebeverine)	C
Aspirin (A.P.C.) (Acetylsalicylic Acid, Acetylsalicylic Acid 'Bayer')	C
Simvastatin (Simvastatin)	C

Date:11/13/03ISR Number: 4234020-7Report Type:Expedited (15-DaCompany Report #WAES 0310CHE00016
Age:68 YR Gender:Female I/FU:F

Outcome	PT
Life-Threatening	Blood Creatinine Increased
Hospitalization - Initial or Prolonged	Bradycardia
	Drug Interaction
	Drug Level Increased
	Electrocardiogram

		Abnormal					
		Headache					
		Hypotension					
		Malaise	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
		Tremor		Vioxx	PS		ORAL
8	DAY						
		Vomiting		Carbamazepine	SS	Merck & Co., Inc	ORAL
				Lithium Carbonate	SS		ORAL
				Propranolol Hydrochloride	SS		ORAL
1	DAY						
				Mirtazapine	C		ORAL
				Pipamperone Hydrochloride	C		ORAL
				Zopiclone	C		ORAL

Date:11/13/03ISR Number: 4234505-3Report Type:Direct Company Report #CTU 205995
Age:17 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization -	Blood Potassium Increased		Eskalith	PS		ORAL
900 MG QAM						
Initial or Prolonged	Drug Toxicity					
ORAL						
Required	Renal Impairment		Neurontin	C		
Intervention to	Thyroid Disorder		Zyprexa	C		
Prevent Permanent			Trazadone	C		
Impairment/Damage			Imipr	C		

Date:11/13/03ISR Number: 4235680-7Report Type:Expedited (15-DaCompany Report #2003040902
Age:54 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization -	Bipolar Disorder	Health	Lithium (Lithium)	PS		ORAL
900 MG						
Initial or Prolonged	Confusional State	Professional				
(DAILY), ORAL						
Other	Insomnia		Ziprasidone			
	Intentional Self-Injury		Hydrochloride			
	Mania		(Ziprasidone			
	Paranoia		Hydrochloride)	C		

	Schizoaffective Disorder						
	Speech Disorder						
	Suicidal Ideation						
	Weight Increased						

Date:11/14/03ISR Number: 4236196-4Report Type:Expedited (15-DaCompany Report #2003116915
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Attention-Seeking	Consumer	Neurontin					
Other	Behaviour		(Gabapentin)	PS		ORAL	300 MG (TID),	
	Blood Pressure Increased							
ORAL								
	Drug Effect Decreased		Lithium (Lithium)					
	Drug Level Decreased		(Lithium)	SS				
	Fluid Retention		Valproate Semisodium					
	Intentional Self-Injury		(Valproate					
	Suicide Attempt		Semisodium)	SS		ORAL		
ORAL								

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/14/03ISR Number: 4236215-5Report Type:Expedited (15-DaCompany Report #2003035153
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Carbon Monoxide Poisoning	Consumer	Geodon (Ziprasidone)	PS		ORAL		
Life-Threatening	Completed Suicide Drug Effect Decreased Lethargy		Lithium (Lithium)	SS				
			Citalopram Hydrobromide (Citalopram Hydrobromide)	SS		ORAL	ORAL	
			Lorazepam (Lorazepam)	SS		ORAL	ORAL	
			Olanzapine (Olanzapine)	C				

Date:11/17/03ISR Number: 4237088-7Report Type:Expedited (15-DaCompany Report #2003040700
Age:37 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Hospitalization - Initial or Prolonged Other	Bipolar I Disorder Seasonal Affective Disorder Sleep Disorder Suicide Attempt	Foreign Consumer Health Professional	Lipitor (Atorvastatin)	PS		ORAL	20 MG	(DAILY), ORAL
			Olanzapine (Olanzapine)	SS			5 MG (DAILY)	
			Lithium (Lithium Carbonate) (Lithium)	SS			100 MG	(DAILY)

Date:11/17/03ISR Number: 4237191-1Report Type:Expedited (15-DaCompany Report #2003UW14438
Age:52 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Hospitalization -	Asthenia	Consumer	Zestril	PS	ORAL
5 MG PO					
Initial or Prolonged	Chest Pain		Zestril	SS	ORAL
10 MG PO					
Disability	Coordination Abnormal		Vasotec	SS	ORAL
5 MG HS PO					
	Coronary Artery Occlusion		Lithium	SS	
	Drug Toxicity		Eskalith	C	
	Dyspnoea		Verapamil	C	
	Gait Disturbance				
	Headache				
	Hyperhidrosis				
	Influenza Like Illness				
	Memory Impairment				
	Nausea				
	Tremor				

Date:11/17/03ISR Number: 4237274-6Report Type:Expedited (15-DaCompany Report #2003034756
Age:50 YR Gender:Male I/FU:F

Outcome	PT
Hospitalization -	Condition Aggravated
Initial or Prolonged	Confusional State
Other	Dehydration
	Drug Toxicity
	Dyspnoea
	Gait Disturbance
	Hypovolaemia
	Lethargy
	Logorrhoea

	Mental Status Changes Oral Intake Reduced Paranoia	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
	Pneumonia	Health	Lithium (Lithium)	PS		ORAL
ORAL						
	Psychomotor Hyperactivity Renal Failure Acute Schizoaffective Disorder Thinking Abnormal Thought Blocking	Professional	Bupropion (Bupropion) Lorazepam (Lorazepam) Olanzapine (Olanzapine) Bupropion Hydrochloride (Bupropion Hydrochloride) Quetiapine Fumarate (Quetiapine Fumarate) Esomeprazole (Esomeprazole)	C C C C C C		

Date:11/18/03ISR Number: 4237618-5Report Type:Expedited (15-DaCompany Report #2003003832
Age:48 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization -	Agitation	Health	Lithium (Lithium)	PS		ORAL
600 MG (BID),						
Initial or Prolonged	Anion Gap Increased	Professional				
ORAL						
	Anxiety Bleeding Time Prolonged		Olanzapine (Olanzapine)	SS		ORAL
20 MG, ORAL						
	Blood Alkaline Phosphatase Increased Blood Bicarbonate Decreased Blood Calcium Decreased Blood Glucose Increased Blood Potassium Increased Blood Sodium Decreased Blood Thyroid Stimulating Hormone Increased Confusional State		Atenolol (Atenolol) Lorazepam (Lorazepam)	C C		

Depression
Disturbance In Attention
Dysarthria
Gait Disturbance
Haematocrit Decreased
Haemoglobin Decreased
Hypertension
Lymphocyte Percentage
Decreased
Mean Platelet Volume
Decreased
Neutrophil Percentage
Increased
Red Blood Cell Count
Decreased
Renal Failure Acute
Schizoaffective Disorder
Therapeutic Agent
Toxicity

Date:11/18/03ISR Number: 4237694-XReport Type:Expedited (15-DaCompany Report #LBID00203003207
Age:0 DY Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Congenital Anomaly	Diabetes Insipidus	Foreign	Lithium	PS		TRANSPLACENTAL	DAILY	PL
	Eyelid Ptosis	Literature						
	Haemangioma Congenital	Health						
	Maternal Drugs Affecting Foetus	Professional						
	Motor Dysfunction	Other						
	Neonatal Disorder							
	Neonatal Respiratory Distress Syndrome							
	Nephrogenic Diabetes Insipidus							
	Polyhydramnios							
	Polyuria							
	Premature Baby							
	Premature Rupture Of Membranes							
	Skin Lesion							
	Supraventricular Tachycardia							
	Weight Decreased							

Date:11/18/03ISR Number: 4237695-1Report Type:Expedited (15-DaCompany Report #LBID00203003206
Age:34 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Complications Of Maternal Exposure To Therapeutic Drugs	Foreign	Lithium	PS		ORAL	DAILY	PO
	Polyhydramnios	Literature						
	Premature Labour	Health						
	Premature Rupture Of Membranes	Professional						
		Other						

Date:11/19/03ISR Number: 4238605-3Report Type:Expedited (15-DaCompany Report #2003-DE-05682GD
Age: Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other Required Intervention to Prevent Permanent Impairment/Damage	Renal Failure	Foreign Literature	Lithium Carbonate (Lithium Carbonate)	PS				

Date:11/24/03ISR Number: 4241286-6Report Type:Periodic Company Report #US-BRISTOL-MYERS SQUIBB COMPANY-12330098
Age:9 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Abdominal Distension Dehydration Drug Level Increased Medication Error Oedema	Health Professional	Abilify Tabs 15 Mg	PS	Otsuka Pharmaceutical Company, Ltd.	ORAL	7.5 mg (1/2 of a 15 mg tablet) once daily in the morning	
			Lithobid	SS				

Date:11/25/03ISR Number: 4242205-9Report Type:Expedited (15-DaCompany Report #2003040902
Age:54 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Bipolar I Disorder Confusional State Delusion Insomnia Mania Paranoia Schizoaffective Disorder Self-Injurious Ideation Sexual Offence Speech Disorder Suicidal Ideation Weight Increased	Health Professional	Lithium (Lithium) Ziprasidone Hydrochloride (Ziprasidone Hydrochloride) Sulfasalazine (Sulfasalazine)	PS C C		ORAL	1200 MG	(DAILY), ORAL

Date:11/25/03ISR Number: 4242297-7Report Type:Expedited (15-DaCompany Report #B0314536A
Age:30 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Creatinine Increased Blood Pressure Increased Body Temperature Increased Cerebral Atrophy Confusional State Delirium Delusion Hallucination, Auditory Heart Rate Increased Insomnia Liver Function Test Abnormal Muscle Rigidity Neuroleptic Malignant Syndrome Speech Disorder	Literature Health Professional	Lithium Salt (Formulation Unknown) (Lithium Salt) Risperidone (Formulation Unknown) (Risperidone) Olanzapine Semisodium Valproate	PS SS C C			450 MG/ TWICE PER DAY	

	Tremor					
	White Blood Cell Count Increased					

Date:11/25/03ISR Number: 4242453-8Report Type:Expedited (15-DaCompany Report #03P-163-0240958-00
Age:32 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Literature	Valproic Acid (Depakene) (Valproic Acid) (Valproic Acid)	PS		ORAL	ORAL	
		Health Professional	Lithium	SS		ORAL	ORAL	

Date:11/25/03ISR Number: 4242455-1Report Type:Expedited (15-DaCompany Report #03P-163-0240949-00
Age:27 YR Gender: I/FU:I

Outcome	PT	Report Source
Death	Completed Suicide	Consumer Health

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Professional

Product	Role	Manufacturer	Route	Dose	Duration
Valproic Acid (Depakene)	PS		ORAL		
Lithium	SS		ORAL		

Date:11/25/03ISR Number: 4242500-3Report Type:Expedited (15-DaCompany Report #B0315125A
Age:35 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Aspartate Aminotransferase Increased Blood Lactate Dehydrogenase Increased Cardiac Failure Cardiotoxicity Culture Urine Positive Dyspnoea Electrocardiogram T Wave Inversion Hypotension Muscle Disorder Neuroleptic Malignant Syndrome Sinus Tachycardia Tachypnoea Ventricular Failure Ventricular Hypokinesia	Foreign Literature Health Professional	Lithium Salt Thioridazine (Thioridazine)	PS SS				

Date:11/25/03ISR Number: 4242596-9Report Type:Expedited (15-DaCompany Report #03P-163-0240950-00
Age:44 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Literature Health Professional	Valproic Acid (Depakene) (Valproic Acid) (Valproic					

			Acid)	PS		ORAL
ORAL						
			Lithium	SS		ORAL
ORAL						
			Sertraline	SS		ORAL
ORAL						

Date:11/26/03ISR Number: 4244314-7Report Type:Expedited (15-DaCompany Report #2003119141
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Drug Ineffective	Health	Lithium (Lithium)	PS		
	Overdose	Professional	Geodon (Ziprasidone)	SS		
SEE IMAGE						
	Renal Failure	Company Representative	Fluphenazaine Hydrochloride (Fluphenazaine Hydrochloride)	C		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/28/03ISR Number: 4243163-3Report Type:Direct Company Report #CTU 206984
Age:38 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Flushing		Lithium	PS				
	Nausea		Citalopram	SS				
	Serotonin Syndrome							
	Tremor							

Date:11/28/03ISR Number: 4245410-0Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20030804621
Age:57 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Blood Glucose Decreased	Consumer	Risperdal (Risperidone)					
Hospitalization - Initial or Prolonged	Coma		Tablets	PS		ORAL	3 MG, 1 IN 1	DAY, ORAL
	Drug Toxicity							
	Myocardial Infarction							
	Pneumonia		Lithium (Lithium) Tablets	SS			600MG IN	AM/300MG IN PM
			Depakote (Valproate Semisodium)	C				
			Lanoxin (Digoxin)	C				
			Aspirin (Acetylsalicylic Acid)	C				
			Insulin	C				
			Monopril (Fosinopril Sodium)	C				

Date:12/01/03ISR Number: 4243461-3Report Type:Expedited (15-DaCompany Report #DE-GLAXOSMITHKLINE-D0042494A
Age:31 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Hospitalization - 675MG per day 19 DAY	Difficulty In Walking		Quilonum Retard	PS	Glaxosmithkline	ORAL
Initial or Prolonged 15MG per day	Parkinsonism		Zyprexa	SS		ORAL
			Zoloft 50MG per day	SS		ORAL
			Convulex 800MG per day	C		ORAL
			Risperdal	C		
UNKNOWN 6 WK						

Date:12/01/03ISR Number: 4243473-XReport Type:Expedited (15-DaCompany Report #PHBS2003DK09352
Age:54 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Coordination Abnormal		Trileptal	PS	Novartis Sector: Pharma	ORAL	600 mg, BID	
	Drug Interaction							
	Dysarthria		Lithium Carbonate	SS		ORAL	750 mg/d	
	Fall							
	Overdose							

Date:12/01/03ISR Number: 4244086-6Report Type:Direct Company Report #CTU 207126
Age: Gender:Male I/FU:I

Outcome
Required
Intervention to
Prevent Permanent

Impairment/Damage

	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Toxicity		Lithium	PS				

Date:12/02/03ISR Number: 4243902-1Report Type:Expedited (15-DaCompany Report #GB-GLAXOSMITHKLINE-B0316024A
Age:37 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Suicide Attempt		Lithium Carbonate	PS	Glaxosmithkline			
							UNKNOWN	100MG Per day
Initial or Prolonged			Olanzapine	SS				
							UNKNOWN	5MG Per day
			Lipitor	SS		ORAL		
							20MG Per day	157 WK

Date:12/02/03ISR Number: 4245181-8Report Type:Direct Company Report #CTU 207224
Age:35 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Blood Creatinine		Lithium	PS				
Initial or Prolonged	Increased							
	Blood Urea Increased							
	Confusional State							
	Drug Toxicity							
	Dysarthria							
	Haemodialysis							
	Lethargy							
	Leukocytosis							
	Tremor							

Date:12/02/03ISR Number: 4245626-3Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20031105516
Age:51 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Feeling Abnormal	Foreign	Risperdal Consta					
Life-Threatening	Intestinal Infarction	Health	(Risperidone)					

Hospitalization -	Treatment Noncompliance	Professional	Microspheres	PS			
INTRAMUSCULAR	INTRA-MUSCULA						
Initial or Prolonged							
R							
			Lithium (Lithium)				
			Unknown	SS			
			Chlorpromazine				
			(Chlorpromazine)	C			

Date:12/02/03ISR Number: 4246000-6Report Type:Expedited (15-DaCompany Report #FRWYE431527NOV03
Age:71 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Renal Failure Chronic	Foreign	Seresta (Oxazepam,					
		Health	Tablet)	PS		ORAL		
50 MG 1X PER								
		Professional						
1 DAY, ORAL								
			Artane					
			(Trihexyphenidyl)	SS		ORAL		
5 MG 2X PER 1								
DAY, ORAL								
			Modecate					
			(Fluphenazine					
			Decanoate)	SS				
INTRAMUSCULAR	75 MG 1X PER							
3 WK,								
INTRAMUSCULAR								
			Teralithe (Lithium					

				Carbonate)	SS		ORAL
375 MG 1X PER							
1 DAY, ORAL							
				Rohypnol (Flunitrazepam)	C		

Date:12/03/03ISR Number: 4244694-2Report Type:Expedited (15-DaCompany Report #PHNU2003DE02382
Age:56 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Bite Blood Pressure Increased Disorientation		Leponex / Clozaril (Clozapine)	PS	Novartis Sector: Pharma	ORAL	25 mg/day	1440 MIN
	Drug Interaction		Anafranil	SS		ORAL	50-175 mg/day	12960MIN
	Drug Level Below Therapeutic Drug Level Increased		Anafranil	SS		ORAL	187.5 mg/day	36000MIN
	Electroencephalogram Abnormal		Quilonum - Slow Release	SS		ORAL	450 mg/day	2880 MIN
	Enuresis Epilepsy		Quilonum - Slow Release	SS		ORAL	1125 mg/day	4320 MIN
	Fall		Haldol "Janssen"	SS		ORAL	225 mg/day	1440 MIN
	Grand Mal Convulsion		Haldol "Janssen"	SS		ORAL	6-10 mg/day	56160MIN
	Hypokinesia		Taxilan	SS		ORAL	5 mg/day	11520MIN
	Myoclonus		Haldol "Janssen"	SS		ORAL	50 mg/day	7200 MIN
	Schizoaffective Disorder		Haldol "Janssen"	SS		ORAL	2.5 mg/day	2880 MIN
	Tongue Biting		Haldol "Janssen"	SS		ORAL	3 mg/day	10080MIN
			Haldol "Janssen"	SS		ORAL	15 mg/day	10080MIN
			Quilonum - Slow Release	SS		ORAL	900 mg/day	2880 MIN
			Quilonum - Slow					

				Release	SS		ORAL
675 mg/day	1440 MIN						
				Leponex / Clozaril (Clozapine)	SS	Novartis Sector: Pharma	ORAL
50 mg/day	1440 MIN						
				Anafranil	SS		
225 mg/day	14400MIN						

Date:12/03/03ISR Number: 4264955-0Report Type:Periodic Company Report #269121
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Other	Anxiety	Consumer	Valium (Diazepam)	PS		ORAL
2 PER WEEK						
	Cognitive Disorder					
ORAL						
	Drug Withdrawal Syndrome		Lithium (Lithium Nos)	SS		

Date:12/04/03ISR Number: 4247564-9Report Type:Expedited (15-DaCompany Report #FRWYE431527NOV03
Age:71 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Disability	Proteinuria	Health Professional	Seresta (Oxazepam, Tablet)	PS		ORAL
50 MG 1X PER	Renal Failure Chronic					
1 DAY ORAL		Other				
			Artane (Trihexyphenidyl, Unspec, 0)	SS		ORAL
5 MG 2X PER 1						
DAY ORAL						
			Modecate (Fluphenazine Decanoate,0)	SS		
INTRAMUSCULAR	75 MG 1X PER					
3 WK IM						

			Teralithe (Lithium Carbonate)	SS		ORAL
375 MG 1X PER 1 DAY ORAL						

Date:12/04/03ISR Number: 4247628-XReport Type:Expedited (15-DaCompany Report #2003-DE-06080GD
Age:1 DY Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other Required INTRA-UTERINE IU	Atrial Flutter Eyelid Ptosis	Foreign Literature	Lithium Carbonate (Lithium Carbonate)	PS		
Intervention to Prevent Permanent Impairment/Damage	Haemangioma Congenital Maternal Drugs Affecting Foetus Motor Dysfunction Neonatal Disorder Neonatal Respiratory Distress Syndrome Nephrogenic Diabetes Insipidus Premature Baby Supraventricular Tachycardia Weight Decreased					

Date:12/04/03ISR Number: 4247631-XReport Type:Expedited (15-DaCompany Report #2003-DE-06076GD
Age:34 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other Required FOR YEARS	Complications Of Maternal Exposure To Therapeutic	Foreign Literature	Lithium Carbonate (Lithium Carbonate)	PS		
Intervention to Prevent Permanent Impairment/Damage	Drugs Polyhydramnios Premature Labour Premature Rupture Of Membranes					

Date:12/05/03ISR Number: 4245935-8Report Type:Expedited (15-DaCompany Report #FR-BRISTOL-MYERS SQUIBB COMPANY-12445540
Age:71 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Proteinuria Renal Failure Chronic		Modecate Inj 25 Mg/Ml	PS	Apothecon	INTRAMUSCULAR	time to onset of event - 10 years 9 months	
			Artane	SS		ORAL	time to onset of events - 10 years 9 months	
			Seresta	SS		ORAL	time to onset of event - 23 years	
			Teralithe	SS		ORAL	time to onset of event - 23 years	
			Rohypnol	C		ORAL		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/08/03ISR Number: 4249396-4Report Type:Expedited (15-DaCompany Report #2003120322
Age:31 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged Other	Drug Level Decreased Mood Swings Somnolence Weight Increased	Consumer	Geodon (Ziprasidone) Lithium (Lithium) Valproate Semisodium (Valproate Semisodium)	PS SS C		ORAL	

Date:12/09/03ISR Number: 4249793-7Report Type:Expedited (15-DaCompany Report #03P-167-0242329-00
Age:37 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Disability	Alopecia Arthralgia Joint Stiffness Lethargy Muscular Weakness Sluggishness	Foreign Health Professional	Valproate Sodium (Sodium Valproate) (Sodium Valproate) (Sodium Valproate) Lithium Prednisolone Salbuamol Fluticasone Olanzapine	PS SS C C C C		ORAL ORAL	1000 MG, 1 IN 1 D, PER ORAL 1000 MG, 1 IN 1 D, PER ORAL

Date:12/11/03ISR Number: 4249643-9Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0425949A
Age:23 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Amnesia Constipation Depressed Mood	Health Professional	Wellbutrin Lithobid	PS SS	Glaxosmithkline Glaxosmithkline	ORAL	1200MG Per day

	Fall		Lexapro	C			
30MG Per day							
	Fatigue		Nortriptyline	C			
150MG At							
	Grand Mal Convulsion						
night							
	Loss Of Consciousness						
	Medication Error						
	Tremor						
	Weight Increased						

Date:12/12/03ISR Number: 4250716-5Report Type:Direct Company Report #CTU 207941
Age:8 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Anxiety		Lithobid 300 Mg					
Required	Nephrogenic Diabetes		Solvay	PS	Solvay	ORAL	300 MG 2	
Intervention to	Insipidus						TIMES ORAL	
Prevent Permanent	Pollakiuria		Topamax	C				
Impairment/Damage			Risperdal	C				

Date:12/12/03ISR Number: 4251796-3Report Type:Expedited (15-DaCompany Report #MK200312-0098-1
Age:31 YR Gender:Female I/FU:I

Outcome	PT
Hospitalization -	Blood Pressure Decreased
Initial or Prolonged	Bradycardia
	Electrocardiogram Qrs

	Complex Prolonged Electrocardiogram Qt Prolonged					
	Overdose	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
	Suicide Attempt	Foreign	Tofranil (Imipramine Hydrochloride)	PS		
5475MG, ONE TIME						
			Lithium Carbonate	SS		
2920MG,ONE TIME						

Date:12/16/03ISR Number: 4252212-8Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0443093A
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Anxiety		Paxil	PS	Glaxosmithkline	ORAL
	Bipolar I Disorder		Wellbutrin	SS	Glaxosmithkline	ORAL
	Drug Ineffective		Lithium	SS	Glaxosmithkline	
UNKNOWN						
	Paranoia		Prozac	SS		
UNKNOWN	2 YR					
	Suicidal Ideation					

Date:12/16/03ISR Number: 4252987-8Report Type:Expedited (15-DaCompany Report #B0316285A
Age:56 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Confusional State	Foreign	Lithium Salt			
	Hyperthyroidism	Literature	(Lithium Salt)	PS		
AT NIGHT/						
Other	Oedema Peripheral	Health	Amitriptyline	C		
	Pitting Oedema	Professional	Isocarboxazid	C		
			Trifluoperazine Hcl	C		
			Diazepam	C		
			Temazepam	C		

Date:12/16/03ISR Number: 4253481-0Report Type:Expedited (15-DaCompany Report #LBID00203003413
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dementia	Health Professional	Lithobid (Lithium Carbonate)	PS		ORAL	300 MG BID PO	
			Thyroid Replacement (Thyroid Replacement)	C				

Date:12/16/03ISR Number: 4253845-5Report Type:Expedited (15-DaCompany Report #2003033768
Age:80 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Calcium Increased	Foreign	Lithium (Lithium)	PS		ORAL	ORAL	
	Blood Creatinine Increased	Health Professional	Glibenclamide (Glibenclamide)	SS		ORAL	ORAL	
	Confusional State		Metformin Hydrochloride (Metformin Hydrochloride)	C				
	Hypoglycaemia		Dipyridamole (Dipyridamole)	C				
	Non-Hodgkin'S Lymphoma		Furosemide (Furosemide)	C				
	Overdose							

Date:12/16/03ISR Number: 4253875-3Report Type:Expedited (15-DaCompany Report #DSA_23672_2003
Age:65 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Choreoathetosis	Foreign	Enalapril Maleate	PS			
	Coordination Abnormal	Literature	Lithium Carbonate	SS		ORAL	1200 MG Q DAY
	Depressed Level Of Consciousness	Health Professional	Lithium Carbonate	SS		ORAL	600 MG Q DAY
	Disorientation	Other					
	Drug Effect Decreased						
	Drug Level Above Therapeutic						
	Drug Toxicity						
	Dyskinesia						
	Electroencephalogram Abnormal						
	Hypomania						
	Renal Impairment						

Date:12/17/03ISR Number: 4254290-9Report Type:Expedited (15-DaCompany Report #A015018
Age:43 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Condition Aggravated	Foreign	Viagra (Sildenafil)	PS		ORAL	100 MG, ORAL
	Drug Interaction	Literature	Lithium (Lithium)	SS		ORAL	ORAL
	Mania	Health Professional	Dothiepin (Dosulepin)	C			
			Flupentixol (Flupentixol)	C			

Date:12/17/03ISR Number: 4254977-8Report Type:Expedited (15-DaCompany Report #MSER20030032
Age:37 YR Gender:Male I/FU:I

Outcome	PT
Death	Alanine Aminotransferase

Life-Threatening Hospitalization - Initial or Prolonged	Increased Aspartate Aminotransferase Increased Blood Creatine Phosphokinase Increased Blood Creatinine Increased Blood Potassium Decreased Blood Urea Increased Body Temperature Increased Completed Suicide Computerised Tomogram Abnormal Convulsion Decerebration Drug Screen Positive Haematemesis Haemodialysis Heart Rate Increased Multiple Drug Overdose Oedema Posturing Tremor

	Troponin Increased Urine Output Decreased						
		Report Source	Product	Role	Manufacturer	Route	Dose Duration
		Literature Health Professional	Morphine Sulfate Er 100 Mg	PS	Endo	ORAL	1000 MG ONCE PO
			Alprazolam	SS		ORAL	PO
			Lithium	SS		ORAL	PO

Date:12/17/03ISR Number: 4269038-1Report Type:Periodic Company Report #USA-2003-0008432
Age:37 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Death	Accidental Overdose Multiple Drug Overdose	Health Professional Other	Oxycontin Tablets (Oxycodone Hydrochloride) Lithium (Lithium) Ethanol (Ethanol) Amitriptyline (Amitriptyline)	PS SS SS SS			

Date:12/18/03ISR Number: 4253920-5Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0439267A
Age:43 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Akathisia Anxiety Blood Creatinine Increased Blood Urea Increased Bradycardia Cognitive Deterioration Cognitive Disorder Fear		Eskalith Klonopin Abilify Seroquel Synthroid	PS C C C C	Glaxosmithkline Glaxosmithkline	ORAL	900MG Twice per day

	Hallucination, Auditory					
	Insomnia					
	Psychotic Disorder					
	Ureteric Dilatation					

Date:12/18/03ISR Number: 4254333-2Report Type:Direct Company Report #CTU 208403
Age:67 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Diarrhoea		Lithium 300 Mg	PS		ORAL	600 BID ORAL	
Initial or Prolonged	Drug Interaction		Lisinopril 10 Mg	SS		ORAL	10 MG QD ORAL	
	Drug Level Above Therapeutic							
	Drug Toxicity							
	Nausea							
	Sinus Bradycardia							
	Tremor							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/18/03ISR Number: 4254849-9Report Type:Direct Company Report #CTU 208386
Age:58 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Asthenia Difficulty In Walking		Lithium Carbonate 300 Mg	PS		ORAL	600 MG BID	
	Drug Toxicity						ORAL	
	Dysarthria							

Date:12/18/03ISR Number: 4255657-5Report Type:Expedited (15-DaCompany Report #2003-DE-06201GD
Age:32 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Alanine Aminotransferase Increased Arthralgia Aspartate Aminotransferase Increased Blood Amylase Increased Blood Creatine Phosphokinase Increased Blood Glucose Increased Blood Potassium Decreased Blood Pressure Increased Cerebellar Ataxia Coma Glomerulosclerosis Haemodialysis Hypercalcaemia Hyperreflexia Hypovolaemia Lipase Increased Muscle Rigidity Nephritis Interstitial Nephropathy Oral Intake Reduced Overdose Parkinsonism Platelet Count Increased Rash	Foreign Literature	Lithium Carbonate (Lithium Carbonate)	PS				

Red Blood Cell
Sedimentation Rate
Increased
Renal Failure
Respiratory Rate
Increased
Rhabdomyolysis
Sinus Tachycardia
Therapeutic Agent
Toxicity
Vomiting
White Blood Cell Count
Increased

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/18/03ISR Number: 4255658-7Report Type:Expedited (15-DaCompany Report #2003-DE-06179GD
Age:35 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Bacterial Infection	Foreign	Lithium Carbonate					
	Cardiac Failure Acute	Literature	(Lithium Carbonate)	PS				
	Cardiac Failure		Thioridazine					
	Congestive		(Thioridazine)	SS				
	Cardiomyopathy							
	Cardiotoxicity							
	Gastritis Erosive							
	Implant Site Infection							
	Myopathy							
	Neuroleptic Malignant							
	Syndrome							
	Upper Gastrointestinal							
	Haemorrhage							

Date:12/18/03ISR Number: 4256487-0Report Type:Expedited (15-DaCompany Report #DSA_23528_2003
Age:41 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Aggression	Foreign	Temesta	PS		ORAL	7.5 MG QD PO	
Other	Coordination Abnormal	Health Professional	Lithiofor	SS			660 MG Q DAY	
	Disorientation	Other	Lithiofor	SS			1320 MG ONCE	
	Drug Interaction		Lithiofor	SS			1320 MG QD	
	Sedation		Seropram	SS			20 MG QD	
	Tremor		Seropram	SS			20 MG ONCE	
	Urinary Incontinence		Tegretol	SS			200 MG QD	
			Tegretol	SS			200 MG ONCE	
			Akineton	C				
			Clopixol (Decanoate)	C				
			Ferrum Hausmann	C				
			Pantozol	C				

Date:12/19/03ISR Number: 4255085-2Report Type:Expedited (15-DaCompany Report #JP-GLAXOSMITHKLINE-B0307825A
Age:42 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Alanine Aminotransferase	Health	Paxil	PS	Glaxosmithkline	ORAL	42	DAY
Initial or Prolonged	Increased	Professional	Limas	SS	Glaxosmithkline	ORAL	800MG per day	35 DAY
	Aspartate		Ethyl Loflazepate	SS		ORAL	35	DAY
	Aminotransferase		Cefdinir	SS		ORAL	300MG per day	2 DAY
	Increased		Aldioxa	SS		ORAL	3G per day	2 DAY
	Blood Lactate		Acetaminophen	SS	Glaxosmithkline	ORAL	200MG per day	1 DAY
	Dehydrogenase Increased		Kakkon-To	C		ORAL		
	Eosinophil Count Increased							
	Hepatic Function Abnormal							
	Lymphadenopathy							
	Oral Discomfort							
	Pruritus							
	Pyrexia							
	Rash Generalised							
	Toxic Skin Eruption							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/19/03ISR Number: 4256579-6Report Type:Expedited (15-DaCompany Report #03P-008-0243915-00
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Atherosclerosis	Foreign	Valproate Sodium					
	Haemorrhage	Literature	(Sodium Valproate)					
	Myocardial Ischaemia	Health	(Sodium Valproate)					
	Overdose	Professional	(Sodium Valproate)	PS			4 GM ONCE	
	Sudden Death	Other	Diazepam	SS			UNKNOWN	UNKNOWN
			Lithium	SS			UNKNOWN	UNKNOWN
			Glibenclamide	SS			UNKNOWN	UNKNOWN

Date:12/19/03ISR Number: 4256581-4Report Type:Expedited (15-DaCompany Report #2003UW14438
Age:52 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Asthenia	Consumer	Zestril	PS		ORAL	5 MG PO	
Initial or Prolonged	Chest Pain		Zestril	SS		ORAL	10 MG PO	
Disability	Coordination Abnormal		Vasotec	SS		ORAL	5 MG HS PO	
	Dialysis		Eskalith	SS				
	Drug Interaction		Verapamil	C				
	Drug Toxicity							
	Dyspnoea							
	Gait Disturbance							
	Headache							
	Hyperhidrosis							
	Influenza Like Illness							
	Memory Impairment							
	Nausea							
	Nerve Injury							
	Therapeutic Agent							
	Toxicity							
	Tremor							

Date:12/24/03ISR Number: 4257805-XReport Type:Expedited (15-DaCompany Report #PHNU2003DE04098
Age:39 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blood Creatine Phosphokinase Increased		Trileptal	PS	Novartis Sector: Pharma	ORAL	600mg/day	
	C-Reactive Protein Increased		Leponex / Clozaril (Clozapine)	SS		ORAL	up to 400mg/day	
	Chills							
	Hyperhidrosis		Hypnorex - Slow Release	SS		ORAL	1.5df/day	
	Leukocytosis							
	Neuroleptic Malignant Syndrome		Saroten "Bayer Vital"	SS		ORAL	75mg/day	
	Pyrexia		Eunerpan	C			UNKNOWN	Unknown
			Solian	C			UNKNOWN	Unknown

Date:12/26/03ISR Number: 4259856-8Report Type:Expedited (15-DaCompany Report #K200301813
Age:38 YR Gender:Male I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Alcohol Use
	Dehydration
	Depression
	Drug Interaction
	Drug Level Decreased

	Mania Paranoia						
		Report Source	Product	Role	Manufacturer	Route	Dose Duration
		Consumer	Altace Capsules(Ramipril) Capsule, 2.5mg	PS		ORAL	2.5 MG, QD, ORAL; 5 MG, QD, ORAL
			Lithium (Lithium)	SS		ORAL	QD, ORAL
			Pain Medication	C			
			Muscle Relaxants	C			

Date:12/29/03ISR Number: 4259770-8Report Type:Direct Company Report #USP 041892
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Medication Error		Sodium Polystyrene Sulfonate	PS	Roxane	SUSPENSION	
			Lithium Citrate	SS	Roxane	SYRUP	

Date:12/29/03ISR Number: 4261190-7Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20031105516
Age:51 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Death Life-Threatening Hospitalization - Initial or Prolonged	Disease Recurrence Feeling Abnormal Intestinal Infarction Malaise Mental Disorder Schizoaffective Disorder	Foreign Health Professional	Risperdal Consta (Risperidone) Microspheres	PS		INTRAMUSCULAR INTRA-MUSCULAR	50 MG, 1 IN 2 WEEK, R

	Sepsis		Lithium (Lithium)	SS			1000 MG, 1 IN
	Treatment Noncompliance						1 DAY,
			Chlorpromazine (Chlorpromazine)	C			
			Aspirin (Acetylsalicylic Acid)	C			
			Ferrous Sulphate (Ferrous Sulfate)	C			

Date:12/30/03ISR Number: 4260727-1Report Type:Expedited (15-DaCompany Report #FR-BRISTOL-MYERS SQUIBB COMPANY-12463857
Age:63 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Asthenia	Health Professional	Aprovel Tabs 300 Mg	PS	Bristol-Myers Squibb Company	ORAL	3 MON
	Blood Pressure Systolic Increased		Teralithe	SS			"1 TABLET/DAY
	Confusional State						1 DAY OF 2
	Disorientation						DAYS & OTHER
	Electrocardiogram Qrs Complex Shortened						DAYS AT 0.5 TAB/DAY". 5,5
	Hyperkalaemia						
	Refusal Of Treatment By Patient						
	Renal Failure Acute						
	Speech Disorder						
	Therapeutic Agent Toxicity						

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/30/03ISR Number: 4262253-2Report Type:Direct Company Report #CTU 208941
Age:35 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Renal Failure		Lithium 600mg	PS			600MG 3 PER DAY	

Date:12/30/03ISR Number: 4262479-8Report Type:Expedited (15-DaCompany Report #S03-GER-05104-01
Age:39 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Coordination Abnormal	Foreign	Cipramil (Citalopram					
	Hallucination, Visual	Health	Hydrobromide)	PS		ORAL	40 MG QD PO	
	Hyperreflexia	Professional	Lithium	SS		ORAL	1000 MG QD PO	
	Serotonin Syndrome	Other	Propanolol	SS		ORAL	160 MG QD PO	
	Tachycardia		Tavor (Lorazepam)	C				
	Tremor							

Date:12/31/03ISR Number: 4262398-7Report Type:Direct Company Report #CTU 209108
Age:39 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Eosinophilia		Lithium	PS			600 MG BEDTIME	
	Fatigue							
Other	Headache		Risperidine	C				
	Leukocytosis		Klonopin	C				
	Mania							
	Pyrexia							

Date:01/02/04ISR Number: 4262090-9Report Type:Expedited (15-DaCompany Report #DE-GLAXOSMITHKLINE-D0042782A
Age:44 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Creatine Phosphokinase Increased		Quilonum Retard	PS	Glaxosmithkline	ORAL		
	Bowel Sounds Abnormal		Trimipramine	SS		ORAL		
	Coma		Zyprexa	SS		ORAL		
	Shock							
	Suicide Attempt							

Date:01/05/04ISR Number: 4264884-2Report Type:Expedited (15-DaCompany Report #DSA_23672_2003
Age:65 YR Gender:Female I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Choreoathetosis
	Coordination Abnormal
	Depressed Level Of Consciousness
	Disorientation
	Drug Interaction
	Dyskinesia
	Electroencephalogram Abnormal
	Hypomania
	Renal Impairment
	Therapeutic Agent

Toxicity

		Report Source	Product	Role	Manufacturer	Route	Dose	Duration
		Foreign	Enalapril Maleate	PS				
		Literature	Lithium Carbonate	SS		ORAL	1200 MG Q DAY	
		Health					PO	
		Professional	Lithium Carbonate	SS		ORAL	600 MG Q DAY	
		Other					PO	

Date:01/06/04ISR Number: 4265922-3Report Type:Expedited (15-DaCompany Report #2003-DE-06467GD
Age:81 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Depressed Level Of Consciousness	Literature Health	Lithium Carbonate (Lithium Carbonate)	PS			42 MG	
	Muscle Rigidity	Professional	Rofecoxib					
	Renal Failure		(Rofecoxib)	SS			25 MG	
	Tremor							

Date:01/06/04ISR Number: 4265924-7Report Type:Expedited (15-DaCompany Report #2003-DE-06466GD
Age:71 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Apathy	Literature	Lithium Carbnoate					
	Drug Interaction	Health	(Lithium Carbonate)	PS			600 MG	
	Drug Level Increased	Professional	Rofecoxib					
	Gait Disturbance		(Rofecoxib)	SS			25 MG	
	Hypertonia							
	Mood Altered							
	Myoclonus							

Date:01/06/04ISR Number: 4265926-0Report Type:Expedited (15-DaCompany Report #2003-DE-06460GD
Age:58 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Interaction Drug Level Increased Neurotoxicity	Literature Health Professional	Lithium Carbonate(Lithium Carbonate) Rofecoxib (Rofecoxib)	PS SS			600 MG	9 DAY

Date:01/06/04ISR Number: 4265927-2Report Type:Expedited (15-DaCompany Report #2003-DE-06459GD
Age:91 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Delirium Drug Interaction Drug Level Increased Dysarthria Sedation	Literature Health Professional	Lithium Carbonate(Lithium Carbonate) Rofecoxib (Rofecoxib)	PS SS			450 MG	LESS THAN 1 MONTH

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/06/04ISR Number: 4265929-6Report Type:Expedited (15-DaCompany Report #2003-DE-06453GD
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Confusional State Coordination Abnormal	Literature Health	Lithium Carbonate (Lithium Carbonate)	PS			900 MG	
	Disorientation Drug Interaction	Professional	Rofecoxib (Rofecoxib)	SS			25 MG	
	Drug Level Increased							

Date:01/06/04ISR Number: 4265930-2Report Type:Expedited (15-DaCompany Report #2003-DE-06455GD
Age:69 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Aphasia Disorientation	Literature Health	Lithium Carbonate (Lithium Carbonate)	PS			ALTERNATING	
	Drug Interaction	Professional					1200 MG/D AND	
	Drug Level Increased						900 MG/D	
	Gait Disturbance Tremor		Rofecoxib (Rofecoxib)	SS				

Date:01/06/04ISR Number: 4265931-4Report Type:Expedited (15-DaCompany Report #2003-DE-06456GD
Age:72 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Asterixis Coordination Abnormal	Literature Health	Lithium Carbonate (Lithium Carbonate)	PS			900 MG	
	Dialysis	Professional	Rofecoxib	SS			25 MG	
	Drug Interaction Drug Level Increased Nystagmus							

Date:01/06/04ISR Number: 4265932-6Report Type:Expedited (15-DaCompany Report #2003-DE-06457GD
Age:62 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Confusional State	Literature	Lithium Carbonate (Lithium Carbonate)	PS			900 MG	
	Drug Interaction	Health						
	Drug Level Increased	Professional	Rofecoxib (Rofecoxib)	SS			25 MG	
	Urinary Tract Infection							

Date:01/06/04ISR Number: 4265933-8Report Type:Expedited (15-DaCompany Report #2003-DE-06449GD
Age:38 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other Required	Drug Interaction	Literature	Lithium Carbonate (Lithium Carbonate)	PS			900 MG	
	Drug Level Increased	Health						
Intervention to Prevent Permanent Impairment/Damage	Dyspepsia	Professional	Celecoxib (Celecoxib)	SS			200 MG	
	Influenza Like Illness							
	Tremor							

Date:01/06/04ISR Number: 4265935-1Report Type:Expedited (15-DaCompany Report #2003-DE-06448GD
Age:67 YR Gender:Female I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Blood Calcium Increased
	Blood Lactic Acid

		Drug Interaction Dysarthria Hemiparesis	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
		Renal Failure Renal Neoplasm	Literature Health	Lithium Carbonate (Lithium Carbonate)	PS		
600 MG							
			Professional	Rofecoxib (Rofecoxib)	SS		
40 MG							

Date:01/06/04ISR Number: 4265936-3Report Type:Expedited (15-DaCompany Report #2003-DE-06444GD
Age:59 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other Required	Coordination Abnormal Drug Interaction	Literature Health	Lithium Carbonate (Lithium Carbonate)	PS		
450 MG						
Intervention to Prevent Permanent	Drug Level Increased Dysarthria	Professional	Celecoxib (Celecoxib)	SS		
200 MG Impairment/Damage	Tremor					

Date:01/06/04ISR Number: 4266182-XReport Type:Expedited (15-DaCompany Report #2003-DE-01909GD
Age:58 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Life-Threatening Hospitalization -	Abdominal Pain Blood Creatine Increased	Foreign Literature	Lithium Carbonate (Lithium Carbonate)	PS		
210 MG (NR, Initial or Prolonged	Bradycardia					
IN THE	Drug Interaction					
MORINING AND	Haemodialysis					
AT NIGHT)	Hypotension Malaise Nausea Renal Impairment		Celecoxib (Antiinflammatory/An tirheumatic Products)	SS		
800 MG (NR,						

	Sinoatrial Block		
TWICE DAILY)			
	Somnolence	Sertraline	
	Therapeutic Agent	(Sertraline)	
	Toxicity	(Sertraline-Hcl)	C
		Ibuprofen	
		(Ibuprofen)	C
		Levomepromazine	
		(Levomepromazine)	C
		Esomeprazole (Drugs	
		For Treatment Of	
		Peptic Ulcer)	C

Date:01/08/04ISR Number: 4266586-5Report Type:Expedited (15-DaCompany Report #FR-BRISTOL-MYERS SQUIBB COMPANY-12463857
Age:63 YR Gender:Female I/FU:F

Outcome	PT
Hospitalization -	Anuria
Initial or Prolonged	Asthenia
	Blood Pressure Systolic
	Increased
	Confusional State
	Disorientation
	Drug Level Decreased
	Electrocardiogram Qrs
	Complex Shortened
	Hyperkalaemia
	Renal Failure Acute

		Speech Disorder Therapeutic Agent Toxicity	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
			Health Professional	Aprovel Tabs 300 Mg	PS	Bristol-Myers Squibb Company	ORAL
3	MON						
				Teralithe	SS		
"1 TABLET/DAY 1 DAY OF 2 DAYS & OTHER DAYS AT 0.5 TAB/DAY". 5,5							
				Lipanthyl	C		

Date:01/08/04ISR Number: 4266694-9Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0350706A
Age:41 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization -	Bipolar I Disorder	Consumer	Eskalith	PS	Glaxosmithkline	ORAL
7	YR					
Initial or Prolonged	Depression		Risperdal	C		
Other	Drug Toxicity		Navane	C		
UNKNOWN	15MG At night					
	Dry Mouth		Cogentin	C		
UNKNOWN						
	Dysgeusia					
	Hallucination, Auditory					
	Libido Decreased					
	Mania					
	Pollakiuria					
	Schizophreniform Disorder					
	Self-Injurious Ideation					
	Somnolence					
	Therapeutic Agent Toxicity					
	Thirst					

Date:01/08/04ISR Number: 4266726-8Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0416594A
Age:43 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Bipolar I Disorder	Consumer	Eskalith Cr	PS	Glaxosmithkline	ORAL	300MG Variable dose	
	Depression							
	Dry Mouth		Eskalith Cr	SS	Glaxosmithkline	ORAL	450MG See dosage text	8 YR
	Hallucination, Auditory							
	Libido Decreased		Eskalith	SS	Glaxosmithkline	ORAL	450MG See dosage text	19 MON
	Mania							
	Periodontal Disease		Navane	C				
	Self-Injurious Ideation		Cogentin	C				
	Therapeutic Agent Toxicity		Dilantin	C				
	Treatment Noncompliance							

Date:01/08/04ISR Number: 4281144-4Report Type:Periodic Company Report #2003-BP-06346RO (0)
Age:18 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Disability	Coma	Consumer	Lithium Carbonate Capsules Usp, 300 Mg (Lithium Carbonate)	PS		ORAL	PO	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/12/04ISR Number: 4269834-0Report Type:Expedited (15-DaCompany Report #HQWYE028805JAN04
Age:34 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Exposure During Pregnancy Drug Withdrawal Syndrome Medication Error Pregnancy Suicide Attempt	Consumer	Effexor Xr (Venlafaxine Hydrochloride, Capsule, Extended Release)	PS		ORAL	75 MG 1X PER 1 DAY, ORAL	
			Klonopin (Clonazepam,)	SS			UNKNOWN; 1 MG 3X PER 1 DAY	
			Lithium (Lithium,)	SS			OVERDOSE AMOUNT 30-40 LITHIUM TABLETS	
			Zyprexa (Olanzapine,)	SS			UNKNOWN; 15 MG 1X PER 1 DAY	

Date:01/12/04ISR Number: 4269872-8Report Type:Direct Company Report #CTU 209812
Age:62 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Toxicity		Lithium	PS		ORAL	600MG, 300 MG BID ORAL	
			Lisinopril	C				

Date:01/12/04ISR Number: 4270184-7Report Type:Expedited (15-DaCompany Report #HQWYE897223DEC03
Age:52 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Balance Disorder Blood Cholesterol Increased Blood Triglycerides Increased Depression Drug Interaction Drug Withdrawal Syndrome Eating Disorder Fall Hypoaesthesia Nausea Oedema Peripheral Paraesthesia Rash Pruritic Scar Stomatitis Swollen Tongue Vertigo Weight Increased	Health Professional	Effexor Xr (Venlafaxine Hydrochloride, Capsule, Colace (Docusate Sodium,) Effexor Xr (Venlafaxine Hydrochloride, Capsule, Extended Release) Effexor Xr (Venlafaxine Hydrochloride, Capsule, Extended Release) Seroquel (Quetiapine) Glucosamine (Glucosamine,) Lithium (Lithium,) Premarin (Conjugated Estrogens) Xanax (Alprazolam) Synthroid	PS SS SS SS SS SS SS C C		ORAL ORAL ORAL	1 225 MG 1X PER 1 DAY, ORAL	WK

(Levothyroxine Sodium)	C
Protonix (Pantoprazole)	C
Hyoscine Hydrobromide (Hyoscine Hydrobromide)	C
Phenobarbital (Phenobarbital)	C
Atropine Sulfate (Atropine Sulfate)	C
Hyoscyamine Sulfate (Hyoscyamine Sulfate)	C
Pepcid (Famotidine)	C
Zyrtec (Cetirizine Hydrochloride)	C
Calcium With Vitamin D (Calcium Phosphate/Calcium Sodium Lactate/Ergocalcifer	C
Lexapro (Escitalopram)	C
Prozac (Fluoxetine Hydrochloride)	C

Date:01/14/04ISR Number: 4270453-0Report Type:Expedited (15-DaCompany Report #JP-GLAXOSMITHKLINE-B0303617A
Age:37 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hypotension	Health	Paroxetine Hydrochloride Hydrate	PS	Glaxosmithkline	ORAL	20MG per day	64 DAY
	Intentional Self-Injury	Professional	Lithium Carbonate	SS	Glaxosmithkline	ORAL		
	Sick Sinus Syndrome		Levomepromazine Maleate	SS		ORAL	50MG per day	
			Perospirone	SS		ORAL	12MG per day	

Date:01/14/04ISR Number: 4271319-2Report Type:Direct Company Report #CTU 210049
Age:15 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Thyroid Disorder		Lithium	PS				

Date:01/14/04ISR Number: 4271322-2Report Type:Direct Company Report #CTU 210050
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Thyroid Disorder		Lithium	PS				

Date:01/14/04ISR Number: 4271323-4Report Type:Direct Company Report #CTU 210051
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Thyroid Disorder		Lithium	PS				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/14/04ISR Number: 4272235-2Report Type:Expedited (15-DaCompany Report #S03-USA-04093-01
Age:27 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Deep Vein Thrombosis Pulmonary Embolism	Health Professional	Lexapro (Escitalopram)	PS		ORAL	10 MG QD PO	
			Lexapro (Escitalopram)	SS		ORAL	20 MG QD PO	
			Lexapro(Escitalopram)	SS		ORAL	10 MG QD PO	
			Risperdal(Risperidone)	SS			2.5 MG QD	
			Lithium	SS			1500 MG QD	

Date:01/16/04ISR Number: 4273152-4Report Type:Expedited (15-DaCompany Report #GB-GLAXOSMITHKLINE-B0319832A
Age:51 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Intestinal Infarction		Lithium	PS	Glaxosmithkline			
Hospitalization - Initial or Prolonged	Schizophrenia Sepsis		Risperidone	SS		INTRAMUSCULAR	50MG Every two weeks	
			Chlorpromazine	C	Glaxosmithkline		200MG per day	
			Ferrous Sulphate	C	Glaxosmithkline			
			Acetylsalicylic Acid	C	Glaxosmithkline		75MG per day	

Date:01/16/04ISR Number: 4273656-4Report Type:Direct Company Report #CTU 210235
Age:44 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required	Acute Prerenal Failure		Lithium Carbonate					

Intervention to 1000MG QAM	Fatigue		300 Mg	PS		ORAL
Prevent Permanent ORAL, 500 MG	Oedema Peripheral					
Impairment/Damage QHS ORAL	Pain In Extremity					
	Pitting Oedema		Zyprexa	C		
	Polyuria		Clonazepam	C		
	Proteinuria		Sonata	C		
	Renal Hypertrophy					
	Urine Output Increased					
	Weight Increased					

Date:01/16/04ISR Number: 4275082-0Report Type:Expedited (15-DaCompany Report #2003033768
Age:80 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Blood Calcium Increased	Foreign	Lithium (Lithium)	PS		ORAL
ORAL						
Initial or Prolonged	Blood Creatine Increased	Health	Metformin			
	Blood Potassium Increased	Professional	Hydrochloride			
	Drug Toxicity		(Metformin			
	Hypoglycaemia		Hydrochloride)	C		
	Non-Hodgkin'S Lymphoma		Dipyridamole			
	Overdose		(Dipyridamole)	C		
			Furosemide			
			(Furosemide)	C		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/20/04ISR Number: 4274081-2Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0396611A
Age:20 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Atrial Tachycardia		Eskalith Cr	PS	Glaxosmithkline	ORAL	450MG Three	
	Bipolar Disorder						times per day	
	Drug Exposure During		Depakote Er	C				
UNKNOWN							500MG Twice	
	Pregnancy						per day	511 DAY
	Mitral Valve Prolapse		Wellbutrin Sr	C	Glaxosmithkline			
UNKNOWN							150MG Twice	
	Pre-Eclampsia						per day	
	Proteinuria		Zyprexa	C				
UNKNOWN							12.5MG Per	
	Syncope						day	

Date:01/20/04ISR Number: 4276323-6Report Type:Direct Company Report #CTU 210433
Age:71 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Dehydration		Lithium	PS			300 MG TID	
Initial or Prolonged	Lethargy		Hctz	SS			12.5 MG QD	
	Nausea		Accu-Chek Comfort Cv					
	Renal Disorder		(Glucose) Test Strip	C				
	Tremor		Albuterol	C				
			Alcohol Prep Pad	C				
			Bupropion Hcl	C				
			Calcipotriene	C				
			Chlorpheniramine Maleate	C				
			Donepezil Hcl	C				
			Enalapril Maleate	C				
			Fluocinonide	C				
			Fluoxetine Hcl	C				
			Hydrochlorothiazide	C				
			Ibuprofen	C				

Insulin Nph Human	C
Insulin Syringe	C
Lancet, Techlite	C
Meclizine Hcl	C
Oxybutynin Chloride	C
Risperidone	C
Scopolamine	C
Terazosin Hcl	C

Date:01/20/04ISR Number: 4276520-XReport Type:Expedited (15-DaCompany Report #2004001344
Age:53 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Asthenia	Literature	Lithium (Lithium)	PS			1350 MG (DAILY)	
	Drug Interaction	Health						
	Potentiation	Professional	Celecoxib (Celecoxib)	SS				
	Drug Level Increased							
	Nausea							
	Tremor							
	Vomiting							

Date:01/20/04ISR Number: 4276527-2Report Type:Expedited (15-DaCompany Report #2004001352
Age:58 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Abdominal Pain Antidepressant Drug Level Increased Dialysis Dizziness Drug Interaction Potentiation Dyspnoea Hypotension Vomiting	Literature Health Professional	Lithium (Lithium) Celecoxib (Celecoxib)	PS SS			800 MG(DAILY)	

Date:01/20/04ISR Number: 4276677-0Report Type:Expedited (15-DaCompany Report #2004001348
Age:51 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Level Increased Lethargy	Literature Health Professional	Lithium (Lithium) Celecoxib (Celecoxib)	PS SS			1200 MG (DAILY) 400 MG (DAILY)	

Date:01/20/04ISR Number: 4277060-4Report Type:Expedited (15-DaCompany Report #HQWYE286113JAN04
Age:46 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Ineffective Drug Interaction Hypomania Nausea Serotonin Syndrome	Study Literature	Efexor Er (Venlafaxine Hydrochloride, Capsule, Extended Release)	PS		ORAL	300 MG DAILY	

Tremor
(PROGRESSIVE

TITRATION FOR

FIRST 3 40 DAY
Lithium (Lithium,) SS ORAL

BASED ON

24-HOUR

SINGLE DOSE

PLASMA LEVEL 12 DAY

Date:01/20/04ISR Number: 4277185-3Report Type:Expedited (15-DaCompany Report #HQWYE201308JAN04
Age:45 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Ineffective Drug Interaction Hypomania Nausea Serotonin Syndrome Tremor	Study Literature	Effexor Er (Venlafaxine Hydrochloride, Capsule, Extended Release)	PS		ORAL	300 MG DAILY	

(PROGRESSIVE

TITRATION FOR

FIRST 3 40 DAY
Lithium (Lithium,) SS ORAL

BASED ON

24-HOUR

SINGLE DOSE

PLASMA LEVEL;

ORAL 12 DAY

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/21/04ISR Number: 4277471-7Report Type:Direct Company Report #CTU 210539
Age:53 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Aggression		Lithium Carbonate Sa					
Hospitalization -	Confusional State		450 Mg	PS		ORAL	1350 MG QHS	
Initial or Prolonged	Drug Level Increased						ORAL	
Required	Fluid Intake Reduced		Carbamazepine	C				
Intervention to	Incoherent		Haldol	C				
Prevent Permanent	Renal Failure Acute		Synthroid	C				
Impairment/Damage	Viral Infection		Diltiazem	C				
			Clonidine	C				
			Ranitidine	C				
			Loratadine	C				
			Candesartan	C				
			Atenolol	C				
			Trazodone	C				

Date:01/22/04ISR Number: 4278870-XReport Type:Direct Company Report #CTU 210746
Age:56 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Blood Creatinine		Lithium 300 Mg	PS		ORAL	300MG/600MG	
Hospitalization -	Increased						QAM/QPM ORAL	
Initial or Prolonged	Coma		Lisinopril 20 Mg	SS		ORAL	10 MG -1/2 TA	
	Convulsion						QD ORAL	
	Dialysis							
	Dizziness							

Date:01/23/04ISR Number: 4279216-3Report Type:Expedited (15-DaCompany Report #2004003686
Age:71 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Hospitalization -	Apathy	Literature	Lithium (Lithium)	PS			
600 MG							
Initial or Prolonged	Drug Interaction	Health					
(DAILY)							
	Drug Level Increased	Professional	Rofecoxib				
	Gait Disturbance		(Rofecoxib)	SS			
25 MG (DAILY)							
	Hypertonia						
	Mood Altered						
	Myoclonus						

Date:01/23/04ISR Number: 4279274-6Report Type:Expedited (15-DaCompany Report #2004003675
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Confusional State	Literature	Lithium (Lithium)	PS				
900 MG								
Initial or Prolonged	Coordination Abnormal	Health						
(DAILY),								
Other	Dialysis	Professional	Rofecoxib					
	Disorientation		(Rofecoxib)	SS				
25 MG (DAILY)								
	Drug Interaction							
	Drug Level Increased							

Date:01/23/04ISR Number: 4279276-XReport Type:Expedited (15-DaCompany Report #2004003671
Age:67 YR Gender:Female I/FU:I

Outcome
Hospitalization -
Initial or Prolonged

Other

	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Interaction	Literature	Lithium (Lithium)	PS			600 MG	
	Drug Level Increased	Health					(DAILY)	
	Dysarthria	Professional	Rofecoxib					
	Hemiparesis		(Rofecoxib)	SS			40 MG (DAILY)	
	Renal Failure							
	Renal Neoplasm							

Date:01/23/04ISR Number: 4279604-5Report Type:Expedited (15-DaCompany Report #2004003677
Age:58 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Drug Interaction	Literature	Lithium	PS			600 MG, DAILY	
Initial or Prolonged	Drug Level Increased	Health	Rofecoxib	SS				
	Neurotoxicity	Professional						

Date:01/23/04ISR Number: 4279606-9Report Type:Expedited (15-DaCompany Report #2004003674
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Drug Level Increased	Literature	Lithium	PS				
Initial or Prolonged		Health	Rofecoxib	SS			25 MG, DAILY	
		Professional						

Date:01/23/04ISR Number: 4279615-XReport Type:Expedited (15-DaCompany Report #2004004014
Age:81 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Depressed Level Of	Literature	Lithium (Lithium)	PS			42 MG, DAILY	

Initial or Prolonged	Consciousness	Health	Rofecoxib	SS			
25 MG, DAILY							
	Drug Interaction	Professional					
	Drug Level Increased						
	Muscle Rigidity						
	Renal Failure						
	Tremor						

Date:01/23/04ISR Number: 4279675-6Report Type:Expedited (15-DaCompany Report #2004003672
Age:72 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Asterixis	Literature	Lithium (Lithium)	PS			900 MG	
Initial or Prolonged	Coordination Abnormal	Health					(DAILY),	
Other	Drug Interaction	Professional					UNKNOWN	
	Nystagmus		Rofecoxib (Rofecoxib)	SS			25 MG (DAILY), UNKNOWN	

Date:01/23/04ISR Number: 4279676-8Report Type:Expedited (15-DaCompany Report #2004003681
Age:91 YR Gender:Female I/FU:I

Outcome	PT
Hospitalization -	Delirium
Initial or Prolonged	Drug Interaction

	Drug Level Increased Dysarthria Sedation	Report Source	Product	Role	Manufacturer	Route	Dose Duration
		Literature	Lithium (Lithium)	PS			450 MG
		Health					(DAILY),
		Professional					UNKNOWN
			Rofecoxib (Rofecoxib)	SS			

Date:01/23/04ISR Number: 4279677-XReport Type:Expedited (15-DaCompany Report #2004003683
Age:69 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Aphasia	Literature	Lithium (Lithium)	PS			UNKNOWN
Initial or Prolonged	Disorientation	Health					(DAILY),
	Drug Interaction Gait Disturbance Tremor	Professional	Rofecoxib (Rofecoxib)	SS			

Date:01/23/04ISR Number: 4280655-5Report Type:Expedited (15-DaCompany Report #2004003685
Age:62 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Confusional State	Literature	Lithium (Lithium)	PS			900 MG
Initial or Prolonged	Drug Interaction	Health					(DAILY),
	Drug Level Increased Urinary Tract Infection	Professional	Rofecoxib (Rofecoxib)	SS			25 MG (DAILY),

Date:01/26/04ISR Number: 4279462-9Report Type:Direct Company Report #CTU 210872
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Acne		Lithium Carbonate 300 Mg	PS		ORAL	750-900 MG QD	ORAL

Date:01/26/04ISR Number: 4280038-8Report Type:Expedited (15-DaCompany Report #2003119149
Age:63 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Abdominal Pain Upper Cardiac Arrest Disease Recurrence Nausea Psychotic Disorder Sudden Cardiac Death Vomiting	Foreign Health Professional Company Representative	Zeldox (Capsules) (Ziprasidone) Lithium Acetate (Lithium Acetate) Olanzapine (Olanzapine) Carbamazepine (Carbamazepine) Antihypertensives All Other Therapeutic Products Diazepam (Diazepam) Flunitrazepam (Flunitrazepam)	PS SS C C C C C C		ORAL ORAL	160 MG (BID), ORAL	ORAL ORAL

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Bisoprolol Fumarate (Bisoprolorl Fumarate)	C

Date:01/27/04ISR Number: 4280479-9Report Type:Expedited (15-DaCompany Report #2004002987
Age:34 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Diabetes Insipidus Electrocardiogram Qrs Complex Erythema Eyelid Ptosis Haemangioma Motor Dysfunction Neonatal Respiratory Distress Syndrome Polyhydramnios Premature Baby Premature Rupture Of Membranes Skin Lesion Tachycardia Foetal	Foreign Literature Health Professional Other	Lithium (Lithium)	PS				

Date:01/27/04ISR Number: 4280556-2Report Type:Expedited (15-DaCompany Report #2004002989
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Diabetes Insipidus Drug Exposure During Pregnancy Electrocardiogram Qrs Complex Erythema Eyelid Ptosis Haemangioma Hypokinesia Motor Dysfunction Neonatal Respiratory Distress Syndrome Skin Lesion	Foreign Literature Health Professional	Lithium (Lithium)	PS				

Supraventricular
Tachycardia
Urine Osmolarity
Decreased
Weight Decreased

Date:01/27/04ISR Number: 4280576-8Report Type:Expedited (15-DaCompany Report #2003119149
Age:63 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Abdominal Pain Upper	Foreign	Zeldox (Capsules)					
	Cardiac Arrest	Health	(Ziprasidone)	PS		ORAL	160 MG BID	
	Loss Of Consciousness	Professional						ORAL
	Nausea	Company	Lithium Acetate					
	Vomiting	Representative	(Lithium Acetate)	SS		ORAL		ORAL
			Olanzapine	C				
			Carbamazepine	C				

Antihypertensives	C
All Other Therapeutic Products	C
Diazepam	C
Carbamazepine	C
Flunitrazepam	C
Bisoprolol Fumarate	C

Date:01/28/04ISR Number: 4281766-0Report Type:Expedited (15-DaCompany Report #LBID00204000185
Age:32 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Arthralgia Blood Amylase Increased Blood Chloride Decreased	Foreign Literature Health	Lithium Carbonate (Lithium Carbonate))	PS		ORAL	DAILY PO	10 YR
	Blood Glucose Increased Blood Potassium Decreased Body Temperature Increased Cerebellar Ataxia Depressed Level Of Consciousness Glomerulosclerosis Haemodialysis Hypercalcaemia Lipase Increased Nephritis Interstitial Occult Blood Positive Parkinsonism Platelet Count Increased Polyuria Proteinuria Rash Renal Failure Acute Respiratory Rate Increased Rhabdomyolysis Sinus Tachycardia Somnolence Therapeutic Agent Toxicity White Blood Cell Count Increased	Professional Other						

Date:01/28/04ISR Number: 4281914-2Report Type:Expedited (15-DaCompany Report #LBID00204000172
Age:45 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Candiduria Diabetes Insipidus Diabetic Hyperosmolar Coma Hypotension	Literature Health Professional	Lithium Carbonate Fluphenazine (Fluphenazine) Thioridazine (Thioridazine) Trihehyphenidyl (Trihexyphenidyl) Carbamazepine (Carbamazepine) L-Thyroxine (L-Thyroxine)	PS C C C C		ORAL	DAILY PO	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/29/04ISR Number: 4283685-2Report Type:Direct Company Report #CTU 211114
Age:65 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Level Increased		Lithium	PS		ORAL	600 MG PO BID	
	Hypotension		Lotensin	SS		ORAL	20 MG PO QID	
	Mental Status Changes		Thioridazine	C				
	Speech Disorder		Metformin	C				
	White Blood Cell Count Increased							

Date:01/30/04ISR Number: 4282241-XReport Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0495767A
Age:49 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Autoimmune Thyroiditis		Eskalith	PS	Glaxosmithkline			
UNKNOWN								4 YR
	Hypothyroidism		Thorazine	C	Glaxosmithkline			

Date:01/30/04ISR Number: 4282245-7Report Type:Expedited (15-DaCompany Report #DE-GLAXOSMITHKLINE-D0042997A
Age:66 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Accidental Overdose	Health Professional	Quilonum Retard	PS	Glaxosmithkline	ORAL		
	Dehydration							
	Renal Failure							
	Speech Disorder							

Date:01/30/04ISR Number: 4284414-9Report Type:Direct Company Report #CTU 211226
Age:67 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Drug Interaction		Lithium	PS				
300 MG BID								

Initial or Prolonged	Tremor	Fosinopril	SS	20 MG BID
		Furosemide	SS	40 MG BID
		Aspirin	C	
		Furosemide	C	
		Glipizide	C	
		Metformin	C	
		Metoprolol	C	
		Primadone	C	
		Simvastatin	C	

Date:02/03/04ISR Number: 4284169-8Report Type:Expedited (15-DaCompany Report #DE-GLAXOSMITHKLINE-D0043012A
Age:44 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Suicidal Ideation		Quilonum Retard	PS	Glaxosmithkline	ORAL	450MG Twenty	
	Suicide Attempt						times per day	
	Vomiting		Tavor	SS		ORAL	.5MG Twenty	
							times per day	

Date:02/04/04ISR Number: 4285990-2Report Type:Direct Company Report #CTU 211533
Age: Gender:Female I/FU:I

Outcome
Required
Intervention to

Prevent Permanent
Impairment/Damage

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Tremor		Lithium 300 Mg	PS		ORAL	900 MG QD	
						ORAL		

Date:02/04/04ISR Number: 4286453-0Report Type:Expedited (15-DaCompany Report #2004196601CH
Age:62 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Coma	Foreign	Luvox (Fluvoxamine					
	Intentional Misuse	Health	Maleate) Tablet	PS		ORAL	800 MG,	
	Multiple Drug Overdose	Professional					SINGLE, ORAL	
	Renal Failure Acute	Other	Priadel (Lithium					
	Serotonin Syndrome		Carbonate)	SS		ORAL	4000 MG,	
	Suicide Attempt						SINGLE, ORAL	
			Tramal (Tramadol					
			Hydrochloride)	SS		ORAL	4500 MG,	
							SINGLE, ORAL	
			Entumin (Clotiapine)	SS		ORAL	4000 MG,	
							SINGLE, ORAL	
			Ponstan (Mefenamic					
			Acid0	SS		ORAL	18000 MG,	
							SINGLE, ORAL	
			Inderal (Propranolol					
			Hydrochloride)	SS		ORAL	300 MG,	
							SINGLE, ORAL	
			Tranxilium					
			(Clorazepate					

			Dipotassium)	SS		ORAL
250 MG, SINGLE, ORAL						
			Detrusitol (Tolterodine) Tablet	SS		ORAL
14 MG, SINGLE, ORAL						
			Dalmadorm (Flurazepam Hydrochloride)	SS		ORAL
1800 MG, SINGLE, ORAL						

Date:02/05/04ISR Number: 4286265-8Report Type:Direct Company Report #CTU 211620
Age:55 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Toxicity		Lithium Carbonate	PS			600 MG TID	
	Gait Disturbance		Diuretic	SS				
	Renal Failure Acute		Bupropion	C				
	Renal Failure Chronic		Celecoxib	C				
			Metoprolol	C				
			Temazepam	C				
			Warfarin	C				
			Augmentin	C				
			Albuterol	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/05/04ISR Number: 4287421-5Report Type:Expedited (15-DaCompany Report #A208548
Age:15 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blood Cholesterol	Health	Lithium(Lithium)	PS				
Required	Increased	Professional	Ziprasidone (Caps)					
Intervention to	Eye Movement Disorder		(Ziprasidone)	SS		ORAL	80 MG (BID),	
Prevent Permanent	Globulins Increased					ORAL		
Impairment/Damage	Pyelonephritis		Clozaril (Clozapine)	C				
	Red Cell Distribution		Depakote (Valproate					
	Width Increased		Semisodium)	C				
			Cogentin					
			(Benzatropine					
			Mesilate)	C				

Date:02/06/04ISR Number: 4286725-XReport Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0414562A
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Abdominal Pain	Consumer	Eskalith Cr	PS	Glaxosmithkline	ORAL	1350MG per	
	Diarrhoea						day	
	Dizziness							
	Fatigue							
	Gastric Disorder							
	Loss Of Consciousness							
	Syncope							
	Temperature Intolerance							
	Tremor							
	Visual Acuity Reduced							
	Vomiting							

Date:02/06/04ISR Number: 4286761-3Report Type:Expedited (15-DaCompany Report #DE-GLAXOSMITHKLINE-D0041890A
Age:50 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Fatigue Suicide Attempt	Health Professional	Quilonum Retard	PS	Glaxosmithkline	ORAL	2TAB Single	
			Amitriptylin	SS		ORAL	5TAB Single	
			Ass Ratiopharm	SS	Glaxosmithkline	ORAL	20TAB Single	

Date:02/06/04ISR Number: 4290789-7Report Type:Direct Company Report #CTU 211809
Age:51 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Dehydration Drug Interaction Drug Toxicity Renal Failure Acute Renal Failure Chronic		Lithium Carbonate 300mg	PS			600 MG AM, 600 MG LUNCH, 900 MG PM	
			Ibuprofen 600mg (Also Advil/Aleve)	SS			600MG QD PRN AND OTC MEDS	14 DAY

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Freedom Of Information (FOI) Report

Date:02/09/04ISR Number: 4288624-6Report Type:Expedited (15-DaCompany Report #DE-GLAXOSMITHKLINE-D0042782A
Age:44 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Anuria	Health	Quilonum Retard	PS	Glaxosmithkline	ORAL	45000TAB per	
Hospitalization -	Aspiration	Professional						day
Initial or Prolonged	Blood Creatine		Trimipramine	SS		ORAL	5000MG per	
	Phosphokinase Increased							day
	Bowel Sounds Abnormal		Zyprexa	SS		ORAL	56TAB per day	
	Coma							
	Completed Suicide							
	Death							
	Pyrexia							
	Shock							
	Vomiting							

Date:02/09/04ISR Number: 4288845-2Report Type:Expedited (15-DaCompany Report #PHFR2004GB00801
Age:37 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Level Increased		Clozaril	PS	Novartis Sector:			
	Drug Toxicity				Pharma	ORAL	650mg/day	
	Eating Disorder		Lithium	SS				
	Malaise							
	Neutrophil Count Increased							
	Oral Intake Reduced							
	White Blood Cell Count Increased							

Date:02/09/04ISR Number: 4289740-5Report Type:Expedited (15-DaCompany Report #LBIDO00204000210
Age:65 YR Gender:Female I/FU:I

Outcome	PT
Death	Atrial Fibrillation

Hospitalization - Initial or Prolonged	Atrioventricular Block
	Blood Creatinine Increased
	Blood Urea Increased
	Bowel Sounds Abnormal
	Coma
	Dehydration
	Diarrhoea
	Disorientation
	Disseminated Intravascular Coagulation
	Drug Level Above Therapeutic
	Electrocardiogram St Segment Depression
	Electrocardiogram T Wave Inversion
	Electromechanical Dissociation
	Haemodialysis
	Hyporeflexia
	Hypotension
	Lethargy
	Nausea
	Obesity

		Oxygen Saturation Decreased Rales Retching Rhabdomyolysis Speech Disorder Toxicologic Test Abnormal Urine Output Decreased Ventricular Fibrillation Vomiting	Report Source Literature Health Professional	Product Lithium Carbonate (Manufacturer Unknown) (Lithium Carbonate (Manufacturer Nifedipine (Nifedipine) Atenolol (Atenolol) Nitroglycerin (Glyceryl Trinitrate)	Role PS C C C	Manufacturer	Route ORAL
Dose 600 MG DAILY PO	Duration 1 YR						

Date:02/09/04ISR Number: 4290299-7Report Type:Expedited (15-DaCompany Report #HQWYE897223DEC03
Age:52 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Disability	Appetite Disorder Balance Disorder Blood Cholesterol Increased Blood Triglycerides Increased Depression Drug Ineffective Drug Interaction Drug Interaction Inhibition Drug Withdrawal Syndrome Fall Hypoaesthesia	Health Professional	Effexor (Venlafaxine Hydrochloride, Tablet) Colace (Docusate Sodium,) Effexor Xr (Venlafaxine Hydrochloride, Capsule, Extended Release)	PS SS SS		ORAL ORAL ORAL
ORAL 1 WK ORAL; 225 MG 1X PER 1 DAY, ORAL; 75 MG 1X PER 1 DAY, ORAL						

Nausea	Glucosamine	
Oedema Peripheral	(Glucosamine,)	SS
Paraesthesia	Lithium (Lithium,)	SS
Rash	Premarin (Conjugated	
Rash Pruritic	Estrogens)	C
Scar	Seroquel	
Stomatitis	(Quetiapine)	C
Swollen Tongue	Xanax (Alprazolam)	C
Vertigo	Synthroid	
Weight Increased	(Levothyroxine	
	Sodium)	C
	Protonix	
	(Pantoprazole)	C
	Hyoscine	
	Hydrobromide	
	(Hyoscine	
	Hydrobromide)	C
	Phenobarbital	
	(Phenobarbital)	C
	Atropine Sulfate	
	(Atropine Sulfate)	C
	Hyoscyamine Sulfate	
	(Hyoscyamine	
	Sulfate)	C
	Pepcid (Famotidine)	C
	Calcium With Vitamin	

			D (Calcium Phosphate/Calcium Sodium Lactate/Ergocalcifer	C		
			Lexapro (Escitalopram)	C		
			Prozac (Fluoxetine Hydrochloride)	C		

Date:02/10/04ISR Number: 4291457-8Report Type:Direct Company Report #CTU 211969
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Confusional State		Eskalth Cr , 450 Mg	PS		ORAL	TWO PO QHS	
	Diarrhoea		Haldol	C				
	Drug Toxicity		Cogentin	C				
	Gait Disturbance		Vit E	C				
	Nausea							
	Tremor							
	Vomiting							

Date:02/10/04ISR Number: 4293433-8Report Type:Direct Company Report #CTU 211989
Age:45 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Convulsion		Tramadol 50 Mg	PS			ONE TABS QID PM	
			Lithium 300 Mg	SS			300 MG AM , 600 MG PM	
			Carbamazepine	C				
			Felodipine	C				
			Fluoxetine	C				
			Simvastatin	C				

Date:02/11/04ISR Number: 4292269-1Report Type:Expedited (15-DaCompany Report #DE-GLAXOSMITHKLINE-D0043090A
Age:52 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Nausea	Health	Quilonum Retard	PS	Glaxosmithkline	ORAL	100TAB	Single
	Suicide Attempt	Professional					dose	
	Urinary Retention							

Date:02/11/04ISR Number: 4294704-1Report Type:Expedited (15-DaCompany Report #JP-JNJFOC-20040104956
Age:24 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Anger	Foreign	Risperdal					
Hospitalization - Initial or Prolonged	C-Reactive Protein Increased	Health Professional	(Risperidone) Unspecified	PS		ORAL	3 MG, IN 1	
Other	Depressed Level Of Consciousness						DAY, ORAL	
	Drug Interaction		Lithium Carbonate				: 4 MG , ORAL	
	Haematuria		(Lithium Carbonate)					
	Injury Asphyxiation		Unspecified	SS		ORAL	400 MG , IN 1	
	Mutism						DAY, ORAL	
	Neuroleptic Malignant Syndrome							
	Pain							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/12/04ISR Number: 4293711-2Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0031767A
Age:42 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Confusional State		Zovirax	PS	Glaxosmithkline	INTRAVENOUS	750MG Three times per day	
	Disorientation							
	Drug Interaction		Lithium	SS	Glaxosmithkline	ORAL	450MG Twice per day	8 YR
	Dysarthria							
	Fall		Valproic Acid	C		ORAL	750MG Per day	
	Hyperreflexia		Decadron	C		ORAL	.5MG Per day	
	Injury		Warfarin	C	Glaxosmithkline	ORAL	2MG Alternate days	
	Lethargy							
	Nausea		Morphine Sulfate	C	Glaxosmithkline	ORAL	15MG Three times per day	
	Therapeutic Agent							
	Toxicity		D5w	C			300ML per day	
	Tremor							
	Vomiting							

Date:02/12/04ISR Number: 4294133-0Report Type:Direct Company Report #CTU 212218
Age:24 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	Alcohol Use		Lithium 300 Mg Tabs	PS		ORAL	300 MG PO	
	Dialysis							
	Medication Error							
	Overdose							
	Somnolence							
	Vomiting							

Date:02/12/04ISR Number: 4295443-3Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20040201566
Age:61 YR Gender:Female I/FU:I

Outcome	PT
Life-Threatening	Abdominal Distension
Hospitalization - Initial or Prolonged	Anaemia
Disability	Blood Urea Decreased
	Bradycardia
	Cogwheel Rigidity
	Coma
	Diarrhoea
	Drug Interaction
	Drug Toxicity
	Electroencephalogram Abnormal
	Gastric Ulcer
	Gastritis Haemorrhagic
	Gastrointestinal Haemorrhage
	Haematemesis
	Haemodialysis
	Heart Rate Increased
	Hyperreflexia
	Hyperventilation
	Hypotension
	Hypoxia
	Metabolic Acidosis
	Miosis
	Multiple Drug Overdose
	Myoclonus
	Oedema Peripheral

	Oliguria						
	Petechiae						
	Pitting Oedema	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Pulse Pressure Decreased	Foreign	Tramal (Tramadol Hydrochloride)				
	Renal Failure Acute	Health	Tablets	PS			
	Scar	Professional	Lithium (Lithium)	SS			
	Serotonin Syndrome		Fluvoxamine (Fluvoxamine)	SS			
	Suicide Attempt		Clotiapine (Clotiapine)	SS			
	Tachycardia		Ponstan (Mefenamic Acid)	SS		ORAL	ORAL
	Tachypnoea		Flurazepam (Flurazepam)	C			
	Thrombocytopenia		Inderal (Propranolol Hydrochloride)	C			
			Tranxilium (Clorazepate Dipotassium)	C			
			Detrusitol (Tolterodine L-Tartrate)	C			

Date:02/12/04ISR Number: 4295466-4Report Type:Expedited (15-DaCompany Report #04-0010-PO
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Life-Threatening	Coma	Foreign	Ponstan (Mefenamic Acid) /Ponstel	PS		ORAL	18G, ONCE, PO
Hospitalization - Initial or Prolonged	Renal Failure Acute	Health	Lithium Carbonate	SS		ORAL	4000MG, ONCE, PO
	Serotonin Syndrome	Professional	Fluvoxamine Maleate	SS		ORAL	800MG, ONCE, PO
	Suicide Attempt	Other	Clorazepate Dipotassium	SS		ORAL	250MG, ONCE,

PO	Clotiapine	SS	ORAL
4000MG, ONCE,			
PO	Flurazepam Hydrochloride	SS	ORAL
1800MG, ONCE,			
PO	Tramadol Hydrochloride	SS	ORAL
450MG, ONCE,			
PO	Propranolol Hydrochloride	SS	ORAL
300MG, ONCE,			
PO			

Date:02/13/04ISR Number: 4295041-1Report Type:Expedited (15-DaCompany Report #FLUV00304000212
Age:31 YR Gender:Female I/FU:I

Outcome	PT
Life-Threatening	Abdominal Distension
Hospitalization - Initial or Prolonged	Anaemia
	Bradycardia
	Coma
	Diarrhoea
	Drug Level Above

	Therapeutic Flatulence Gastric Ulcer Gastritis Haemorrhagic	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Haematemesis Haemodialysis Hyperreflexia	Foreign Other	Floxyfral (Fluvoxamine Maleate)	PS		ORAL	800 MG DAILY
	Hypotension						PO
	Hypoxia Metabolic Acidosis		Priadel (Lithium Carbonate)	SS		ORAL	4000 MG DAILY
	Miosis						PO
	Multiple Drug Overdose Myoclonus		Tramal (Tramadol Hydrochloride)	SS		ORAL	4500 MG DAILY
	Oedema Peripheral						PO
	Petechiae Pitting Oedema		Entumine (Clotiapine)	SS		ORAL	4000 MG DAILY
	Pulse Abnormal						PO
	Renal Failure Acute Serotonin Syndrome		Ponstan (Mefenamic Acid)	SS		ORAL	18000 MG
	Suicide Attempt						DAILY PO
	Tachycardia Tachypnoea		Inderal (Propranolol Hydrochloride)	SS		ORAL	300 MG DAILY
	Thrombocytopenia						PO
			Tranxilium (Clorazepate Dipotassium)	SS		ORAL	250 MG DAILY
							PO
			Detrusitol (Tolterodine L-Tartrate)	SS		ORAL	14 MG DAILY
							PO

			Dalmadorm (Flurazepam Hydrochloride)	SS		ORAL
1800 MG DAILY						
PO						

Date:02/13/04ISR Number: 4296334-4Report Type:Direct Company Report #CTU 212303
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Hallucination, Visual		Eskalith Cr	PS		ORAL
450 MG PO TID						
Initial or Prolonged	Leukocytosis		Seroquel	C		
			Risperdal	C		

Date:02/16/04ISR Number: 4294840-XReport Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0393194A
Age:53 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
	Depressed Mood		Lamictal	PS	Glaxosmithkline	ORAL
25MG Per day 12 DAY						
	Depression		Lithobid	SS	Glaxosmithkline	
UNKNOWN						
	Feeling Abnormal		Klonopin	C		
.5MG At night						
	Mood Swings		Vitamins	C		
	Tremor		Amiloride	C		
			Hctz	C		
			Augmentin	C	Glaxosmithkline	

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Date:02/16/04ISR Number: 4295228-8Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0405196A
Age:55 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Extrapyramidal Disorder		Lamictal	PS	Glaxosmithkline	ORAL	200MG Three times per day	
			Lithium Co3	SS	Glaxosmithkline	ORAL	450MG Three times per day	
			Zyprexa	C				
			Wellbutrin	C	Glaxosmithkline	ORAL	150MG Twice per day	
			Lorazepam	C		ORAL	.5MG As required	

Date:02/16/04ISR Number: 4295727-9Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0430891A
Age:53 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Nasal Congestion		Lamictal	PS	Glaxosmithkline	ORAL	100MG Twice per day	6 MON
	Rhinitis							
			Lithium Carbonate	SS	Glaxosmithkline	ORAL		
			Zestril	C				
			Topamax	C				
			Synthroid	C	Glaxosmithkline			
			Pravachol	C				

Date:02/16/04ISR Number: 4295799-1Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0433288A
Age:14 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

	Acne		Lamictal	PS	Glaxosmithkline	ORAL
25MG per day 19 DAY						
	Fatigue		Paxil	SS	Glaxosmithkline	
	Mania		Eskalith Cr	SS	Glaxosmithkline	
	Pruritus		Eskalith Cr	C	Glaxosmithkline	
	Weight Increased					

Date:02/16/04ISR Number: 4295913-8Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0442083A
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
	Psychotic Disorder		Lamictal	PS	Glaxosmithkline	ORAL
			Wellbutrin	SS	Glaxosmithkline	ORAL
			Lithium	SS	Glaxosmithkline	
UNKNOWN						

Date:02/18/04ISR Number: 4299900-5Report Type:Expedited (15-DaCompany Report #B0321403A
Age:54 YR Gender:Male I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Anorexia
	Aphasia
	Apraxia
	Asthenia
	Confusional State
	Coordination Abnormal
	Delirium
	Drug Toxicity
	Dysarthria
	Dysgeusia

		Fatigue					
		Haemodialysis					
		Hypercalcaemia	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
		Irritability	Foreign	Lithium Carbonate			
		Nausea	Literature	(Generic) (Lithium			
		Renal Failure Acute	Health	Carbonate)	PS		
300 MG/ FIVE							
		Restlessness	Professional				
TIMES PER							
		Somnolence	Other				
DAY/ UNKNOW	15 YR						
		Tremor		Thioridazine			
				(Formulation			
				Unknown)			
				(Thioridazine)	SS		
100 MG/ AT							
NIGHT/							
UNKNOWN	10 YR						

Date:02/18/04ISR Number: 4300200-5Report Type:Expedited (15-DaCompany Report #2004007832
Age:79 YR Gender:Female I/FU:I

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Hospitalization -		Agitation	Foreign	Lithium (Lithium)	PS		
250 MG (EVERY							
Initial or Prolonged		Anaemia	Literature				
12 HOURS)							
		Arthralgia	Health	Tiaprofenic Acid			
		Blood Creatinine	Professional	(Tiaprofenic Acid)	SS		
600 MG (THREE							
		Increased					
TIMES A DAY)							
		Drug Interaction		Fosinopril			
		Drug Level Decreased		(Fosinopril)	SS		
10 MG (DAILY)							
		Drug Level Increased		Oxazepam (Oxazepam)	C		
		Fall		Primidone			
		Flight Of Ideas		(Primidone)	C		
		Hypertension		Haloperidol			
		Hypomania		(Haloperidol)	C		
		Insomnia		Nifedipine			

	Normochromic Normocytic Anaemia Paranoia Persecutory Delusion Pressure Of Speech Renal Impairment Treatment Noncompliance Tremor		(Nifedipine)	C	

Date:02/18/04ISR Number: 4300425-9Report Type:Direct Company Report #CTU 212582
Age:55 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Abnormal Behaviour		Lithium 300 Mg	PS		ORAL	2 PO TID
	Aggression		Augmentin	C			
	Anxiety		Celecoxib	C			
	Asthenia		Warfarin	C			
	Cough		Metoprolol	C			
	Drug Toxicity		Tamazepam	C			
	Lethargy		Bupropion	C			
	Mental Status Changes Nausea Tremor Vomiting						

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Date:02/18/04ISR Number: 4300538-1Report Type:Expedited (15-DaCompany Report #JP-JNJFOC-20040104956
Age:24 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Death	Abulia	Foreign	Risperdal				
Hospitalization - Initial or Prolonged	Anxiety	Health Professional	(Risperidone) Unspecified	PS		ORAL	3 MG, IN 1
Other	Autism						DAY, ORAL
	C-Reactive Protein Increased		Lithium Carbonate (Lithium Carbonate) Unspecified)	SS		ORAL	600 MG, IN 1
	Cardiac Arrest						DAY, ORAL
	Condition Aggravated		Psychotropic Agents (Antipsychotics) Unspecified	C			
	Depressed Level Of Consciousness		Nitrazepam (Nitrazepam) Unspecified)	C			
	Drug Interaction		Trihexyphenidyl Hydrochloride (Trihexyphenidyl Hydrochloride) Unspecified	C			
	Dysphagia		Levomepromazine Maleate (Levomepromazine Maleate) Unspecified	C			
	Fall		Flunitrazepam (Flunitrazepam) Unspecified	C			
	Haematuria						
	Injury Asphyxiation						
	Insomnia						
	Neuroleptic Malignant Syndrome						
	Psychotic Disorder						

Date:02/18/04ISR Number: 4300554-XReport Type:Expedited (15-DaCompany Report #2004008145
Age:71 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Aggression	Health Professional	Lithium (Lithium)	PS			
	Bipolar Disorder		Oxcarbazepine (Oxcarbazepine)	C			
	Condition Aggravated						
	Delusion		Olanzapine				

Dialysis	(Olanzapine)	C
Renal Failure Chronic	Acetylsalicylic Acid (Acetylsalicylic Acid)	C
Schizophrenia	Docusate Sodium (Docusate Sodium)	C
	Lisinopril (Lisinopril)	C
	Metoprolol Tartrate (Metoprolol Tartrate)	C
	Nephrocaps (Folic Acid, Vitamins Nos)	C
	Pantoprazole (Pantoprazole)	C
	Pyridoxine Hydrochloride (Pyridoxine Hydrochloride)	C
	Sevelamer Hydrochloride (Sevelamer	

Hydrochloride)	C
Simvastatin (Simvastatin)	C
Erythropoetin (Erythropoetin)	C
Paricalcitol (Paricalcitol)	C
Dimeticone, Activated (Simeticone)	C

Date:02/18/04ISR Number: 4300636-2Report Type:Expedited (15-DaCompany Report #2004196601CH
Age:31 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Anaemia	Foreign	Luvox (Fluvoxamine					
Hospitalization - Initial or Prolonged	Bradycardia Cogwheel Rigidity	Health Professional	Maleate) Tablet	PS		ORAL	800 MG, SINGLE, ORAL	
	Coma	Other	Priadel(Lithium					
	Diarrhoea		Carbonate)	SS		ORAL	4000 MG, SINGLE, ORAL	
	Gastric Ulcer							
	Gastritis Haemorrhagic		Tramal (Tramadol					
	Haematemesis		Hydrochloride)	SS		ORAL	4500 MG, SINGLE, ORAL	
	Haemodialysis							
	Hyperreflexia		Entumin (Clotiapine)	SS		ORAL	4000 MG, SINGLE, ORAL	
	Hypotension							
	Hypoxia		Ponstan (Mefenamic					
	Metabolic Acidosis		Acid)	SS		ORAL	18000 MG, SINGLE, ORAL	
	Miosis							
	Multiple Drug Overdose		Inderal (Propanolol					
	Myoclonus		Hydrochloride)	SS		ORAL	300 MG, SINGLE, ORAL	
	Oedema Peripheral							
	Petechiae		Tranxilium					

	Pitting Oedema		(Clorazepate			
	Renal Failure Acute		Dipotassium)	SS		ORAL
250 MG,						
	Serotonin Syndrome					
SINGLE, ORAL						
	Suicide Attempt		Detrusitol			
	Tachycardia		(Tolterodine) Tablet	SS		ORAL
14 MG,						
	Tachypnoea					
SINGLE, ORAL						
	Thrombocytopenia		Dalmadorm			
			(Flurazepam			
			Hydrochloride)	SS		ORAL
1800 MG,						
SINGLE, ORAL						

Date:02/19/04ISR Number: 4300491-0Report Type:Direct Company Report #CTU 212592
Age:38 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Drug Toxicity		Lithium	PS		ORAL
600 MG PO BID 8 YR						
Initial or Prolonged	Renal Failure		Glyburide	C		
	Tremor		Metformin	C		
			Simvastatin	C		
			Olanzepine	C		
			Valproic Acid	C		

Date:02/20/04ISR Number: 4302166-0Report Type:Expedited (15-DaCompany Report #2004008916
Age:73 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Aortic Valve Replacement Confusional State Coronary Artery Surgery Gait Disturbance Irritability Osteitis Pain Somnolence Therapeutic Agent Toxicity Tremor	Foreign Literature Health Professional	Lithium (Lithium) Rofecoxib (Rofecoxib)	PS SS			168 MG (BID) 12.5 MG (DAILY)	

Date:02/20/04ISR Number: 4302175-1Report Type:Expedited (15-DaCompany Report #2004007841
Age:80 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dehydration Diabetes Insipidus Drug Level Increased Duodenal Ulcer Hypovolaemia Renal Failure Vomiting	Foreign Literature Health Professional	Lithium (Lithium) Ketorolac (Ketorolac) Acetylsalicylic Acid (Acetylsalicylic Acid) Digoxin (Digoxin) Haloperidol (Haloperidol) Procyclidine (Procyclidine) Clonazepam (Clonazepam)	PS SS C C C C C			450 MG 30 MG	

Date:02/20/04ISR Number: 4302570-0Report Type:Expedited (15-DaCompany Report #GBWYE583316FEB04
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Confusional State Coordination Abnormal Drug Interaction Multiple Myeloma Pathological Fracture Renal Failure Stupor	Health Professional Other	Advil (Ibuprofen, Tablet, 0) Lithium (Lithium, 0)	PS SS		ORAL ORAL	400 MG 4X PER 1 DAY, ORAL	

Date:02/20/04ISR Number: 4302578-5Report Type:Expedited (15-DaCompany Report #GBWYE583316FEB04
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Confusional State Coordination Abnormal Drug Interaction Humerus Fracture Multiple Myeloma Pathological Fracture Renal Failure Stupor	Health Professional Other	Advil (Ibuprofen, Tablet, 0) Lithium (Lithium, 0)	PS SS		ORAL ORAL	400 MG 4X PER 1 DAY, ORAL	

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Date:02/20/04ISR Number: 4302581-5Report Type:Expedited (15-DaCompany Report #GBWYE583416FEB04
Age:64 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blood Creatinine Increased	Health Professional	Advil (Ibuprofen, Tablet, 0)	PS		ORAL	400 MG 3X PER	1 DAY, ORAL
	Blood Urea Increased	Other						
	Drug Level Increased Drug Toxicity		Chlorpromazine (Chlorpromazine, 0)	SS		ORAL	300 MG 1X PER	1 DAY, ORAL
			Lithium (Lithium, 0)	SS		ORAL	600 MG 2X PER	1 DAY, ORAL

Date:02/20/04ISR Number: 4302675-4Report Type:Expedited (15-DaCompany Report #A208548
Age:15 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Blood Cholesterol Increased Eye Movement Disorder Globulins Increased Pyelonephritis	Health Professional	Lithium (Manufacturer Unknown) (Lithium) Ziprasidone (Caps) (Ziprasidone)	PS SS		ORAL	80 MG (BID), ORAL	
	Red Cell Distribution Width Increased		Clozaril (Clozapine) Depakote (Valproate Semisodium) Cogentin (Benzatropine Mesilate)	C C C				

Date:02/23/04ISR Number: 4301846-0Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-B0197455A
Age:42 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Interaction		Lithium	PS	Glaxosmithkline		450MG Twice per day	
	Nausea							
	Therapeutic Agent		Acyclovir	C	Glaxosmithkline			
INTRAVENOUS	Toxicity						10MGK Three times per day	
	Vomiting		Valproic Acid	C			750MG per day	
			Morphine Sulphate Slow Release	C	Glaxosmithkline		15MG Three times per day	
			Warfarin	C	Glaxosmithkline		2MG Alternate days	
			Dexamethasone	C			.5MG per day	
			D5w	C			25ML Twenty four times per day	

Date:02/23/04ISR Number: 4301856-3Report Type:Expedited (15-DaCompany Report #GB-GLAXOSMITHKLINE-B0322547A
Age:78 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Renal Impairment		Lithium	PS	Glaxosmithkline	ORAL	1	MON
			Lithium	SS	Glaxosmithkline		21	YR
			Thyroxine	C	Glaxosmithkline	ORAL	100MCG Per day	24 YR
			Olanzapine	C		ORAL	2.5MG Per day	1 YR

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Date:02/23/04ISR Number: 4302687-0Report Type:Direct Company Report #CTU 212862
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Chest Pain Dyspnoea Rash		Lithium Carbonate 300 Mg Able Laboratories, Inc.	PS	Able Laboratories, Inc.			

Date:02/23/04ISR Number: 4302817-0Report Type:Direct Company Report #CTU 212850
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Level Increased		Lithium Carbonate 300 Mg Able Laboratories, Inc	PS	Able Laboratories, Inc			

Date:02/23/04ISR Number: 4302828-5Report Type:Direct Company Report #CTU 212839
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Feeling Jittery		Lithium Carbonate 300 Mg Able Laboratories, Inc	PS	Able Laboratorites Inc			

Date:02/23/04ISR Number: 4302830-3Report Type:Direct Company Report #CTU 212842
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Irritability		Lithium Carbonate 300 Mg Able Laboratories, Inc Lithium Carbonate 300 Mg Able	PS	Able Laboratories Inc			

Laboratories,Inc	SS	Able Laboratories, Inc

Date:02/23/04ISR Number: 4303224-7Report Type:Expedited (15-DaCompany Report #2004009355
Age: Gender:Male I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Abdominal Pain
Other	Back Disorder
	Back Pain
	Blood Cholesterol Increased
	Chest Pain
	Drug Effect Decreased
	Drug Intolerance
	Erectile Dysfunction
	Facial Pain
	Feeling Cold
	Gastrooesophageal Reflux Disease
	Hypersomnia

	Medication Error Neck Pain Pain In Jaw	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Sleep Disorder Somnolence	Consumer	Neurontin (Gabapentin)	PS		ORAL	1800 MG (TID), ORAL
	Tremor		Lipitor (Atorvastatin)	SS		ORAL	20 MG (DAILY), ORAL
			Lithium (Lithium) (Lithium)	SS			
			Naproxen (Naproxen)	SS			
			Rofecoxib (Rofecoxib)	SS			
			Amoxicillin (Amoxicillin)	SS		ORAL	1000 MG (BID), ORAL
			All Other Therapeutic Products	C			
			Levothyroxine Sodium (Levothyroxine Sodium)	C			
			Vitamins	C			
			Diltiazem Hydrochloride (Diltiazem Hydrochloride)	C			

Date:02/24/04ISR Number: 4303000-5Report Type:Expedited (15-DaCompany Report #GB-GLAXOSMITHKLINE-B0322996A
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Confusional State Coordination Abnormal Drug Interaction		Lithium	PS	Glaxosmithkline	ORAL	
			Ibuprofen	SS	Glaxosmithkline	ORAL	400MG Four times per day

	Multiple Myeloma					
	Pathological Fracture					
	Renal Failure					
	Stupor					

Date:02/24/04ISR Number: 4303792-5Report Type:Direct Company Report #CTU 212971
Age:68 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Chills		Lithium 300 Mg				
Initial or Prolonged	Diarrhoea		Roxane	PS	Roxane	ORAL	900 MG QD
	Drug Level Increased						ORAL
	Myalgia		Lisinopril	C			
	Pyrexia						

Date:02/24/04ISR Number: 4303823-2Report Type:Direct Company Report #CTU 213095
Age:38 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Dysgeusia		Lithium 600 Mg	PS		ORAL	600 MG PO BID 60 DAY
Initial or Prolonged	Dysphemia		Lithobid 600 Mg	SS		ORAL	600 MG PO BID 60 DAY
	Tremor		Mirtazapine	C			
	Visual Disturbance		Trazodone	C			

			Sertraline	C			
			Lamotrigine	C			
			Combivir	C			
			Viracept	C			
			Fluconazole	C			
			Clonazepam	C			

Date:02/24/04ISR Number: 4304565-XReport Type:Expedited (15-DaCompany Report #JP-JNJFOC-20040201927
Age:68 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Anaemia	Foreign	Risperdal					
	Disorientation	Health	(Risperidone)					
	Drug Interaction	Professional	Unspecified	PS		ORAL	0.5 MG, IN 1	
	Erythropenia						DAY, ORAL; 1	
	Hepatic Function Abnormal						MG, IN 1 DAY,	
	Hepatic Steatosis						ORAL	
	Hepatocellular Damage		Mianserin					
	Insomnia		Hydrochloride					
	Leukopenia		(Mianserin					
	Liver Disorder		Hydrochloride)					
	Neutropenia		Unspecified	SS		ORAL	10 MG, IN 1	
	Pyrexia						DAY, ORAL; 30	
							MG, IN 1 DAY,	
							ORAL	
			Nicergoline					
			(Nicergoline)					
			Unspecified	SS		ORAL	15 MG, IN 1	
							DAY, ORAL	
			Zopiclone					
			(Zopiclone)					
			Unspecified	SS		ORAL	10 MG, IN 1	

DAY, ORAL

Lithium Carbonate (Lithium Carbonate) Unspecified	SS	ORAL
Zolpidem Tartrate (Zolpidem Tartrate) Unspecified	SS	ORAL

ORAL

10 MG, IN 1

DAY, ORAL; 5

MG, IN 1 DAY,

ORAL

Paroxetine Hydrochloride Hydrate (Paroxetine) Unspecified	C
Nitrazepam (Nitrazepam) Unspecified	C
Brotizolam (Brotizolam) Unspecified	C
Amoxapine (Amoxapine) Unspecified	C
Sulpiride (Sulpiride)	C
Etizolam (Etizolam)	C

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/25/04ISR Number: 4304150-XReport Type:Expedited (15-DaCompany Report #PHFR2004GB00772
Age:48 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Confusional State Drug Toxicity		Clozaril	PS	Novartis Sector: Pharma	ORAL	600mg/day	312 DAY
	Fall		Depakote	C		UNKNOWN		
	General Physical Health Deterioration Heart Rate Decreased Hypotension White Blood Cell Count Decreased		Lithium Carbonate	I		UNKNOWN		

Date:02/25/04ISR Number: 4304519-3Report Type:Direct Company Report #CTU 213137
Age:58 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Azotaemia		Lithium	PS		ORAL	PO	
Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Depressed Level Of Consciousness Diabetes Insipidus Hypernatraemia Necrosis Pneumonitis Urine Output Urine Output Increased							

Date:02/25/04ISR Number: 4306778-XReport Type:Expedited (15-DaCompany Report #2004-DE-00698GD
Age:56 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abnormal Behaviour Agitation	Foreign Literature	Lithium Carbonate (Lithium Carbonate)	PS			600 MG (NR,	

	Confusional State					
ONCE), NR						
	Disinhibition					
	Dysarthria					
	Hyperthyroidism					
	Incoherent					
	Insomnia					
	Pitting Oedema					
	Rebound Effect					
	Restlessness					

Date:02/26/04ISR Number: 4305198-1Report Type:Expedited (15-DaCompany Report #GB-GLAXOSMITHKLINE-B0323849A
Age:38 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Cardiomegaly		Lithium	PS	Glaxosmithkline		UNKNOWN	
Initial or Prolonged	Drug Interaction		Clozaril	SS		ORAL	400MG Per day	2 YR
	Drug Level Increased							

Date:02/26/04ISR Number: 4307319-3Report Type:Expedited (15-DaCompany Report #2004009355
Age: Gender:Male I/FU:F

Outcome
Hospitalization -
Initial or Prolonged

Other

	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Abdominal Pain	Consumer	Neurontin					
	Back Disorder		(Gabapentin)	PS		ORAL	1800 MG	
	Back Pain						(TID), ORAL	
	Blood Cholesterol		Lipitor					
	Increased		(Atorvastatin)	SS		ORAL	20 MG	
	Chest Pain						(DAILY), ORAL	
	Drug Ineffective		Lithium (Lithium)					
	Drug Intolerance		(Lithium)	SS				
	Erectile Dysfunction		Naproxen (Naproxen)	SS				
	Facial Pain		Rofecoxib					
	Feeling Cold		(Rofecoxib)	SS				
	Gastrooesophageal Reflux		Amoxicillin					
	Disease		(Amoxicillin)	SS		ORAL	1000 MG	
	Glossodynia						(BID), ORAL	
	Hypersomnia		All Other					
	Medication Error		Therapeutic Products	C				
	Neck Pain		Levothyroxine Sodium					
	Oesophageal Spasm		(Levothyroxine					
	Pain In Jaw		Sodium)	C				
	Sleep Disorder		Vitamins	C				
	Tooth Abscess		Diltiazem					
	Tremor		Hydrochloride					
			(Diltiazem					
			Hydrochloride)	C				

Date:02/26/04ISR Number: 4307498-8Report Type:Expedited (15-DaCompany Report #2004196601CH
Age:61 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Abdominal Distension	Foreign	Luvox (Fluvoxamine					
Hospitalization -	Anaemia	Health	Maleate)	PS		ORAL	800 MG,	
Initial or Prolonged	Bradycardia	Professional					SINGLE; ORAL	

	Cogwheel Rigidity Coma Diarrhoea Extensor Plantar Response Gastric Ulcer Gastritis Haemorrhagic Haematemesis Haemodialysis Hyperreflexia Hypotension Hypoxia Metabolic Acidosis Miosis Multiple Drug Overdose Myoclonus Oedema Peripheral Petechiae Pitting Oedema Renal Failure Acute Serotonin Syndrome Suicide Attempt Tachycardia Tachypnoea Thrombocytopenia	Other	Priadel (Lithium Carbonate) Tramal (Tramadol Hydrochloride) Entumin (Clotiapine) Ponstan (Mefenamic Acid) Inderal (Proranolol Hydrochloride) Tranxilium (Clorazepate Dipotassium) Detrusitol (Tolterodine) Tablet Dalmadorm (Flurazepam Hydrochloride)	SS SS SS SS SS SS SS SS	ORAL ORAL ORAL ORAL ORAL ORAL ORAL ORAL
4000 MG, SINGLE; ORAL 4500 MG, SINGLE; ORAL 4000 MG, SINGLE; ORAL 18000 MG, SINGLE; ORAL 300 MG, SINGLE; ORAL 250 MG, SINGLE; ORAL 14 MG, SINGLE; ORAL 1800 MG, SINGLE; ORAL					

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/26/04ISR Number: 4307614-8Report Type:Expedited (15-DaCompany Report #2004-DE-00747GD (0)
Age:63 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Abasia	Foreign	Lithium Carbonate					
Hospitalization - Initial or Prolonged	Activated Partial Thromboplastin Time Prolonged	Literature	(Lithium Carbonate)	PS			1200 MG	
	Blood Fibrinogen Increased							
	Brain Oedema							
	Cerebral Venous Thrombosis							
	Coma							
	Coordination Abnormal							
	Dehydration							
	Delirium							
	Depressed Level Of Consciousness							
	Diet Refusal							
	Drug Level Above Therapeutic							
	Electrocardiogram Qt Prolonged							
	Electrocardiogram T Wave Inversion							
	Fibrin D Dimer Increased							
	Heart Rate Increased							
	Hypernatraemia							
	Hypertonia							
	Hyposthenuria							
	Hypovolaemia							
	Infarction							
	Nephrogenic Diabetes Insipidus							
	Nervous System Disorder							
	Nystagmus							
	Polyuria							
	Psychomotor Agitation							
	Pupils Unequal							
	Respiratory Rate Increased							
	Subarachnoid Haemorrhage							
	Therapeutic Agent Toxicity							

	Thrombocytopenia					
	Tremor					

Date:02/27/04ISR Number: 4306890-5Report Type:Expedited (15-DaCompany Report #GB-GLAXOSMITHKLINE-B0323823A
Age:37 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Level Increased		Lithium	PS	Glaxosmithkline		UNKNOWN	
	Eating Disorder		Clozaril	SS		ORAL	650MG Per day	
	Malaise							
	Neutrophilia							
	White Blood Cell Count Increased							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/27/04ISR Number: 4307639-2Report Type:Direct Company Report #CTU 213367
Age:50 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Confusional State		Lithium 300 Mg	PS		ORAL	1200 MG DAILY	
Hospitalization -	Dialysis						ORAL	
Initial or Prolonged	Diarrhoea		Insulin	C				
Required	Dizziness		Actos	C				
Intervention to	Headache		Clonazepam	C				
Prevent Permanent	Lactic Acidosis		Zyprexa	C				
Impairment/Damage	Nausea		Lisinopril	C				
	Therapeutic Agent		Glucophage	C				
	Toxicity							
	Vomiting							

Date:02/27/04ISR Number: 4308723-XReport Type:Expedited (15-DaCompany Report #2004200446US
Age:60 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Ineffective	Consumer	Celebrex (Celecoxib)					
	Therapeutic Agent		Capsule	PS				
	Toxicity		Lithium (Lithium)	SS				
	Thrombosis							

Date:03/01/04ISR Number: 4308026-3Report Type:Periodic Company Report #US-BRISTOL-MYERS SQUIBB COMPANY-12221040
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Interaction	Health Professional	Metformin Hcl	PS	Bristol-Myers Squibb Company			
			Lithium	I				

Date:03/01/04ISR Number: 4308447-9Report Type:Expedited (15-DaCompany Report #US-ROCHE-352193
Age:61 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Bipolar Disorder Dehydration Haemorrhage Rectal Haemorrhage Red Blood Cell Count Abnormal Red Blood Cell Count Decreased Self Injurious Behaviour Suicidal Ideation Suicide Attempt Therapeutic Agent Toxicity White Blood Cell Count Decreased		Pegasys Pegasys Copegus Lithium Glucophage Blood Pressure Medication Nos	PS SS SS SS C C	Roche Roche Roche		36 DAY SUBCUTANEOUS ORAL 3 IN THE AM AND 2 IN THE PM. UNKNOWN ORAL ORAL STRENGHT WAS REPORTED AS 250	

Date:03/01/04ISR Number: 4308814-3Report Type:Direct Company Report #CTU 213433
Age:58 YR Gender:Female I/FU:I

Outcome
Hospitalization -
Initial or Prolonged

Required Intervention to Prevent Permanent Impairment/Damage	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Asthenia		Lithium 28:28	PS			150 MG QD	
	Drooling		Eskalith Cr	SS		ORAL	450 MG PO BID	
	Facial Palsy		Imipramine	C				
	Medication Error		Nasacort	C				
	Pain		Clozapine	C				
			Multivitamins	C				

Date:03/02/04ISR Number: 4309092-1Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0499816A
Age: YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Intentional Misuse		Eskalith	PS	Glaxosmithkline			

Date:03/02/04ISR Number: 4311064-8Report Type:Expedited (15-DaCompany Report #2004008145
Age:71 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Bipolar Disorder	Health Professional	Lithium (Lithium)	PS				
	Delusion		Oxcarbazepine (Oxcarbazepine)	C				
	Dialysis		Olanzapine (Olanzapine)	C				
	Renal Failure Chronic		Acetylsalicylic Acid (Acetylsalicylic Acid)	C				
	Schizophrenia		Docusate Sodium (Docusate Sodium)	C				
			Lisinopril (Lisinopril)	C				
			Metoprolol Tartrate (Metoprolol Tartrate)	C				
			Nephrocaps (Folic Acid, Vitamins Nos)	C				
			Pantoprazole					

(Pantoprazole)	C
Pyridoxine Hydrochloride (Pyridoxine Hydrochloride)	C
Sevelamer Hydrochloride (Sevelamer Hydrochloride)	C
Simvastatin (Simvastatin)	C
Erythropoietin (Erythropoietin)	C
Paricalcitol (Paricalcitol)	C
Dimeticone, Activated (Simeticone)	C

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/02/04ISR Number: 4311085-5Report Type:Direct Company Report #CTU 213599
Age:55 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	Fall Vomiting		Lithium Bupropion (Wellbutrin Sr) Doxepin Fluoxetine Quetiapine Estratest	PS C C C C				

Date:03/03/04ISR Number: 4310475-4Report Type:Expedited (15-DaCompany Report #IE-BRISTOL-MYERS SQUIBB COMPANY-12520615
Age:73 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Interaction Drug Level Increased	Health Professional	Sinemet-Plus Nu-Seals Aspirin Lipitor Mirapexin Flurazepam Risperidone Asasantin Retard Lithium	PS C C C C C C I	Bristol-Myers Squibb Company	ORAL	increased from 2 tablets 3 times daily to 2.5	at night

Date:03/03/04ISR Number: 4310570-XReport Type:Expedited (15-DaCompany Report #DE-GLAXOSMITHKLINE-D0043105A
Age:46 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Other	Panic Reaction	Health	Quilonum Retard	PS	Glaxosmithkline	ORAL
	Sluggishness	Professional	Taxilan	SS		ORAL
	Somnolence					

Date:03/03/04ISR Number: 4311665-7Report Type:Direct Company Report #CTU 213755
Age:61 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Blood Creatinine		Lithium	PS		ORAL	300 MG TWICE	
Initial or Prolonged	Increased						DAIL ORAL	
	Bradycardia							
	Depressed Level Of Consciousness							
	Drug Level Increased							
	Hypotension							
	Nodal Rhythm							
	Sinus Tachycardia							

Date:03/04/04ISR Number: 4313397-8Report Type:Expedited (15-DaCompany Report #04-0010-PO
Age: Gender:Female I/FU:F

Outcome
Life-Threatening
Hospitalization -

Initial or Prolonged

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Anaemia	Foreign	Ponstan (Mefenamic					
	Bowel Sounds Abnormal	Health	Acid)(Ponstel Nda					
	Bradycardia	Professional	15-034	PS		ORAL	18G, ONCE, PO	
	Coma	Other	Lithium Carbonate	SS		ORAL	4000MG, ONCE,	
	Diarrhoea						PO	
	Gastritis Haemorrhagic		Fluvoxamine Malelate	SS		ORAL	800 MG ONCE	
	Haematemesis		Clorazepate					
	Haemodialysis		Dipotassium	SS		ORAL	250MG ONCE PO	
	Hypotension		Clotiapine	SS		ORAL	4000MG ONCE	
	Hypoxia						PO	
	Metabolic Acidosis		Flurazepam					
	Miosis		Hydrochloride	SS		ORAL	1800MG ONCE	
	Multiple Drug Overdose						PO	
	Myoclonus		Tramadol					
	Oedema Peripheral		Hydrochloride	SS		ORAL	450MG ONCE PO	
	Oliguria		Propranolol					
	Petechiae		Hydrochloride	SS		ORAL	300MG ONCE PO	
	Pitting Oedema							
	Pulse Pressure Decreased							
	Renal Failure Acute							
	Scar							
	Serotonin Syndrome							
	Suicide Attempt							
	Thrombocytopenia							

Date:03/04/04ISR Number: 4313809-XReport Type:Periodic Company Report #2003122959
Age:38 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Hospitalization - Initial or Prolonged	Akathisia	Health Professional	Geodon (Ziprasidone)	PS
	Asthenia		Lithium (Lithium) (Lithium)	SS
	Confusional State		Diphenhydramine (Diphenhydramine)	SS
	Coordination Abnormal		Pseudoephedrine (Pseudoephedrine)	SS
	Drug Ineffective		Fluoxetine Hydrochloride (Fluoxetine Hydrochloride)	SS
	Gait Disturbance		Quetiapine Fumarate (Quetiapine Fumarate)	SS
	Hypomania		Topiramate (Topiramate)	C
	Malaise		Valproate Semisodium (Valproate Semisodium)	C
	Mania		Trazodone (Trazodone)	C
	Masked Facies		Hyoscyamine (Hyoscyamine)	C
	Memory Impairment		Antidepressants	C
	Meniere'S Disease			
	Muscle Twitching			
	Myalgia			
	Pain Of Skin			
	Sleep Disorder			

Date:03/05/04ISR Number: 4316096-1Report Type:Expedited (15-DaCompany Report #B0323313A
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	Abulia Anorexia Asthenia Blood Creatinine Increased Blood Urea Increased Confusional State Csf Glucose Increased Csf Protein Increased Depressed Level Of Consciousness Drug Level Increased Drug Toxicity Encephalopathy Haemodialysis Hypoglycaemia Myoclonus Somnolence Transient Ischaemic Attack Tremor	Foreign Literature Health Professional	Lithium Carbonate (Formulation Unknown) (Generic) (Lithium Carbonate) Venlafaxine Hydrochloride Metformin Hydrochloride Gliclazide Pravastatin Aspirin Asasantin	PS C C C C C			400 MG / TWICE PER DAY / UNKNOWN	

Date:03/08/04ISR Number: 4314268-3Report Type:Expedited (15-DaCompany Report #2004UW03554
Age:53 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	Health Professional	Seroquel	PS		ORAL	600 MG DAILY	PO
	Blood Creatine Phosphokinase Increased		Seroquel	SS		ORAL	300 MG PO	
	Confusional State		Seroquel Lithobid	SS SS		ORAL	1200 MG PO	

	Drug Interaction	Inderal	SS	ORAL 40 MG PO
	Muscle Rigidity	Docusate	SS	ORAL 100 MG PO
	Musculoskeletal Stiffness			
	Neuroleptic Malignant Syndrome			
	Pyrexia			

Date:03/08/04ISR Number: 4314423-2Report Type:Expedited (15-DaCompany Report #2004009355
Age: Gender:Male I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Abdominal Pain
Other	Back Disorder
	Back Pain
	Blood Cholesterol Increased
	Chest Pain
	Condition Aggravated
	Erectile Dysfunction
	Facial Pain
	Feeling Cold
	Gastrooesophageal Reflux Disease
	Glossodynia
	Hypersomnia

	Medication Error Movement Disorder Neck Pain	Report Source	Product	Role	Manufacturer	Route Dose Duration
	Oesophageal Spasm Oral Mucosal Disorder	Consumer	Neurontin (Gabapentn)	PS		ORAL 1800 MG
	Pain In Jaw					(TID), ORAL
	Sleep Disorder Tooth Abscess		Lipitor (Atorvsatatin)	SS		ORAL 20 MG
	Tremor					(DAILY), ORAL
			Lithium (Lithium)	SS		
			Naproxen (Naproxen)	SS		
			Rofecoxib (Rofecoxib)	SS		
			Amoxicillin (Amoxicillin)	SS		ORAL 1000 MG
						(BID), ORAL
			Levothyroxine Sodium (Levothyroxine Sodium)	C		
			Vitamins	C		
			Diltiazem Hydrocloride (Diltiazem Hydrochloride)	C		

Date:03/08/04ISR Number: 4314574-2Report Type:Expedited (15-DaCompany Report #2004-DE-00851GD
Age:78 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Hospitalization - Initial or Prolonged	Aortic Stenosis Bundle Branch Block Left	Foreign Literature	Lithium Carbonate (Lithium Carbonate)	PS		250 - 500
	Cardiac Failure					MG/DAY
	Cardiotoxicity Dilatation Ventricular		Furosemide (Furosemide)	SS		60 MG

	Dyspnoea Exertional Hypokalaemia Oedema Peripheral Pulmonary Arterial Pressure Increased Renal Failure Ventricular Extrasystoles Ventricular Hypertrophy		Imipramine (Imipramine)	SS			100 -125 MG/DAY
			Amineptine (Amineptine)	SS			150 MG
			Levopromazne (Levopromazine)	SS			25 MG
			Captopril (Captopril)	SS			50 MG
			Lorazepam (Lorazepam)	SS			2.5 MG

Date:03/09/04ISR Number: 4314520-1Report Type:Expedited (15-DaCompany Report #FLUV00304000393
Age:68 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Cerebral Infarction Serotonin Syndrome Subdural Haematoma	Foreign Health Professional Other	Luvox 25 (Fluvoxamine Maleate)	PS		ORAL	50 MG DAILY PO, 75 MG DAILY PO	
			Lithium Carbonate (Lithium Carbonate)	SS		ORAL	300 MG DAILY; PO	

Date:03/09/04ISR Number: 4316081-XReport Type:Expedited (15-DaCompany Report #B0324744A
Age:65 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	Alanine Aminotransferase Increased Ammonia Increased Aspartate Aminotransferase Increased Blood Alkaline Phosphatase Increased Blood Creatine Phosphokinase Increased Coma Convulsion Creutzfeldt-Jakob Disease Decreased Appetite Diarrhoea Electrocardiogram T Wave Inversion Gait Disturbance Hyporeflexia Hypotonia Memory Impairment Myoclonus Sleep Disorder Therapeutic Agent Toxicity Visual Disturbance	Foreign Literature Health Professional	Lithium Carbonate (Formulation Unknown) (Lithium Carbonate) (Generic) Methotrimeprazine (Methotrimeprazine) Phenobarbitone (Phenobarbital) Chlorpromazine Hcl	PS SS SS C		INTRAMUSCULAR INTRAMUSCULAR	200 MG/ PER DAY/ 10 MG/ PER DAY/ 200 MG/ PER DAY/ 2 DAY

Date:03/10/04ISR Number: 4315663-9Report Type:Expedited (15-DaCompany Report #HQWYE897223DEC03
Age:52 YR Gender:Female I/FU:F

Outcome	PT
Disability	Anxiety Appetite Disorder

Balance Disorder
Blood Cholesterol Increased
Blood Pressure Increased
Blood Triglycerides Increased
Condition Aggravated
Coordination Abnormal
Depression
Drug Interaction
Drug Interaction Inhibition
Drug Withdrawal Syndrome
Fall
Hypoaesthesia
Joint Swelling
Nausea
Oedema Peripheral
Paraesthesia
Rash
Rash Pruritic
Scar
Swollen Tongue
Tongue Ulceration

Vertigo
Weight Increased

Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Health Professional	Effexor (Venlafaxine Hydrochloride, Tablet)	PS		ORAL	ORAL	
	Colace (Docusate Sodium)	SS				1 WK
	Effexor Xr (Venlafaxine Hydrochloride, Capsule, Extrended Release)	SS		ORAL	SEE IMAGE	
	Glucosamine (Glucosamine)	SS				
	Lithium (Lithium)	SS				
	Premarin (Conjugated Estrogens)	C				
	Seroquel (Quetiapine)	C				
	Xanax (Alprazolam)	C				
	Synthroid (Levothyroxine Sodium)	C				
	Protonix (Pantoprazole)	C				
	Hyoscine Hydrobromide (Hyoscine Hydrobromide)	C				
	Phenobarbital (Phenobarbital)	C				
	Atropine Sulfate (Atropine Sulfate)	C				
	Hyoscyamine Sulfate (Hyoscyamine Sulfate)	C				
	Pepcid (Famotidine)	C				
	Zyrtec (Cetirizine Hydrochloride)	C				
	Calcium With Vitamin D (Calcium Phosphate/Calcium					

			Sodium Lactate/Ergocalcifer	C		
			Lexapro (Escitalopram)	C		
			Prozac (Fluoxetine Hydrochloride)	C		

Date:03/10/04ISR Number: 4315844-4Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20040301190
Age: Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Acidosis	Health Professional	Topamax (Topiramate) Unspecified	PS		ORAL		
	Blood Chloride Increased							
	Therapeutic Agent Toxicity		Lithium (Lithium) Unknown	SS				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/10/04ISR Number: 4315937-1Report Type:Expedited (15-DaCompany Report #JP-JNJFOC-20040104956
Age:24 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Abulia	Foreign	Risperdal					
Hospitalization -	Autism	Health	(Risperidone)	PS		ORAL		
SEE IMAGE								
Initial or Prolonged	Cardiac Arrest	Professional	Lithium Carbonate					
Other	Chromaturia		(Lithium Carbonate)	SS		ORAL		
SEE IMAGE								
	Drug Interaction		Psychotropic Agents					
	Dysphagia		(Antipsychotics)	C				
	Dystonia		Nitrazepam					
	Fall		(Nitrazepam)	C				
	Injury Asphyxiation		Trihexyphenidyl					
	Insomnia		Hydrochloride					
	Neuroleptic Malignant		(Trihexyphenidyl					
	Syndrome		Hydrochloride)	C				
	Tremor		Levomepromazine					
			Maleate					
			(Levomepromazine					
			Maleate)	C				
			Flunitrazepam					
			(Flunitrazepam)	C				

Date:03/11/04ISR Number: 4315942-5Report Type:Direct Company Report #CTU 214296
Age:18 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Effect Decreased		Eskalith 450 Mg	PS				
1 Q AM AND 1								
1/2 QHS								
			Risperidal	C				

Date:03/11/04ISR Number: 4316358-8Report Type:Expedited (15-DaCompany Report #LBID00204000603
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Agitation	Foreign	Lithium					

Initial or Prolonged	Anxiety	Literature	(Manufacturer		
	Blood Creatinine	Health	Unknown) (Lithium)	PS	ORAL 1050 MG DAILY
	Increased	Professional			PO
	Gastrointestinal Necrosis	Other			
	Hypomania				
	Hyponatraemia				
	Megacolon				
	Nephrogenic Diabetes				
	Insipidus				
	Post Procedural				
	Complication				
	Sleep Disorder				

Date:03/11/04ISR Number: 4316388-6Report Type:Expedited (15-DaCompany Report #LBID00204000602
Age:54 YR Gender:Male I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Anorexia
	Apraxia
	Asthenia
	Confusional State
	Coordination Abnormal
	Delirium

	Drug Level Above Therapeutic						
	Dysarthria	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Dysgeusia	Foreign	Lithium Carbonate	PS		ORAL	1500 MG DAILY
	Fatigue	Literature					PO 15 YR
	Food Aversion	Health	Thiodazine				
	Haemodialysis	Professional	Hydrochloride	C			
	Hypercalcaemia	Other					
	Irritability						
	Nausea						
	Renal Failure Acute						
	Restlessness						
	Somnolence						
	Tremor						

Date:03/12/04ISR Number: 4316214-5Report Type:Expedited (15-DaCompany Report #DE-GLAXOSMITHKLINE-D0043364A
Age:50 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Other	Diarrhoea		Quilonum Retard	PS	Glaxosmithkline	ORAL	12TAB Single
	Drug Level Increased						dose
	Suicide Attempt						
	Vomiting						

Date:03/12/04ISR Number: 4316219-4Report Type:Expedited (15-DaCompany Report #WAES 0204SWE00002
Age:81 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Blood Creatinine		Vioxx	PS	Merck & Co., Inc	ORAL	25 DAY
Initial or Prolonged	Increased		Lithium Sulfate	SS		ORAL	
	Depressed Level Of		Calcium Carbonate				
	Consciousness		And Cholecalciferol	C			
	Drug Interaction		Dipyridamole	C			
	Drug Level Increased		Zolpidem Tartrate	C			
	Extrapyramidal Disorder		Tramadol				

	Fatigue		Hydrochloride	C		
	Renal Failure		Lofepramine Hydrochloride	C		
			Levothyroxine Sodium	C		

Date:03/12/04ISR Number: 4316503-4Report Type:Expedited (15-DaCompany Report #WAES 00101917
Age:67 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Drug Interaction		Vioxx	PS	Merck & Co., Inc	ORAL	2 WK
Initial or Prolonged	Drug Level Increased		Lithobid	SS		ORAL	9 YR
Other	Dysarthria		Lithobid	SS		ORAL	
	Hemiparesis						
	Mental Status Changes						
	Renal Failure						
	Renal Neoplasm						
	Therapeutic Agent Toxicity						

Date:03/12/04ISR Number: 4316504-6Report Type:Expedited (15-DaCompany Report #WAES 00091582
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Interaction Drug Level Increased		Vioxx Lithium Carbonate	PS SS	Merck & Co., Inc	ORAL	2	WK

Date:03/12/04ISR Number: 4316506-XReport Type:Expedited (15-DaCompany Report #WAES 00030893
Age:68 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Confusional State Disorientation Drug Interaction Drug Level Increased Therapeutic Agent Toxicity		Vioxx Lithium Carbonate [Therapy Unspecified] [Therapy Unspecified] Estrogenic Preparations (Composition Unspecified)	PS SS C C C	Merck & Co., Inc	ORAL ORAL		

Date:03/12/04ISR Number: 4316507-1Report Type:Expedited (15-DaCompany Report #WAES 00110445
Age:62 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Confusional State Disorientation Drug Interaction Therapeutic Agent Toxicity Urinary Tract Infection		Vioxx Lithium Carbonate (Roxane)	PS SS	Merck & Co., Inc	ORAL ORAL	5 10	DAY YR

Date:03/12/04ISR Number: 4316508-3Report Type:Expedited (15-DaCompany Report #WAES 01060813
Age:71 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Apathy		Vioxx	PS	Merck & Co., Inc	ORAL	5	DAY
	Drug Interaction		Lithium Carbonate	SS		ORAL		
	Drug Level Increased		Clonazepam	C				
	Gait Disturbance		Zyprexa	C				
	Hypersomnia							
	Hypertonia							
	Mood Altered							
	Myoclonus							
	Oedema Peripheral							
	Speech Disorder							

Date:03/12/04ISR Number: 4316510-1Report Type:Expedited (15-DaCompany Report #WAES 0204USA02770
Age:72 YR Gender:Female I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Asterixis
	Coordination Abnormal
	Dehydration
	Dizziness
	Drug Interaction
	Drug Level Increased

Nystagmus

Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Vioxx	PS	Merck & Co., Inc	ORAL	3	MON
	Lithium Carbonate	SS		ORAL	20	YR

Date:03/12/04ISR Number: 4316511-3Report Type:Expedited (15-DaCompany Report #WAES 01031627
Age:69 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Amnesia		Vioxx	PS	Merck & Co., Inc	ORAL		
	Blindness		Lithium Carbonate	SS		ORAL		
	Confusional State		Lithium Carbonate	SS		ORAL		
	Disorientation		Lortab	C				
	Drug Interaction		Fosamax	C				
	Gait Disturbance		Prempro	C				
	Goitre		Prevacid	C				
	Haematocrit Decreased		Zestril	C				
	Haemoglobin Decreased							
	Hallucination							
	Headache							
	Incoherent							
	Kyphosis							
	Medication Error							
	Mental Status Changes							
	Neuropathy Peripheral Sensory							
	Neuropathy Pollakiuria							
	Supraventricular Extrasystoles							
	Therapeutic Agent Toxicity							
	Tremor							
	Visual Disturbance							
	Weight Decreased							

Date:03/12/04ISR Number: 4316520-4Report Type:Expedited (15-DaCompany Report #WAES 0401USA01556
Age:58 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Drug Interaction		Vioxx	PS	Merck & Co., Inc	ORAL		9 DAY
Initial or Prolonged	Neurotoxicity Therapeutic Agent Toxicity		Lithium Carbonate	SS				

Date:03/12/04ISR Number: 4316521-6Report Type:Expedited (15-DaCompany Report #WAES 0401USA01557
Age:91 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Delirium		Vioxx	PS	Merck & Co., Inc	ORAL		3 WK
Initial or Prolonged	Drug Interaction Drug Level Increased Dysarthria Sedation		Lithium Carbonate	SS		ORAL		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/12/04ISR Number: 4316590-3Report Type:Direct Company Report #USP 56403
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Interaction		Lithium	PS				
	Medication Error		Lisinopril	SS				

TABLET

Date:03/12/04ISR Number: 4316591-5Report Type:Direct Company Report #USP 56404
Age:67 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Interaction		Lithium	PS				
	Medication Error		Lisinopril	SS				

TABLET

Date:03/12/04ISR Number: 4317562-5Report Type:Expedited (15-DaCompany Report #2004-00893
Age:35 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardiac Failure Acute	Foreign	Thioridazine (Watson					
Other	Neuroleptic Malignant	Literature	Laboratories)					
	Syndrome	Health	(Thioridazine					
		Professional	Hydrochloride)					
		Other	Tablet, 25 Mg	PS	Watson Laboratories			

50 TABLET,

SINGLE

			Lithium (Lithium)					
			Capsule, 300mg	SS				

Date:03/15/04ISR Number: 4317296-7Report Type:Direct Company Report #CTU 214420
Age:56 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required	Depression		Lithium 300 Mg Po Q					

Intervention to	Drug Level Increased	Am	PS	ORAL
300 MG PO Q				
Prevent Permanent	Fluid Intake Reduced			
AM				
Impairment/Damage	Mental Status Changes	Lithium 600 Mg Po		
		Qhs	SS	
600 MG PO QHS				
		Lisinopril	C	
		Risperidone	C	
		Asa	C	
		Humalog	C	
		Metoprolol	C	

Date:03/15/04ISR Number: 4317630-8Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0350706A
Age:41 YR Gender:Male I/FU:F

Outcome	PT
Hospitalization -	Bipolar I Disorder
Initial or Prolonged	Depression
Other	Drug Level Decreased
	Drug Level Increased
	Dry Mouth
	Dysgeusia
	Hallucination, Auditory
	Libido Decreased
	Mania
	Periodontal Disease
	Pollakiuria
	Psychotic Disorder

	Schizophrenia					
	Self-Injurious Ideation					
	Somnolence	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
	Therapeutic Agent		Eskalith	PS	Glaxosmithkline	ORAL
7 YR						
	Toxicity		Lithium Carbonate	SS	Glaxosmithkline	ORAL
450MG See						
	Thirst					
dosage text						
	Visual Disturbance		Risperdal	C		
	Vomiting		Navane	C		
UNKNOWN	15MG At night					
			Cogentin	C		
UNKNOWN						

Date:03/15/04ISR Number: 4318900-XReport Type:Expedited (15-DaCompany Report #2004008145
Age:71 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization - Initial or Prolonged	Aggression	Health Professional	Lithium (Lithium)	PS		
	Bipolar Disorder		Oxcarbazepine (Oxcarbazepine)	C		
	Condition Aggravated		Acetylsalicylic Acid (Acetylsalicylic Acid)	C		
	Delusion		Docusate Swodium (Docusate Sodium)	C		
	Dialysis		Lisinopril (Lisinopril)	C		
	Renal Failure Chronic		Metoprolol Tartrate (Metoprolol Tartrate)	C		
	Schizophrenia		Nephrocaps (Folic Acid, Vitamins Nos)	C		
			Pantoprazole (Pantoprazole)	C		
			Pyridoxine Hydrochloride (Pyridoxine Hydrochloride)	C		
			Sevelamer Hydrochloride (Sevelamer			

Hydrochloride)	C
Simvastatin (Simvastatin)	C
Erythropoietin (Erythropoietin)	C
Paricalcitol (Paricalcitol)	C
Dimeticone, Activated (Simeticone)	C
Olanzapine (Olanzapine)	C

Date:03/15/04ISR Number: 4319556-2Report Type:Expedited (15-DaCompany Report #2004015892
Age:55 YR Gender:Female I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Blood Creatinine Increased
Other	Blood Sodium Increased
	Cerebral Atrophy

	Confusional State					
	Dehydration					
	Gait Disturbance	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
	Lethargy	Literature	Lithium (Lithium)	PS		
	Nephrogenic Diabetes	Health	Risperidoe			
	Insipidus	Professional	(Risperidone)	SS		
			Enalapril Maleate			
			(Enalapril Maleate)	C		
			Valproic Acid			
			(Valproic Acid)	C		
			Trazodone			
			(Trazodone)	C		
			Pilocarpine			
			(Pilocarpine)	C		
			Iron (Iron)	C		
			Calcium (Calcium)	C		
			Phenylpropanolamine			
			W/Guaifenesin			
			(Guaifenesin)	C		

Date:03/17/04ISR Number: 4318116-7Report Type:Expedited (15-DaCompany Report #FR-BRISTOL-MYERS SQUIBB COMPANY-12530614
Age:65 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization -	Disturbance In Attention	Health	Sinemet	PS	Bristol-Myers Squibb	
Initial or Prolonged	Drug Interaction	Professional			Company	ORAL
4 WK						
	Drug Level Increased		Teralithe	I		
	Dysarthria		Zestril	I		
3 WK						
	Gait Disturbance					

Date:03/17/04ISR Number: 4320339-8Report Type:Expedited (15-DaCompany Report #2004015781
Age:56 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization -	Chills	Foreign	Norvasc (Amlodipine)	PS		ORAL
5 MG, ORAL						
Initial or Prolonged	Confusional State	Health	Lithium Carbonate			

	Drug Toxicity	Professional	(Lithium Carbonate)	SS	ORAL 900 MG, ORAL
	Hypokinesia	Company	Esomeprazole		
	Stupor	Representative	(Esomeprazole)	SS	ORAL 40 MG, ORAL
			Citalopram Hydrobromide (Citalopram Hydrobromide)	C	
			Trimipramine (Trimipramine)	C	
			Oxazepam (Oxazepam)	C	
			Insulin (Insulin)	C	

Date:03/18/04ISR Number: 4318764-4Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0350706A
Age:41 YR Gender:Male I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Bipolar I Disorder
	Depression
Other	Drug Level Decreased
	Drug Level Increased
	Dry Mouth
	Dysgeusia

	Hallucination, Auditory					
	Irritability					
	Libido Decreased	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
	Mania	Consumer	Eskalith	PS	Glaxosmithkline	ORAL
7 YR						
	Periodontal Disease		Lithium Carbonate	SS	Glaxosmithkline	ORAL
450MG See						
	Pollakiuria					
dosage text						
	Psychotic Disorder		Risperdal	C		
	Schizophrenia		Navane	C		
UNKNOWN	15MG At night					
	Self-Injurious Ideation		Cogentin	C		
UNKNOWN						
	Somnolence					
	Therapeutic Agent					
	Toxicity					
	Thirst					
	Treatment Noncompliance					
	Visual Disturbance					
	Vomiting					

Date:03/19/04ISR Number: 4319347-2Report Type:Expedited (15-DaCompany Report #PHFR2004GB01355
Age:47 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Other	Blood Creatinine Increased		Clozaril	PS	Novartis Sector: Pharma	
	Confusional State		Lithium	SS		
800mg/day						
	Renal Disorder		Lithium	SS		
400mg/day						

Date:03/19/04ISR Number: 4319702-0Report Type:Expedited (15-DaCompany Report #IE-BRISTOL-MYERS SQUIBB COMPANY-12520615
Age:73 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Other	Drug Interaction	Health	Sinemet-Plus	PS	Bristol-Myers Squibb	
	Drug Level Increased	Professional			Company	ORAL
increased						

from 2

tablets 3

times daily

to 2.5

			Nu-Seals Aspirin	C	
			Lipitor	C	
			Mirapexin	C	
			Flurazepam	C	
at night					
			Priadel	C	
			Nitrate	C	
patch					
			Risperidone	C	ORAL
			Asasantin Retard	C	
			Lithium	I	

Date:03/19/04ISR Number: 4322007-5Report Type:Expedited (15-DaCompany Report #2004-DE-01024GD(0)
Age:82 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Cerebrovascular Disorder Cogwheel Rigidity	Literature	Lithium Carbonate (Lithium Carbonate)	PS			450 MG (IN DIVIDED DOSES)	
	Delusion Dysarthria Gait Disturbance Pleurothotonus		Clozapine (Clozapine)	SS			150 MCG	
	Therapy Non-Responder Tremor		Aripiprazole (Aripiprazole)	SS			15 MG	

			Venlafaxine (Venlafaxine)	C		

Date:03/22/04ISR Number: 4321092-4Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0350706A
Age:41 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Bipolar I Disorder		Eskalith	PS	Glaxosmithkline	ORAL	7	YR
Initial or Prolonged	Depression		Lithium Carbonate	SS	Glaxosmithkline	ORAL	450MG	See
Other	Drug Ineffective						dosage text	
	Drug Level Decreased		Risperdal	C				
	Drug Level Increased		Navane	C			UNKNOWN	15MG At night
	Dry Mouth		Cogentin	C			UNKNOWN	
	Dysgeusia							
	Hallucination, Auditory							
	Irritability							
	Libido Decreased							
	Mania							
	Periodontal Disease							
	Pollakiuria							
	Psychotic Disorder							
	Schizophrenia							
	Self-Injurious Ideation							
	Somnolence							
	Therapeutic Agent							
	Toxicity							
	Thirst							
	Visual Disturbance							
	Vomiting							

Date:03/22/04ISR Number: 4321112-7Report Type:Expedited (15-DaCompany Report #JP-GLAXOSMITHKLINE-B0317499A
Age:39 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Hepatic Necrosis		Paroxetine					
	Renal Failure Acute		Hydrochloride					

Hydrate	PS	Glaxosmithkline	ORAL	
20MG per day 41 DAY				
Cerekinon	SS		ORAL	
Limas	SS	Glaxosmithkline	ORAL	
Anafranil	SS			
UNKNOWN				
Lendormin	SS		ORAL	
Triazolam	SS		ORAL	
Lofepramine Hydrochloride	SS			
UNKNOWN				

Date:03/23/04ISR Number: 4322257-8Report Type:Expedited (15-DaCompany Report #FLUV00304000212
Age:61 YR Gender:Female I/FU:F

Outcome	PT
Life-Threatening	Abdominal Distension
Hospitalization - Initial or Prolonged	Anaemia
	Bowel Sounds Abnormal
	Bradycardia
	Coma
	Diarrhoea
	Gastric Ulcer
	Gastritis Haemorrhagic
	Haematemesis

		Haemodialysis Hyperreflexia Hypotension	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
		Hypoxia Miosis Multiple Drug Overdose	Foreign Other	Floxyfral (Fluvoxamine Maleate)	PS		ORAL
800 MG DAILY							
		Myoclonus					
PO							
		Oedema Peripheral Petechiae		Priadel (Lithium Carbonate)	SS		
4000 MG DAILY							
		Pitting Oedema					
PO							
		Pulse Abnormal Renal Failure Acute		Tramal (Tramadol Hydrochloride)	SS		
4500 MG DAILY							
		Serotonin Syndrome					
PO							
		Suicide Attempt Tachycardia		Entumine (Clotiapine)	SS		
4000 MG DAILY							
		Tachypnoea					
PO							
		Thrombocytopenia		Ponstan (Mefenamic Acid)	SS		
18000 MG							
DAILY PO							
				Inderal (Propranolol Hydrochloride)	SS		
300 MG DAILY							
PO							
				Tranxilium (Clorazepate Dipotassium)	SS		
250 MG DAILY							
PO							
				Detrusitol (Tolterodine L-Tartrate)	SS		
14 MG DAILY							
PO							

	Dalmadorm (Flurazepam Hydrochloride)	SS

1800 MG DAILY

PO

Date:03/23/04ISR Number: 4323698-5Report Type:Expedited (15-DaCompany Report #KII-2003-0008082
Age:44 YR Gender:Female I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Activated Partial Thromboplastin Time Prolonged
Other	Agitation
	Alcohol Poisoning
	Alcohol Withdrawal Syndrome
	Anaemia Macrocytic
	Anion Gap Abnormal
	Aspartate Aminotransferase Increased
	Blood Albumin Decreased
	Blood Creatine Increased
	Blood Glucose Increased
	Blood Potassium Decreased
	Body Temperature Decreased
	Coma
	Confusional State
	Crackles Lung

		Dialysis					
		Heart Rate Increased					
		Liver Function Test	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
		Abnormal	Study	Oxycontin Tablets			
		Metabolic Acidosis	Health	(Oxycodone			
		Multiple Drug Overdose	Professional	Hydrochloride) Cr			
		Pyrexia	Other	Tablet	PS		
		Respiratory Arrest		Benzodiazepine			
		Restlessness		Derivatives()	SS		
		Urine Analysis Abnormal		Acetylsalicylic Acid			
		Vomiting		(Acetylsalicylic			
				Acid)	SS		
				Lithium (Lithium)	SS		

Date:03/23/04ISR Number: 4324692-0Report Type:Expedited (15-DaCompany Report #2004200446US
Age:51 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Other	Drug Ineffective	Consumer	Celebrex (Celecoxib)	PS		
	Muscle Disorder		Lithium	SS		
	Therapeutic Agent					
	Toxicity					
	Thrombosis					

Date:03/23/04ISR Number: 4325335-2Report Type:Expedited (15-DaCompany Report #2004-DE-01205GD
Age:60 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Disability	Bipolar I Disorder	Foreign	Lithium Carbonate			
	Cerebrovascular Disorder	Literature	(Lithium Carbonate)	PS		
	Erythema		Alpha Interferon			
	Foot Amputation		(Interferon Alfa)	SS		
	Gangrene					
	Impaired Healing					
	Lacunar Infarction					
	Pain In Extremity					
	Pulmonary Hypertension					
	Skin Ulcer					
	Vasculitis					

Date:03/24/04ISR Number: 4325244-9Report Type:Expedited (15-DaCompany Report #2004196601CH
Age:61 YR Gender:Female I/FU:F

Outcome	PT
Life-Threatening	Abdominal Distension
Hospitalization - Initial or Prolonged	Anaemia
	Bipolar Disorder
	Bowel Sounds Abnormal
	Bradycardia
	Cogwheel Rigidity
	Coma
	Extensor Plantar Response
	Gastric Ulcer
	Gastritis Haemorrhagic
	Haemodialysis
	Hypotension
	Hypoxia
	Metabolic Acidosis

		Miosis Multiple Drug Overdose Oedema Peripheral					
Dose	Duration		Report Source	Product	Role	Manufacturer	Route
		Pulse Pressure Decreased Pupillary Reflex Impaired	Foreign Health	Luvox (Fluvoxamine Maleate)	PS		ORAL
800 MG,		Renal Failure Acute	Professional				
SINGLE, ORAL		Serotonin Syndrome Suicide Attempt		Priadel (Lithium Carbonate)	SS		ORAL
4000 MG,		Tachycardia					
SINGLE ORAL		Tachypnoea Thrombocytopenia		Tramal (Tramadol Hydrochloride)	SS		ORAL
4500 MG,							
SINGLE, ORAL				Entumin (Clotiapine)	SS		ORAL
4000 MG,							
SINGLE, ORAL				Ponstan (Mefenamic Acid)	SS		ORAL
18000 MG,							
SINGLE, ORAL				Inderal (Propranolol Hydrochloride)	SS		ORAL
300 MG,							
SINGLE, ORAL				Tranxilium (Clorazepate Dipotassium)	SS		ORAL
250 MG,							
SINGLE, ORAL				Detrusitol (Tolterodine) Tablet	SS		ORAL
14 MG,							
SINGLE, ORAL				Dalmadorm (Flurazepam			

			Hydrochloride)	SS		ORAL

1800 MG,

SINGLE, ORAL

Date:03/24/04ISR Number: 4325254-1Report Type:Expedited (15-DaCompany Report #LBID00204000676
Age:74 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anorexia Arthralgia Asterixis Blood Creatinine Increased Blood Urea Increased Blood Uric Acid Increased Creatinine Renal Clearance Decreased Dehydration Delirium Drug Level Above Therapeutic Dry Skin Electroencephalogram Abnormal Fall Gait Disturbance Myoclonus Parkinsonism Renal Disorder Tongue Dry Tremor	Foreign Literature Health Professional Other	Lithium Carbonate Zaltoprofen (Zaltoprofen)	PS SS		ORAL ORAL	300 MG DAILY PO 240 MG DAILY PO	40 YR

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/24/04ISR Number: 4325945-2Report Type:Expedited (15-DaCompany Report #2004009355
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain Back Disorder	Consumer Health	Neurontin (Gabapentin)	PS		ORAL	1800 MG	Other (TID), ORAL
	Back Pain	Professional						
	Blood Cholesterol Increased		Lipitor (Atorvastatin)	SS		ORAL	20 MG	(DAILY), ORAL
	Cardiac Disorder Chest Pain Drug Ineffective Drug Intolerance Drug Level Increased Erectile Dysfunction Facial Pain Feeling Cold		Lithium (Lithium) (Lithium) Naproxen (Naproxen) Rofecoxib (Rofecoxib) Amoxicillin (Amoxicillin)	SS SS SS SS		ORAL	1000 MG	(BID), ORAL
	Gastrointestinal Disorder Gastrooesophageal Reflux Disease Glossodynia Hypersomnia Neck Pain Oesophageal Spasm Pain In Jaw Paralysis Post Procedural Pain Sleep Disorder Tooth Abscess Treatment Noncompliance Tremor		All Other Therapeutic Products Levothyroxine Sodium (Levothyroxine Sodium) Vitamins Diltiazem Hydrochloride (Diltiazem Hydrochloride)	C C C				

Date:03/25/04ISR Number: 4323369-5Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0350706A
Age:41 YR Gender:Male I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Bipolar I Disorder Depression

Other	Drug Ineffective
	Drug Level Decreased
	Drug Level Increased
	Drug Toxicity
	Dry Mouth
	Dysgeusia
	Hallucination, Auditory
	Irritability
	Libido Decreased
	Mania
	Medication Error
	Nocturia
	Periodontal Disease
	Pollakiuria
	Psychotic Disorder
	Schizophrenia
	Self-Injurious Ideation
	Somnolence
	Suicidal Ideation
	Therapeutic Agent
	Toxicity
	Thirst
	Treatment Noncompliance

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Visual Disturbance Vomiting							
		Consumer	Eskalith	PS	Glaxosmithkline	ORAL	7	YR
			Lithium Carbonate	SS	Glaxosmithkline	ORAL	450MG	See dosage text
			Risperdal	C				
			Navane	C				
			Cogentin	C			UNKNOWN	UNKNOWN

Date:03/25/04ISR Number: 4327869-3Report Type:Expedited (15-DaCompany Report #AU-JNJFOC-20040304307
Age:52 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anorexia Confusional State Drug Interaction Drug Level Increased Drug Toxicity Psychotic Disorder Restlessness Speech Disorder	Foreign Health Professional	Tramal (Tramadol Hydrochloride) Unspecified	PS		ORAL	50 MG, 3 IN 1	DAY, ORAL
			Vioxx (Rofecoxib) Unknown	SS		ORAL	12.5 MG, 1 IN	1 DAY, ORAL
			Lithium Carbonate (Lithium Carbonate) Unknown	SS		ORAL	250 MG, 4 IN	1 DAY, ORAL
			Zoloft (Sertraline Hydrochloride) Unknown	SS		ORAL	100 MG, 1 IN	

1 DAY, ORAL

Date:03/25/04ISR Number: 4328048-6Report Type:Expedited (15-DaCompany Report #2004203927FR
Age:75 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Coma	Foreign	Celebrex (Celecoxib)					
	Drug Interaction	Health	Capsule	PS		ORAL	200 MG, QD,	
	Overdose	Professional				ORAL		
		Other	Tramadol /Paracetamol	SS				
			Lithium (Lithium)	SS				

Date:03/26/04ISR Number: 4323802-9Report Type:Expedited (15-DaCompany Report #US-BRISTOL-MYERS SQUIBB COMPANY-12517470
Age:66 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Interaction		Olanzapine	PS				
	Face Oedema		Lamictal	C			taken for	
							several years	
			Abilify	I	Otsuka Pharmaceutical Company, Ltd.	ORAL	1	MON
			Lithium	I			taken for	
							several years	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/26/04ISR Number: 4324577-XReport Type:Expedited (15-DaCompany Report #FR-BRISTOL-MYERS SQUIBB COMPANY-12530614
Age:65 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Disturbance In Attention Drug Interaction	Health Professional	Sinemet	PS	Bristol-Myers Squibb Company	ORAL	4 WK
	Drug Level Increased		Teralithe	I			
	Dysarthria		Zestril	I		ORAL	3 WK
	Gait Disturbance						

Date:03/26/04ISR Number: 4325480-1Report Type:Direct Company Report #CTU 215363
Age:66 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Drug Toxicity Medication Error		Lithium Citrate 8 Meq/5ml Roxane	PS	Roxane	ORAL	300 MG QAM
							ORAL
			Lithium Citrate 8 Meq/5ml Roxane	SS	Roxane	ORAL	450 MG QHS
							ORAL

Date:03/29/04ISR Number: 4325965-8Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0504062A
Age:75 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Abasia Confusional State Drug Level Increased Dysarthria Fluid Retention Gait Disturbance Incoherent Incontinence Memory Impairment	Consumer	Lithium Carbonate Paxil Aricept Namenda Lipitor	PS SS SS SS C	Glaxosmithkline Glaxosmithkline	ORAL ORAL	

	Renal Impairment					
	Restlessness					

Date:03/29/04ISR Number: 4326357-8Report Type:Direct Company Report #CTU 215438
Age:64 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Disturbance In Attention		Eskalith Sk			
	Drug Effect Decreased		(Generic)	PS		
450 MG BID						
	Mood Altered		Synthroid	C		
	Pharmaceutical Product Complaint					

Date:03/29/04ISR Number: 4330950-6Report Type:Expedited (15-DaCompany Report #B0326936A
Age:39 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Basedow'S Disease	Foreign	Lithium Salt			
		Literature	(Generic) (Lithium			
		Health	Salt)	PS		
18 YR						
		Professional	Amitriptyline	C		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/29/04ISR Number: 4332255-6Report Type:Expedited (15-DaCompany Report #A001-002-006014
Age:78 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Creatinine Increased	Health Professional	Aricept (Donepezil Hydrochloride)	PS		ORAL	10 MG, 1 IN 1	
	Confusional State						D, ORAL	
	Encephalopathy		Namenda (Memantine)	SS		ORAL	5 MG, 1IN 1	
	Therapeutic Agent						D, ORAL	
	Toxicity		Lithium (Lithium)	SS		ORAL	300 MG, ORAL	

Date:03/30/04ISR Number: 4327099-5Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0350706A
Age:41 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Bipolar I Disorder	Consumer	Eskalith	PS	Glaxosmithkline	ORAL	450MG See dosage text	7 YR
	Depression		Lithium Carbonate	SS	Glaxosmithkline	ORAL	UNKNOWN	15MG At night
	Drug Ineffective							
	Drug Level Decreased		Risperdal	C				
	Drug Level Increased		Navane	C				
	Dry Mouth		Cogentin	C				
	Dysgeusia							
	Hallucination							
	Hallucination, Auditory							
	Irritability							
	Libido Decreased							
	Mania							
	Periodontal Disease							
	Pollakiuria							
	Psychotic Disorder							
	Schizophrenia							
	Self-Injurious Ideation							
	Somnolence							

	Suicidal Ideation					
	Therapeutic Agent					
	Toxicity					
	Thirst					
	Visual Disturbance					
	Vomiting					

Date:03/30/04ISR Number: 4327168-XReport Type:Expedited (15-DaCompany Report #DE-GLAXOSMITHKLINE-D0043479A
Age:54 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blood Creatinine	Health	Quilonum Retard	PS	Glaxosmithkline	ORAL	33 YR	
	Increased	Professional	Melleril	C			UNKNOWN	
	Blood Potassium Increased		Ramipril	C			UNKNOWN	5MG Per day
	Glomerulonephritis							
	Chronic							
	Hyperparathyroidism							
	Hypertension							
	Nephropathy							
	Nocturia							
	Oedema Peripheral							
	Renal Failure							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/30/04ISR Number: 4332814-0Report Type:Expedited (15-DaCompany Report #S04-USA-01400-01
Age:76 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abasia	Health	Namenda (Memantine)	PS		ORAL	10 MG QD PO	
	Activities Of Daily Living Impaired	Professional	Namenda (Memantine)	SS		ORAL	5 MG QD PO	
	Amnesia		Aricept (Donepezil Hydrochloride)	SS			10 MG QD	
	Asthenia		Lithium	SS			300 MG BID	
	Confusional State		Lipitor (Atorvastatin)	C				
	Dehydration		Aciphex (Rabeprazole Sodium)	C				
	Drug Interaction		Vioxx (Rofecoxib)	C				
	Drug Level Increased		Mysoline	C				
	Drug Toxicity		Nexium (Esomeprazole)	C				
	Dysarthria		Alphagan (Brimonidine Tartrate)	C				
	Dysstasia		Xalatan (Latanoprost)	C				
	Encephalopathy		Hydrochlorothiazide	C				
	Faecal Incontinence		Metamucil	C				
	Fatigue		Vitamin E	C				
	General Physical Health Deterioration		Vitamin C	C				
	Insomnia							
	Mental Status Changes							
	Renal Failure Chronic							
	Tremor							
	Urinary Incontinence							

Date:04/01/04ISR Number: 4329765-4Report Type:Expedited (15-DaCompany Report #DE-GLAXOSMITHKLINE-D0043364A
Age:50 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Diarrhoea	Health	Quilonum Retard	PS	Glaxosmithkline	ORAL	12TAB Single	
	Suicide Attempt	Professional					dose	
	Vomiting							

Date:04/02/04ISR Number: 4330140-7Report Type:Expedited (15-DaCompany Report #PHRM2004FR01382
Age:24 HR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agitation Neonatal		Tegretol Lp	PS	Novartis Sector: Pharma			
	Caesarean Section						TRANSPLACENTAL	400 mg, UNK
	Drug Exposure During		Teralithe	SS				
	Pregnancy		Vitamin D	C			TRANSPLACENTAL	
	Irritability							

Date:04/02/04ISR Number: 4333974-8Report Type:Expedited (15-DaCompany Report #2003033768
Age:80 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Bipolar I Disorder	Foreign	Lithium (Lithium)	PS		ORAL	ORAL	
	Blood Calcium Increased	Health Professional	Glibenclamide (Glibenclamide)	SS		ORAL	ORAL	
	Blood Creatine Increased							
	Confusional State		Metformin Hydrochloride	C				
	Hyperglycaemia		Dipyridamole	C				
	Hypoglycaemia		Furosemide	C				
	Non-Hodgkin'S Lymphoma							
	Overdose							
	Therapeutic Agent Toxicity							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/05/04ISR Number: 4332838-3Report Type:Direct Company Report #CTU 215962
Age:57 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Confusional State		Lithium	PS		ORAL	300 MG TID BY MOUTH	
	Disorientation							
	Hypotension		Diltiazem (Tiazac)	C				
	Lethargy		Propanolol Hcl	C				
	Tremor		Folic Acid	C				
			Topiramate	C				
			Glyburide	C				
			Lisinopril	C				

Date:04/06/04ISR Number: 4335395-0Report Type:Expedited (15-DaCompany Report #2004UW06116
Age:13 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Conjunctivitis	Other	Seroquel	PS				
	Granulocytopenia		Depakote	SS				
	Neuroleptic Malignant Syndrome		Lithium	SS				
			Loxitane	SS				
	Polyuria		Risperdal	SS				

Date:04/07/04ISR Number: 4334488-1Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0505935A
Age:25 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Euphoric Mood	Consumer	Lithium Carbonate	PS	Glaxosmithkline	ORAL	2	YR
	Hallucination		Motion Sickness Medication	SS		INTRADERMAL		
	Infertility							
	Memory Impairment		Effexor	C				
	Mental Impairment		Xanax	C				
	Rash		Albuterol	C	Glaxosmithkline			
	Skin Disorder		Nebulizer	C				
			Flovent	C	Glaxosmithkline			

Date:04/07/04ISR Number: 4334492-3Report Type:Expedited (15-DaCompany Report #JP-GLAXOSMITHKLINE-B0317499A
Age:39 YR Gender:Male I/FU:F

Outcome	PT
Death	Alanine Aminotransferase Increased
	Aspartate Aminotransferase Increased
	Blood Lactate Dehydrogenase Increased
	Drug Level Below Therapeutic
	Gamma-Glutamyltransferase Increased
	Haemodialysis
	Haemoglobin Decreased
	Hepatic Necrosis
	Hepatitis Fulminant
	International Normalised Ratio Increased
	Renal Failure Acute
	White Blood Cell Count

Decreased

Dose	Duration	Report Source	Product	Role	Manufacturer	Route
		Health Professional	Paroxetine Hydrochloride Hydrate	PS	Glaxosmithkline	ORAL
20MG per day	41 DAY					
			Cerekinon	SS		ORAL
300MG per day	41 DAY					
			Limas	SS	Glaxosmithkline	ORAL
9 YR						
			Anafranil	SS		
UNKNOWN	60MG per day					
			Lendormin	SS		ORAL
.25MG per day						
			Triazolam	SS		ORAL
.25MG per day	10 YR					
			Lofepramine Hydrochloride	SS		
UNKNOWN	30MG per day	3 DAY				
			Promethazine Hydrochloride	SS	Glaxosmithkline	ORAL
75MG per day						
			Haemodialysis	C		

Date:04/07/04ISR Number: 4336382-9Report Type:Expedited (15-DaCompany Report #2004008145
Age:71 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization - Initial or Prolonged	Bipolar Disorder Dialysis Renal Failure Chronic Schizophrenia	Health Professional	Lithium (Lithium)	PS		
			Oxcarbazepine (Oxcarbazepine)	C		
			Acetylsalicylic Acid (Acetylsalicylic Acid)	C		
			Docusate Sodium (Docusate Sodium)	C		
			Lisinopril (Lisinopril)	C		
			Metoprolol Tartrate			

(Metoprolol Tartrate)	C
Nephrocaps (Folic Acid, Vitamins Nos)	C
Pantoprazole (Pantoprazole)	C
Pyridoxine Hydrochloride (Pyridoxine Hydrochloride)	C
Sevelamer Hydrochloride (Sevelamer Hydrochloride)	C
Simvastatin (Simvastatin0	C
Erythropoietin (Erythropoietin)	C
Paricalcitol (Paricalcitol)	C
Dimeticone, Activated (Simeticone)	C
Olanzapine (Olanzapine)	C

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/07/04ISR Number: 4336557-9Report Type:Expedited (15-DaCompany Report #KII-2004-0009234
Age:43 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Drug Screen Positive Lung Infiltration Mental Status Changes Miosis Overdose Pneumonia	Study Health Professional Other	Morphine Sulfate (Similar To Nda 19-516) (Morphine Sulfate) Unknown Phenobarbital (Phenobarbital) Benzodiazepine Derivatives () Lithium (Lithium) Antiepileptics() Opioids ()	PS SS SS SS SS SS				

Date:04/08/04ISR Number: 4334633-8Report Type:Expedited (15-DaCompany Report #PHBS2003JP00627
Age:40 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Depressed Level Of Consciousness		Voltaren	PS	Novartis Sector: Pharma	ORAL	25 mg/day	
	Drug Interaction		Lithium Carbonate	SS			400 mg/day	
	Drug Toxicity Mouth Breathing Therapeutic Agent Toxicity							

Date:04/08/04ISR Number: 4335031-3Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0505473A
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Renal Failure		Lithium Carbonate	PS	Glaxosmithkline	ORAL		

Date:04/09/04ISR Number: 4335340-8Report Type:Expedited (15-DaCompany Report #PHBS2003JP00627
Age:40 YR Gender:Male I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Anorexia
	Blood Pressure Decreased
	C-Reactive Protein Increased
	Depressed Level Of Consciousness
	Drug Interaction
	Heart Rate Increased
	Inflammation
	Intubation
	Mouth Breathing
	Neutrophil Count Increased
	Oxygen Saturation Decreased
	Red Blood Cell Sedimentation Rate Increased
	Respiratory Distress
	Therapeutic Agent Toxicity

	White Blood Cell Count Increased						
		Report Source	Product	Role	Manufacturer		Route
Dose	Duration						
			Voltaren	PS	Novartis Sector: Pharma		
RECTAL	25 mg,						
ONCE/SINGLE	1440 MIN						
			Lithium Carbonate	SS			
400 mg/day							
			Haloperidol	C			
12 mg/day							
			Biperiden	C			
4 mg/day							
			Levomepromazine	C			
175 mg/day							
			Flunitrazepam	C			
4 mg/day							
			Promethazine Hydrochloride	C			
20 mg/day							

Date:04/09/04ISR Number: 4335342-1Report Type:Expedited (15-DaCompany Report #PHBS2003JP00626
Age:83 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization - Initial or Prolonged	Anorexia C-Reactive Protein		Voltaren	PS	Novartis Sector: Pharma	ORAL
25 mg, TID	1440 MIN					
	Increased		Lithium Carbonate	SS		
600 mg/day	10080MIN					
	Depressed Level Of		Lithium Carbonate	SS		
200 mg/day	21600MIN					
	Consciousness		Lithium Carbonate	SS		
400 mg/day	10080MIN					
	Drug Interaction		Lithium Carbonate	SS		
800 mg/day	10080MIN					
	Drug Toxicity		Haloperidol	C		
2.25 mg/day						
	Dyspnoea Inflammation		Tiapride Hydrochloride	C		
200 mg/day						

	Loss Of Consciousness		Biperiden	C			
3 mg/day							
	Neutrophil Count		Rilmazafone	C			
4 mg/day							
	Increased						
	Pyrexia						
	Red Blood Cell						
	Sedimentation Rate						
	Increased						
	Respiratory Depression						
	Shift To The Left						
	White Blood Cell Count						
	Increased						

Date:04/09/04ISR Number: 4335705-4Report Type:Expedited (15-DaCompany Report #GB-GLAXOSMITHKLINE-B0328406A
Age:47 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blood Creatinine	Consumer	Lithium	PS	Glaxosmithkline			
UNKNOWN								
	Increased		Clozaril	SS				
UNKNOWN								
	Confusional State							
	Renal Disorder							

Date:04/09/04ISR Number: 4339011-3Report Type:Expedited (15-DaCompany Report #LBID00204000882
Age:57 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Angiopathy	Foreign	Lithium Carbonate	PS		ORAL		
300 MG TID PO								
Initial or Prolonged	Hypotension	Literature	Atenolol (Atenolol)	C				
	Paralysis	Health	Carvedilol					
	Self-Medication	Professional	(Carvedilol)	C				
		Other	Amlodipine					
			(Amlodipine)	C				

			Nitrates (Nitrates)	C		
			Aspirin (Aspirin)	C		
			Ace Inhibitor (Ace Inhibitor)	C		

Date:04/09/04ISR Number: 4339012-5Report Type:Expedited (15-DaCompany Report #LBID00204000881
Age:68 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Coronary Artery Surgery Procedural Hypotension	Foreign Literature Health Professional	Lithium Carbonate {Manufacturer Unknown}(Lithium Carbonate)	PS			300 MG TID PO	
			Atenolol (Atenolol)	C				
			Carvedilol (Carvedilol)	C				
			Amlodipine (Amlodipine)	C				
			Nitrates (Nitrates)	C				
			Aspirine (Acetylsalicylic Acid)	C				

Date:04/13/04ISR Number: 4337254-6Report Type:Expedited (15-DaCompany Report #PHFR2004GB00801
Age:37 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Level Above Therapeutic		Clozaril	PS	Novartis Sector: Pharma	ORAL	650mg/day	
	Neutrophil Count Increased Oral Intake Reduced Urinary Tract Infection White Blood Cell Count Increased		Lithium	SS				

Date:04/13/04ISR Number: 4341027-8Report Type:Expedited (15-DaCompany Report #2004022403
Age:40 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Drug Toxicity Haemodialysis	Foreign Literature	Hydroxyzine Hydrochloride	PS		ORAL		
	Multiple Drug Overdose Suicide Attempt	Health Professional	Alprazolam (Alprazolam)	SS		ORAL		
			Trazadone (Trazadone)	SS		ORAL		
			Lithium Carbonate (Lithium Carbonate)	SS		ORAL		
			Clomipramine (Clomipramine)	SS		ORAL		
			Milnacipran (Milnacipran)	SS		ORAL		
			Tricyclic Antidepressants (Tricyclic Antidepressant) Benzodiazepine Derivatives	C				

			(Benzodiazepine Derivatives)	C			

Date:04/13/04ISR Number: 4341031-XReport Type:Expedited (15-DaCompany Report #2004022838
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Interaction	Foreign	Sortis					
	Thrombocytopenia	Health Professional Company Representative Other	(Atorvastatin)	PS				
			Lithium (Lithium)	SS				

Date:04/14/04ISR Number: 4340515-8Report Type:Expedited (15-DaCompany Report #DSA_24040_2004
Age:74 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Coma	Literature	Lorazepam	PS				
	Drug Toxicity	Health	Lorazepam	SS		ORAL	1 MG PRN PO	
	Medication Error	Professional	Clozapine	SS			100 MG ONCE	
	Miosis	Other	Lithium Carbonate	SS			400 MG	
	Red Blood Cell		Acetaminophen	SS			500 MG TID	
	Sedimentation Rate		Temazepam	SS			10 MG QHS	
	Increased Somnolence		Pimozide	C				

Date:04/19/04ISR Number: 4340777-7Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0379274A
Age:59 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Gastric Disorder		Eskalith	PS	Glaxosmithkline	ORAL	300MG See	

	Psoriasis					
dosage text						
			Avandia	C	Glaxosmithkline	
			Diovan	C		
			Tricor	C		
			Metoprolol	C		
			Neurontin	C		
			Carafate	C		
			Lithium	C	Glaxosmithkline	

Date:04/19/04ISR Number: 4340778-9Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0382769A
Age:66 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
	Tinnitus		Eskalith	PS	Glaxosmithkline	ORAL
750MG Per day						
	Tremor		Tylenol	C	Glaxosmithkline	ORAL

Date:04/19/04ISR Number: 4340779-0Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0406260A
Age:58 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Therapeutic Agent		Lithium Carbonate	PS	Glaxosmithkline	ORAL
DAY						
Initial or Prolonged	Toxicity		Depakote	C		ORAL
			Keflex	C	Glaxosmithkline	
INTRAVENOUS						
			Keflex	C	Glaxosmithkline	ORAL
			Clozaril	C		
UNKNOWN						

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/19/04ISR Number: 4340780-7Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0406563A
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Rash		Eskalith	PS	Glaxosmithkline	ORAL		

Date:04/19/04ISR Number: 4340781-9Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0409170A
Age:44 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Difficulty In Walking		Lithium Carbonate	PS	Glaxosmithkline		UNKNOWN	
	Dysarthria		Clozapine	C		ORAL		
	Dysstasia							
	Therapeutic Agent Toxicity							

Date:04/19/04ISR Number: 4340782-0Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0411047A
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Blood Creatinine Increased		Eskalith	PS	Glaxosmithkline	ORAL		

Date:04/19/04ISR Number: 4340783-2Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0411048A
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Rash		Eskalith	PS	Glaxosmithkline	ORAL		

Date:04/19/04ISR Number: 4340784-4Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0411194A
Age:53 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

	Abdominal Pain Upper		Eskalith Cr	PS	Glaxosmithkline	ORAL
450MG See						
	Flatulence					
dosage text 7 YR						

Date:04/19/04ISR Number: 4340785-6Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0411784A
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
	Hypoaesthesia		Eskalith Cr	PS	Glaxosmithkline	ORAL

Date:04/19/04ISR Number: 4340786-8Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0412835A
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
	Cognitive Deterioration		Lithium Carbonate	PS	Glaxosmithkline	ORAL

Date:04/19/04ISR Number: 4340787-XReport Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0422165A
Age:11 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
	Aggression		Lithium Carbonate	PS	Glaxosmithkline	
UNKNOWN 5 YR						
	Depression		Nardil	C		
			Concurrent			

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Medications C

Date:04/19/04ISR Number: 4340788-1Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0422166A
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Level Below Therapeutic Mania		Lithium Carbonate	PS	Glaxosmithkline	ORAL		

Date:04/19/04ISR Number: 4340789-3Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0422319A
Age:40 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Ineffective		Eskalith	PS	Glaxosmithkline	ORAL	300MG Twice per day	3 YR

Date:04/19/04ISR Number: 4340790-XReport Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0422742A
Age: YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Somnolence		Eskalith	PS	Glaxosmithkline	ORAL	300MG Per day	25 YR
	Tremor		Tegretol Pamelor	C C				

Date:04/19/04ISR Number: 4340791-1Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0423420A
Age:86 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Rash		Eskalith	PS	Glaxosmithkline	ORAL	40 YR	
			Lasix Lipitor	C C	Glaxosmithkline			

				Cozaar	C		
				Aspirin	C	Glaxosmithkline	

Date:04/19/04ISR Number: 4340792-3Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0423984A
Age:43 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Vision Blurred		Eskalith	PS	Glaxosmithkline	ORAL	900MG	Unknown
			Unknown	C				

Date:04/19/04ISR Number: 4340793-5Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0427034A
Age: YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Food Allergy		Eskalith	PS	Glaxosmithkline			
	Nervousness							

Date:04/19/04ISR Number: 4340794-7Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0429799A
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Electrocardiogram T Wave Amplitude Decreased		Eskalith	PS	Glaxosmithkline			

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/19/04ISR Number: 4340795-9Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0432006A
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Therapeutic Agent		Lithium Carbonate	PS	Glaxosmithkline		UNKNOWN	
	Toxicity							

Date:04/19/04ISR Number: 4340796-0Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0492572A
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Fatigue		Eskalith	PS	Glaxosmithkline	ORAL	300MG Three	
	Headache							
	Lethargy		Synthroid	C	Glaxosmithkline		times per day	10 YR
	Nausea		Unknown Medication	C			75MG Per day	
	Pharmaceutical Product		Toprol Xl	C			50MG per day	
	Complaint							

Date:04/19/04ISR Number: 4340797-2Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0494547A
Age:42 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Intolerance		Eskalith	PS	Glaxosmithkline	ORAL		

Date:04/19/04ISR Number: 4340798-4Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0371715A
Age:43 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Medication Error		Eskalith	PS	Glaxosmithkline		450MG Three	
	No Adverse Effect						times per day	

	Pollakiuria		Navane	C		
			Cogentin	C		

Date:04/19/04ISR Number: 4340799-6Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0376989A
Age:10 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Parkinsonism		Eskalith Cr	PS	Glaxosmithkline	ORAL		
			Guanfacine	C				
			Benztropine	C				
			Concerta	C				
			Prozac	C				
			Zyprexa	C				
			Depakote	C				

Date:04/19/04ISR Number: 4340800-XReport Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0386800A
Age:17 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Stool Analysis Abnormal		Eskalith Cr	PS	Glaxosmithkline	ORAL	450MG Twice	per day
			Wellbutrin Sr	C	Glaxosmithkline	ORAL	100MG Twice	per day
			Seroquel	C		ORAL	100MG Three	times per day
			Mircette	C		ORAL		
			Claritin-D	C		ORAL		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/19/04ISR Number: 4340801-1Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0389656A
Age:31 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Bipolar I Disorder		Eskalith Cr	PS	Glaxosmithkline		450MG Twice	
	Drug Level Decreased						per day	

Date:04/19/04ISR Number: 4340802-3Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0398131A
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Somnolence		Eskalith	PS	Glaxosmithkline	ORAL	450MG Twice	
							per day	

Date:04/19/04ISR Number: 4340803-5Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0398133A
Age:19 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Ineffective		Eskalith	PS	Glaxosmithkline	ORAL	450MG Twice	
							per day	
			Paxil	C	Glaxosmithkline	ORAL		
			Klonopin	C		ORAL	.5MG Three	
							times per day	
			Centrum	C				

Date:04/19/04ISR Number: 4340804-7Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0399097A
Age:48 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

	Diarrhoea		Eskalith	PS	Glaxosmithkline	ORAL
900MG per day 13 YR						

Date:04/19/04ISR Number: 4340805-9Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0400605A
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
	Diarrhoea		Eskalith	PS	Glaxosmithkline	ORAL
	Drug Withdrawal Syndrome		Lithobid	C	Glaxosmithkline	
UNKNOWN						
	Feeling Abnormal					
	Headache					
	Sinus Disorder					
	Tremor					

Date:04/19/04ISR Number: 4340809-6Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0400779A
Age:10 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
	Drug Level Below		Eskalith	PS	Glaxosmithkline	ORAL
450MG Twice						
	Therapeutic					
per day YR						
			Diuretic	C		
UNKNOWN						
			Amiloride	C		
UNKNOWN						

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/19/04ISR Number: 4340810-2Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0402275A
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Gingival Disorder		Eskalith	PS	Glaxosmithkline	ORAL		

Date:04/19/04ISR Number: 4340811-4Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0402673A
Age:43 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Pollakiuria		Eskalith	PS	Glaxosmithkline	ORAL	450MG Three times per day	9 YR
	Thirst							
			Navane	C				
			Cogentin	C				

Date:04/19/04ISR Number: 4340812-6Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0406276A
Age:30 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Polydipsia		Eskalith	PS	Glaxosmithkline	ORAL	450MG Twice per day	
	Polyuria							

Date:04/19/04ISR Number: 4340813-8Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0408570A
Age: Gender: I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Interaction		Eskalith	PS	Glaxosmithkline	ORAL		
	Feeling Jittery		Augmentin	SS	Glaxosmithkline		UNKNOWN	
	Tremor		Lithobid	C	Glaxosmithkline		UNKNOWN	

Date:04/19/04ISR Number: 4340814-XReport Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0413753A
Age:13 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Cyanosis		Eskalith	PS	Glaxosmithkline	ORAL	450MG Twice	
	Peripheral Coldness						per day	2 MON

Date:04/19/04ISR Number: 4340815-1Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0416595A
Age:20 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Joint Swelling		Eskalith	PS	Glaxosmithkline	ORAL	900MG Per day	WK

Date:04/19/04ISR Number: 4340816-3Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0418076A
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Level Increased		Eskalith	PS	Glaxosmithkline	ORAL		
	Ill-Defined Disorder							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/19/04ISR Number: 4340817-5Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0418796A
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Alopecia		Eskalith	PS	Glaxosmithkline	ORAL	450MG Per day	MON
			Seroquel	C				

Date:04/19/04ISR Number: 4340818-7Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0419718A
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Muscle Spasms		Eskalith	PS	Glaxosmithkline	ORAL	450MG Per day	6 YR
	Premenstrual Syndrome		Xanax	C				

Date:04/19/04ISR Number: 4340819-9Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0423749A
Age:43 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Toxicity		Eskalith	PS	Glaxosmithkline	ORAL	450MG Three	
	Dysgeusia							
							times per day	7 YR
	Hot Flush		Navane	C				
	Nausea		Cogentin	C				

Date:04/19/04ISR Number: 4340820-5Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0425421A
Age:14 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Diarrhoea		Eskalith	PS	Glaxosmithkline	ORAL	450Z See	
							dosage text	2 MON
			Trileptal	C				
			Aleve	C				

			Antacid	C			

Date:04/19/04ISR Number: 4340821-7Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0425941A
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Depression		Eskalith	PS	Glaxosmithkline	ORAL	900MG Per day	
	Pharmaceutical Product		Depakote	C				
	Complaint		Zyrtec	C	Glaxosmithkline			
			Colchicine	C				
			Ritalin	C				
			Tricor	C				
			Proventil	C	Glaxosmithkline			
			Advair	C	Glaxosmithkline			
			B-100 Complex	C				
			Flaxseed Oil	C				
			Boron	C				

Date:04/19/04ISR Number: 4340823-0Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0427841A
Age:17 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Rash		Eskalith	PS	Glaxosmithkline	ORAL	450MG Twice per day	1 MON
			Vicodin	C				
			Penicillin	C	Glaxosmithkline			

			Abilify	C		
			Lexapro	C		

Date:04/19/04ISR Number: 4340824-2Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0428961A
Age:30 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Exposure During		Eskalith	PS	Glaxosmithkline	ORAL	450MG Twice	
	Pregnancy						per day	1 YR
			Wellbutrin Sr	C	Glaxosmithkline		2 WK	
			Naltrexone	C				
			Zonegran	C				
			Seroquel	C				

Date:04/19/04ISR Number: 4340825-4Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0430613A
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Acne		Eskalith	PS	Glaxosmithkline	ORAL	450MG Twice	
	Condition Aggravated						per day	
			Bextra	C				

Date:04/19/04ISR Number: 4340829-1Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0432600A
Age:55 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Headache		Eskalith	PS	Glaxosmithkline	ORAL	450MG Twice	
							per day	4 MON
			Prozac	SS				
			Ambien	C				
			Klonopin	C				

Date:04/19/04ISR Number: 4340830-8Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0432622A
Age:66 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Pyrexia		Eskalith	PS	Glaxosmithkline	ORAL	450MG Per day	4 DAY
			Lithobid	C	Glaxosmithkline			
			Haloperidol	C				
			Zyprexa	C				
			Risperdal	C				
			Lamictal	C	Glaxosmithkline			
			Trazodone	C				
			Fluvastatin	C				
			Aspirin	C	Glaxosmithkline			
			Atenolol	C				
			Clonazepam	C				
			Ibuprofen	C	Glaxosmithkline			
			Nitroglycerin	C	Glaxosmithkline			
			Diltiazem	C	Glaxosmithkline			
			Loperamide	C				
			Combivent Inhaler	C				
			Atrovent Inhaler	C				
			Tylenol	C	Glaxosmithkline			
			Multivitamin	C				
			Vitamin E	C				
			Calcium Carbonate					

			With Vitamin D	C		
			Tuberculin Skin Test	C		

Date:04/19/04ISR Number: 4340831-XReport Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0440180A
Age:46 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Abdominal Distension		Eskalith	PS	Glaxosmithkline	ORAL	450MG Twice	
	Diarrhoea						per day	2 MON
	Muscle Spasms		Dilantin	C				
	Rectal Haemorrhage		Klonopin	C				
			Sinequan	C				
			Risperdal	C				
			Ibuprofen	C	Glaxosmithkline			
			Prevacid	C				

Date:04/19/04ISR Number: 4340832-1Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0440598A
Age:56 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Blood Calcium Increased		Eskalith	PS	Glaxosmithkline	ORAL		
			Insulin	C				
			Blood Pressure Medication	C				

Date:04/19/04ISR Number: 4340833-3Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0441522A
Age:41 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Renal Impairment		Eskalith	PS	Glaxosmithkline	ORAL	450MG	
							Variable dose	16 YR
			Lithobid	SS	Glaxosmithkline			
UNKNOWN							900MG Per day	8 YR

Date:04/19/04ISR Number: 4340834-5Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0443177A
Age:57 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Psychomotor Hyperactivity		Eskalith	PS	Glaxosmithkline	ORAL	450MG Three times per day	5 YR
			Synthroid	C	Glaxosmithkline			
			Aspirin	C	Glaxosmithkline			

Date:04/19/04ISR Number: 4340835-7Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0492911A
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Menstrual Disorder		Eskalith	PS	Glaxosmithkline	ORAL	300MG Twice per day	
			Claritin	C				
			Flovent	C	Glaxosmithkline			
			Flonase	C	Glaxosmithkline			

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/19/04ISR Number: 4340836-9Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0493269A
Age:46 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Blood Creatinine		Eskalith	PS	Glaxosmithkline	ORAL	225MG Per day	23 YR
	Increased		Lamictal	SS	Glaxosmithkline	ORAL	125MG per day	2 MON
	Confusional State		Zyprexa	SS				
	Dizziness		Valium	C				
	Erectile Dysfunction		Seizure Medication	C			UNKNOWN	
	Extrapyramidal Disorder		Gabapentin	C				
	Fatigue		Gabatril	C				
	Insomnia							
	Renal Disorder							
	Sexual Dysfunction							

Date:04/19/04ISR Number: 4340837-0Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0496688A
Age:66 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Anticonvulsant Drug Level		Eskalith	PS	Glaxosmithkline	ORAL	300MG Twice	
	Below Therapeutic						per day	
			Lexapro	C		ORAL		
			Celebrex	C			UNKNOWN	100MG

Alternate

days

Date:04/19/04ISR Number: 4340939-9Report Type:Expedited (15-DaCompany Report #JP-BRISTOL-MYERS SQUIBB COMPANY-12553707
Age:40 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Drug Toxicity		Trazodone Hcl Tabs	PS	Apothecon	ORAL		

Hospitalization - maintenance	Haemodialysis		Lithium Carbonate	SS		ORAL
Initial or Prolonged therapy of	Suicide Attempt					
400 mg daily						
			Lithium Carbonate	SS		ORAL
maintenance						
therapy of						
400 mg daily						
			Lithium Carbonate	SS		ORAL
maintenance						
therapy of						
400 mg daily						
			Alprazolam	SS		ORAL
			Clomipramine Hcl	SS		ORAL
			Hydroxyzine Hcl	SS		ORAL
			Milnacipran	SS		ORAL

Date:04/20/04ISR Number: 4342329-1Report Type:Direct Company Report #CTU 216931
Age:54 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Anxiety		Lithium	PS		ORAL	450 MG PO TID	
Initial or Prolonged	Dysphagia		Resperdone	SS		ORAL	1.5 MG PO QHS	
Required	Tremor							
Intervention to Prevent Permanent Impairment/Damage	Vision Blurred							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/21/04ISR Number: 4343579-0Report Type:Direct Company Report #CTU 217099
Age:73 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Coma		Lithium Carbonate	PS			SEE IMAGE	
	Drug Level Increased		.	C				
	Drug Toxicity		Aggrenox	C				
	Haemodialysis		Proscar	C				
	Hypotension		Gabapentin	C				
	Lethargy		Gatifloxacin	C				
	Medication Error		Glimepiride	C				
	Mental Status Changes		Insulin	C				
	Renal Failure Acute		Atrovent	C				
			Lisinopril	C				
			Pioglitazone	C				
			Terazosin	C				
			Metformin	C				

Date:04/21/04ISR Number: 4343646-1Report Type:Direct Company Report #CTU 217041
Age:68 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Diarrhoea		Lithium Carb 300mg					
	Drug Level Increased		Roxanne	PS	Roxanne	ORAL	300 MG PO BID	
	Fatigue							

Date:04/21/04ISR Number: 4343872-1Report Type:Direct Company Report #CTU 217061
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Mental Status Changes		Diazepam	PS			10 MG BID 20 MG Q HS	
			Trazodone	SS		ORAL	250 MG PO Q HS	

			Risperidone 5 Mg Q Hs	SS		5 MG QHS
			Lithium 600 Qhs And 300 Mg Q Am	SS		600 QHS & 300 MG QAM

Date:04/21/04ISR Number: 4345383-6Report Type:Expedited (15-DaCompany Report #2004022838
Age:72 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Aspiration Bone Marrow Abnormal	Foreign Health Professional	Sortis (Atorvastatin)	PS		ORAL	20 MG DAILY	
Other	Calcium Ionised Increased							
	Cataract	Company Representative	Lithium Carbonate (Lithium Carbonate)	SS		ORAL	ORAL	
	Cholelithiasis							
	Drug Interaction		Multivitamins (Ascorbic Acid, Ergocalciferol, Folic Acid, Nicotinamide,	C				
	Haematoma							
	Hepatic Steatosis							
	Hypercalcaemia							
	Idiopathic Thrombocytopenic Purpura							
	Petechiae							
	Thrombocytopenia							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/21/04ISR Number: 4345683-XReport Type:Expedited (15-DaCompany Report #2004025168
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Overdose	Health	Geodon (Ziprasidone)	PS				
	Tachycardia	Professional	Lithium (Lithium)	SS				
		Company						
		Representative						

Date:04/22/04ISR Number: 4344062-9Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0507912A
Age:20 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Anticonvulsant Drug Level	Health	Lamictal	PS	Glaxosmithkline	ORAL	150MG Twice	
	Below Therapeutic	Professional					per day	
	Convulsion		Lithium	SS	Glaxosmithkline			
	Drug Interaction		Ambien	SS				

Date:04/22/04ISR Number: 4348204-0Report Type:Expedited (15-DaCompany Report #HQWYE433012APR04
Age:61 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anaemia	Health	Inderal (Propranolol					
	Bradycardia	Professional	Hydrochloride,					
	Coma	Other	Tablet)	PS		ORAL	APPROXIMATELY	
	Diarrhoea						300 MG, TOTAL	
	Gastric Ulcer						ORAL	1 DAY
	Gastritis Haemorrhagic		Dalmadorm					
	Haematemesis		(Flurazepam					
	Haemodialysis		Hydrochloride,)	SS			APPROXIMATELY	
	Hypotension						1800 MG,	
	Hypoxia						TOTAL	1 DAY

		Metabolic Acidosis		Detrusitol (Tolterodine L-Tartrate,)	SS
		Miosis			
		Multiple Drug Overdose			
APPROXIMATELY 14 MG, TOTAL	1	DAY	Pitting Oedema		
		Renal Failure Acute		Entumin (Clotiapine,)	SS
		Serotonin Syndrome			
APPROXIMATELY 4000 MG TOTAL			Thrombocytopenia		
				Floxyfral (Fluvoxamine Maleate,)	SS
APPROXIMATELY 800 MG, TOTAL	1	DAY			
				Ponstan (Mefenamic Acid,)	SS
APPROXIMATELY 18000 MG TOTAL	1	DAY			
				Priadel (Lithium Carbonate,)	SS
APPROXIMATELY 4000 MG, TOTAL	1	DAY			
				Tramal (Tramadol, Hydrochloride,)	SS
APPROXIMATELY 4500 MG, TOTAL	1	DAY			
				Tranxilium (Clorazepate Dipotassium,)	SS
APPROXIMATELY 250 MG, TOTAL	1	DAY			

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/26/04ISR Number: 4349825-1Report Type:Expedited (15-DaCompany Report #2004-03-2204
Age:47 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Anaemia	Health	Vioxx (Rofecoxib)	PS		ORAL	25 MG QD	
Hospitalization - Initial or Prolonged	Coordination Abnormal	Professional	Altace	SS		ORAL	10 MG QD	
	Jaundice	Company	Aspirin Tablets	SS		ORAL	81 MG QD	
	Mental Status Changes	Representative	Peg-Intron (Peginterferon Alfa-2b) Injectable Powder	SS		SUBCUTANEOUS	96 MCG	QWK
	Therapeutic Agent Toxicity		Rebetol (Ribavirin) Capsules	SS		ORAL	800 MG QD	
			Lithium	SS		ORAL	300	BID
			Geodon (Ziprasidone)	C				
			Zyprexa (Olanzapine)	C				
			Lexapro (Escitalopram)	C				
			Protonix (Pantoprazole Sodium)	C				
			Neurontin	C				
			Clonazepam	C				
			Hydrocodone	C				
			Phenergan	C				

Date:04/27/04ISR Number: 4348289-1Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0350706A
Age:41 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Bipolar I Disorder		Eskalith	PS	Glaxosmithkline	ORAL	7	YR

Initial or Prolonged		Depression	Lithium Carbonate	SS	Glaxosmithkline	ORAL
450MG See						
		Drug Ineffective				
dosage text						
		Drug Level Decreased	Risperdal	C		
		Drug Level Increased	Navane	C		
UNKNOWN	15MG At night					
		Dry Mouth	Cogentin	C		
UNKNOWN						
		Dysgeusia				
		Hallucination, Auditory				
		Irritability				
		Libido Decreased				
		Mania				
		Periodontal Disease				
		Pollakiuria				
		Psychotic Disorder				
		Schizophrenia				
		Self-Injurious Ideation				
		Somnolence				
		Suicidal Ideation				
		Therapeutic Agent				
		Toxicity				
		Thirst				
		Visual Disturbance				
		Vomiting				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/28/04ISR Number: 4349542-8Report Type:Expedited (15-DaCompany Report #US-MERCK-0404USA02196
Age:47 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Agitation		Vioxx	PS	Merck & Co., Inc	ORAL		
Hospitalization -	Anaemia		Aspirin	SS		ORAL		
Initial or Prolonged	Coordination Abnormal		Lithium Carbonate	SS				
UNKNOWN								
	Depression		Lithium Carbonate	SS				
UNKNOWN								
	Haematocrit Decreased		Altace	SS		ORAL		
	Jaundice		Rebetol	SS		ORAL		
40 DAY								
	Therapeutic Agent		Peg-Intron	SS				
SUBCUTANEOUS							40	DAY
	Toxicity		Hydrocodone/Apap	C		ORAL		
			Geodon	C		ORAL		
			Zyprexa	C		ORAL		
			Phenergan Tablets/Suppositorie s	C		ORAL		
			Protonix	C		ORAL		
			Clonazepam	C		ORAL		
			Lexapro	C		ORAL		
			Neurontin	C		ORAL		

Date:04/28/04ISR Number: 4350864-5Report Type:Expedited (15-DaCompany Report #2004026021
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Aggression	Consumer	Zoloft (Sertraline)	PS		ORAL		
200 MG (BID),								
Initial or Prolonged	Feeling Drunk							
ORAL								
Other	Impaired Work Ability		Lithium (Lithium)	SS		ORAL		
ORAL								
	Intentional Misuse		Drug, Unspecified					
	Irritability		(Drug , Unspecified)	C				
	Mental Impairment							
	Mood Altered							
	Suicide Attempt							

Date:04/28/04ISR Number: 4350878-5Report Type:Expedited (15-DaCompany Report #2004025806
Age:48 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Chloride Increased	Literature	Lithium (Lithium)	PS			600 MG	(DAILY)
	Blood Creatinine Increased	Health Professional						
	Blood Urea Increased							
	Dehydration							
	Drug Ineffective							
	Femur Fracture							
	Heart Rate Increased							
	Hypernatraemia							
	Ileus							
	Mania							
	Multiple Fractures							
	Nephrogenic Diabetes Insipidus							
	Radius Fracture							
	Road Traffic Accident							
	Ulna Fracture							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/28/04ISR Number: 4352543-7Report Type:Expedited (15-DaCompany Report #2004022403
Age:40 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Haemodialysis	Foreign	Atarax (Tablet)					
	Hallucination	Literature	(Hydroxyzine					
	Paranoia	Health	Hydrochloride)	PS		ORAL	ORAL	
	Therapeutic Agent	Professional	Lithium (Lithium					
	Toxicity	Company	Carbonate) (Lithium)	SS		ORAL	ORAL	
		Representative	Alprazolam					
			(Alprazolam)	SS		ORAL	ORAL	
			Trazodone Hydrochloride (Trazodone					
			Hydrochloride)	SS		ORAL	ORAL	
			Clomipramine					
			(Clomipramine)	SS		ORAL	ORAL	
			Milnacipran					
			(Milnacipran)	SS		ORAL	ORAL	
			Tricyclic Antidepressants (Tricyclic					
			Antidepressants)	C				
			Benzodiazepine Derivatives (Benzodiazepine					
			Derivatives)	C				

Date:04/29/04ISR Number: 4350048-0Report Type:Expedited (15-DaCompany Report #PHBS2004DE05575
Age:79 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Chills		Carbamazepine	PS	Novartis Sector:			
	Difficulty In Walking				Pharma			
UNKNOWN							400 mg/day	
	Dysphagia		Lithium Carbonate	SS				
UNKNOWN								

		Parkinsonism		Amisulpride	SS		
UNKNOWN	800 mg/day						
		Weight Decreased		Amisulpride	SS		
UNKNOWN	600 mg/day						

Date:04/29/04ISR Number: 4350087-XReport Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0508560A
Age:47 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Agitation		Lithium	PS	Glaxosmithkline			
UNKNOWN	300MG Twice							
Hospitalization -	Anaemia							
per day								
Initial or Prolonged	Coordination Abnormal		Aspirin	SS	Glaxosmithkline	ORAL		
81MG Per day								
	Depression		Peg-Intron	SS				
SUBCUTANEOUS	96MCG Weekly	40 DAY						
	Drug Toxicity		Rebetol	SS		ORAL		
800MG Per day	40 DAY							
	Haematocrit Decreased		Vioxx	SS		ORAL		
25MG Per day								
	Jaundice		Altace	SS		ORAL		
10MG Per day								
	Mental Status Changes		Escitalopram	C		ORAL		
10MG Per day								
	Therapeutic Agent		Protonix	C		ORAL		
40MG Per day								
	Toxicity		Neurontin	C		ORAL		
100MG Three								
times per day								
			Clonazepam	C		ORAL		
1MG Twice per								
day								
			Hydrocodone	C		ORAL		
			Phenergan	C	Glaxosmithkline	ORAL		
25MG As								
required								
			Geodon	C		ORAL		
40MG Per day								
			Zyprexa	C		ORAL		
15MG Per day								

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/29/04ISR Number: 4350096-0Report Type:Expedited (15-DaCompany Report #JP-GLAXOSMITHKLINE-B0323722A
Age:79 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Blood Creatine		Paxil	PS	Glaxosmithkline	ORAL	10MG Per day	3 DAY
Initial or Prolonged	Phosphokinase Increased		Dogmatyl	SS		ORAL		
	Blood Creatinine		Etizolam	SS		ORAL		
	Increased		Limas	SS	Glaxosmithkline	ORAL	46	DAY
	Blood Urea Increased		Tecipul	C		ORAL		
	Blood Uric Acid Increased		Noritren	C		ORAL	75MG per day	
	Decreased Appetite		Nitrazepam	C		ORAL		
	Dehydration							
	Difficulty In Walking							
	Gait Disturbance							
	Hallucination							
	Hyperhidrosis							
	Muscle Rigidity							
	Serotonin Syndrome							
	Tremor							
	White Blood Cell Count Increased							

Date:04/30/04ISR Number: 4350874-8Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0350706A
Age:41 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Bipolar I Disorder		Eskalith	PS	Glaxosmithkline	ORAL	7	YR
Initial or Prolonged	Depression		Lithium Carbonate	SS	Glaxosmithkline	ORAL	450MG See	
	Drug Ineffective						dosage text	
	Drug Level Decreased		Risperdal	C				
	Drug Level Increased		Navane	C			UNKNOWN	15MG At night
	Dry Mouth		Cogentin	C			UNKNOWN	
	Dysgeusia							
	Hallucination, Auditory							
	Irritability							

	Libido Decreased
	Mania
	Periodontal Disease
	Pollakiuria
	Psychotic Disorder
	Schizophrenia
	Self-Injurious Ideation
	Somnolence
	Suicidal Ideation
	Therapeutic Agent
	Toxicity
	Thirst
	Visual Disturbance
	Vomiting

Date:04/30/04ISR Number: 4353496-8Report Type:Expedited (15-DaCompany Report #2003111631
Age:21 YR Gender:Female I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Basedow'S Disease
Other	Benign Breast Neoplasm
	Blood Pressure Decreased
	Cataract
	Drug Ineffective
	Euphoric Mood

	Mania						
	Pharmaceutical Product						
	Complaint	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Thyroid Disorder	Consumer	Lithium (Lithium)	PS			
	Tonsillectomy	Health	Nardil (Phenelzine				
	Victim Of Crime	Professional	Sulfate)	SS		ORAL	45 MG (TID), ORAL
			Cetirizine Hydrochloride	C			
			Alprazolam (Alprazolam)	C			

Date:05/03/04ISR Number: 4353216-7Report Type:Direct Company Report #CTU 217807
Age:61 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - 21 YR	Drug Level Increased		Lithium	PS			
Initial or Prolonged	Mental Status Changes		Seroquel	C			
	Tremor		Lisinopril	C			

Date:05/03/04ISR Number: 4354062-0Report Type:Expedited (15-DaCompany Report #JP-JNJFOC-20040404761
Age:52 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Death	Drug Interaction	Foreign	Risperdal				
	Hypokinesia	Health	(Risperidone)				
	Hypothermia	Professional	Unspecified	PS		ORAL	6 MG, IN 1 DAY, ORAL
	Hypothyroidism						
	Loss Of Consciousness		Biperiden				
	Meningitis		Hydrochloride				
	Pallor		(Biperiden				
	Somnolence		Hydrochloride)				
	Subdural Hygroma		Unspecified	SS		ORAL	6 MG, IN 1

DAY, ORAL			
	Lithium Carbonate		
	Trihexyphenidyl Hydrochloride (Trihexyphenidyl Hydrochloride)	SS	ORAL
3 MG, IN 1			
DAY, ORAL			
	Stomachics And Digestives (Stomachic Mixture /Tha/) Unspecified	SS	ORAL
0.72 G, IN 1			
DAY, ORAL			
	Sennoside (All Other Therapeutic Products) Unspecified	SS	ORAL
24 MG, IN 1			
DAY, ORAL			
	Zotepine (Zotepine) Unspecified	SS	ORAL
150 MG, IN			
1 DAY, ORAL			
	Hydroxyzine Pamoate (Hydroxyzine Embonate) Unspecified	SS	ORAL
90 MG, IN 1			
DAY, ORAL			
	Sodium Valpoate		

			(Valproate Sodium) Unspecified	SS		ORAL	600 MG, IN 1 DAY, ORAL
			Midodrine Hydrochloride (Midodrine Hydrochloride) Unspecified	SS		ORAL	6 MG, IN 1 DAY, ORAL
			Flunitrazepam (Flunitrazepam) Unspecified	SS		ORAL	2 MG, IN 1 DAY, ORAL
			Lithium Carbonate (Lithium Carbonate) Unspecified	C		ORAL	1.2 G, IN 1 DAY, ORAL

Date:05/04/04ISR Number: 4355224-9Report Type:Expedited (15-DaCompany Report #2004014114
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Agitation	Consumer	Geodon (Ziprasidone)	PS		ORAL	ORAL
Other	Alopecia		Lithium (Lithium) (Lithium)	SS			
	Anger						
	Anorexia		Perphenazine (Perphenazine)	SS			
	Anxiety						
	Dizziness		Benzatropine Mesilate (Benzatropine Mesilate)	C			
	Drug Effect Decreased						
	Drug Hypersensitivity						
	Feeling Abnormal						
	Hypertension		Diazepam (Diazepam)	C			
	Insomnia		Zolpidem Tartrate (Zolpidem Tartrate)	C			
	Irritability						
	Joint Swelling		Simvastatin (Simvastatin)	C			
	Oedema Peripheral						

	Pain	Levothyroxine Sodium (Levothyroxine Sodium)	C
	Paraesthesia		
	Paranoia		
	Rash	Folic Acid (Folic Acid)	C
	Rash Erythematous		
	Weight Decreased	Gabapentin (Gabapentin)	C
	Weight Increased		
		All Other Therapeutic Products (All Other Therapeutic Products)	C

Date:05/04/04ISR Number: 4355261-4Report Type:Expedited (15-DaCompany Report #B0330875A
Age:65 YR Gender:Female I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Choreoathetosis
	Coordination Abnormal
	Disorientation
	Dyskinesia
	Loss Of Consciousness
	Renal Impairment
	Therapeutic Agent

Toxicity

			Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
			Foreign Literature Health Professional	Lithium Carbonate (Formulation Unknown) (Generic) (Lithium Carbonate)	PS		
1200 MG PER DAY							

Date:05/05/04ISR Number: 4353558-5Report Type:Expedited (15-DaCompany Report #INV0229
Age:46 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Other	Blood Creatinine		Eskalith	PS	Glaxosmithkline	ORAL
225MG Per day	23 YR					
	Increased		Lamictal	SS	Glaxosmithkline	ORAL
25MG Per day						
	Confusional State		Zyprexa	SS		
	Dizziness		Topamax	SS		
	Erectile Dysfunction		Valium	C		
	Extrapyramidal Disorder		Seizure Medication	C		
UNKNOWN						
	Fatigue		Gabapentin	C		
	Insomnia		Gabatril	C		
	Rash Erythematous					
	Rash Pruritic					
	Renal Failure					
	Sexual Dysfunction					

Date:05/05/04ISR Number: 4353562-7Report Type:Expedited (15-DaCompany Report #INV0229
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Other	Renal Failure		Lithium Carbonate	PS	Glaxosmithkline	ORAL

Date:05/06/04ISR Number: 4356346-9Report Type:Expedited (15-DaCompany Report #2004026021
Age:28 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Accidental Overdose	Consumer	Zoloft (Sertraline)	PS		ORAL	200 MG (BID), ORAL	
Other	Activities Of Daily Living Impaired		Lithium (Lithium)	SS		ORAL		
	Aggression		Drug Unspecified	C				
	Cognitive Disorder							
	Divorced							
	Feeling Abnormal							
	Intentional Misuse							
	Irritability							
	Mental Disorder							
	Speech Disorder							
	Suicide Attempt							
	Thinking Abnormal							

Date:05/06/04ISR Number: 4356368-8Report Type:Expedited (15-DaCompany Report #K200400654
Age:47 YR Gender:Female I/FU:I

Outcome	PT
Life-Threatening	Agitation
Hospitalization - Initial or Prolonged	Anaemia
	Coordination Abnormal

		Depression Drug Level Increased Drug Toxicity Jaundice Mental Status Changes	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
			Health Professional Other	Altace Capsules (Ramipril) Capsule, 10 Mg	PS		ORAL
10 MG, QD,							
ORAL							
				Vioxx (Rofecoxib) 25 Mg	SS		ORAL
25 MG, QD,							
ORAL							
				Aspirin "Bayer" (Acetylsalicylic Acid) Tablet 81 Mg	SS	Bayer	
				Pegintron "Schering-Plough (Peginterferon Alfa-2b) Injection, 96mcg	SS		
SUBCUTANEOUS	96 MCG, QWK,						
SUBCUTANEOUS							
				Rebetol (Ribavirin) Capsule, 800 Mcg	SS		ORAL
800 MG, QD,							
ORAL							
				Lithium (Lithium) 300 Mg	SS		
300 MG, BID							
				Geodon (Ziprasidone Hydrochloride)	C		
				Zyprexa (Olanzapine)	C		
				Lexapro (Escitalopram Oxalate)	C		
				Protonix (Pantoprazole)	C		
				Neurontin	C		
				Clonazepam (Clonazepam)	C		
				Hydrocodone	C		
				Phenergan			

			(Promethazine Hydrochloride)	C		

Date:05/10/04ISR Number: 4356276-2Report Type:Direct Company Report #CTU 218292
Age:73 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Life-Threatening	Constipation		Lithium Cap Oral	PS		ORAL 300 MG TI
Hospitalization - Initial or Prolonged	Dehydration		Fluphenazine	C		
Required Intervention to Prevent Permanent Impairment/Damage	Dementia		Benzotropine	C		
	Dysuria					
	Hypercalcaemia					
	Hyperkalaemia					
	Hyperparathyroidism					
	Leukocytosis					
	Nausea					
	Neuropathy					
	Renal Failure					
	Vomiting					

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/10/04ISR Number: 4357018-7Report Type:Expedited (15-DaCompany Report #DSA_24304_2004
Age:67 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Asthenia	Foreign	Tavor	PS		ORAL	1 MG QD PO	
	Depressed Level Of Consciousness	Health Professional	Tavor	SS		ORAL	0.5 MG QD PO	
	Drug Interaction	Other	Tavor	SS		ORAL	2 MG QD PO	
	Electroencephalogram Abnormal		Eunerpan	SS		ORAL	50 MG QD PO	
	Fatigue		Eunerpan	SS		ORAL	200 MG QD PO	
	Gait Disturbance		Eunerpan	SS		ORAL	250 MG Q DAY PO	
	Memory Impairment		Hypnorex	SS		ORAL	600 MG QD PO	
	Mental Retardation		Hypnorex	SS		ORAL	400 MG QD PO	
	Severity Unspecified		Orfiril	SS		ORAL	1200 MG QD PO	
	Sedation		Orfiril	SS		ORAL	600 MG QD PO	
			Orfiril	SS		ORAL	900 MG QD PO	
			Orfiril	SS		ORAL	600 MG QD PO	
			Orfiril	SS		ORAL	300 MG QD PO	
			Timonil	SS		ORAL	600 MG QD PO	
			L-Thyroxin	C				

Date:05/10/04ISR Number: 4357502-6Report Type:Expedited (15-DaCompany Report #IE-JNJFOC-20040405911
Age:73 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Interaction Drug Level Increased	Foreign Health	Risperdal (Rispeidone)					

		Professional	Unspecified	PS			ORAL
ORAL							
			Sinemet Plus (Sinemet)	SS			ORAL
7.5 MG, IN 1 DAY, ORAL							
			Priadel (Lithium Carbonate)	SS			ORAL
600 MG, ORAL							
			Asasantin	C			
			Lipitor (Atorvastatin)	C			
			Mirapexin (Pramipexole Dihydrochloride)	C			
			Nu-Seals (Acetylsalicylic Acid)	C			
			Flurazepam	C			

Date:05/12/04ISR Number: 4358997-4Report Type:Expedited (15-DaCompany Report #2004-BP-03196RO
Age:49 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Cardio-Respiratory Arrest	Consumer	Lithium Carbonate					
Hospitalization - Initial or Prolonged	Diarrhoea		Capsules Usp, 300 Mg (Lithium Carbonate)	PS		ORAL	900 MG/DAY	
	Headache							
	Loss Of Consciousness						(300 MG), PO	8 YR
	Therapeutic Agent		Enalapril (Enalapril)	C				
	Toxicity		Topamax (Topiramate)	C				
	Tremor		Pravachol (Pravastatin Sodium)	C				
	Viral Infection		Proxac (Fluoxetine Hydrochloride)	C				
	Vision Blurred		Valium (Diazepam)	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/13/04ISR Number: 4357729-3Report Type:Expedited (15-DaCompany Report #2004006834
Age:44 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Life-Threatening	Drug Level Increased	Health	Quilonum Retard	PS	Glaxosmithkline	ORAL	450MG Unknown 1 DAY
Hospitalization - Initial or Prolonged	Intentional Misuse	Professional					
	Suicide Attempt						
	Vomiting						

Date:05/13/04ISR Number: 4359586-8Report Type:Expedited (15-DaCompany Report #2004029319
Age:47 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Other	Drug Level Increased	Health	Geodon (Ziprasidone)	PS			80 MG (UNK, 2
	Medication Error	Professional					IN 1 D),
	Neuroleptic Malignant	Company					UNKNOWN
	Syndrome	Representative	Lithium (Lithium)	SS			1500
	Renal Failure Acute						(UNKNOWN)
			Fluphenazine Decanoate (Fluphenazine Decanoate)	C			

Date:05/13/04ISR Number: 4359996-9Report Type:Expedited (15-DaCompany Report #AU-JNJFOC-20040501168
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Other	Intracranial Pressure Increased	Foreign Health	Risperidone (Risperidone)	PS			1 MG
		Professional	Lithium (Lithium)	SS			1000 MG

Date:05/13/04ISR Number: 4360229-8Report Type:Expedited (15-DaCompany Report #HQWYE683003MAY04
Age:39 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Coordination Abnormal Hallucination, Visual Hyperreflexia Serotonin Syndrome	Health Professional Other	Dociton (Propranolol Hydrochloride, Tablet)	PS		ORAL	160 MG 1X PER 1 DAY	44 MON
	Tachycardia Tremor		Dociton (Propranolol Hydrochloride, Tablet)	SS		ORAL	40 MG 1X PER 1 DAY	8 MON
			Hypnorex (Lithium Carbonate,)	SS		ORAL	1000 MG 1X PER 1 DAY	8 MON

Date:05/14/04ISR Number: 4358311-4Report Type:Expedited (15-DaCompany Report #US-MERCK-00101917
Age:67 YR Gender:Female I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged Other	Blood Calcium Increased Drug Interaction Drug Level Increased Dysarthria Hemiparesis Mental Status Changes Renal Failure

		Renal Neoplasm Therapeutic Agent Toxicity	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
			Health	Vioxx	PS	Merck & Co., Inc	ORAL
2	WK						
			Professional	Lithobid	SS		ORAL
9	YR						
				Lithobid	SS		ORAL

Date:05/14/04ISR Number: 4358316-3Report Type:Expedited (15-DaCompany Report #US-MERCK-00030893
Age:68 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Confusional State		Vioxx	PS	Merck & Co., Inc	ORAL
Initial or Prolonged	Coordination Abnormal		Lithium Carbonate	SS		
UNKNOWN						
	Dialysis		[Therapy			
	Disorientation		Unspecified]	C		
UNKNOWN						
	Drug Interaction		[Therapy			
	Drug Level Increased		Unspecified]	C		ORAL
	Therapeutic Agent		Estrogenic			
	Toxicity		Preparations			
			(Composition			
			Unspecified)	C		
UNKNOWN						

Date:05/14/04ISR Number: 4358326-6Report Type:Expedited (15-DaCompany Report #SE-MERCK-0204SWE00002
Age:81 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Blood Creatinine	Health	Vioxx	PS	Merck & Co., Inc	ORAL
25 DAY						
Initial or Prolonged	Increased	Professional	Lithium Sulfate	SS		ORAL
	Depressed Level Of		Calcium Carbonate			
	Consciousness		And Cholecalciferol	C		
UNKNOWN						
	Drug Effect Decreased		Dipyridamole	C		
UNKNOWN						

	Drug Interaction		Zolpidem Tartrate	C			
UNKNOWN							
	Drug Level Increased		Tramadol				
	Extrapyramidal Disorder		Hydrochloride	C			
UNKNOWN							
	Renal Failure		Lofepramine				
			Hydrochloride	C			
UNKNOWN							
			Levothyroxine Sodium	C			
UNKNOWN							

Date:05/14/04ISR Number: 4358327-8Report Type:Expedited (15-DaCompany Report #US-MERCK-00110445
Age:62 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Confusional State	Health	Vioxx	PS	Merck & Co., Inc	ORAL	5 DAY
Initial or Prolonged	Disorientation	Professional	Lithium Carbonate				
	Drug Interaction		(Roxane)	SS		ORAL	10 YR
	Therapeutic Agent Toxicity						

Date:05/14/04ISR Number: 4358575-7Report Type:Expedited (15-DaCompany Report #US-MERCK-0204USA02770
Age:72 YR Gender:Female I/FU:F

Outcome	PT
Hospitalization -	Asterixis
Initial or Prolonged	Asthenia
	Coordination Abnormal
	Dehydration
	Dizziness

	Drug Interaction					
	Drug Level Increased					
	Nausea	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
	Nystagmus		Vioxx	PS	Merck & Co., Inc	ORAL
3	MON					
			Lithium Carbonate (Roxane)	SS		ORAL
20	YR					

Date:05/17/04ISR Number: 4358960-3Report Type:Expedited (15-DaCompany Report #US-MERCK-01060813
Age:71 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization -	Apathy	Health	Vioxx	PS	Merck & Co., Inc	ORAL
5	DAY					
Initial or Prolonged	Drug Interaction	Professional	Lithium Carbonate	SS		ORAL
	Drug Level Increased		Clonazepam	C		
UNKNOWN						
	Gait Disturbance		Zyprexa	C		
UNKNOWN						
	Hypersomnia					
	Hypertonia					
	Mood Altered					
	Myoclonus					
	Oedema Peripheral					
	Speech Disorder					

Date:05/17/04ISR Number: 4358963-9Report Type:Expedited (15-DaCompany Report #US-MERCK-01031627
Age:69 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization -	Blindness	Health	Vioxx	PS	Merck & Co., Inc	ORAL
Initial or Prolonged	Confusional State	Professional	Lithium Carbonate	SS		ORAL
	Drug Interaction		Lithium Carbonate	SS		ORAL
	Haematocrit Decreased		Lortab	C		
UNKNOWN						
	Haemoglobin Decreased		Fosamax	C		
UNKNOWN						
	Hallucination		Prempro	C		
UNKNOWN						

	Headache		Prevacid	C			
UNKNOWN							
	Incoherent		Zestril	C			
UNKNOWN							
	Mental Status Changes						
	Neuropathy						
	Oedema Peripheral						
	Therapeutic Agent						
	Toxicity						
	Treatment Noncompliance						
	Tremor						

Date:05/17/04ISR Number: 4358974-3Report Type:Expedited (15-DaCompany Report #US-MERCK-0401USA01557
Age:91 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Delirium	Health	Vioxx	PS	Merck & Co., Inc	ORAL		3 WK
Initial or Prolonged	Drug Interaction	Professional	Lithium Carbonate	SS		ORAL		
	Drug Level Increased							
	Dysarthria							
	Sedation							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/17/04ISR Number: 4358977-9Report Type:Expedited (15-DaCompany Report #US-MERCK-0401USA01556
Age:58 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - 9 DAY	Drug Interaction	Health	Vioxx	PS	Merck & Co., Inc	ORAL	
Initial or Prolonged UNKNOWN	Neurotoxicity	Professional	Lithium Carbonate	SS			
	Therapeutic Agent Toxicity						

Date:05/17/04ISR Number: 4359166-4Report Type:Direct Company Report #CTU 218730
Age:59 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - 300 MG TID	Drug Toxicity		Lithium	PS			
Initial or Prolonged			Rabeprazole	C			
			Chlorpromazine	C			

Date:05/17/04ISR Number: 4360321-8Report Type:Expedited (15-DaCompany Report #C02-C-002
Age:50 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Other	Feeling Jittery	Consumer	Lithium Carbonate Capsules, Usp 300 Mg	PS	Able Labs		

Date:05/17/04ISR Number: 4360332-2Report Type:Expedited (15-DaCompany Report #C03-C-029
Age:50 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Other	Unevaluable Event	Consumer	Lithium Carbonate Capsules, Usp 300 Mg	PS	Able Labs.		

Date:05/17/04ISR Number: 4360348-6Report Type:Expedited (15-DaCompany Report #C02-C-003
Age:50 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Irritability	Consumer	Lithium Carbonate Capsules, Usp 300 Mg	PS	Able Labs.			
			Lithium Carbonate Capsules, Usp 300 Mg	SS	Able Labs.			

Date:05/17/04ISR Number: 4360386-3Report Type:Expedited (15-DaCompany Report #C02-T-062
Age:50 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Chest Pain	Consumer	Lithium Carbonate Capsules, Usp 300 Mg	PS	Able Labs.			

Date:05/18/04ISR Number: 4359779-XReport Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0510934A
Age:31 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Cardiomyopathy		Lamictal	PS	Glaxosmithkline	ORAL	200MG Per day	
	Vasculitis		Lithium	SS	Glaxosmithkline			
	Gastrointestinal		Prozac	C				
			Toprol	C				
			Pain Medications	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/19/04ISR Number: 4364364-XReport Type:Expedited (15-DaCompany Report #2004-BP-03638RO
Age:47 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Coma	Consumer	Lithium Carbonate					
Hospitalization - Initial or Prolonged	Cystitis Diarrhoea		Capsules Usp, 300 Mg (Lithium Carbonate)	PS		ORAL	2100 MG/DAY	
Disability	Drug Level Above Therapeutic		Soma (Carisoprodol)	C			(300 MG), PO	
	Drug Toxicity Incoherent							
	Influenza							
	Nervous System Disorder							
	Renal Failure							

Date:05/20/04ISR Number: 4363990-1Report Type:Direct Company Report #CTU 219096
Age:45 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Biliary Colic		Lithium 300 Mg	PS		ORAL	900 MG QD	
Hospitalization - Initial or Prolonged	Confusional State Hypernatraemia							
	Nephrogenic Diabetes Insipidus							
	Oral Intake Reduced							
	White Blood Cell Count Increased							

Date:05/24/04ISR Number: 4401845-4Report Type:Direct Company Report #USP 56684
Age:16 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Medication Error		Lithium	PS				

Date:05/25/04ISR Number: 4364443-7Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0511859A
Age: Gender: I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Renal Injury Therapeutic Agent Toxicity		Eskalith	PS	Glaxosmithkline	ORAL		

Date:05/25/04ISR Number: 4369303-3Report Type:Expedited (15-DaCompany Report #2004-DE-02806GD
Age:72 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other Required Intervention to Prevent Permanent Impairment/Damage	Difficulty In Walking Drug Ineffective Muscular Weakness	Literature	Pramipexole (Pramipexole Dihydrochloride) Lithium Carbonate (Lithium Carbonate)	PS SS				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/25/04ISR Number: 4370480-9Report Type:Expedited (15-DaCompany Report #LBID00204001387
Age:39 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Acute Myeloid Leukaemia Acute Myeloid Leukaemia (In Remission) Allogenic Bone Marrow Transplantation Therapy Basedow'S Disease Blood Thyroid Stimulating Hormone Decreased Graft Versus Host Disease	Literature Health Professional	Lithium Carbonate (Manufacturer Unknown) (Lithium Carbonate (Manufacturer Amitriptyline (Amitriptyline)	PS C		ORAL	DAILY PO	

Date:05/26/04ISR Number: 4364762-4Report Type:Expedited (15-DaCompany Report #PHFR2004GB02162
Age:62 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Level Increased		Lamisil	PS	Novartis Sector: Pharma	ORAL	250 mg, QD	
			Priadel	SS		ORAL	600mg/day	
			Priadel	SS			400mg/day	
			Olanzapine	C		ORAL	2.5mg/day	
			Diazepam	C		ORAL	5 mg, TID	
			Venlafaxine	C		ORAL	7.5mg 2 qd	

Date:05/26/04ISR Number: 4365525-6Report Type:Expedited (15-DaCompany Report #PHFR2004GB00801
Age:37 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Level Increased		Lithium	PS	Glaxosmithkline		UNKNOWN	

	Eating Disorder		Clozaril	SS		ORAL
650MG Per day						
	Malaise					
	Neutrophilia					
	White Blood Cell Count Increased					

Date:05/26/04ISR Number: 4365550-5Report Type:Expedited (15-DaCompany Report #2004009477
Age:26 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Intentional Misuse		Quilonum Retard	PS	Glaxosmithkline	ORAL	20TAB Single	
Hospitalization -	Somnolence							
dose							1	DAY
Initial or Prolonged	Suicide Attempt		Trimipramine	C		ORAL	20TAB Single	
dose							1	DAY

Date:05/26/04ISR Number: 4365560-8Report Type:Expedited (15-DaCompany Report #JP-BRISTOL-MYERS SQUIBB COMPANY-12588513
Age:53 YR Gender:Male I/FU:I

Outcome	PT
Hospitalization -	Abnormal Behaviour
Initial or Prolonged	Anxiety
	Decreased Appetite
	Deep Vein Thrombosis
	Dysphagia
	Dysuria
	Erythema
	Gait Disturbance

		Oedema Peripheral Parkinson'S Disease Restlessness	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
		Stupor		Reslin	PS	Apothecon	ORAL
				Lithium Carbonate	SS		ORAL
				Zotepine	SS		ORAL
				Trihexyphenidyl Hcl	SS		ORAL
				Sultopride Hcl	SS		ORAL
				Promethazine Hcl	SS		ORAL
				Sulpiride	SS		ORAL
				Paroxetine Hcl	SS		ORAL

Date:05/27/04ISR Number: 4367332-7Report Type:Expedited (15-DaCompany Report #FLUV00304000393
Age:68 YR Gender:Female I/FU:F

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Other		Cerebral Infarction Disease Progression Serotonin Syndrome	Foreign Health Professional	Luvox 25 (Fluvoxamine Maleate)	PS		ORAL
50 MG DAILY							
		Subdural Haematoma	Other				
PO, 75 MG							
DAILY PO							
				Lithium Carbonate (Lithium Carbonate)	SS		ORAL
300 MG DAILY							
PO							

Date:05/27/04ISR Number: 4369046-6Report Type:Expedited (15-DaCompany Report #LBID00204001388
Age:50 YR Gender:Female I/FU:I

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Other		Alanine Aminotransferase Increased	Health Professional	Lithobid (Lithium Carbonate)	PS		ORAL
300 MG BID PO							
		Aspartate Aminotransferase Increased					

Date:05/27/04ISR Number: 4369477-4Report Type:Expedited (15-DaCompany Report #2004UW07284
Age:64 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required	Nausea	Health	Crestor /Unk/	PS		ORAL	10 MG QD PO	
Intervention to	Therapeutic Agent	Professional	Lithium	SS		ORAL	300 MG BID PO	
Prevent Permanent	Toxicity		Lithium	SS		ORAL	300 MG QD PO	
Impairment/Damage	Tremor		Lithium	SS		ORAL	300 MG BID PO	
	Vomiting		Fosamax	C				
			Glyburide	C				
			Premarin	C				
			Hydrochlorothiazide	C				
			Diltiazem	C				
			Gemfibrozil	C				
			Lisinopril	C				

Date:05/27/04ISR Number: 4370033-2Report Type:Expedited (15-DaCompany Report #2004UW09490
Age:43 YR Gender:Male I/FU:F

Outcome	PT
Life-Threatening	Blood Amylase Increased
	Blood Creatinine

	Increased Confusional State Haematocrit Decreased Haemoglobin Decreased	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Red Blood Cell Count	Foreign	Crestor	PS		ORAL	20 MG DAILY
	Decreased	Health					PO
	Therapeutic Agent	Professional	Lithium	SS			1500 MG DAILY
	Toxicity	Other	Lithium	SS			
	Tremor		Lipidil Micro	SS			200 MG DAILY
			Haldol	C			
			Cogentin	C			
			Allopurinol	C			
			Altace	C			

Date:05/27/04ISR Number: 4370491-3Report Type:Expedited (15-DaCompany Report #2004-BP-03831AU
Age:75 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Renal Failure	Foreign	Mobic (Meloxicam)	PS		ORAL	15 MG (15 MG,
Initial or Prolonged		Consumer					15 MG DAILY),
		Health					PO
		Professional	Lithium (Lithium)	SS		ORAL	375 MG (250
							MG, 375 MG
							DAILY), PO
			Lasix	SS		ORAL	40 MG (40 MG,
							40MG DAILY),
							PO
			Coversyl (Perindopril)	C			
			Zocor	C			

Date:05/28/04ISR Number: 4369733-XReport Type:Expedited (15-DaCompany Report #2004009355
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain Back Disorder	Consumer Health	Neurontin (Gabapentin)	PS		ORAL	1800 MG	
Other	Blood Cholesterol Increased	Professional	Lipitor (Atorvastatin)	SS		ORAL	20 MG	(DAILY),
	Chest Pain Drug Ineffective Drug Intolerance Erectile Dysfunction Facial Pain Feeling Cold Gastrooesophageal Reflux Disease General Physical Health Deterioration Gingival Disorder Glossodynia Medication Error Mobility Decreased Neck Pain Oesophageal Spasm Pain In Jaw Sleep Disorder Somnolence Tooth Abscess Tremor		Lithium (Lithium) (Lithium) Naproxen (Naproxen) Rofecoxib (Rofecoxib) Amoxicillin (Amoxicillin) All Other Therapeutic Products (All Other Therapeutic Products) Levothyroxine Sodium (Levothyroxine Sodium) Vitamins (Vitamins) Diltiazem Hydrochloride	SS SS SS SS C C C		ORAL	1000 MG	(BID),

			(Diltiazem Hydrochloride)	C			

Date:06/01/04ISR Number: 4370943-6Report Type:Expedited (15-DaCompany Report #PERI00204001456
Age:60 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Confusional State Drug Toxicity	Foreign Health	Coversyl (Perindopril)	PS		ORAL	2 MG QD PO	
		Professional Other	Lithium Carbonate (Lithium Carbonate)	SS		ORAL	400 MG BID PO	
			Procyclidine (Procyclidine)	C				
			Chlorpromazine (Chlorpromazine)	C				
			Venlafaxine (Venlafaxine)	C				
			Carbamazepine (Carbamazepine)	C				
			Nitrazepam (Nitrazepam)	C				

Date:06/02/04ISR Number: 4372072-4Report Type:Expedited (15-DaCompany Report #LBID00204001466
Age:56 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abnormal Behaviour Agitation Confusional State Dysarthria Goitre	Foreign Literature Health Professional Other	Lithium Carbonate (Manufacturer Unknown) (Lithium Carbonate [Manufacturer	PS		ORAL	300 MG BID PO	
	Hyperthyroidism Incoherent Insomnia Oedema Peripheral Pitting Oedema Rebound Effect Restlessness Thinking Abnormal		Amitriptyline Isocarboxazid Trifluoperazine Diazepam Temazepam	C C C C C				

Outcome	PT
Hospitalization - Initial or Prolonged	Abnormal Behaviour
	Aggression
	Agitation
	Anxiety
	Blood Creatine Phosphokinase Increased
	Confusional State
	Depressed Level Of Consciousness
	Diarrhoea
	Dysuria
	Hyperkinesia
	Lacrimation Increased
	Locked-In Syndrome
	Masked Facies

		Muscle Rigidity Pyrexia Restlessness	Report Source	Product	Role	Manufacturer	Route	Dose Duration
		Rhinorrhoea		Paxil	PS	Glaxosmithkline	ORAL	100MG Three times per day 3 DAY
		Serotonin Syndrome		Limas	SS	Glaxosmithkline	ORAL	25MG Three times per day 3 DAY
		Speech Disorder						
		Stupor		Amoxan	SS		ORAL	INTRAVENOUS 8.33MG Three times per day 3 DAY
		Tremor						
				Anafranil	SS			10MG Per day 22 DAY
				Benzalin	C		ORAL	.5MG per day
				Alosenn	C		ORAL	

Date:06/03/04ISR Number: 4373405-5Report Type:Expedited (15-DaCompany Report #2004-DE-02978GD
Age:39 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Other Required Intervention to Prevent Permanent Impairment/Damage	Acute Myeloid Leukaemia Allogenic Bone Marrow Transplantation Therapy Basedow'S Disease Graft Versus Host Disease Hyperthyroidism Smoker	Foreign Literature	Lithium Carbonate (Lithium Carbonate) Cyclophosphamide (Cyclophosphamide) Methotrexate (Methotrexate) Cyclosporine (Ciclosporin) Cytarabine (Cytarabine)	PS SS SS SS C		INTRAVENOUS INTRAVENOUS CONTINUOUS	50 MG/KG, IV 100 MG/M2

Date:06/03/04ISR Number: 4374547-0Report Type:Expedited (15-DaCompany Report #2004-DE-03011GD (0)
Age:54 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anorexia Aphasia Apraxia Asthenia Confusional State Coordination Abnormal Delirium Diet Refusal Drug Level Above Therapeutic Drug Toxicity Dysarthria Dysgeusia Fatigue Food Aversion Haemodialysis Hypercalcaemia Irritability Nausea Renal Failure Acute Restlessness Somnolence Tremor	Foreign Literature	Lithium Carbonate (Lithium Carbonate) Thioridazine Hydrochloride (Thioridazine Hydrochloride)	PS SS			1500 MG (, FIVE TIMES DAILY), 100 MG (, ONCE DAILY, AT BEDTIME),	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/04/04ISR Number: 4371066-2Report Type:Expedited (15-DaCompany Report #PHFR2004GB02162
Age:62 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Level Increased		Lamisil	PS	Novartis Sector: Pharma	ORAL	250 mg, QD	
			Priadel	SS		ORAL	600mg/day	
			Priadel	SS			400mg/day	
			Olanzapine	C		ORAL	2.5mg/day	
			Diazepam	C		ORAL	5 mg, TID	
			Venlafaxine	C		ORAL	7.5mg 2 qd	

Date:06/04/04ISR Number: 4371282-XReport Type:Expedited (15-DaCompany Report #GB-MERCK-0405GBR00189
Age:38 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Asthenia		Vioxx	PS	Merck & Co., Inc	ORAL		
	Convulsion		Clozapine	SS		ORAL		
	Drug Interaction		Clozapine	SS		ORAL		
			Clozapine	SS		ORAL	77	DAY
			Clozapine	SS		ORAL		
			Lithium Acetate	SS			UNKNOWN	
			Tramadol Hydrochloride	C			UNKNOWN	

Date:06/07/04ISR Number: 4375455-1Report Type:Expedited (15-DaCompany Report #2002066670
Age:34 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accident	Health	Lithane (Lithium)	PS				
	Drug Toxicity	Professional						

Date:06/07/04ISR Number: 4376192-XReport Type:Expedited (15-DaCompany Report #2004034908
Age:39 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Acute Myelomonocytic	Foreign	Lithium (Lithium)	PS				
	Leukaemia	Literature	Amitriptyline	C				
	Asthenia	Health						
	Basedow'S Disease	Professional						
	Blood Pressure Increased							
	Blood Thyroid Stimulating Hormone Decreased							
	Bone Marrow Transplant							
	Goitre							
	Graft Versus Host Disease							
	Heart Rate Increased							
	Hyperhidrosis							
	Hyperthyroidism							
	Thyroxine Free Increased							
	Tremor							
	Weight Decreased							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/08/04ISR Number: 4374350-1Report Type:Direct Company Report #CTU 220287
Age:45 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Diabetes Insipidus		Lithium	PS			DAILY	
	Gout		Vitamin D	C				
	Hepatitis		Diovan	C				
	Hypertension		Lithium	C				
	Lupus-Like Syndrome		Dilantin	C				
	Renal Disorder		Carbamazepine	C				
	Transient Ischaemic Attack							
	Vitamin D Deficiency							

Date:06/08/04ISR Number: 4376922-7Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20040502855
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Coordination Abnormal	Foreign	Haldol - Janssen					
	Drug Interaction	Health	(Haloperidol)					
	Dysarthria	Professional	Unspecified	PS			5 MG, IN 1	DAY,
			Clomipramin (Clomipramine)	SS				
			Maprotilin (Maprotiline)	SS				
			Lithium (Lithium)	SS				

Date:06/09/04ISR Number: 4378456-2Report Type:Expedited (15-DaCompany Report #2004035659
Age:54 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anorexia	Foreign	Lithium (Lithium)	PS			1500 MG (5 IN 1 D)	15 YR
Other	Aphasia	Literature						
	Apraxia		Thioridazine					

	Asthenia	Hydrochloride	C
	Confusional State		
	Coordination Abnormal		
	Delirium		
	Drug Level Above Therapeutic		
	Dysarthria		
	Dysgeusia		
	Fatigue		
	Haemodialysis		
	Hypercalcaemia		
	Irritability		
	Nausea		
	Renal Failure Acute		
	Restlessness		
	Somnolence		
	Tremor		

Date:06/10/04ISR Number: 4378822-5Report Type:Expedited (15-DaCompany Report #LBID00204001549
Age:70 YR Gender:Male I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Apraxia
	Blood Pressure Diastolic

		Decreased					
		Cerebral Ischaemia					
		Cerebrovascular Accident					
		Cerebrovascular Disorder	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
		Electrocardiogram	Foreign	Lithium Carbonate	PS		ORAL
PO							
		Abnormal	Literature				
		Electroencephalogram	Health				
		Abnormal	Professional				
		Myoclonus	Other				
		Nodal Rhythm					
		Personality Change Due To					
		A General Medical					
		Condition					
		Renal Failure					
		Sinoatrial Block					
		Sinus Bradycardia					
		Therapeutic Agent					
		Toxicity					
		Transient Ischaemic					
		Attack					

Date:06/11/04ISR Number: 4375841-XReport Type:Expedited (15-DaCompany Report #PHFR2004GB02162
Age:62 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Other	Drug Level Increased		Lamisil	PS	Novartis Sector: Pharma	ORAL
250 mg, QD						
			Priadel	SS		ORAL
600mg/day						
			Priadel	SS		
400mg/day						
			Olanzapine	C		ORAL
2.5mg/day						
			Diazepam	C		ORAL
5 mg, TID						
			Venlafaxine	C		ORAL
7.5mg 2 qd						

Date:06/11/04ISR Number: 4376102-5Report Type:Expedited (15-DaCompany Report #JP-GLAXOSMITHKLINE-B0329669A
Age:53 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Insomnia		Paxil	PS	Glaxosmithkline	ORAL	10MG Three times per day	27 DAY
	Irritability							
	Psychomotor Hyperactivity		Lithium Carbonate	SS	Glaxosmithkline	ORAL	400MG per day	128 DAY

Date:06/14/04ISR Number: 4379294-7Report Type:Expedited (15-DaCompany Report #2004-BP-03638RO
Age:47 YR Gender:Male I/FU:F

Outcome	PT
Life-Threatening	Accidental Overdose
Hospitalization - Initial or Prolonged	Agitation
	Alanine Aminotransferase Increased
Disability	Aspartate Aminotransferase Increased
	Cerebral Atrophy
	Coma
	Cystitis
	Delirium
	Haematocrit Decreased
	Haemodialysis
	Haemoglobin Decreased

	Incoherent Influenza Mental Status Changes	Report Source	Product	Role	Manufacturer	Route Dose Duration
	Metabolic Disorder Nervous System Disorder Platelet Count Decreased	Consumer	Lithium Carbonate Capsules Usp, 300 Mg (Lithium Carbonate)	PS	Usp	ORAL 2100 MG/DAY
	Renal Failure					(300 MG), PO
	Therapeutic Agent Toxicity		Soma (Carisoprodol) Xanax (Alprazolam) Sinemet (Sinemet)	C C C		

Date:06/17/04ISR Number: 4379758-6Report Type:Expedited (15-DaCompany Report #2004009477
Age:26 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Life-Threatening	Intentional Misuse	Health	Quilonum Retard	PS	Glaxosmithkline	ORAL 20TAB Single
Hospitalization -	Somnolence	Professional				
dose 1 DAY						
Initial or Prolonged	Suicide Attempt		Trimipramine	C		ORAL 20TAB Single
dose 1 DAY						

Date:06/17/04ISR Number: 4381026-3Report Type:Direct Company Report #USP 56638
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
	Medication Error		Lithobid	PS		CAPSULE

Date:06/17/04ISR Number: 4381089-5Report Type:Direct Company Report #USP 56632
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration

	Abnormal Behaviour		Lithobid	PS		
CAPSULE						
	Medication Error					

Date:06/17/04ISR Number: 4381106-2Report Type:Direct Company Report #USP 56623
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
	Medication Error		Loperamide Hci	PS	Roxane	
LIQUID						
			Calcium Carbonate	SS	Roxane	
LIQUID						
			Lidocaine Viscous	SS	Roxane	
LIQUID						
			Lithium Citrate	SS	Roxane	
LIQUID						
			Digoxin	SS	Roxane	
LIQUID						
			Theophylline	SS	Roxane	

Date:06/18/04ISR Number: 4380592-1Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0513975A
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Renal Failure	Consumer	Eskalith	PS	Glaxosmithkline	
35 YR						
Initial or Prolonged			Quilonum	SS	Glaxosmithkline	
35 YR						

Date:06/18/04ISR Number: 4383433-1Report Type:Expedited (15-DaCompany Report #200412822BCC
Age:45 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Balance Disorder Coordination Abnormal Drug Abuser	Foreign Other	Aleve (Naproxen Sodium) Quilonorm Retard	PS				
	Drug Interaction		(Lithium Carbonate)	SS		ORAL	450 MG, TOTAL	
	Drug Level Increased						DAILY, ORAL	
	Drug Toxicity		Brufen (Ibuprofen)	SS		ORAL	1200 MG,	
	Dysarthria						TOTAL DAILY,	
	Dysstasia						ORAL	
	Haemoconcentration Haemodialysis		Seroquel (Quetiapine Fumarate)	SS		ORAL	25 MG, TOTAL	
	Nervous System Disorder						DAILY, ORAL	
	Renal Failure Acute		Bekunis Bisacodyl	C				
	Somnolence		Novalgine	C				
	Urine Analysis Abnormal		Zelmac	C				
			Buscopan	C				
			Demetrin	C				
			Panadol	C				
			Solatran	C				
			Xanax	C				

Date:06/18/04ISR Number: 4384188-7Report Type:Expedited (15-DaCompany Report #LBID00204001388
Age:50 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hepatitis C	Health Professional	Lithobid (Lithium Carbonate)	PS		ORAL	300 MG BID PO	

Date:06/21/04ISR Number: 4381501-1Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0514691A
Age:50 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drooling		Eskalith	PS	Glaxosmithkline	ORAL	450MG Twice per day	20 YR
	Drug Interaction							
	Drug Level Increased		Advair	SS	Glaxosmithkline	RESPIRATORY (INHALATION)	1PUFF Twice per day	2 WK
	Dyskinesia							
	Hypersomnia							
	Influenza		Cipro	SS	Glaxosmithkline			
	Skin Infection		Zyrtec	SS	Glaxosmithkline			
	Therapeutic Agent		Navane	C			10MG Three times per day	
	Toxicity							
	Tremor		Benztropine Mesylate	C			2MG Twice per day	
			Risperdal	C			3MG Per day	
			Lotensin	C	Glaxosmithkline			

Date:06/22/04ISR Number: 4382277-4Report Type:Expedited (15-DaCompany Report #PHFR2004GB01844
Age:20 YR Gender:Female I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Back Pain
	Blood Urine
Other	Drug Interaction
	Drug Toxicity
	Encephalopathy
	Neutrophil Count

	Increased Proteinuria Pyelonephritis Pyrexia	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Renal Failure Acute Renal Impairment		Clozaril	PS	Novartis Sector: Pharma	ORAL	200mg/day
	Sepsis		Valproate Sodium	SS		ORAL	1 g, BID
	Somnolence		Lithium Carbonate	SS		ORAL	400 mg, BID
	Therapeutic Agent		Clonazepam	C		ORAL	1 mg, QID 80640MIN
	Toxicity Urinary Tract Infection White Blood Cell Count Increased						

Date:06/22/04ISR Number: 4385380-8Report Type:Expedited (15-DaCompany Report #2004UW12511
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Required Intervention to Prevent Permanent Impairment/Damage	Blood Creatine Phosphokinase Increased Drug Interaction	Health Professional	Seroquel Lithium	PS SS			

Date:06/23/04ISR Number: 4383683-4Report Type:Expedited (15-DaCompany Report #2004011396
Age:66 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Bradycardia Overdose	Health Professional	Quilonum Retard Lamictal	PS SS	Glaxosmithkline Glaxosmithkline	ORAL ORAL	150MG per day WK
	Psychotic Disorder		Taxilan	SS		ORAL	50MG per day WK
	Renal Failure		Xanef	SS		ORAL	WK
	Somnolence		Dytide H	SS	Glaxosmithkline	ORAL	WK
	Suicide Attempt						

Date:06/24/04ISR Number: 4384253-4Report Type:Expedited (15-DaCompany Report #CH-MERCK-0310CHE00016
Age:68 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Blood Creatinine	Health	Vioxx	PS	Merck & Co., Inc	ORAL	8	DAY
Hospitalization - Initial or Prolonged	Increased Bradycardia Drug Interaction Electrocardiogram	Professional	Carbamazepine	SS		ORAL		
			Lithium Carbonate	SS		ORAL		
			Propranolol Hydrochloride	SS		ORAL	1	DAY
	Abnormal Headache Hypotension Malaise Therapeutic Agent Toxicity Tremor Vomiting		Mirtazapine	C		ORAL		
			Pipamperone Hydrochloride	C		ORAL		
			Zopiclone	C		ORAL		

Date:06/24/04ISR Number: 4386090-3Report Type:Periodic Company Report #LBID00203001215
Age:14 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Level Decreased	Health Professional	Lithobid (Lithium Carbonate)	PS		ORAL	DAILY	PO

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/24/04ISR Number: 4386091-5Report Type:Periodic Company Report #LBID00203001202
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Depression	Health	Lithobid (Lithium					
	Drug Ineffective	Professional	Carbonate)	PS		ORAL	1200 MG DAILY	
	Drug Level Decreased	Company					PO	
		Representative	Parnate (Tranylcypromine Sulfate)	C				

Date:06/25/04ISR Number: 4385430-9Report Type:Direct Company Report #CTU 221550
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Toxicity		Lithium 300mg Cap	PS			300 MG BID	
	Tremor		Furosemide 40mg Tab	SS			40 MG BID	
			Losartan 25mg Q1	SS				

Date:06/25/04ISR Number: 4385536-4Report Type:Direct Company Report #CTU 221584
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	Bipolar Disorder		Lithium	PS		ORAL	PO	
	Condition Aggravated							
	Confusional State							
	Dehydration							
	Dialysis							
	Drug Toxicity							
	Encephalopathy							
	Oral Intake Reduced							
	Renal Failure Acute							
	Tremor							
	Urinary Tract Infection							
	Vaginal Mycosis							

Date:06/28/04ISR Number: 4386197-0Report Type:Direct Company Report #CTU 221660
Age:25 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dehydration Mental Impairment Nephrogenic Diabetes Insipidus		Lithium Carbonate (Eskalith Cr) 450mg) Glaxo Smith Kline	PS	Glaxo Smith Kline		450 MG Q AM, 900 MG Q PM	
Required Intervention to Prevent Permanent Impairment/Damage			Depakote Lovenox Zyprexa Clonidine Doss	C C C C C				

Date:06/28/04ISR Number: 4389204-4Report Type:Expedited (15-DaCompany Report #2004-DE-03406AG
Age:40 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Haemodialysis Multiple Drug Overdose	Foreign Health	Desyrel (Trazodone Hydrochloride)	PS		ORAL	NR (NR), PO	
	Suicide Attempt	Professional	Atarax	SS		ORAL	NR (NR); PO	
			Solanax (Alprazolam)	SS		ORAL	NR (NR); PO	

			Lithium Carbonate (Lithium Carbonate)	SS		ORAL	5600 MG (NR); PO
			Clomipramine Hydrochloride (Clomipramine Hydrochloride)	SS		ORAL	NR (NR); PO
			Milnacipran Hydrochloride (Milnacipran Hydrochloride)	SS		ORAL	NR (NR); PO

Date:06/28/04ISR Number: 4389527-9Report Type:Expedited (15-DaCompany Report #IE-JNJFOC-20040405911
Age:73 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Interaction Drug Level Increased	Foreign Health Professional	Risperdal (Risperidone)	PS		ORAL	SEE IMAGE	
			Sinemet Plus (Sinemet)	SS		ORAL	SEE IMAGE	
			Priadel (Lithium Carbonate)	SS		ORAL	3600 MG, ORAL	
			Asasantin (Asasantin)	C				
			Lipitor (Atorvastatin)	C				
			Mirapexin (Pramipexole Dijydrochloride)	C				
			Nu-Seals (Acetylsalicylic Acid)	C				
			Flurazepam (Flurazepam)	C				

Date:06/30/04ISR Number: 4389922-8Report Type:Direct Company Report #CTU 221840
Age:64 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Condition Aggravated		Lithium Carbonate Er 450 Mg Tablet	PS			450 MG BID	
	Disturbance In Attention							
	Mood Altered		Synthroid	C				
	Pharmaceutical Product Complaint							

Date:07/01/04ISR Number: 4388792-1Report Type:Expedited (15-DaCompany Report #CH-MERCK-0310CHE00016
Age:68 YR Gender:Female I/FU:F

Outcome	PT
Life-Threatening	Blood Creatinine Increased
Hospitalization - Initial or Prolonged	Bradycardia
	Drug Interaction
	Electrocardiogram Abnormal
	Headache
	Hypotension
	Malaise

		Therapeutic Agent Toxicity Tremor	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
		Vomiting	Health	Vioxx	PS	Merck & Co., Inc	ORAL
8	DAY						
			Professional	Carbamazepine	SS		ORAL
12	YR						
				Carbamazepine	SS		ORAL
				Lithium Carbonate	SS		ORAL
12	YR						
				Lithium Carbonate	SS		ORAL
				Mirtazapine	C		ORAL
3	MON						
				Zopiclone	C		ORAL
				Pipamperone Hydrochloride	C		ORAL
6	YR						

Date:07/01/04ISR Number: 4389145-2Report Type:Direct Company Report #CTU 221953
Age: Gender:Male I/FU:I

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Hospitalization - Initial or Prolonged [CHRONIC LONG-TERM]		Dehydration Drug Level Increased		Lithium Carbonate	PS		ORAL
				Lisinopril	C		
				Naproxen	C		

Date:07/01/04ISR Number: 4391984-9Report Type:Expedited (15-DaCompany Report #B0335917A
Age:57 YR Gender:Male I/FU:I

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Life-Threatening		Hypotension Self-Medication	Foreign Literature Health	Lithium Carbonate (Generic) (Lithium Carbonate)	PS		ORAL
300 MG/THREE							

		Professional					
TIMES PER							
DAY/ORAL							
			Benzodiazepines	C			
			Atenolol	C			
			Carvedilol	C			
			Amlodipine	C			

Date:07/01/04ISR Number: 4391985-0Report Type:Expedited (15-DaCompany Report #B0335921A
Age:68 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Procedural Hypotension	Foreign	Lithium Carbonate	PS		ORAL	300 MG /	
		Literature						
THREE TIMES								
		Health						
PER DAY/ ORAL								
		Professional	Benzodiazepines	C				
			Atenolol	C				
			Carvedilol	C				
			Amlodipine	C				

Date:07/02/04ISR Number: 4393213-9Report Type:Expedited (15-DaCompany Report #2004041993
Age:26 YR Gender:Female I/FU:I

Outcome	PT
Disability	Anorexia
Other	Goitre
	Hyperhidrosis
	Iodine Uptake Decreased

		Palpitations					
		Thyroiditis					
		Tremor	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
			Foreign	Lithium (Lithium)	PS		
800 MG							
			Literature				
			Health				
			Professional				

Date:07/02/04ISR Number: 4393215-2Report Type:Expedited (15-DaCompany Report #2004041544
Age: Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Other	Blood Calcium Increased	Foreign	Lithium (Lithium)	PS		
623 MG						
	Cyst	Literature				
	Hypocalcaemia	Health				
	Parathyroid Disorder	Professional				
	Urine Calcium Decreased					

Date:07/02/04ISR Number: 4393982-8Report Type:Expedited (15-DaCompany Report #200418705BWH
Age:49 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization -	Drooling	Consumer	Cipro (Ciprofloxacin			
Initial or Prolonged	Influenza	Other	Hydrochloride)	PS		
500 MG						
	Movement Disorder		Eskalith Tablet -			
	Respiratory Disorder		Controlled Release			
	Skin Infection		(Lithium Carbonate)	SS		ORAL
450 MG , BID,						
	Somnolence					
ORAL						
	Therapeutic Agent		Advair	SS		
RESPIRATORY						
	Toxicity					
(INHALATION)	250/50 UG ,					
	Tremor					
BID,						

RESPIRATORY

(INHALATION)

			Zyrtec (Cetirizine Hydrochloride)	SS			
10 MG							
			Navane	C			
			Benztropine Mesylate	C			
			Risperidone	C			
			Lotensin	C			

Date:07/06/04ISR Number: 4393578-8Report Type:Direct Company Report #CTU 222254
Age:60 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Bradycardia Lethargy Therapeutic Agent Toxicity		Lithium 300 Mg Capsules	PS			600 MG QAM AND 900 MG Q HS	
			Fosinopril	SS			10MG QD	
			Diltiazem (180 Mg Po Bid)	SS			180MG PO BID	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/06/04ISR Number: 4394883-1Report Type:Expedited (15-DaCompany Report #04P-056-0264709-00
Age:53 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Alanine Aminotransferase Anaemia Macrocytic Diabetes Insipidus Nephritis Interstitial Renal Failure	Foreign Health Professional Company Representative	Depakine Tablets (Sodium Valproate) (Sodium Valproate) (Sodium Valproate)	PS		ORAL	500 MG, 2 IN 1 D, PER ORAL	
			Depakote Tablets (Depakote) (Divalproex Sodium) (Divalproex Sodium)	SS		ORAL	500 MG, 2 IN 1 D, PER ORAL	
			Lithium Carbonate	SS		ORAL	PER ORAL	
			Propranolol Levothyroxine Sodium	C C				

Date:07/06/04ISR Number: 4396128-5Report Type:Expedited (15-DaCompany Report #B0336326A
Age:47 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agitation Anxiety Blood Creatinine Increased Hypomania Hyponatraemia Megacolon Nephrogenic Diabetes Insipidus Sleep Disorder	Foreign Literature Health Professional	Lithium Salt (Generic) (Lithium Salt) Haloperidol Valproic Acid Methotrimeprazine	PS C C C			SEE DOSAGE TEXT	

Date:07/07/04ISR Number: 4393366-2Report Type:Direct Company Report #CTU 222290
Age:55 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Convulsion		Lithium Carbonate					
Required	Loss Of Consciousness		300 Mg	PS		ORAL	300 MG 1 QAM	
Intervention to	Open Wound						AND 2 ORAL	
Prevent Permanent			Lidocaine Injection	SS			SUBCUTANEOUS	SQ
Impairment/Damage								

Date:07/07/04ISR Number: 4421077-3Report Type:Periodic Company Report #364807
Age:40 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hypoaesthesia	Consumer	Fuzeon (Enfuvirtide)					
	Injection Site Erythema		90 Mg	PS			SUBCUTANEOUS	90 MG 2 PER
	Injection Site Reaction						DAY,	
	Mania						SUBCUTANEOUS	
	Memory Impairment		Lithium (Lithium					
	Neuropathy Peripheral		Nos)	SS		ORAL	900 MG DAILY,	
	Post Procedural						ORAL	
	Complication		Viread (Tenofovir)	C				
			Unknkown Medications (Generic					
			Component(S)	C				
			Norvir (Ritonavir)	C				

Depakote (Divalproex Sodium)	C
Reyataz (Atazanavir)	C
Bactrim (Sulfamethoxazole/Trimethoprim)	C

Date:07/09/04ISR Number: 4393736-2Report Type:Expedited (15-DaCompany Report #GB-GLAXOSMITHKLINE-B0337124A
Age:75 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Anorexia		Lithium	PS	Glaxosmithkline	ORAL	400MG Per day	
Hospitalization -	Constipation		Fluvastatin	C			UNKNOWN	
Initial or Prolonged	Dyspnoea		Frusemide	C	Glaxosmithkline	ORAL	40MG Monthly	
Other	Hypothyroidism		Aspirin	C	Glaxosmithkline	ORAL	75MG Per day	
	Renal Impairment		Atenolol	C		ORAL	50MG Per day	
	Therapeutic Agent		Amlodipine	C		ORAL	10MG Per day	
	Toxicity		Isosorbide Mononitrate	C		ORAL	90MG Per day	
			Thyroxine	C	Glaxosmithkline	ORAL	50MCG Per day	
			Omeprazole	C		ORAL	40MG Per day	
			Mebeverine	C		ORAL		
			Fybogel	C			UNKNOWN	
			Senna	C	Glaxosmithkline		UNKNOWN	
			Gastrocote	C			UNKNOWN	
			Nitrazepam	C		ORAL	5MG As required	

Date:07/09/04ISR Number: 4393740-4Report Type:Expedited (15-DaCompany Report #GB-GLAXOSMITHKLINE-B0337315A
Age:46 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Serotonin Syndrome		Lithium Carbonate	PS	Glaxosmithkline	ORAL	600MG per day	
			Venlafaxine	SS		ORAL		
			Risperdal	C		ORAL	2MG per day	14 DAY

Date:07/12/04ISR Number: 4394953-8Report Type:Expedited (15-DaCompany Report #GB-GLAXOSMITHKLINE-B0338002A
Age:20 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Back Pain		Lithium Carbonate	PS	Glaxosmithkline	ORAL	400MG Twice	
	Encephalopathy						per day	
	Haematuria		Clozaril	SS		ORAL	200MG Per day	
	Neutrophil Count		Sodium Valproate	SS		ORAL	1G Twice per	
	Increased						day	
	Proteinuria		Clonazepam	C		ORAL	1MG Four	
	Pyelonephritis						times per day	56 DAY
	Pyrexia							
	Renal Failure Acute							
	Sepsis							
	Somnolence							
	Therapeutic Agent							
	Toxicity							
	Urinary Tract Infection							
	White Blood Cell Count							
	Increased							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/12/04ISR Number: 4399233-2Report Type:Expedited (15-DaCompany Report #2004044191
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Accidental Overdose Confusional State	Consumer	Neurontin (Gabapentin)	PS		ORAL	2400 MG (500 MG, QID	
Other	Contusion							
	Convulsion							
	Drug Interaction							
	Drug Toxicity							
	Feeling Jittery Loss Of Consciousness Memory Impairment Mental Disorder		Atarax (Hydroxyzine Hydrochloride)	SS				
			Vistaril (Hydroxyzine Hydrochloride)	SS				
			Lithium Carbonate (Lithium Carbonate)	SS				
			Tiagabine Hydrochloride (Tiagabine Hydrochloride)	C				
			Escitalopram (Escitalopram)	C				
			Tetrabenazine (Tetrabenazine)	C				
			Rofecoxib (Rofecoxib)	C				
			Zolpidem Tartrate (Zolpidem Tartrate)	C				
			Ramipril (Ramipril)	C				
			Tolterodine L-Tartrate (Tolterodine L-Tartrate)	C				
			Esomeprazole (Esomeprazole)	C				
			Atorvastatin					

(Atorvastatin)	C
Pioglitazone (Pioglitazone)	C

Date:07/12/04ISR Number: 4399255-1Report Type:Expedited (15-DaCompany Report #2004044086
Age:46 YR Gender:Female I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Affective Disorder
Other	Anxiety
	Arteriosclerosis
	Blood Cholesterol Increased
	Condition Aggravated
	Depression
	Eye Disorder
	Fatigue
	Feeling Abnormal
	Headache
	Insomnia

Intentional Self-Injury Medication Error Self-Injurious Ideation Suicidal Ideation Tongue Ulceration Treatment Noncompliance Tremor Weight Decreased Weight Increased	Health Professional	Geodon (Ziprasidone) Lipitor (Atrovastatin) Zoloft (Sertraline) Valproate Semisodium (Valproate Semisodium) Topiramate (Topiramate) Quetiapine Fumarate (Quetiapine Fumarate) Lithium Carbonate (Lithium Carbonate) Docusate (Docusate) Trazodone (Trazodone) Tocopherol (Tocopherol) Hydroxyzine Embonate (Hydroxyzine Embonate) Estradiol (Estradiol) Estratest Hs (Estrogens Esterified, Methyltestosterone) Desloratadine (Desloratadine) Calcium (Calcium) Centrum (Minerals Nos, Vitamins Nos) Bupropion	PS SS SS SS SS SS SS C C C C C C C C		ORAL ORAL

Dose	Duration
40 MG (20 MG, 2 IN 1 D), ORAL	
200 MG (UNK, 1 IN 1 D)	

				Hydrochloride (Bupropion Hydrochloride)	C		

Date:07/12/04ISR Number: 4399397-0Report Type:Expedited (15-DaCompany Report #2004043493
Age:50 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drooling Drug Interaction	Consumer	Zyrtec (Cetirizine)	PS			UNKNOWN	UNKNOWN (10
Other	Drug Toxicity Dyskinesia Influenza Movement Disorder Skin Infection		Ciprofloxacin (Ciprofloxacin)	SS			UNKNOWN	UNKNOWN (500
	Somnolence Tremor							

			Lithium Carbonate				

			(Lithium Carbonate)	SS			ORAL 900 MG (450 MG, 2 IN 1 D); ORAL (SEE IMAGE)
			Seretide Mite (Fluticasone Propionate Salmeterol Xinafoate)	SS			RESPIRATORY (INHALATION) 2 PUFF(S) (1 PUFF(S), 2 IN 1 D), INHALATION (SEE IMAGE)
			Tiotixene	C			
			Benzatropine Mesilate	C			
			Risperidone	C			
			Benazepril Hydrochloride	C			

Date:07/12/04ISR Number: 4399422-7Report Type:Expedited (15-DaCompany Report #04-07-0967
Age:28 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Toxicity	Health Professional Other	Clozapine Tablets - Ivax Pharmaceuticals, Inc.	PS	Ivax Pharmaceuticals, Inc.	ORAL	400 MG BID	ORAL

			Lithium Carbonate	SS		
300 MG TID						
			Zantac	C		
			Haloperidol	C		
			Geodon	C		
			Ativan	C		

Date:07/13/04ISR Number: 4396304-1Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0517829A
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Alopecia		Eskalith	PS	Glaxosmithkline	ORAL	1CAP Three	
	Blood Glucose Increased						times per day	20 YR
	Disturbance In Attention		Lamictal	SS	Glaxosmithkline	ORAL	200MG Per day	9 MON
	Hyperglycaemia		Lexapro	C				
	Hyperthyroidism		Abilify	C				
	Pollakiuria							
	Weight Increased							

Date:07/13/04ISR Number: 4396865-2Report Type:Direct Company Report #CTU 222709
Age:13 YR Gender:Female I/FU:I

Outcome
Life-Threatening
Hospitalization -
Initial or Prolonged
Disability

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Required Intervention to Prevent Permanent Impairment/Damage	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Abortion		Neurontin	PS				
GENERIC								
	Adoption							
NEURONTIN								
	Congenital Anomaly							
PILLS								
	Drug Exposure During		Lithium	SS				
LITHIUM PILLS								
	Pregnancy		Haldol	SS				
HALDOL DEC								
	Injury							
SHOT								
	Pregnancy		Respridol	SS				
RESPRIDAL								
	Road Traffic Accident							
PILLS								

Date:07/14/04ISR Number: 4397334-6Report Type:Expedited (15-DaCompany Report #JP-GLAXOSMITHKLINE-B0338264A
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Alanine Aminotransferase	Health	Paxil	PS	Glaxosmithkline	ORAL	51	DAY
	Increased	Professional	Limas	SS	Glaxosmithkline	ORAL	400MG Per day	4 DAY
	Aspartate		Hirnamin	SS			UNKNOWN	15MG Per day 4 DAY
	Aminotransferase		Lexotan	SS		ORAL	6MG Per day	4 DAY
	Increased		Evamyl	C		ORAL	1MG Per day	4 WK
	Blood Alkaline		Chlorpromazine	C	Glaxosmithkline	ORAL	37.5MG Per day	4 WK
	Phosphatase Increased							
	Gamma-Glutamyltransferase Increased							
	Hepatic Function Abnormal							

Date:07/14/04ISR Number: 4401613-3Report Type:Expedited (15-DaCompany Report #2004044086
Age:46 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anxiety	Health Professional	Geodon (Ziprasidone)	PS		ORAL	40 MG (20 MG, 2 IN 1 D), Other	
	Blood Cholesterol Increased						ORAL	
	Depression		Lipitor (Atorvastatin)	SS				
	Eye Disorder		Zoloft (Sertraline)	SS				
	Fatigue		Valproate Semisodium (Valproate Semisodium)	SS				
	Feeling Abnormal		Topiramate (Topiramate)	SS				
	Headache		Quetiapine Fumarate (Quetiapine Fumarate)	SS			200 MG (1 IN 1 D)	
	Insomnia							
	Intentional Self-Injury							
	Medication Error							
	Self-Injurious Ideation							
	Suicidal Ideation							
	Tongue Ulceration							
	Tremor							
	Weight Decreased		Lithium Carbonate (Lithium Carbonate)	SS		ORAL	ORAL	
	Weight Increased		Trazodone (Trazodone)	C				
			Tocopherol (Tocopherol)	C				
			Hydroxyzine Embonate (Hydroxyzine Embonate)	C				
			Estradiol (Estradiol)	C				
			Estratest Hs (Estrogens					

Esterified, Methyltestosterone)	C
Desloratadine (Desloratadine)	C
Calcium (Calcium)	C
Centrum (Minerals Nos, Vitamins Nos)	C
Docusate (Docusate)	C
Bupropion Hydrochloride (Bupropion Hydrochloride)	C

Date:07/16/04ISR Number: 4399541-5Report Type:Expedited (15-DaCompany Report #GB-GLAXOSMITHKLINE-B0322547A
Age:78 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Pyelonephritis	Consumer	Lithium	PS	Glaxosmithkline	ORAL	1	MON
	Renal Failure		Lithium	SS	Glaxosmithkline		21	YR
	Renal Impairment		Thyroxine	C	Glaxosmithkline	ORAL	100MCG Per day	24 YR
			Olanzapine	C		ORAL	2.5MG Per day	1 YR

Date:07/19/04ISR Number: 4401832-6Report Type:Direct Company Report #USP 56691
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Medication Error		Lithium Carbonate	PS	Roxane	CAPSULE		
			Lithium Carbonate	SS	Roxane	TABLET		

Date:07/19/04ISR Number: 4404128-1Report Type:Expedited (15-DaCompany Report #DSA_24535_2004
Age:79 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Cerebral Ischaemia	Foreign	Teveten-Hct	PS				
	Cerebrovascular Accident	Health	Teveten					
	Circulatory Collapse	Professional						
	Clostridium Colitis	Other	/Sch/	SS	Sch	ORAL	600 MG PO	
	Hypercalcaemia		Teveten					
	Limb Immobilisation		/Sch/	SS	Sch	ORAL	600 MG PO	
	Salivary Hypersecretion		Lithicarb	SS		ORAL	250 MG Q DAY	
	Therapeutic Agent						PO	
	Toxicity		Actonel	SS		ORAL	70 MG QWK PO	
	Walking Aid User		Caltrate	SS		ORAL	600 MG Q DAY	
							PO	
			Norvasc	C				
			Risperidone	C				

Date:07/20/04ISR Number: 4402276-3Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0518724A
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Abdominal Discomfort		Lamictal	PS	Glaxosmithkline	ORAL		
	Drug Interaction		Lithobid	SS	Glaxosmithkline			
	Therapeutic Agent							
	Toxicity							
	Tremor							

Date:07/20/04ISR Number: 4403433-2Report Type:Expedited (15-DaCompany Report #LBID00204001388
Age:50 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hepatitis C	Health Professional	Lithobid (Lithium Carbonate)	PS			300 MG BID	
							PO, 300 MG	
							TID PO	

Date:07/20/04ISR Number: 4404268-7Report Type:Expedited (15-DaCompany Report #2004045757
Age:50 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Parathyroid Hormone Increased	Foreign Literature	Lithium (Lithium)	PS				
Other	Hyperparathyroidism	Health Professional	Carbamazeine (Carbamazepine)	SS				
	Hypomania							
	Osteoporosis							
	Parathyroid Tumour Benign							

Date:07/20/04ISR Number: 4404269-9Report Type:Expedited (15-DaCompany Report #2004045755
Age:48 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hyperparathyroidism	Foreign Literature	Lithium (Lithium)	PS				
Other	Osteoporosis	Health Professional	Carbamazepine (Carbamazepine)	C				
			All Other Therapeutic Products (All Other Therapeutic Products)	C				

Date:07/20/04ISR Number: 4404353-XReport Type:Expedited (15-DaCompany Report #2004045480
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Agitation Blood Parathyroid Hormone Increased Calcium Ionised Increased Hypercalcaemia Hyperplasia Hypertension Hypomania Mania Parathyroid Disorder Rash Refusal Of Treatment By Patient Sinoatrial Block Sinus Bradycardia Urine Calcium Decreased	Literature Consumer	Lithium (Lithium)	PS				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/20/04ISR Number: 4404766-6Report Type:Expedited (15-DaCompany Report #B0337868A
Age:30 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Akathisia Depression Erectile Dysfunction Muscle Rigidity Priapism	Foreign Literature Health Professional	Lithium Salt (Formulation Unknown) (Generic) (Lithium Salt)	PS			UNKNOWN	1200 MG/PER DAY/UNKNOWN
	Therapy Non-Responder Tremor		Olanzapine (Formulation Unknown) (Olanzapine)	SS			UNKNOWN	5MG/PER DAY/UNKNOWN
			Haloperidol	C				
			Benzhexol	C				
			Sildenafil Citrate	C				

Date:07/21/04ISR Number: 4404411-XReport Type:Direct Company Report #CTU 223265
Age:45 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Blood Creatinine Increased		Lithium	PS				

Date:07/21/04ISR Number: 4407285-6Report Type:Expedited (15-DaCompany Report #2004046507
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Benign Prostatic Hyperplasia	Consumer	Lithium (Lithium)	PS				

	Bladder Cancer					
	Feeling Abnormal					
	Hearing Impaired					
	Meningioma					
	Stress					

Date:07/21/04ISR Number: 4407318-7Report Type:Expedited (15-DaCompany Report #200418705BWH
Age:49 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Disease Recurrence Drooling Movement Disorder Skin Infection Somnolence Therapeutic Agent Toxicity Tremor	Consumer Other	Cipro (Ciproloxacin Hydrochloride) Eskalith Tablet - Controlled Release (Lithium Carbonate) Advair	PS SS SS		ORAL ORAL RESPIRATORY (INHALATION)	1000 MG, TOTAL DAILY, 450 MG, BID, 250/50 UG, BID,	

				Zyrtec (Cetirizine Hydrochloride)	SS		
10 MG							
				Navane	C		
				Benztropine Mesylate	C		
				Risperidone	C		
				Lotensin	C		

Date:07/21/04ISR Number: 4407606-4Report Type:Expedited (15-DaCompany Report #2004-DE-03755GD (0)
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Therapeutic Agent Toxicity	Foreign Literature	Lithium Carbonate (Lithium Carbonate)	PS				

Date:07/21/04ISR Number: 4407813-0Report Type:Expedited (15-DaCompany Report #AU-JNJFOC-20040501168
Age:44 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Coordination Abnormal	Foreign	Risperidone					
	Csf Pressure Increased	Health	(Risperidone)					
Other	Headache	Professional	Unspecified	PS		ORAL	SEE IMAGE	
	Hypomania		Lithium Carbonate					
	Hypothyroidism		(Lithium Carbonate)	SS		ORAL	1000 MG, IN 1	DAY, ORAL
	Intracranial Pressure							
	Increased		Antitriptyline					
	Papilloedema		(Amitriptyline)	C				
	Retinal Haemorrhage		Metformin (Metformin)	C				

Date:07/22/04ISR Number: 4408300-6Report Type:Expedited (15-DaCompany Report #PERI00204002310
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Abdominal Pain Upper	Foreign	Coversyl					

Initial or Prolonged 4 MG QD PO	Anorexia	Health	(Perindopril)	PS	ORAL
	Blood Creatinine Increased	Professional Other	Lithium Carbonate (Lithium Carbonate)	SS	ORAL 250 MG DAILY PO
	Dehydration				
	Lethargy		Frusemide		
	Therapeutic Agent		(Furosemide)	C	ORAL 20 MG DAILY PO
	Toxicity				
	Vomiting		Lipidex (Simvastatin)	C	
			Losec (Omeprazole)	C	
			Astrix (Acetylsalicylic Acid)	C	
			Neulactil (Periciazine)	C	
			Zoloft (Sertraline Hydrochloride)	C	
			Isosorbide (Isosorbide)	C	
			Atenolol (Atenolol)	C	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/23/04ISR Number: 4406557-9Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0511859A
Age:42 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Mania		Eskalith	PS	Glaxosmithkline	ORAL	450MG Twice per day	10 YR
	Renal Failure							
	Renal Injury		Zyprexa	C			20MG At night	
	Therapeutic Agent Toxicity							

Date:07/23/04ISR Number: 4406589-0Report Type:Expedited (15-DaCompany Report #NL-GLAXOSMITHKLINE-B0338522A
Age:49 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Bedridden		Paroxetine Hydrochloride Hydrate	PS	Glaxosmithkline		UNKNOWN	20MG Per day 3 YR
	Drug Withdrawal Syndrome							
	Mood Altered							
	Nervous System Disorder		Camcolit	SS	Glaxosmithkline		UNKNOWN	800MG Unknown
	Pain In Extremity		Zopiclon	C			UNKNOWN	7.5MG Per day
	Sensory Disturbance							
	Walking Disability							

Date:07/23/04ISR Number: 4406593-2Report Type:Expedited (15-DaCompany Report #GB-GLAXOSMITHKLINE-B0338768A
Age:71 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Therapeutic Agent		Paroxetine	PS	Glaxosmithkline	ORAL	30MG per day	
	Toxicity		Lithium	SS	Glaxosmithkline	ORAL	600MG At night	

Date:07/23/04ISR Number: 4406610-XReport Type:Expedited (15-DaCompany Report #2004011396
Age:66 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Bradycardia		Quilonum Retard	PS	Glaxosmithkline	ORAL	3TAB per day	
Initial or Prolonged	Dehydration		Lamictal	SS	Glaxosmithkline	ORAL	150MG per day	WK
	Drug Toxicity		Taxilan	SS		ORAL	50MG per day	WK
	Overdose		Xanef	SS		ORAL		WK
	Psychotic Disorder		Dytide H	SS	Glaxosmithkline	ORAL		WK
	Renal Failure							
	Somnolence							
	Suicide Attempt							
	Urinary Tract Infection							

Date:07/23/04ISR Number: 4406933-4Report Type:Expedited (15-DaCompany Report #PHBS2004JP09703
Age:62 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Neuroleptic Malignant		Ludiomil	PS	Novartis Sector:			
Hospitalization -	Syndrome				Pharma	ORAL	30 mg/d	
Initial or Prolonged			Lithium Carbonate	SS		ORAL	800 mg/d	
			Levomepromazine Maleate	SS		ORAL	50 mg/d	
			Flunitrazepam	SS		ORAL	2 mg/d	
			Nitrazepam	SS		ORAL	10 mg/d	
			Tetramide	SS		ORAL	10 mg/d	
			Triazolam	C		ORAL	0.5 mg/d	
			Gefarnate	C		ORAL	150 mg/d	

			Magnesium	C		ORAL 3 g/d
			Urso	C		ORAL 300 mg/d
			Proheparum	C		ORAL 3 DF/d
			Sennoside A	C		ORAL 48 mg/d

Date:07/23/04ISR Number: 4408583-2Report Type:Expedited (15-DaCompany Report #2004223559CH
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Hospitalization - Initial or Prolonged	Cardiac Failure Confusional State	Foreign Health	Celebrex (Celecoxib) Capsule	PS		ORAL 200 MG, BID , ORAL
	Coordination Abnormal	Professional				
	Difficulty In Walking Drug Interaction	Other	Priadel(Lithium Carbonate) Tablet	SS		ORAL 400 MG, QD, ORAL
	Drug Level Above Therapeutic Fall		Lithiofor(Lithium Sulfate)	SS		ORAL 660 MG, QD, ORAL
	General Physical Health Deterioration Haematoma Speech Disorder Therapy Non-Responder		Co-Reniten(Hydrochlorothiazide, Enalapril Maleate) Tablet, 12.5/20 Mg	SS		ORAL 20/12.5 ORAL
	Tremor		Lasix(Furosemide)	SS		ORAL 40 MG QD, ORAL
			Renitec	C		
			Zoloft	C		
			Aspirine	C		
			Aldactone	C		
			Amomel	C		
			Sintrom	C		
			Duofer	C		

			Supradyn (Ferrous Carbonate, Molybdenum Sesquioxide, Sodium Borate, Zinc	C		
			Novomix 30	C		
			Nexium	C		

Date:07/26/04ISR Number: 4407848-8Report Type:Expedited (15-DaCompany Report #GB-GLAXOSMITHKLINE-B0339637A
Age:36 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Nephritis Interstitial	Consumer	Lithium	PS	Glaxosmithkline			
UNKNOWN								
	Therapeutic Agent		Clozaril	SS		ORAL		
	Toxicity		Valproate Sodium	C				

Date:07/26/04ISR Number: 4410481-5Report Type:Expedited (15-DaCompany Report #DSA_24663_2004
Age:72 YR Gender:Female I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Confusional State
	Coordination Abnormal
	Drug Interaction
	Drug Level Increased
	Fall
	Haematoma
	Speech Disorder

Tremor

Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Foreign Health Professional	Enalapril Maleate W/Hydrochlorothiazide	PS		ORAL	1 TAB Q DAY	PO
Other	Enalapril Maleate	SS		ORAL	20 MG Q DAY	PO
	Priadel	SS		ORAL	400 MG Q DAY	PO
	Priadel	SS		ORAL	400 MG Q DAY	PO
	Lithiofor	SS		ORAL	660 MG Q DAY	PO
	Lasix	SS			DF DAILY	
	Celebrex	SS			DF DAILY	
	Aldactone	SS		ORAL	100 MG Q DAY	PO
	Sintron	C				
	Duofer/Ascorbic Acid/Ferrous Sulfate	C				
	Aspirine	C				
	Reniten	C				
	Nexium	C				
	Novomix	C				
	Supradyn	C				
	Anomel	C				
	Zoloft	C				

Date:07/26/04ISR Number: 4410654-1Report Type:Expedited (15-DaCompany Report #04P-167-0267290-00
Age:20 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Back Pain Encephalopathy Neutrophil Count Increased Pyelonephritis Renal Failure Acute Schizophrenia Sepsis Somnolence Therapeutic Agent Toxicity Urinary Tract Infection White Blood Cell Count Increased	Foreign Health Professional	Valproate Sodium (Sodium Valproate)	PS		ORAL	1 GM, 2 IN 1 D, ORAL	
			Lithium Carbonate	SS		ORAL	400 MG, 2 IN 1 D, ORAL	
			Clozapine	SS		ORAL	200 MG, 1 IN 1 D, ORAL	
			Clonazepam	C				

Date:07/27/04ISR Number: 4408883-6Report Type:Expedited (15-DaCompany Report #DE-GLAXOSMITHKLINE-D0044301A
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Infertility Male Sperm Count Zero		Quilonum Retard	PS	Glaxosmithkline	ORAL	1.5TAB Twice per day	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/29/04ISR Number: 4413564-9Report Type:Expedited (15-DaCompany Report #B0339617A
Age:68 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Required	Atrioventricular Block Complete	Foreign Literature Health Professional	Lithium Salt (Lithium Salt)	PS			200 MG /TWICE PER DAY	12 YR
Intervention to Prevent Permanent Impairment/Damage	Blood Pressure Diastolic Decreased Blood Pressure Increased Drug Toxicity		Rofecoxib (Rofecoxib)	SS			25 MG/TWICE PER DAY	8 DAY
	Dysarthria		Carbamazepine	C				
	Electrocardiogram T Wave Inversion		Pimpamperone	C				
	Extrapyramidal Disorder		Mirtazapine	C				
	Headache		Propranolol Hydrochloride	C				
	Nausea		Paracetamol	C				
	Pain In Extremity							
	Sinus Arrest							
	Sinus Bradycardia							
	Somnolence							
	Vomiting							

Date:07/29/04ISR Number: 4444007-7Report Type:Periodic Company Report #US-JNJFOC-20030906650
Age:27 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Deep Vein Thrombosis Pulmonary Embolism	Health Professional	Risperdal (Risperidone) Tablets	PS		ORAL	2.5 MG, 1 IN 1 DAY, ORAL	
			Lithium (Lithium)	SS			1500 MG, 1 IN 1 DAY	
			Escitalopram Oxalate (All Other Therapeutic					

			Products)	SS		
10 MG, 1 IN 1 DAY						

Date:07/30/04ISR Number: 4412914-7Report Type:Expedited (15-DaCompany Report #2004UW09490
Age:43 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Blood Creatinine	Foreign	Crestor	PS		ORAL	20 MG DAILY	
	Increased	Health					PO	
	Confusional State	Professional	Lithium	SS			1500 MG DAILY	
	Drug Level Increased	Other	Lithium	SS				
	Therapeutic Agent		Lipidil Micro	SS			200 MG DAILY	
	Toxicity		Haldol	C				
	Tremor		Cogentin	C				
			Allopurinol	C				
			Altace	C				

Date:07/30/04ISR Number: 4413210-4Report Type:Direct Company Report #CTU 223984
Age:46 YR Gender:Female I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Aspiration
	Coma
	Hypoxia

	Overdose Respiratory Failure						
		Report Source	Product	Role	Manufacturer	Route	Dose Duration
			Lithium	PS			

Date:07/30/04ISR Number: 4416115-8Report Type:Expedited (15-DaCompany Report #AU-JNJFOC-20040501168
Age:44 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged Other	Coordination Abnormal Headache Hypomania	Foreign Health Professional	Risperidone (Risperidone) Unspecified	PS		ORAL	SEE IMAGE
	Intracranial Pressure Increased		Lithium Carbonate (Lithium Carbonate)	SS		ORAL	1000 MG, IN 1 DAY, ORAL
	Optic Disc Disorder Papilloedema Retinal Haemorrhage Therapy Non-Responder		Amitriptyline Metformin (Metformin)	C C			

Date:08/02/04ISR Number: 4413172-XReport Type:Expedited (15-DaCompany Report #JP-GLAXOSMITHKLINE-B0338264A
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Other	Alanine Aminotransferase	Health	Limas	PS	Glaxosmithkline	ORAL	400MG Per day 4 DAY
	Increased	Professional	Paxil	SS	Glaxosmithkline	ORAL	51 DAY
	Aspartate		Hirnamin	SS			UNKNOWN 15MG Per day 4 DAY
	Aminotransferase		Lexotan	SS		ORAL	6MG Per day 4 DAY
	Increased		Evamyl	C		ORAL	1MG Per day 4 WK
	Blood Alkaline		Chlorpromazine	C	Glaxosmithkline	ORAL	37.5MG Per
	Phosphatase Increased						day 4 WK

Gamma-Glutamyltransferase Increased
Hepatic Function Abnormal

Date:08/02/04ISR Number: 4413208-6Report Type:Expedited (15-DaCompany Report #PHBS2004JP09703
Age:62 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Cholecystitis	Health	Ludiomil	PS	Novartis Sector:			
Hospitalization -	Neuroleptic Malignant	Professional			Pharma	ORAL	30 mg/d	
Initial or Prolonged	Syndrome		Lithium Carbonate	SS		ORAL	800 mg/d	
			Levomepromazine Maleate	SS		ORAL	50 mg/d	
			Flunitrazepam	SS		ORAL	2 mg/d	
			Nitrazepam	SS		ORAL	10 mg/d	
			Tetramide	SS		ORAL	10 mg/d	
			Triazolam	C		ORAL	0.5 mg/d	
			Gefarnate	C		ORAL	150 mg/d	
			Magnesium	C		ORAL	3 g/d	
			Urso	C		ORAL	300 mg/d	
			Proheparum	C		ORAL	3 DF/d	
			Sennoside A	C		ORAL	48 mg/d	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/03/04ISR Number: 4414057-5Report Type:Expedited (15-DaCompany Report #DE-GLAXOSMITHKLINE-D0044301A
Age:32 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Infertility Male	Health Professional	Quilonum Retard	PS	Glaxosmithkline	ORAL	1.5TAB Twice per day	

Date:08/04/04ISR Number: 4416199-7Report Type:Expedited (15-DaCompany Report #2004UW09490
Age:43 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Blood Creatinine Increased	Foreign Health	Crestor	PS		ORAL	20 MG DAILY PO	
	Confusional State	Professional	Lithium	SS			1500 MG DAILY	
	Drug Interaction	Other	Lipidil Micro	SS			200 MG DAILY	
	Therapeutic Agent Toxicity Tremor		Haldol Cogentin Allopurinol Altace	C C C C				

Date:08/05/04ISR Number: 4420050-9Report Type:Direct Company Report #CTU 224355
Age:40 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Stomach Discomfort		Generic Eskalith 450 Mg	PS		ORAL	900 MG BID ORAL	

Date:08/05/04ISR Number: 4423255-6Report Type:Expedited (15-DaCompany Report #LBID00204002545
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Abdominal Discomfort Drug Interaction Therapeutic Agent Toxicity Tremor	Health Professional	Lithobid (Lithium Carbonate) Lamictal (Lamotrigine)	PS SS		ORAL ORAL	600 MG DAILY PO, 650 MG DAILY PO 225 MG DAILY PO , 250 MG DAILY PO	

Date:08/06/04ISR Number: 4417257-3Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0520948A
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Renal Failure		Eskalith Flomax	PS C	Glaxosmithkline	ORAL	300MG Twice per day	15 YR

Date:08/06/04ISR Number: 4417258-5Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0520975A
Age:44 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Bipolar I Disorder Mania Psychotic Disorder		Eskalith Lithium Seroquel	PS SS C	Glaxosmithkline Glaxosmithkline	ORAL		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/06/04ISR Number: 4417277-9Report Type:Expedited (15-DaCompany Report #GB-GLAXOSMITHKLINE-B0340784A
Age:84 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Interaction		Avandia	PS	Glaxosmithkline	ORAL	4MG per day	7 MON
	Drug Level Decreased		Camcolit	SS	Glaxosmithkline	ORAL	600MG per day	
			Dothiepin	C		ORAL	75MG per day	

Date:08/06/04ISR Number: 4417323-2Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0520948A
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Renal Failure	Health	Eskalith	PS	Glaxosmithkline	ORAL	300MG Twice	
		Professional					per day	15 YR
			Flomax	C				

Date:08/06/04ISR Number: 4417324-4Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0520975A
Age:44 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Bipolar I Disorder	Health	Eskalith	PS	Glaxosmithkline	ORAL		
	Mania	Professional	Lithium	SS	Glaxosmithkline			
	Psychotic Disorder		Seroquel	C				

Date:08/06/04ISR Number: 4417342-6Report Type:Expedited (15-DaCompany Report #GB-GLAXOSMITHKLINE-B0340784A
Age:84 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Interaction	Consumer	Avandia	PS	Glaxosmithkline	ORAL	4MG per day	7 MON
	Drug Level Decreased		Camcolit	SS	Glaxosmithkline	ORAL	600MG per day	

			Dothiepin	C		ORAL

75MG per day

Date:08/06/04ISR Number: 4419102-9Report Type:Direct Company Report #CTU 224454
Age:56 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Antidepressant Drug Level Increased		Lithium Carbonate 300mg Capsule	PS		
600 MG QAM AND 900 MG HS	Cognitive Deterioration					
	Dysarthria		Loratadine	C		
			Atenolol	C		
			Docusate	C		
			Sennosides	C		
			Gemfibrozil	C		
			Lisinopril	C		
			Mystatin Cream	C		
			Olanzapine	C		
			Lovastatin	C		
			Topirimate	C		
			Clomipramine	C		

Date:08/06/04ISR Number: 4419108-XReport Type:Direct Company Report #CTU 224455
Age:58 YR Gender:Male I/FU:I

Outcome
Hospitalization -
Initial or Prolonged

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Freedom Of Information (FOI) Report

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Chest Wall Pain Drug Toxicity Gait Disturbance Muscle Strain Sleep Disorder		Lithium Carbonate 300mg Tablets Ibuprofen 800mg Tablets Ferrous Sulfate Gemfibrozil Propranolol Benztropine Olanzapine Diphenhydramine	PS SS C C C C C C		ORAL ORAL	300MG PO Q PM AND 600 MG PO HS 800MG PO TID	

Date:08/06/04ISR Number: 4419399-5Report Type:Direct Company Report #CTU 224457
Age:50 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Alcohol Use Antidepressant Drug Level Increased Coordination Abnormal Dizziness		Lithium 300 Mg Capsule Asprin Cyclobenzaprine Naproxen Omeprazole Propranolol Citalopram Trazodone	PS C C C C C C C			300 MG AM/600 MG HS	

Date:08/06/04ISR Number: 4422138-5Report Type:Expedited (15-DaCompany Report #C04-C-115
Age:28 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Therapeutic Agent Toxicity	Health Professional	Clozapine Tablets - Ivax Pharmaceuticals, Inc.	PS	Ivax Pharmaceuticals, Inc.	ORAL	400MG BID	
			Lithium Carbonate - Able Laboratories	SS	Able Laboratories	ORAL	300MG TID	
			Zantac	C				
			Haloperidol	C				
			Haloperidol	C				
			Geodon	C				
			Geodon	C				
			Ativan	C				
			Ativan	C				

Date:08/10/04ISR Number: 4422336-0Report Type:Expedited (15-DaCompany Report #2004014971
Age:19 YR Gender:Female I/FU:I

Outcome	PT
Other	Intentional Misuse
	Loss Of Consciousness

	Overdose Suicide Attempt						
		Report Source	Product	Role	Manufacturer	Route	Dose Duration
		Health Professional	Quilonum Retard	PS	Glaxosmithkline	ORAL	16TAB Single dose
			Doneurin	SS		ORAL	50TAB Single dose
			Truxal	SS		ORAL	2000MG Single dose
			Zolpidem	SS		ORAL	30TAB Single dose

Date:08/11/04ISR Number: 4426076-3Report Type:Expedited (15-DaCompany Report #B0339181A
Age:76 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Death	Aggression Blood Creatinine Increased Blood Potassium Increased Blood Sodium Increased Blood Urea Increased Cachexia Clubbing Delirium Depressed Level Of Consciousness Gastrointestinal Haemorrhage Hypercalcaemia Hypotension Lung Neoplasm Malignant Mass Nephrogenic Diabetes Insipidus	Foreign Literature Health Professional	Lithium Salt (Lithium Salt) Chlopromazine Hcl Procyclidine Hcl Nitrazepam Zopiclone Frusemide	PS C C C C C			

	Pneumonia					
	Superinfection					
	Vomiting					

Date:08/11/04ISR Number: 4427336-2Report Type:Expedited (15-DaCompany Report #2004-BP-06119RO
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Abdominal Pain Upper	Foreign	Lithium Carbonate			
	Blood Creatinine Increased	Health Professional	Capsules Usp, 300 Mg (Lithium Carbonate)	PS		
	Decreased Appetite		Coversyl			
	Dehydration		(Perindopril)	SS		
4 MG QD						
	Lethargy		Furosemide			
	Therapeutic Agent Toxicity		(Furosemide)	SS		
	Vomiting					

Date:08/11/04ISR Number: 4427360-XReport Type:Expedited (15-DaCompany Report #2004-BP-06118RO
Age:59 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agitation Blood Chloride Decreased Blood Creatinine Increased Blood Urea Increased Delusion Dysarthria Formication Grandiosity Hyperhidrosis Hyponatraemia Inappropriate Antidiuretic Hormone Secretion Mental Impairment Mental Status Changes Psychotic Disorder Suicidal Ideation Thinking Abnormal	Study Health Professional	Lithium Carbonate Capsules Usp, 300 Mg (Lithium Carbonate) Bifeprunox - Study Hydrochlorothiazide (Hydrochlorothiazide) Novolin Insulin (Insulin Human Injection, Isophane) Lisinopril (Lisinopril) Gemfibrozil (Gemfibrozil) Ativan (Lorazepam) Zithromax (Azithromycin) Zyprexa (Olanzapine)	PS SS SS C C C C C				

Date:08/12/04ISR Number: 4427684-6Report Type:Expedited (15-DaCompany Report #2004046507
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Benign Prostatic Hyperplasia Bladder Cancer Feeling Abnormal Flat Affect Hearing Impaired Meningioma Stress	Consumer Health Professional	Lithium	PS				

Date:08/13/04ISR Number: 4425418-2Report Type:Expedited (15-DaCompany Report #2004015076
Age:79 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Apathy	Health	Quilonum Retard	PS	Glaxosmithkline	ORAL	.5TAB Twice per day	20 YR
	Confusional State	Professional						
	Disorientation		Arelix	C		ORAL	1TAB In the morning	
	Drug Level Increased							

Date:08/13/04ISR Number: 4427262-9Report Type:Direct Company Report #CTU 224942
Age:56 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Headache		Lithium Carbonate	PS		ORAL	300 MG PO BID	

Date:08/17/04ISR Number: 4427731-1Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0522109A
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Renal Failure		Eskalith	PS	Glaxosmithkline			

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/17/04ISR Number: 4427735-9Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0522245A
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Alanine Aminotransferase Increased		Eskalith Risperdal	PS C	Glaxosmithkline	ORAL		

Date:08/17/04ISR Number: 4429394-8Report Type:Direct Company Report #CTU 225125
Age:37 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	Abnormal Behaviour Confusional State Drug Level Increased		Lithium Carbonate 300 Mg Capsule Clonazepam Olanzapine	PS C C		ORAL	600 MG PO BID PATIENT WAS NOT TAKING	

Date:08/18/04ISR Number: 4429293-1Report Type:Direct Company Report #CTU 225202
Age:67 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Hospitalization - Initial or Prolonged	Asthenia Diarrhoea Dizziness Dyspnoea Fall Renal Impairment Therapeutic Agent Toxicity		Lithium Carbonate 300 Mg Hydrochlorothiazide 25 Mg	PS SS		ORAL ORAL	300 MG QHS 12.5 MG QD	

Date:08/18/04ISR Number: 4429294-3Report Type:Direct Company Report #CTU 225196
Age:45 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Disorientation		Lithium Carbonate					
Hospitalization - Initial or Prolonged	Hypotension		450 Mg	PS		ORAL	450 MG BID	
	Lethargy							
	Renal Impairment							
	Sedation							
	Therapeutic Agent Toxicity							

Date:08/18/04ISR Number: 4429322-5Report Type:Direct Company Report #CTU 225184
Age:61 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Mental Status Changes		Simvastatin 20 Mg	PS		ORAL	10 MG QHS	
	Oral Intake Reduced							
Required Intervention to Prevent Permanent Impairment/Damage	Renal Failure Acute		Lithium 300 Mg	SS		ORAL	600 MG BID	
	Rhabdomyolysis							
	Therapeutic Agent Toxicity							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/18/04ISR Number: 4429345-6Report Type:Direct Company Report #CTU 225224
Age:43 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Interaction		Lithium 300mg	PS		ORAL	300MG	TID
	Drug Level Increased						ORAL	
			Enalapril	SS				

Date:08/18/04ISR Number: 4430778-2Report Type:Expedited (15-DaCompany Report #2003UW14438
Age:52 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Asthenia	Consumer	Zestril	PS		ORAL	5 MG PO	
Initial or Prolonged	Balance Disorder		Zestril	SS		ORAL	10 MG PO	
Disability	Chest Pain		Vasotec	SS		ORAL	5 MG HS PO	
Other	Chorea		Eskalith	SS				
	Coordination Abnormal		Verapamil	C				
	Coronary Artery Occlusion							
	Drug Interaction							
	Dyspnoea							
	Gait Disturbance							
	General Physical Health Deterioration							
	Headache							
	Hyperhidrosis							
	Hyperreflexia							
	Hypoaesthesia							
	Hypoaesthesia Oral							
	Influenza Like Illness							
	Medication Error							
	Memory Impairment							
	Muscular Weakness							
	Nausea							
	Nerve Injury							
	Nervous System Disorder							
	Pain							
	Paraesthesia							
	Paraesthesia Oral							

	Therapeutic Agent
	Toxicity
	Tremor

Date:08/18/04ISR Number: 4431273-7Report Type:Expedited (15-DaCompany Report #B0341219A
Age:75 YR Gender:Female I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Band Neutrophil Count Increased
	Blood Sodium Increased
	Blood Urea Increased
	Chapped Lips
	Coma
	Dehydration
	Gastroenteritis Norwalk Virus
	Lethargy
	Lip Dry
	Liver Function Test Abnormal
	Neutrophil Count Abnormal

	Therapeutic Agent Toxicity						
		Report Source	Product	Role	Manufacturer	Route	Dose Duration
		Foreign Literature Health Professional	Lithium Salt (Formulation Unknown) (Lithium Salt) (Generic)	PS			

Date:08/19/04ISR Number: 4429539-XReport Type:Expedited (15-DaCompany Report #04-05-0777
Age:47 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Leukopenia		Eskalith Cr	PS	Glaxosmithkline	ORAL	450MG At night
	Neutrophil Count Decreased		Clozapine	SS		ORAL	300MG Per day 44 MON

Date:08/19/04ISR Number: 4429560-1Report Type:Expedited (15-DaCompany Report #GB-GLAXOSMITHKLINE-B0342137A
Age:74 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Life-Threatening	Agitation		Lithium	PS	Glaxosmithkline	ORAL	200MG per day 6 DAY
	Coordination Abnormal		Thyroxine	C	Glaxosmithkline	ORAL	25MCG per day
	Gait Disturbance		Vitamin B Complex	C		ORAL	
	Haematemesis		Lansoprazole	C		ORAL	15MG Per day
	Heart Rate Increased		Zopiclone	C		ORAL	7.5MG Per day
	Hypertension		Venlafaxine	C		ORAL	300MG Per day
	Movement Disorder						

Date:08/20/04ISR Number: 4429801-0Report Type:Expedited (15-DaCompany Report #NL-BRISTOL-MYERS SQUIBB COMPANY-12669727
Age:75 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Confusional State Drug Interaction Drug Level Increased Hypercholesterolaemia Therapeutic Agent Toxicity	Health Professional	Coaprovel Tabs 300mg/12.5mg	PS	Bristol-Myers Squibb Company	ORAL	150+12.5mg from 11-Mar-2004 to 18-May-2004; Dose reduced in half on 10-Jun-2004; later discontinued
			Crestor	C		ORAL	
			Nitroglycerin Spray	C		NASAL	one inhaled dose when necessary
			Temazepam	C		ORAL	at night
			Metamucil	C			
			Cardura	C		ORAL	
			Propranolol Hcl	C		ORAL	
			Priadel	I		ORAL	tablet (controlled-release)
			Lithium Carbonate	I		ORAL	start date < 2003, at least one year; capsule

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/23/04ISR Number: 4431729-7Report Type:Direct Company Report #CTU 225463
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Nausea Pruritus Retching Vomiting		Lithobid	PS				

Date:08/23/04ISR Number: 4433173-5Report Type:Expedited (15-DaCompany Report #2004054658
Age:46 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Aspartate Aminotransferase Increased	Literature Health Professional	Lithium (Lithium) Clozapine (Clozapine)	PS SS			500 MG	5 WK
	Blood Alkaline Phosphatase Increased Blood Creatine Increased Blood Glucose Increased Blood Osmolarity Increased Blood Ph Decreased Blood Urea Increased Glucose Urine Present Stupor Therapeutic Response Decreased Urine Ketone Body Present		Verapamil (Verapamil) Bethanechol (Bethanechol) All Other Therapeutic Products (All Other Therapeutic Products)	 C C C				

Date:08/24/04ISR Number: 4431412-8Report Type:Expedited (15-DaCompany Report #US013094
Age:53 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Activities Of Daily Living Impaired		Lithium	PS	Glaxosmithkline	ORAL	1500MG per day	

Disability	Anxiety	Provigil	SS		ORAL
50MG per day 2 DAY					
	Bipolar I Disorder	Lamictal	C	Glaxosmithkline	
	Depression	Risperdal	C		
	Dissociation				
	Disturbance In Attention				
	Drug Level Increased				
	Energy Increased				
	Hypomania				
	Impaired Driving Ability				
	Mania				
	Obsessive Thoughts				
	Psychotic Disorder				
	Somnolence				

Date:08/24/04ISR Number: 4433410-7Report Type:Expedited (15-DaCompany Report #LBID00204002795
Age:76 YR Gender:Male I/FU:I

Outcome	PT
Death	Aggression
Hospitalization - Initial or Prolonged	Blood Creatinine Increased
	Blood Osmolarity Increased

	Blood Potassium Increased C-Reactive Protein Increased	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
	Cachexia	Foreign	Lithium Carbonate	PS		ORAL
UNK DAILY PO						
	Clubbing	Literature	Chlorpromazine			
	Dehydration	Health	(Chlorpromazine)	C		
	Delirium	Professional	Procyclidine			
	Depressed Level Of Consciousness	Other	(Procyclidine)	C		
	Gastrointestinal Haemorrhage		Nitrazepam (Nitrazepam)	C		
	Glasgow Coma Scale Abnormal		Zopiclone (Zopiclone)	C		
	Hypercalcaemia		Furosemide (Furosemide)	C		
	Hyponatraemia					
	Hypotension					
	Lung Consolidation					
	Lung Neoplasm Malignant					
	Malaise					
	Nephrogenic Diabetes Insipidus					
	Pneumonia					
	Polyuria					
	Pulmonary Mass					
	Vomiting					

Date:08/25/04ISR Number: 4432417-3Report Type:Expedited (15-DaCompany Report #20040016052
Age:39 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Other	Intentional Misuse		Quilonum Retard	PS	Glaxosmithkline	ORAL
10TAB	Single					
	No Adverse Effect					
dose						
	Suicide Attempt		Dominal Forte	SS		ORAL
39TAB	Single					
dose						
			Equilibrin	SS		ORAL
4TAB	Single					
dose						

			Tavor	SS		ORAL

5TAB Single

dose

Date:08/26/04ISR Number: 4433520-4Report Type:Expedited (15-DaCompany Report #200418251GDDC
Age:69 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dehydration		Fludex	PS	Aventis			
	Drug Interaction				Pharmaceuticals Inc.	ORAL		
	Drug Level Increased		Lithium Carbonate	SS		ORAL		
	Hypertension		Eltroxin	C				
	Influenza Like Illness							
	Renal Failure Acute							

Date:08/26/04ISR Number: 4433855-5Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0523449A
Age:8 YR Gender:Male I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Amnesia
	Aphasia
	Convulsion
	Delirium

	Diarrhoea						
	Drooling						
	Fall	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Muscle Disorder		Lithium Carbonate	PS	Glaxosmithkline	ORAL	450MG Twice
	Mydriasis						per day 5 WK
	Therapeutic Agent		Risperdal	C			
	Toxicity		Clonazepam	C			
	Vomiting		Strattera	C			

Date:08/26/04ISR Number: 4433887-7Report Type:Expedited (15-DaCompany Report #2004016101
Age:41 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Diarrhoea		Quilonum Retard	PS	Glaxosmithkline	ORAL	70TAB Single
Initial or Prolonged	Fatigue						dose
	Intentional Misuse		Amitriptylin	SS		ORAL	75TAB Single
	Myoclonus						dose
	Suicide Attempt		Beer	SS		ORAL	4BT Single
	Vomiting						dose
			Wine	SS		ORAL	

Date:08/26/04ISR Number: 4435554-2Report Type:Expedited (15-DaCompany Report #2004-DE-04375GD
Age:39 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Blastocystis Infection	Foreign	Nevirapine				
Initial or Prolonged	Cytomegalovirus Antibody	Literature	(Nevirapine)	PS			400 MG TWICE
	Positive						DAILY
	Economic Problem		Sertraline				
	Epstein-Barr Virus		(Sertraline)	SS			

	Antigen Positive	Diazepam (Diazepam)	SS
	Gastroenteritis	Lithium Carbonate	
	Cryptosporidial	(Lithium Carbonate)	SS
	Hepatitis Toxic	Zidovudine +	
	Hyperaemia	Lamivudine	
	Oral Intake Reduced	(Zidovudine	
	Seborrhoeic Dermatitis	W/Lamivudine)	SS
2 X 1/DAY			
	Treatment Noncompliance		
	Viral Load Decreased		

Date:08/26/04ISR Number: 4435993-XReport Type:Expedited (15-DaCompany Report #2003UW14438
Age:52 YR Gender:Male I/FU:F

Outcome	PT
Hospitalization -	Asthenia
Initial or Prolonged	Chest Pain
Disability	Chorea
Other	Coordination Abnormal
	Coronary Artery Occlusion
	Drug Interaction
	Dyspnoea
	Gait Disturbance
	General Physical Health
	Deterioration
	Headache
	Hyperhidrosis
	Hypoaesthesia
	Hypoaesthesia Oral

	Influenza Like Illness					
	Injury					
	Medication Error	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
	Memory Impairment	Consumer	Zestril	PS		ORAL
5 MG PO						
	Motor Dysfunction		Zestril	SS		ORAL
10 MG PO						
	Muscular Weakness		Vasotec	SS		ORAL
5 MG HS PO						
	Nausea		Eskalith	SS		
	Nerve Injury		Verapamil	C		
	Nervous System Disorder					
	Pain					
	Paraesthesia					
	Paraesthesia Oral					
	Therapeutic Agent					
	Toxicity					
	Tremor					

Date:08/27/04ISR Number: 4435222-7Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0523362A
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Other	Back Injury		Eskalith	PS	Glaxosmithkline	
20 YR						
	Bone Disorder		Seroquel	C		
	Diarrhoea					
	Disturbance In Sexual Arousal					
	Dry Mouth					
	Hypotrichosis					
	Premature Ageing					
	Somnolence					

Date:08/27/04ISR Number: 4437536-3Report Type:Expedited (15-DaCompany Report #GBWYE994523AUG04
Age:33 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Life-Threatening	Pancreatitis	Health	Efexor (Venlafaxine			
Hospitalization -	Renal Tubular Necrosis	Professional	Hydrochloride,			

Initial or Prolonged		Other	Tablet, 0)	PS			ORAL
150 MG 1X PER							
Disability							
1 DAY ORAL							
			Dianette (Cyproterone Acetate/Ethinylestradiol, , 0)	SS			ORAL
ORAL							
			Lithium (Lithium, , 0)	SS			ORAL
800 MG 1X PER							
1 DAY ORAL							
			Risperidone (Risperidone, 0)	SS			ORAL
3 MG 1X PER 1							
DAY ORAL							

Date:08/27/04ISR Number: 4443638-8Report Type:Expedited (15-DaCompany Report #B0342010A
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Drug Toxicity	Foreign Study Literature Health Professional	Lithium Salt (Formulation Unknown) (Lithium Salt)	PS		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/30/04ISR Number: 4437064-5Report Type:Expedited (15-DaCompany Report #GB-GLAXOSMITHKLINE-B0343205A
Age:33 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Pancreatitis	Consumer	Lithium	PS	Glaxosmithkline	ORAL	800MG Per day	187 WK
Hospitalization -	Renal Tubular Necrosis		Venlafaxine	SS		ORAL	150MG Per day	48 WK
Initial or Prolonged			Risperidone	SS		ORAL	3MG Per day	105 WK
Disability			Dianette	SS		ORAL	31	WK

Date:08/30/04ISR Number: 4438680-7Report Type:Direct Company Report #CTU 225910
Age:69 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Mental Status Changes		Lithium	PS			300 MG QD ,	
Initial or Prolonged							600 MG HS	
			Lisinopril	C				
			Valproic Acid	C				

Date:08/31/04ISR Number: 4437962-2Report Type:Expedited (15-DaCompany Report #DE-GLAXOSMITHKLINE-D0043770A
Age:68 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Hypoaesthesia	Health	Quilonum Retard	PS	Glaxosmithkline	ORAL	675MG per day	14 YR
Hospitalization -		Professional	Aponal	C			UNKNOWN	150MG per day 4 MON
Initial or Prolonged			Tafil	C		ORAL	1MG As	
Disability							required	
Other								

Date:09/01/04ISR Number: 4440359-2Report Type:Direct Company Report #CTU 226051
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Abdominal Pain Upper		Lithium Carbonate Cr (Westward Brand)	PS	Westward Brand		450 MG 1 AM 1	
	Nausea							
	Pharmaceutical Product						NOON	
	Complaint							
	Retching							
	Vomiting							

Date:09/01/04ISR Number: 4440378-6Report Type:Direct Company Report #CTU 226091
Age:50 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Level Increased		Lithium 300 Mg	PS		ORAL	300 MG TID	
							ORAL	
			Lithium 750 Mg	SS		ORAL	750 MG HS	
							ORAL	

Date:09/03/04ISR Number: 4440853-4Report Type:Expedited (15-DaCompany Report #2004015076
Age:79 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Apathy	Health Professional	Quilonum Retard	PS	Glaxosmithkline	ORAL	.5TAB Twice per day	20 YR
	Confusional State							
	Disorientation		Arelix	C		ORAL	1TAB In the morning	
	Drug Level Increased							
			Doxepin	C		ORAL	1TAB Per day	

			Biperiden	C		ORAL
1TAB Per day						

Date:09/07/04ISR Number: 4442063-3Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20040807491
Age:33 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Life-Threatening	Drug Interaction	Health	Risperdal	PS		
OROPHARINGEAL						
Hospitalization -	Pancreatitis	Professional	Venlafaxine	SS		
OROPHARINGEAL						
Initial or Prolonged	Renal Tubular Necrosis		Lithium	SS		
OROPHARINGEAL						
Disability			Dianette	SS		
OROPHARINGEAL						
			Dianette	SS		
OROPHARINGEAL						

Date:09/07/04ISR Number: 4442931-2Report Type:Direct Company Report #CTU 226369
Age:57 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Life-Threatening	Abasia		Lithium 900 Mg/Day			
Hospitalization -	Balance Disorder		Va Label	PS		
Initial or Prolonged	Coma		Enalpril 10mg /			
Disability	Dysarthria		Twice Daily Va Label	SS		
	Pneumonia					
	Sepsis					
	Shock					
	Sinus Tachycardia					

Date:09/07/04ISR Number: 4446342-5Report Type:Expedited (15-DaCompany Report #LBID00204002460
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Life-Threatening	Idiopathic	Health	Lithium Carbonate			
Hospitalization -	Thrombocytopenic Purpura	Professional	(Lithium Carbonate)	PS		ORAL
600 MG BID PO						

Initial or Prolonged	Thrombocytopenia	Clozaril (Clozapine)	C
		Haldol (Haloperidol)	C
		Thyroxin (Levothyroxine Sodium)	C
		Metformin (Metformin)	C
		Niacin (Niacin)	C
		Benztropine (Benztropine Mesylate)	C
		Depakote (Valproate Semisodium)	C

Date:09/07/04ISR Number: 4446397-8Report Type:Expedited (15-DaCompany Report #2004059627
Age: Gender:Female I/FU:I

Outcome	PT
Other	Asthenia
	Balance Disorder
	Body Height Decreased
	Cerebrovascular Accident
	Difficulty In Walking
	Drug Level Increased
	Gastrointestinal Disorder
	Headache

	Irritability Nausea Parkinson'S Disease	Report Source	Product	Role	Manufacturer	Route	Dose Duration
		Consumer	Navane (Capsules) (Thiothixene)	PS			
			Tikosyn (Dofetilide)	SS		ORAL	1 MG (0.5 MG, 2 IN 1 D),
			Lithium (Lithium)	SS		ORAL	600 MG, ORAL
			Metoclopramide (Metoclopramide)	SS			
			Digoxin (Digoxin)	SS			
			Sinemet (Carbidopa, Levodopa)	SS			
			Entacapone (Entacapone)	C			
			Famotidine (Famotidine)	C			
			Penicillamine (Penicillamine)	C			
			Levothyroxine Sodium (Levothyroxine Sodium)	C			
			Lorazepam (Lorazepam)	C			
			Mesalazine (Mesalazine)	C			

Date:09/07/04ISR Number: 4455137-8Report Type:Expedited (15-DaCompany Report #GB-GLAXOSMITHKLINE-B0343935A
Age:89 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Death	Dizziness		Lithium Carbonate	PS	Glaxosmithkline	ORAL	400MG per day
Hospitalization -	Fall		Aspirin	C	Glaxosmithkline	ORAL	75MG per day
Initial or Prolonged	Therapeutic Agent Toxicity						

Date:09/08/04ISR Number: 4443849-1Report Type:Expedited (15-DaCompany Report #PHRM2004FR02704
Age:40 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Bradycardia	Health Professional	Ritaline	PS	Novartis Sector: Pharma	ORAL	30 mg daily	
			Zoloft	SS				
			Lithium	SS				

Date:09/08/04ISR Number: 4444916-9Report Type:Direct Company Report #CTU 226627
Age:67 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Drug Toxicity Renal Failure Acute		Lithium	PS				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/08/04ISR Number: 4446946-XReport Type:Expedited (15-DaCompany Report #LBID00204002460
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Idiopathic Thrombocytopenic Purpura	Health Professional	Lithium Carbonate (Lithium Carbonate)	PS		ORAL	600 MG BID PO	Initial or Prolonged
			Clozaril (Clozapine)	C				
			Haldol (Haloperidol)	C				
			Thyroxin (Levothyroxine Sodium)	C				
			Metformin (Metformin)	C				
			Niacin (Niacin)	C				
			Benztropine (Benztropine Mesylate)	C				
			Depakote (Valproate Semisodium)	C				

Date:09/08/04ISR Number: 4447156-2Report Type:Direct Company Report #CTU 226640
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Drooling Drug Ineffective Dysarthria Mania Renal Impairment Sedation Therapeutic Agent Toxicity		Lithium Carbonate 300mg Mwf, Sun 450mgt,Th,Sat	PS		ORAL	300MG MWF, SUN PO 450MG T-TH-SAT PO	
			Aspirin	C				
			Lamotrigine	C				
			Atorvastatin	C				
			Losartan	C				
			Lantus	C				
			Risperidone	C				
			Atenolol	C				
			Trazodone	C				
			Benzotropine	C				

Date:09/08/04ISR Number: 4447217-8Report Type:Direct Company Report #CTU 226577
Age:57 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Rash Pruritic		Lithium 300 Mg Roxane	PS	Roxane	ORAL	450MG EVERY DAY	ORAL
			Depakote	C				
			Geodon	C				
			Topamax	C				
			Zyprexa	C				
			Lamisil	C				

Date:09/09/04ISR Number: 4449415-6Report Type:Expedited (15-DaCompany Report #B0343317A
Age:10 YR Gender:Male I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Abdominal Pain
	Atrioventricular Block First Degree

	Chest Pain					
	Conduction Disorder					
	Diarrhoea	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
	Disorientation	Literature	Eskalith (Lithium			
	Dizziness	Health	Carbonate)	PS		
600 MG/	TWICE					
	Drug Level Above	Professional				
PER DAY						
	Therapeutic		Methylphenidate	C		
	Electrocardiogram Qrs		Citalopram	C		
	Complex Prolonged		Oxcarbazepine	C		
	Hyperhidrosis		Clonidine	C		
	Hypotension					
	Oral Intake Reduced					
	Pallor					
	Palpitations					
	Rhythm Idioventricular					
	Tachyarrhythmia					
	Tachycardia					
	Therapeutic Agent					
	Toxicity					
	Thyroid Disorder					
	Ventricular Extrasystoles					
	Ventricular Tachycardia					
	Vomiting					
	White Blood Cell Count					
	Increased					

Date:09/09/04ISR Number: 4473772-8Report Type:Periodic Company Report #A03200401594
Age:46 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
	Drug Interaction	Health	Eloxatin -			
	Drug Level Fluctuating	Professional	Oxaliplatin -			
			Solution - 170 Mg/M2	PS		
INTRAVENOUS	85 MG/M2					
OTHER -						
INTRAVENOUS						
NOS						
			Eskalith - Lithium			

			Carbonate	SS			ORAL
ORAL							
			Fluorouracil	C			
			Leucovorin	C			
			Dexamethasone	C			
			Aloxiprin	C			
			Warfarin	C			
			Liothyronine Sodium	C			
			Simvastatin	C			
			Ferrous Sulfate	C			
			Topiramate	C			
			Lisinopril	C			
			Metoprolol Succinate	C			
			Rabeprazole Sodium	C			
			Amlodipine Besilate	C			

Date:09/10/04ISR Number: 4448284-8Report Type:Expedited (15-DaCompany Report #C04-C-139
Age:46 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Antidepressant Drug Level Decreased Somnolence	Consumer	Lithium Carbonate Capsules 300mg	PS				

Date:09/13/04ISR Number: 4449142-5Report Type:Expedited (15-DaCompany Report #LBID00204003065
Age:10 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain Atrioventricular Block First Degree Blood Thyroid Stimulating Hormone Decreased Chest Pain Conduction Disorder Diarrhoea Disorientation Dizziness Drug Level Above Therapeutic Electrocardiogram Qrs Complex Prolonged Fluid Intake Reduced Hyperhidrosis Hypotension Mania Oral Intake Reduced Pallor Palpitations Tachyarrhythmia Therapeutic Agent Toxicity Ventricular Extrasystoles Ventricular Tachycardia Vomiting White Blood Cell Count Increased	Literature Health Professional	Lithium Carbonate(Lithium Carbonate) Methylphenidate (Methylphenidate Hydrochloride) Escitalopram (Escitalopram) Clonodine (Clonodine)	PS SS SS SS		ORAL	PO, 300 MG QID PO	

Date:09/14/04ISR Number: 4450703-8Report Type:Direct Company Report #CTU 227024
Age:46 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Condition Aggravated Depression		Lithium Carbonate 450 Mg Ext Release					

	Drug Effect Decreased	West-Ward	PS	West-Ward	ORAL
450 MG DAILY					
	Dry Mouth				
ORAL					
	Pharmaceutical Product Complaint				
	Thinking Abnormal				

Date:09/15/04ISR Number: 4449913-5Report Type:Expedited (15-DaCompany Report #US013094
Age:53 YR Gender:Female I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Activities Of Daily Living Impaired
Disability	Anxiety
Other	Bipolar I Disorder
	Depression
	Dissociation
	Disturbance In Attention
	Drug Level Increased
	Energy Increased
	Hypomania

Impaired Driving Ability Mania Obsessive Thoughts	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Psychotic Disorder	Health	Lithium	PS	Glaxosmithkline	ORAL	1500MG per
Somnolence	Professional					day
		Provigil	SS		ORAL	50MG per day 2 DAY
		Lamictal	C	Glaxosmithkline		
		Risperdal	C			

Date:09/15/04ISR Number: 4449947-0Report Type:Expedited (15-DaCompany Report #DE-GLAXOSMITHKLINE-D0044646A
Age:40 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Other	Hepatitis	Consumer	Quilonum Retard	PS	Glaxosmithkline	ORAL	70 DAY
			Zoloft	SS		ORAL	29 DAY
			Saroten Retard	SS	Glaxosmithkline	ORAL	70 DAY
			Voltaren	C	Glaxosmithkline	ORAL	1TAB Three times per day
			Voltaren	C	Glaxosmithkline	OTHER	
			Analgesics (Unknown Type)	C		ORAL	

Date:09/15/04ISR Number: 4451835-0Report Type:Direct Company Report #CTU 227158
Age:53 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Drug Toxicity Dysarthria Gait Disturbance Hypertension		Lithium 600 Mg Bid Lisinopril 10 Mg Daily	PS SS		ORAL ORAL	600 MG BID PO 10 MG QD PO
			Cogentin	C			

	Mental Status Changes		Trifluperazone	C		

Date:09/15/04ISR Number: 4452247-6Report Type:Expedited (15-DaCompany Report #CA-2004-028532
Age:53 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Anxiety Condition Aggravated Drug Interaction	Foreign Consumer Other	Betaseron (Interferon Beta - 1b) Injection, 250ug	PS		SUBCUTANEOUS	9.6 MIU, 3X/WEEK NEW AUTOINJECTION ,	
	Mania Multiple Sclerosis Paranoia							
			Lithium (Lithium)	SS		SUBCUTANEOUS	300 MG, 3X/DAY,	
			Amitriptyline (Amitriptyline)	C				

Date:09/16/04ISR Number: 4452910-7Report Type:Expedited (15-DaCompany Report #2004-DE-04634GD
Age:10 YR Gender:Male I/FU:I

Outcome
Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent

Impairment/Damage

PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Abdominal Pain Atrioventricular Block First Degree Chest Pain Conduction Disorder Diarrhoea Disorientation Dizziness Drug Interaction Drug Level Increased Electrocardiogram Qrs Complex Prolonged Hyperhidrosis Hypotension Hypothyroidism Oral Intake Reduced Pallor Palpitations Tachyarrhythmia Tachycardia Therapeutic Agent Toxicity Ventricular Extrasystoles Ventricular Tachycardia Vomiting White Blood Cell Count	Literature	Lithium Carbonate (Lithium Carbonate) Clonidine (Clonidine) Methylphenidate (Methylphenidate) Escitalopram (Escitalopram) Oxacarbazine (Antiepileptics) Depakote (Valproate Semisodium) Levothyroxine (Levothyroxine)	PS SS SS SS SS SS			1200 MG (TWICE DAILY), 0.4 MG (TWICE DAILY) 36 MG (ONCE DAILY), IN THE MORNING 10 MG (ONCE DAILY), 600 MG (ONCE DAILY) 1500 MG (ONE THIRD OF DAILY DOSE IN THE MORNING AND TWO	

	Increased

Date:09/17/04ISR Number: 4456707-3Report Type:Expedited (15-DaCompany Report #04US000001
Age:74 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dialysis Hyperkalaemia Renal Failure	Consumer	Lithobid (Lithium Carbonate 300 Mg) Tablet	PS		ORAL		
SEE IMAGE,								
ORAL								
			Lipitor (Atorvastatin)	C				
			Lopressor (Metoprolol Tartrate)	C				
			Protonix "Pharmacia" (Pantoprazole)	C				
			Acetylsalicylic Acid (Acetylsalicylic Acid)	C				
			Renapro	C				

Date:09/17/04ISR Number: 4458556-9Report Type:Periodic Company Report #US-JNJFOC-20031100548
Age:39 YR Gender:Female I/FU:I

Outcome	PT
Other	Bipolar Disorder Bladder Discomfort Calculus Bladder Cystitis Interstitial

	Dysuria Haematuria Micturition Disorder	Report Source	Product	Role	Manufacturer	Route Dose Duration
	Nausea	Health	Topamax (Topiramate)	PS		ORAL 300 MG, 2 IN
	Nephrolithiasis	Professional				 1 DAY, ORAL;
	Nocturia					 225 MG, IN 1
	Pneumonia					 DAY, ORAL;IN
	Psychomotor Hyperactivity					 1 DAY, ORAL
	Therapeutic Agent Toxicity		Amitriptyline (Amitriptyline)	SS		
	Therapeutic Response		Lithium	SS		
	Unexpected		Allegra (Fexofenadine Hydrochloride)	C		
	Urinary Tract Disorder		Prosed (Prosed;Ds)	C		
	Urinary Tract Infection		Elmiron (Pentosan Polysulfate Sodium)	C		
	Urine Analysis Abnormal		Ditropan Xl (Oxybutynin Hydrochloride)	C		
	Vomiting		Neurontin (Gabapentin)	C		
			Trazodone (Trazodone)	C		

Date:09/20/04ISR Number: 4453727-XReport Type:Expedited (15-DaCompany Report #PHBS2004BE12164
Age:48 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Hospitalization - Initial or Prolonged	Blood Creatinine Increased	Health Professional	Diovan	PS	Novartis Sector: Pharma	ORAL 80 mg/day
	Condition Aggravated		Maniprex	SS		
	Creatinine Renal Clearance Decreased		Duovent	C		
			Inderal	C		
	Renal Failure		L-Thyroxin	C		 75 mg, UNK
	Respiratory Tract		Nozinan	C		

	Infection		Remergon	C		
			Staurodorm	C		

Date:09/20/04ISR Number: 4453980-2Report Type:Expedited (15-DaCompany Report #PHFR2004GB03333
Age:29 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Alanine Aminotransferase Increased	Consumer	Lithium	PS	Glaxosmithkline			
UNKNOWN								
	Aspartate Aminotransferase Increased		Clozaril	SS		ORAL		
	Liver Function Test Abnormal							

Date:09/20/04ISR Number: 4454752-5Report Type:Direct Company Report #CTU 227553
Age:58 YR Gender:Male I/FU:I

Outcome
Hospitalization - Initial or Prolonged
Required

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Intervention to Prevent Permanent Impairment/Damage	Chest Wall Pain Drug Level Above Therapeutic		Lithium Carbonate 300 Mg Tablet Ibuprofen	PS SS		ORAL ORAL	SEE IMAGE 800MG PO TID	
	Gait Disturbance Muscle Strain Sleep Disorder Therapeutic Agent Toxicity		Ferrous Sulfate Gemfibrozil Propranolol Benztropine Olanzapine Diphenhydramine	C C C C C C				

Date:09/20/04ISR Number: 4454754-9Report Type:Direct Company Report #CTU 227555
Age:50 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Alcohol Use Coordination Abnormal Disease Recurrence Dizziness Drug Level Above Therapeutic Refusal Of Treatment By Patient		Lithium 300 Mg Capsule Aspirin Cyclobenzaprine Omeprazole Propranolol Citalopram Trazodone Naprosyn	PS C C C C C C C			SEE IMAGE	

Date:09/20/04ISR Number: 4454755-0Report Type:Direct Company Report #CTU 227556
Age:56 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Cognitive Disorder Drug Level Above Therapeutic		Lithium Carbonate 300 Mg Cap	PS			600 MG QAM AND 900 MG	

Dysarthria

QHS

Loratadine	C
Atenolol	C
Docusate (Senna)	C
Gemfibrozil	C
Lisinopril	C
Nystatin Cream	C
Olanzapine	C
Lovastatin	C
Topirimate	C
Clomipramine	C

Date:09/20/04ISR Number: 4455775-2Report Type:Expedited (15-DaCompany Report #S04-FRA-04095-01
Age:40 YR Gender:Female I/FU:I

Outcome	PT
Death	Arrhythmia
	Asphyxia
	Drug Interaction
	Foreign Body Aspiration
	Hepatic Steatosis
	Overdose
	Pulmonary Embolism
	Pulmonary Oedema

Toxicologic Test Abnormal

		Report Source	Product	Role	Manufacturer	Route	Dose Duration
		Foreign Health Professional Other	Seropram (Citalopram Hydrobromide)	PS			
			Teralithe (Lithium Carbonate)	SS			
			Prothiaden (Dosulepin)	SS			
			Nordazepam	C			

Date:09/21/04ISR Number: 4456601-8Report Type:Expedited (15-DaCompany Report #2004064568
Age:47 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Death	Overdose	Foreign Literature Health Professional	Lithium (Lithium)	PS		ORAL	ORAL

Date:09/21/04ISR Number: 4457422-2Report Type:Expedited (15-DaCompany Report #D0044666A
Age:48 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Intentional Misuse Suicidal Ideation Suicide Attempt	Foreign Health Professional	Quinolonum Retard Tablet (Lithium Carbonate)	PS		ORAL	450 MG/ ORAL
	Tremor Vomiting		Sertraline Hydrochloride Tablet (Sertraline Hydrochloride)	SS		ORAL	100 MG/ ORAL

Date:09/22/04ISR Number: 4457736-6Report Type:Expedited (15-DaCompany Report #2004-DE-04634GD
Age:10 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Abdominal Pain Atrioventricular Block First Degree Chest Pain Diarrhoea Disorientation Dizziness Drug Interaction Hyperhidrosis Hypotension Hypothyroidism Oral Intake Reduced Pallor Palpitations Rhythm Idioventricular Therapeutic Agent Toxicity Ventricular Extrasystoles Ventricular Tachycardia Vomiting White Blood Cell Count Increased	Literature	Lithium Carbonate (Lithium Carbonate) (Lithium Carbonate) Clonidine (Clonidine) (Clonidine-Hcl) Methylphenidate (Methylphenidate) Escitalopram (Escitalopram) Oxacarbazine (Antiepileptics) Depakote (Valproate Semisodium) Levothyroxine (Levothyroxine)	PS SS SS SS SS SS			1200 MG TWICE DAILY 0.4 MG (TWICE DAILY) 36 MG (ONCE DAILY) (IN THE MORNING) 10 MG (ONCE DAILY) 600 MG (ONCE DAILY) SEE IMAGE 0.05 MG (ONCE

DAILY)

Date:09/27/04ISR Number: 4462926-2Report Type:Expedited (15-DaCompany Report #CA-2004-028532
Age:53 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Anxiety	Foreign	Betaseron					
	Bipolar Disorder	Consumer	(Interferon Beta -					
	Condition Aggravated	Health	1b) Injection, 250ug	PS		SUBCUTANEOUS	9.6 MIU,	
	Drug Interaction	Professional						3X/WEEK,
	Mania	Other				SUBCUTANEOUS		
	Paranoia		Lithium (Lithium)	SS		SEE IMAGE		
	Stress		Amitriptyline					
			(Amitriptyline)	C				
			Hydrochlorothiazide	C				

Date:09/28/04ISR Number: 4461253-7Report Type:Expedited (15-DaCompany Report #FR-ROCHE-381229
Age:54 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Encephalopathy	Consumer	Rivotril	PS	Roche	UNKNOWN		
Initial or Prolonged	Muscular Weakness		Teralithe	SS		ORAL		
	Somnolence		Atarax	SS		ORAL		
	Stupor		Leponex	C				
			Lamictal	C				
			Levothyrox	C				

Date:09/28/04ISR Number: 4464626-1Report Type:Expedited (15-DaCompany Report #B0344805A
Age:30 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Autoimmune Thyroiditis	Foreign	Lithium Salt					
	Drug Level Decreased	Literature	(Generic) (Lithium					

Mania	Health Professional	Salt)	PS

Date:09/29/04ISR Number: 4463718-0Report Type:Expedited (15-DaCompany Report #B0344913A
Age:70 YR Gender:Male I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Aphasia
	Apraxia
	Blood Potassium Increased
	Blood Pressure Diastolic Decreased
	Cerebrovascular Accident
	Dysarthria
	International Normalised Ratio Increased
	Motor Dysfunction
	Myoclonus
	Nodal Rhythm
	Nuclear Magnetic Resonance Imaging Brain Abnormal
	Personality Change Due To A General Medical Condition

	Renal Impairment					
	Sinoatrial Block					
	Sinus Bradycardia	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
	Somnolence	Foreign	Lithium Salt			
	Therapeutic Agent	Literature	(Formulation Unknown			
	Toxicity	Health	(Lithium Salt)			
	Transient Ischaemic	Professional	(Generic	PS		
	Attack		Beta-Blocker	C		
	Ultrasound Doppler		Aspirin	C		
	Abnormal		Ace Inhibitor	C		
			Benzodiazepines	C		
			Hypnotic	C		
			Antivtimins K	C		

Date:09/30/04ISR Number: 4463278-4Report Type:Expedited (15-DaCompany Report #2004018526
Age:36 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Other	Electrocardiogram Qt	Health	Quilonum Retard	PS	Glaxosmithkline	ORAL
675MG per day						
	Prolonged	Professional				
	Gait Disturbance					
	Mental Retardation					
	Severity Unspecified					

Date:10/01/04ISR Number: 4463889-6Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20040908824
Age:25 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Death	Completed Suicide	Health	Ultram	PS		
OROPHARINGEAL						
	Intentional Misuse	Professional	Ultracet	SS		
OROPHARINGEAL						
			Lithium	SS		
OROPHARINGEAL						

Date:10/04/04ISR Number: 4465420-8Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0528232A
Age:43 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blood Creatinine Increased		Eskalith Cr	PS	Glaxosmithkline	ORAL	450MG Twice per day	
	Blood Thyroid Stimulating Hormone Decreased							
	Blood Urea Increased							
	Dizziness							
	Immune System Disorder							
	Liver Function Test Abnormal							
	Proteinuria							
	Renal Impairment							
	Weight Decreased							

Date:10/04/04ISR Number: 4465444-0Report Type:Expedited (15-DaCompany Report #2004019017
Age:54 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Intentional Misuse	Health	Quilonum Retard	PS	Glaxosmithkline	ORAL	10TAB Single dose	
	Suicide Attempt	Professional						
	Vomiting		Aponal	SS		ORAL	110TAB Single dose	

			Diclo	SS	Glaxosmithkline	ORAL
10TAB Single dose						
			Risperdal	SS		ORAL
10TAB Single dose						
			Dogmatil	SS		ORAL
10CAP Single dose						
			Cipramil	SS		ORAL
20TAB Single dose						
			Dihydroergotoxine Mesylate	SS		ORAL
50TAB Single dose						

Date:10/04/04ISR Number: 4467804-0Report Type:Expedited (15-DaCompany Report #2004068312
Age:54 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Cerebral Ischaemia Depressed Level Of Consciousness	Foreign Health Professional	Atarax (Tablet) (Hydroxyzine Hydrochloride)	PS		ORAL		
	Encephalopathy Muscular Weakness Peripheral Coldness Somnolence		Clonazepam (Clonazepam)	SS				
			Lithium Carbonate (Lithium Carbonate)	SS		ORAL	1000 MG, ORAL	
	Stupor		Lamotrigine (Lamotrigine)	C				
			Clozapine (Clozapine)	C				
			Levothyroxine (Levothyroxine)	C				

Date:10/04/04ISR Number: 4468005-2Report Type:Expedited (15-DaCompany Report #2004235149CH
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Myoclonus Personality Disorder Polydipsia Therapeutic Agent Toxicity Tremor	Foreign Health Professional Other	Celebrex (Celecoxib) Capsule	PS		ORAL	200 MG, BID,	
			Quilonorm Retard(Lithium Carbonate)	SS		ORAL		
			Hydrochlorothiazide(Hydrochlorothiazide)	SS		ORAL	1 DF, QD,	
			Irbesartan(Irbesartan)	SS		ORAL	1 DF, QD,	
			Aspirin "Bayer"	C				
			Inderal	C				
			Simvastatin (Simvastatin)	C				
			Surmontil (Trimipraminde)	C				
			Seresta	C				
			Sirdalud (Tizanidine Hydrochloride)	C				
			Neurontin	C				
			Tramal (Tramadol Hydrochloride)	C				
			Phlebodril N					

			(Dextran Sulfate , Ruscus Acueatus)	C			

Date:10/05/04ISR Number: 4466351-XReport Type:Expedited (15-DaCompany Report #DE-GLAXOSMITHKLINE-D0044301A
Age:32 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Aspermia	Health	Quilonum Retard	PS	Glaxosmithkline	ORAL	1.5TAB Twice	
	Infertility Male	Professional					per day	

Date:10/05/04ISR Number: 4469569-5Report Type:Direct Company Report #CTU 228888
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Confusional State		Lithium Carbonate 300 Mg	PS		ORAL	300 MG BID	
	Mental Status Changes						ORAL	
			Lithium Carbonate 150 Mg	SS		ORAL	150 MG HS	
							ORAL	
			Risperidone	C				
			Clopidogrel	C				
			Melatonin	C				
			B12	C				
			Asa	C				
			Toprol Xl	C				
			Cozaar	C				
			Atorvastatin	C				

Date:10/06/04ISR Number: 4466961-XReport Type:Expedited (15-DaCompany Report #200418251GDDC
Age:69 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Other	Dehydration	Fludex	PS	Aventis	
	Drug Interaction			Pharmaceuticals Inc.	ORAL
	Drug Level Increased	Lithium Carbonate	SS		ORAL
	Influenza Like Illness	Eltroxin	C		
	Renal Failure Acute				

Date:10/06/04ISR Number: 4467216-XReport Type:Expedited (15-DaCompany Report #FR-ABBOTT-04P-056-0275099-00
Age:48 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Agitation		Depakote Tablets	PS		ORAL		
Hospitalization -	Aphasia		Lithium	SS		ORAL		
Initial or Prolonged	Blood Creatinine		Olanzapine	SS		ORAL		
	Increased							
	Blood Glucose Increased							
	Confusional State							
	Hypernatraemia							
	Mutism							
	Nephrogenic Diabetes							
	Insipidus							
	Pyrexia							
	Tremor							
	Urinary Incontinence							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/07/04ISR Number: 4468393-7Report Type:Expedited (15-DaCompany Report #2004018526
Age:36 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Other	Electrocardiogram Qt		Quilonum Retard	PS	Glaxosmithkline	ORAL	675MG per day
	Prolonged						
	Gait Disturbance						
	Mental Retardation						
	Severity Unspecified						
	Speech Disorder						

Date:10/08/04ISR Number: 4473837-0Report Type:Direct Company Report #CTU 229125
Age:66 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Nephrogenic Diabetes Insipidus		Lithium Carbonate	PS		ORAL	300 MG TID PO

Date:10/11/04ISR Number: 4470845-0Report Type:Expedited (15-DaCompany Report #PHRM2004FR02704
Age:40 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Other	Bradycardia	Health Professional	Ritaline	PS	Novartis Sector: Pharma	ORAL	30 mg daily
			Zoloft	SS		ORAL	
			Teralithe	SS		ORAL	
			Seresta	C		ORAL	

Date:10/12/04ISR Number: 4472841-6Report Type:Direct Company Report #CTU 229352
Age:32 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - (HOME MED)	Abdominal Pain		Lithium (Home Med)	PS			

Initial or Prolonged	Confusional State					
Other	Haematochezia					
	Mental Status Changes					

Date:10/12/04ISR Number: 4474770-0Report Type:Expedited (15-DaCompany Report #04NO000005
Age:59 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Catatonia	Foreign	Lithium Carbonate			
Initial or Prolonged	Delusion	Literature	(Lithium Carbonate)			
Required	Depression	Other	Tablet	PS		
Intervention to	Hypercalcaemia		Thyroxine Sodium			
Prevent Permanent	Hyperparathyroidism		(Levothyroxine			
Impairment/Damage	Hypothyroidism		Sodium)	C		
	Mania		Venlafaxine			
	Oral Intake Reduced		(Venlafaxine)	C		
	Parathyroid Tumour Benign		Olanzapine			
	Polydipsia		(Olanzapine)	C		
	Polyuria					
	Psychotic Disorder					
	Stupor					
	Treatment Noncompliance					

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/12/04ISR Number: 4474773-6Report Type:Expedited (15-DaCompany Report #04IN000004
Age:30 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Akathisia Drug Interaction Potentiation Erectile Dysfunction Idiosyncratic Drug Reaction Muscle Rigidity Priapism Tremor	Foreign Literature Other	Lithium Carbonate(Lithium Carbonate) Tablet Haloperidol (Haloperidol) Olanzapine (Olanzapine)	PS C C			1200 MG, QD	

Date:10/12/04ISR Number: 4475305-9Report Type:Expedited (15-DaCompany Report #2004071160
Age:51 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide Intentional Misuse	Literature Health Professional	Lithium (Lithium)	PS		ORAL	ORAL	

Date:10/12/04ISR Number: 4475974-3Report Type:Expedited (15-DaCompany Report #2004071162
Age:21 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardio-Respiratory Arrest	Literature	Lithium (Lithium)	PS		ORAL	ORAL	
Other	Completed Suicide Intentional Misuse	Health Professional	Olanzapine (Olanzapine) Venlafaxine (Venlafaxine) All Other Therapeutic Products	SS SS SS		ORAL ORAL ORAL	ORAL ORAL ORAL	

Date:10/12/04ISR Number: 4476465-6Report Type:Expedited (15-DaCompany Report #2004071181
Age:25 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Literature	Lithium (Lithium)	PS		ORAL	ORAL	
	Intentional Misuse	Health Professional	Clonazepam (Clonazepam)	SS		ORAL	ORAL	

Date:10/12/04ISR Number: 4476478-4Report Type:Expedited (15-DaCompany Report #2004071156
Age:55 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Therapeutic Agent	Literature	Lithium (Lithium)	PS		ORAL	ORAL	
	Toxicity	Health Professional						

Date:10/12/04ISR Number: 4476479-6Report Type:Expedited (15-DaCompany Report #2004071158
Age:51 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Overdose	Literature	Lithium (Lithium)	PS		ORAL	ORAL	
		Health Professional						

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/12/04ISR Number: 4476534-0Report Type:Expedited (15-DaCompany Report #2004071167
Age:41 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardio-Respiratory Arrest	Literature	Lithium (Lithium)	PS		ORAL	ORAL	
Other	Completed Suicide Intentional Misuse	Health Professional	Paroxetine (Paroxetine)	SS		ORAL	ORAL	

Date:10/12/04ISR Number: 4477434-2Report Type:Expedited (15-DaCompany Report #2004071163
Age:25 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Literature	Lithium (Lithium)	PS		ORAL	ORAL	
	Intentional Misuse	Health Professional	Tramadol (Tramadol)	SS				
			Tramadol/Acetaminophen (Paracetamol, Tramadol)	SS				
			All Other Therapeutic Products (All Other Therapeutic Products)	SS				

Date:10/12/04ISR Number: 4477453-6Report Type:Expedited (15-DaCompany Report #2004071173
Age:30 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Literature	Lithium (Lithium)	PS		ORAL	ORAL	
	Intentional Misuse	Health Professional	Verapamil (Verapamil)	SS				
			Perphenazine (Perphenazine)	SS				
			All Other Therapeutic Products (All Other Therapeutic					

			Products)	SS		

Date:10/12/04ISR Number: 4477564-5Report Type:Expedited (15-DaCompany Report #2004071161
Age:58 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Literature	Lithium (Lithium)	PS		ORAL		
	Intentional Misuse	Health Professional	Nortriptyline (Nortriptyline)	SS		ORAL		
			Citalopram (Citalopram)	SS		ORAL		

Date:10/12/04ISR Number: 4678760-4Report Type:Direct Company Report #CTU 237117
Age:39 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Hyperhidrosis		Lithium Carbonate	PS			300 MG	TID
	Mania							
	Pharmaceutical Product Complaint							

Date:10/13/04ISR Number: 4472909-4Report Type:Expedited (15-DaCompany Report #AU-JNJFOC-20040501168
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - OROPHARINGEAL	Coordination Abnormal	Health	Risperidone	PS				
Initial or Prolonged	Csf Pressure Increased	Professional						
Other	Headache							
	Hypomania		Risperidone	SS		OROPHARINGEAL		
	Hypothyroidism		Lithium Carbonate	SS		OROPHARINGEAL		
	Intervertebral Disc Disorder		Risperidone	SS		OROPHARINGEAL		
	Intracranial Pressure Increased		Antitriptyline	C		OROPHARINGEAL		
	Major Depression		Metformin	C		OROPHARINGEAL		
	Papilloedema							
	Retinal Haemorrhage							
	Therapy Non-Responder							

Date:10/13/04ISR Number: 4473982-XReport Type:Direct Company Report #CTU 229531
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Drug Ineffective		Lithium Carbonate (Generic)	PS			300 MG ONE AM TWO HS	
	Mania							
	Pharmaceutical Product Complaint							

Date:10/13/04ISR Number: 4476709-0Report Type:Expedited (15-DaCompany Report #KII-2004-0013524
Age:37 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Aggression	Study	Oxycodone					
Life-Threatening	Agitation	Health	Hydrochloride					
Hospitalization - Initial or Prolonged	Alcohol Use	Professional	(Oxycodone					
	Blood Pressure Systolic	Other	Hydrochloride)	PS		ORAL		
Other	Increased		Acetaminophen					
	Cardio-Respiratory Arrest		W/Hydrocodone					
	Depressed Level Of Consciousness		Bitartrate(Paracetamol, Hydrocodone					
	Heart Rate Increased		Bitartrate)	SS		ORAL		
	Hypotension		Benzodiazepine					
	Hypovolaemia		Derivatives()	SS		ORAL		
	Multiple Drug Overdose		Carisoprodol					
	Nodal Rhythm		(Carisoprodol)	SS		ORAL		
	Respiratory Rate		Ephedra (Ephedra)	SS		ORAL		
	Increased		Lithium (Lithium)	SS		ORAL		
	Self Injurious Behaviour		Acetylsalicylic Acid					
	Somnolence		(Acetylsalicylic					
	Therapeutic Agent Toxicity		Acid)	SS				
	Troponin Increased							

Date:10/15/04ISR Number: 4475812-9Report Type:Expedited (15-DaCompany Report #DE-GLAXOSMITHKLINE-D0044619A
Age:79 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Muscular Weakness	Consumer	Quilonum Retard	PS	Glaxosmithkline	UNKNOWN	1.5TAB per day	
			Bisomerck	C		UNKNOWN	5MG Twice per	

day

		Thyroxin	C	Glaxosmithkline	
UNKNOWN	100MG Per day				
		Lanzor	C		
UNKNOWN	15MG Per day				
		Corangin	C		
UNKNOWN	40MG Per day				
		Marcumar	C		
UNKNOWN					

Date:10/15/04ISR Number: 4479507-7Report Type:Expedited (15-DaCompany Report #2004235709US
Age:30 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide Intentional Misuse	Literature Health	Calan (Verapamil) Tablet	PS		ORAL	ORAL	
		Professional	Lithium (Lithium)	SS		ORAL	ORAL	
			Perphenazine (Perphenazine)	SS		ORAL	ORAL	

Date:10/18/04ISR Number: 4477056-3Report Type:Expedited (15-DaCompany Report #PHFR2004GB03786
Age:15 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Red Blood Cell Sedimentation Rate Increased Therapeutic Agent Toxicity		Clozaril	PS	Novartis Sector: Pharma	ORAL		
			Lithium	SS				

Date:10/18/04ISR Number: 4477485-8Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0412673A
Age:89 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Hospitalization - Initial or Prolonged	Fall Haemorrhage Hallucination Head Injury Hypothyroidism	Consumer	Eskalith 600MG Per day 2 YR	PS	Glaxosmithkline	ORAL

Date:10/18/04ISR Number: 4478423-4Report Type:Direct Company Report #CTU 229809
Age:58 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Life-Threatening Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Akinesia Blood Pressure Increased Heart Rate Increased Hyperthermia Leukocytosis Muscle Rigidity Respiratory Depression Respiratory Failure Speech Disorder		Fluphanazine 10 Mg Qd In Divided Doses Lithium Carbonate	PS SS		ORAL ORAL

Date:10/20/04ISR Number: 4481131-7Report Type:Direct Company Report #CTU 230100
Age:55 YR Gender:Male I/FU:I

Outcome
Life-Threatening Required Intervention to

Prevent Permanent
Impairment/Damage

	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Convulsion		Lithium Carbonate	PS				

Date:10/21/04ISR Number: 4481263-3Report Type:Expedited (15-DaCompany Report #PHFR2004GB03786
Age:15 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Red Blood Cell Sedimentation Rate Increased		Clozaril	PS	Novartis Sector: Pharma	ORAL		
	Therapeutic Agent Toxicity		Lithium	SS				

Date:10/21/04ISR Number: 4481338-9Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0530647A
Age:34 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Osteonecrosis		Eskalith	PS	Glaxosmithkline	ORAL	600MG Twice per day	15 YR
			Wellbutrin Xl	C	Glaxosmithkline			
			Lexapro	C				
			Seroquel	C				
			Zelnorm	C				

Date:10/22/04ISR Number: 4484549-1Report Type:Expedited (15-DaCompany Report #2004AL000795
Age:30 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide Multiple Drug Overdose	Literature	Verapamil Hydrochloride Tablets, 120 Mg (Purepac)	PS		ORAL	PO	

			Lithium	SS		ORAL	
PO							
			Perhenazine	SS			

Date:10/22/04ISR Number: 4484636-8Report Type:Expedited (15-DaCompany Report #2004AL000708
Age:25 YR Gender:Not SpecifiI/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide Multiple Drug Overdose	Literature	Tramadol Hydrochloride Tablets, 50 Mg (Purepac)	PS	Purepac	ORAL	PO	
			Lithium	SS		ORAL	PO	
			Acetaminophen/Tramadol	SS		ORAL	PO	

Date:10/22/04ISR Number: 4485438-9Report Type:Expedited (15-DaCompany Report #2004AL000819
Age:25 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide Intentional Misuse	Literature	Clonazepam Tablets Usp, 0.5mg, 1mg, And 2mg (Purepac)	PS	Purepac	ORAL	PO	

			Lithium	SS		ORAL
PO						

Date:10/22/04ISR Number: 4487342-9Report Type:Expedited (15-DaCompany Report #04CH000007
Age:68 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Bradycardia	Foreign	Lithium Carbonate(Lithium			
	Hypokinesia	Literature	Carbonate) Tablet	PS		
	Renal Impairment	Other	Carbamazepine			
	Therapeutic Agent		(Carbamazepine)	C		
	Toxicity		Pipamperone			
	Tremor		(Pipamerone)	C		
			Mirtazapine			
			(Mirtazapine)	C		
			Rofecoxib			
			(Rofecoxib)	C		

Date:10/22/04ISR Number: 4487398-3Report Type:Expedited (15-DaCompany Report #2004-BP-09374RO
Age:47 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Multiple Drug Overdose	Foreign	Lithium Carbonate			
		Literature	Capsules Usp, 300 Mg			
		Health	(Lithium Carbonate)	PS		ORAL
PO						
		Professional				

Date:10/25/04ISR Number: 4484269-3Report Type:Expedited (15-DaCompany Report #2004019017
Age:54 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Coma		Quilonum Retard	PS	Glaxosmithkline	ORAL
10TAB Single						
Initial or Prolonged	Intentional Misuse					
dose						

	Suicide Attempt	Aponal	SS		ORAL
110TAB Single dose	Vomiting				
		Diclo	SS	Glaxosmithkline	ORAL
10TAB Single dose					
		Risperdal	SS		ORAL
10TAB Single dose					
		Dogmatil	SS		ORAL
10CAP Single dose					
		Cipramil	SS		ORAL
20TAB Single dose					
		Dihydroergotoxine Mesylate	SS		ORAL
50TAB Single dose					

Date:10/25/04ISR Number: 4484406-0Report Type:Expedited (15-DaCompany Report #PHBS2003CH11264
Age:68 YR Gender:Female I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Atrioventricular Block Complete
	Blood Creatinine Increased
	Chills
	Creatinine Renal

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Clearance Decreased							
	Drug Level Increased							
	Dysarthria							
	Electrocardiogram T Wave Inversion	Health Professional	Tegretol Cr	PS	Novartis Sector: Pharma	ORAL	400 mg, BID	
	Extrapyramidal Disorder							
	Fall		Tegretol Cr	SS	Novartis Sector: Pharma	ORAL	400 mg, BID	
	Headache							
	Hypokinesia		Priadel	SS			200 mg, BID	
	Hypotension		Priadel	SS			UNKNOWN	200 mg, BID
	Kyphosis		Vioxx	SS			UNKNOWN	25 mg, BID 11520MIN
	Lordosis		Dipiperon	C			UNKNOWN	60 mg/day
	Malaise		Mirtazapine	C			UNKNOWN	30 mg/day
	Myalgia		Imovane	C			UNKNOWN	
	Nausea							
	Osteochondrosis							
	Pain In Extremity							
	Pancytopenia							
	Renal Impairment							
	Sinus Arrest							
	Sinus Bradycardia							
	Somnolence							
	Tremor							
	Vomiting							

Date:10/25/04ISR Number: 4485393-1Report Type:Direct Company Report #CTU 230355
Age:16 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Diarrhoea		Lithobid (Lithium Carbonate 300 Mg) Tablet	PS				
	Gastritis							
	Vomiting							

Date:10/27/04ISR Number: 4487021-8Report Type:Expedited (15-DaCompany Report #PHNU2004DE03653
Age:25 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Interaction Grand Mal Convulsion		Leponex / Clozaril (Clozapine)	PS	Novartis Sector: Pharma	ORAL	300 to 400 mg/day	
			Leponex / Clozaril (Clozapine)	SS	Novartis Sector: Pharma	ORAL	400 to 500 mg/day	50400MIN
			Leponex / Clozaril (Clozapine)	SS	Novartis Sector: Pharma	ORAL	550 to 600 mg/day	50400MIN
			Leponex / Clozaril (Clozapine)	SS	Novartis Sector: Pharma	ORAL	650 mg/day	30240MIN
			Leponex / Clozaril (Clozapine)	SS	Novartis Sector: Pharma	ORAL	700 mg/day	8640 MIN
			Leponex / Clozaril (Clozapine)	SS	Novartis Sector: Pharma	ORAL	800 mg/day	12960MIN
			Leponex / Clozaril (Clozapine)	SS	Novartis Sector:			

						Pharma	ORAL
600 mg/day	86400MIN						
				Leponex / Clozaril (Clozapine)	SS	Novartis Sector: Pharma	ORAL
650 mg/day	69120MIN						
				Leponex / Clozaril (Clozapine)	SS	Novartis Sector: Pharma	ORAL
500 mg/day							
				Solian	SS		ORAL
200 to 400							
mg/day	61920MIN						
				Solian	SS		ORAL
600 mg/day							
				Hypnorex	SS		ORAL
600 mg/day	30240MIN						
				Hypnorex	SS		ORAL
800 mg/day	11520MIN						
				Hypnorex	SS		ORAL
100(?) mg/day	15840MIN						
				Hypnorex	SS		ORAL
1200 mg/day	2880 MIN						
				Hypnorex	SS		ORAL
1400 mg/day							
				Tavor	C		ORAL
2.5 mg/day							
				Tavor	C		ORAL
2 to 2.5							
mg/day							

Date:10/27/04ISR Number: 4487116-9Report Type:Expedited (15-DaCompany Report #DE-GLAXOSMITHKLINE-D0045037A
Age:48 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Interaction Weight Increased	Consumer	Quilonum Retard	PS	Glaxosmithkline	ORAL	1150MG per day	4 YR
			Leponex	C		ORAL	75MG per day	4 YR
			Seroxat	C	Glaxosmithkline	ORAL	40MG per day	

			Lamictal	C	Glaxosmithkline	
UNKNOWN						
			Zeldox	C		
UNKNOWN						

Date:10/28/04ISR Number: 4488096-2Report Type:Expedited (15-DaCompany Report #DE-GLAXOSMITHKLINE-D0044619A
Age:79 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Muscular Weakness	Health	Quilonum Retard	PS	Glaxosmithkline	ORAL	1TAB per day	
Initial or Prolonged	Polyneuropathy	Professional	Bisomerck	C				
UNKNOWN							5MG Twice per	
	Spinal Column Stenosis						day	
			L -Thyroxine	C	Glaxosmithkline			
UNKNOWN							100MG Per day	
			Lanzor	C				
UNKNOWN							15MG Per day	
			Corangin	C				
UNKNOWN							40MG Per day	
			Marcumar	C				
UNKNOWN								

Date:10/28/04ISR Number: 4488101-3Report Type:Expedited (15-DaCompany Report #DE-GLAXOSMITHKLINE-D0045023A
Age:65 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Drug Interaction	Health	Quilonum Retard	PS	Glaxosmithkline	ORAL	675MG per day	181 DAY
Initial or Prolonged	Parkinsonism	Professional	Cipramil	SS		ORAL	80MG per day	7 MON
			Zyprexa	SS		ORAL	2.5MG per day	
			Dociton	C		ORAL	10MG per day	
			Euthyrox	C	Glaxosmithkline			
UNKNOWN							100UG per day	

Date:10/28/04ISR Number: 4488145-1Report Type:Expedited (15-DaCompany Report #CA-JNJFOC-20041005317
Age:26 YR Gender:Female I/FU:I

Outcome
Hospitalization -
Initial or Prolonged

Other

PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Antipsychotic Drug Level Above Therapeutic	Health Professional	Topamax	PS				
		Topamax	SS				
Confusional State							
Disturbance In Attention							
Drug Toxicity							
Lethargy		Topamax	SS				
Mania							
Mental Disorder							
		Valproate	C				
		Clonazepam	C				
		Lithium	I				
		Lithium	I				
		Lithium	I				

Dose started on Day 39 posthospitalization.

Dose started on Day 32 posthospitalization.

Dose started on Day 19 posthospitalization.

Dose started on Day 8 posthospitalization.

Date:10/28/04ISR Number: 4490027-6Report Type:Expedited (15-DaCompany Report #2004079254
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Drug Toxicity Electrocardiogram Qt Corrected Interval Prolonged Torsade De Pointes	Health Professional	Ziprasidone (Caps) (Ziprasidone) Lithium (Lithium) Fluconazole (Fluconazole)	PS SS SS				

Date:10/29/04ISR Number: 4491899-1Report Type:Direct Company Report #CTU 230823
Age:78 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Antipsychotic Drug Level Increased Belligerence Coordination Abnormal Disorientation Drug Interaction		Lithium Atenolol Benazepril Asirin Premarin Medroxyprogesterone Ducosate Acetaminophen	PS C C C C C C C		ORAL	600 MG AT BEDTIME ORAL	

Date:10/29/04ISR Number: 4520165-0Report Type:Periodic Company Report #US013094
Age:53 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Bipolar I Disorder	Health Professional Company Representative	Provigil Lithium Lithium Lamictal	PS SS C C		ORAL ORAL	50 MG QD 1500 MG QD	

			Risperdal	C			

Date:11/01/04ISR Number: 4489483-9Report Type:Expedited (15-DaCompany Report #PHNU2004DE03633
Age:48 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Interaction Weight Increased		Leponex / Clozaril (Clozapine)	PS	Novartis Sector: Pharma	ORAL	75 mg/day	
			Quilonum - Slow Release	SS		ORAL	up to 1150 mg/day	
			Seroxat "Smithkline Beecham"	C		ORAL	40 mg/day	

Date:11/01/04ISR Number: 4489648-6Report Type:Expedited (15-DaCompany Report #PHBS2004CH14112
Age:36 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Cushing'S Syndrome Cushingoid		Tegretol	PS	Novartis Sector: Pharma		800 mg/day	
	Dexamethasone Suppression		Stocrin	SS		ORAL	1 Tablet/day	
	Test Positive		Combivir	SS			zido 150/ lamiv 300 mg/day	
			Lithiofor	SS		ORAL	4.5 Tablet/day	
			Prazine	SS			100 mg/day	

			Zoloft	SS		
250 mg/day						
			Humalog	C		

Date:11/01/04ISR Number: 4489970-3Report Type:Expedited (15-DaCompany Report #PHFR2004GB03786
Age:15 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Red Blood Cell	Consumer	Lithium	PS	Glaxosmithkline	
UNKNOWN						
Initial or Prolonged	Sedimentation Rate Increased		Clozaril	SS		ORAL
	Therapeutic Agent Toxicity					

Date:11/02/04ISR Number: 4490663-7Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0443660A
Age:51 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Asthenia		Combivir	PS	Glaxosmithkline	ORAL
	Diarrhoea		Lithium Carbonate	SS	Glaxosmithkline	ORAL
900MG Per day						
	Drug Interaction		Bactrim	SS	Glaxosmithkline	
	Nausea		Concerta	SS		
54MG per day						
	Therapeutic Agent		Sustiva	SS		
	Toxicity		Zocor	SS		ORAL
80MG Per day						
	Vomiting		Zyprexa	C		
2.5MG Per day						

Date:11/02/04ISR Number: 4490685-6Report Type:Expedited (15-DaCompany Report #A01200405023
Age:76 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Blood Calcium Increased		Lithium	PS	Glaxosmithkline	ORAL		
Hospitalization - Initial or Prolonged	Blood Creatinine Increased		Chlorpromazine	C	Glaxosmithkline	ORAL		
			Procyclidine	C	Glaxosmithkline			UNKNOWN
Other	Blood Urea Increased		Nitrazepam	C				UNKNOWN
	Clubbing		Zopiclone	C				UNKNOWN
	Dehydration							
	Depressed Level Of Consciousness							
	Gastrointestinal Haemorrhage							
	Hypernatraemia							
	Hypoventilation							
	Lung Consolidation							
	Malaise							
	Nephrogenic Diabetes Insipidus							
	Pneumonia							
	Po2 Decreased							
	Renal Failure							
	Vomiting							

Date:11/02/04ISR Number: 4493327-9Report Type:Expedited (15-DaCompany Report #2003034801
Age:52 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Diabetic Hyperglycaemic	Health	Geodon (Ziprasidone)	PS		ORAL	10 MG (1 IN 1 D), ORAL	
Hospitalization - Initial or Prolonged	Coma	Professional						
	Paranoia	Company Representative	Lithium (Lithium) (Lithium)	SS		ORAL	900 MG (2 IN 1 D), ORAL	
			Bupropion Hydrochloride					

			(Bupropion Hydrochloride)	C		
			Anti-Diabetics (Anti-Diabetics)	C		

Date:11/03/04ISR Number: 4492159-5Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0531945A
Age:60 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Dizziness		Lamictal	PS	Glaxosmithkline	ORAL		
	Fall		Lithium	SS	Glaxosmithkline			
			Seroquel	SS				

Date:11/03/04ISR Number: 4495095-3Report Type:Expedited (15-DaCompany Report #2004-BP-10351RO
Age:21 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardio-Respiratory Arrest	Literature	Lithium Carbonate Capsules Usp, 300 Mg(Lithium Carbonate)	PS				
	Completed Suicide		Olanzapine (Olanzapine)	SS				
	Multiple Drug Overdose							

			Venlafaxine (Venlafaxine)	SS		

Date:11/03/04ISR Number: 4495097-7Report Type:Expedited (15-DaCompany Report #2004-BP-10348RO
Age:51 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Overdose	Literature	Lithium Carbonate Capsules Usp, 300 Mg (Lithium Carbonate)	PS		

Date:11/03/04ISR Number: 4495099-0Report Type:Expedited (15-DaCompany Report #2004-BP-10347RO
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Overdose	Literature	Lithium Carbonate Capsules Usp, 300 Mg (Lithium Carbonate)	PS		

Date:11/03/04ISR Number: 4495102-8Report Type:Expedited (15-DaCompany Report #2004-BP-10445RO
Age:30 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Completed Suicide Multiple Drug Overdose	Literature	Lithium Carbonate Capsules Usp, 300 Mg (Lithium Carbonate)	PS		
			Verapamil (Verapamil)	SS		
			Perphenazine (Perphenazine)	SS		

Date:11/03/04ISR Number: 4495107-7Report Type:Expedited (15-DaCompany Report #2004-BP-10350RO
Age:58 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						

Outcome	PT	Report Source	Product	Role
Death	Completed Suicide Multiple Drug Overdose	Literature	Lithium Carbonate Capsules Usp, 300 Mg (Lithium Carbonate)	PS
			Nortriptyline (Nortriptyline)	SS
			Citalopram (Citalopram)	SS

Date:11/03/04ISR Number: 4495598-1Report Type:Expedited (15-DaCompany Report #2004-BP-10461RO
Age:25 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide Intentional Misuse	Literature	Lithium Carbonate Capsules Usp, 300 Mg (Lithium Carbonate)	PS				
			Clonazepam (Clonazepam)	SS				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/03/04ISR Number: 4495608-1Report Type:Expedited (15-DaCompany Report #2004-BP-10354RO
Age:41 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardio-Respiratory Arrest	Literature	Lithium Carbonate Capsules Usp, 300 Mg					
	Completed Suicide		(Lithium Carbonate)	PS				
	Intentional Misuse		Paroxetine (Paroxetine)	SS				

Date:11/03/04ISR Number: 4495665-2Report Type:Expedited (15-DaCompany Report #2004-BP-10352RO
Age:25 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Literature	Lithium Carbonate Capsules Usp, 300 Mg					
	Intentional Misuse		(Lithium Carbonate)	PS				
			Tramadol (Tramadol)	SS				
			Acetaminophen W/Tramadol	SS				

Date:11/04/04ISR Number: 4493151-7Report Type:Expedited (15-DaCompany Report #PHRM2004FR03234
Age:65 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Antipsychotic Drug Level Above Therapeutic	Health Professional	Trileptal	PS	Novartis Sector: Pharma	ORAL	600 mg, BID	
	Balance Disorder		Lithium	SS		ORAL	1.5 Tabs per day	
	Confusional State							
	Drug Interaction		Seresta	C				
	Tremor		Soprol	C				
	Vertigo							

Date:11/04/04ISR Number: 4495183-1Report Type:Expedited (15-DaCompany Report #2004-BP-10349RO
Age:51 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide Intentional Misuse	Literature	Lithium Carbonate Capsules Usp, 300 Mg (Lithium Carbonate)	PS				

Date:11/04/04ISR Number: 4497410-3Report Type:Expedited (15-DaCompany Report #2004083706
Age:62 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Apathy Erythema Fatigue Feeling Abnormal Loss Of Employment Nervousness	Consumer	Neurontin (Gabapentin)	PS		ORAL	600 MG (300 MG, 2 IN 1 D), ORAL	
			Lithium (Lithium)	SS				
			Esomeprazole (Esomeprazole)	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/05/04ISR Number: 4493642-9Report Type:Expedited (15-DaCompany Report #US-ABBOTT-04P-163-0279332-00
Age:30 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide		Verapamil (Isoptin Sr)	PS		ORAL		
			Lithium	SS		ORAL		
			Perphenazine	SS		ORAL		

Date:11/08/04ISR Number: 4495815-8Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0530395A
Age:56 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Alanine Aminotransferase		Lamictal	PS	Glaxosmithkline	ORAL	3	WK
Other	Increased		Eskalith	SS	Glaxosmithkline	ORAL	300MG Per day	7 DAY
	Dizziness		Valium	C				
	Headache		Vicodin	C				
	Irritable Bowel Syndrome		Neurontin	C				
	Visual Disturbance							

Date:11/08/04ISR Number: 4495845-6Report Type:Expedited (15-DaCompany Report #CH-GLAXOSMITHKLINE-B0350605A
Age:22 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Interaction		Deroxat	PS	Glaxosmithkline	ORAL	40MG Per day	
	Electrocardiogram Qt		Methadone	SS	Glaxosmithkline	ORAL	20MG Per day	
	Prolonged		Surmontil	SS		ORAL	50MG Per day	10 DAY
	Transaminases Increased		Lithium Sulphate	SS		ORAL	1320MG Per day	
			Berocca	SS		ORAL		
			Valium	SS		ORAL	10MG Per day	

Date:11/08/04ISR Number: 4498744-9Report Type:Expedited (15-DaCompany Report #2004079254
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Blood Magnesium Decreased Blood Potassium Decreased Electrocardiogram Qt Corrected Interval Prolonged Torsade De Pointes	Health Professional	Geodon (Ziprasidone) Lithium (Lithium) Fluconazole (Fluconazole)	PS SS SS				

Date:11/09/04ISR Number: 4496871-3Report Type:Expedited (15-DaCompany Report #DE-GLAXOSMITHKLINE-D0045136A
Age:48 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Consciousness Fluctuating Delirium Disorientation Drug Interaction Hallucination Hallucinations, Mixed Sedation Somnolence	Health Professional	Quilonum Retard Leponex Belladonna Herb Diazepam Orfiril Haldol	PS SS SS C C C	Glaxosmithkline	ORAL ORAL ORAL ORAL ORAL ORAL	450MG Per day 20DROP Per day 	 21 DAY 35 DAY

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/10/04ISR Number: 4497534-0Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20040908881
Age:31 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide		Tylox	PS		OROPHARINGEAL		
	Intentional Misuse		Clonidine	SS		OROPHARINGEAL		
			Benzodiazepine	SS		OROPHARINGEAL		
			Hydromorphone	SS				
			Lithium	SS				

Date:11/10/04ISR Number: 4497865-4Report Type:Expedited (15-DaCompany Report #DE-GLAXOSMITHKLINE-D0045137A
Age:53 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Confusional State	Health Professional	Quilonum Retard	PS	Glaxosmithkline	ORAL	2.5TAB Per day	
	Dehydration							
	Disorientation		Risperdal	SS		ORAL	1MG Per day	
	Eyelid Oedema		Ergenyl	SS		ORAL	150MG Per day	
	Nephropathy		Haldol Decanoate	C		INTRAMUSCULAR	1ML	Monthly
	Oedema Peripheral		Perazin	C		UNKNOWN		
	Renal Failure		Benalapril	C		ORAL	5MG Per day	
	Salt Intoxication		Diazepam	C		ORAL	40MG Per day	
	Somnolence		Thyronajod	C		ORAL	.1MG Per day	
	Urinary Tract Infection		Kalinor	C	Glaxosmithkline	ORAL	1TAB Per day	
			Lasix	C	Glaxosmithkline		UNKNOWN	40MG Per day DAY
			Hct	C			UNKNOWN	25MG Per day
			Taxilan	C			UNKNOWN	900MG per day

UNKNOWN	60MG per day	Haldol	C
UNKNOWN	1TAB Per day	Akineton	C
UNKNOWN	75MG per day	Gastrozepin	C
UNKNOWN	40MG Per day	Pantozol	C
SUBCUTANEOUS	.4U Per day	Clexane	C
UNKNOWN	100MG Unknown	Zoloft	C
UNKNOWN		Neurocil	C

Date:11/10/04ISR Number: 4499059-5Report Type:Direct Company Report #CTU 231723
Age:19 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Bradycardia Drug Toxicity Electrocardiogram Pr Prolongation Haemodialysis Mental Status Changes Pancytopenia Renal Failure Acute Urinary Retention		Lithium 675 Mg	PS		ORAL	675 MG BID	

Date:11/10/04ISR Number: 4502396-9Report Type:Expedited (15-DaCompany Report #T04-GER-07359-01
Age:65 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Atrophy Drug Interaction Parkinsonism Prescribed Overdose	Foreign Study Health Professional Other	Cipramil (Citalopram Hydrobromide)	PS		ORAL	80 MG QD PO	
			Quilonum - Slow Release (Lithium Carbonate)	SS		ORAL	675 MG QD PO	
			Zyprexa (Olanzapine)	SS		ORAL	2.5 MG QD PO	

				Dociton (Propranolol Hydrochloride)	C		
				Euthyrox (Levothyroxine Sodium)	C		

Date:11/11/04ISR Number: 4499256-9Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20040908824
Age:25 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Coma		Ultram	PS		OROPHARINGEAL		
	Completed Suicide		Ultracet	SS		OROPHARINGEAL		
	General Physical Health Deterioration		Risperidone	SS				
			Lithium	SS		OROPHARINGEAL		
	Haemodialysis		Alprazolam	SS				
	Heart Rate Increased		Diazepam	SS				
	Hypotension		Nefazodone	SS				
	Intentional Misuse		Olanzapine	SS				
	Loss Of Consciousness		Nalbuphine	SS				
	Pneumothorax							
	Therapy Non-Responder							

Date:11/12/04ISR Number: 4500102-5Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0533598A
Age:55 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hypoaesthesia Oral		Eskalith	PS	Glaxosmithkline	ORAL	450MG Three times per day	17 YR
			Klonopin	C				

Date:11/12/04ISR Number: 4500120-7Report Type:Expedited (15-DaCompany Report #2004021788
Age:48 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Intentional Misuse Nausea Suicide Attempt Vomiting	Health Professional	Quilonum Retard	PS	Glaxosmithkline	ORAL		

Date:11/12/04ISR Number: 4500513-8Report Type:Direct Company Report #CTU 231778
Age:57 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide Psychotic Disorder		Dexamethasone Lithium	PS SS				

Date:11/15/04ISR Number: 4501018-0Report Type:Expedited (15-DaCompany Report #DE-GLAXOSMITHKLINE-D0044619A
Age:79 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Muscular Weakness Polyneuropathy Spinal Column Stenosis		Quilonum Retard Bisomerck L -Thyroxine Lanzor Corangin	PS C C C C	Glaxosmithkline Glaxosmithkline	ORAL	1TAB per day 5MG Twice per day 100MG Per day 15MG Per day 40MG Per day	UNKNOWN UNKNOWN UNKNOWN

			Marcumar	C		

UNKNOWN

Date:11/15/04ISR Number: 4501822-9Report Type:Direct Company Report #CTU 231942
Age:49 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Agitation		Lithium	PS				
Hospitalization - Initial or Prolonged	Balance Disorder		Quetiapine	C				
	Confusional State		Tramadol	C				
Required Intervention to Prevent Permanent Impairment/Damage	Diarrhoea		Estratest	C				
	Nausea		Clidinium/Chlordiazepoxide	C				
	Tremor		Pancrelipase	C				
	Vomiting							

Date:11/15/04ISR Number: 4501961-2Report Type:Direct Company Report #CTU 231999
Age:70 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Cognitive Disorder		Lithium	PS				
	Decreased Appetite		Diltiazem Sa 240 Mg Cap	SS				
Required Intervention to Prevent Permanent Impairment/Damage	Dizziness		Atorvastatin	C				
	Nausea		Hyoscine 0.25% Orhth Soln	C				
	Therapeutic Agent		Lubricating Ophth Oint	C				
	Toxicity		Polyvinyl Alcohol 1% Ophth Sol	C				
	Tremor		Atenolol	C				
	Vomiting		Prednisone 1% Ophth Susp	C				
			Multivitamin With Minerals	C				
			Clotrimazole 1% Cream	C				
			Hydrocortisone 1% Cream	C				

Date:11/16/04ISR Number: 4502368-4Report Type:Expedited (15-DaCompany Report #PHFR2004GB03786
Age:15 YR Gender:Female I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Agitation
Other	Blood Potassium Decreased
	Blood Urea Decreased
	C-Reactive Protein Increased
	Fatigue
	Grand Mal Convulsion
	Hypotension
	Malaise
	Mycoplasma Infection
	Mycoplasma Serology Positive
	Nausea
	Neutrophil Count Decreased
	Psychotic Disorder

	Pyrexia Red Blood Cell Sedimentation Rate Increased	Report Source Health Professional	Product Clozaril	Role PS	Manufacturer Novartis Sector: Pharma	Route ORAL
Dose 200mg/day	Duration 97920MIN					
	Therapeutic Agent Toxicity		Lithium	SS		ORAL
1400mg/day						
	Viral Infection		Clonazepam	SS		ORAL
2mg/day	67680MIN					
	White Blood Cell Count Decreased					

Date:11/16/04ISR Number: 4505328-2Report Type:Expedited (15-DaCompany Report #2004088201
Age:68 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Hospitalization -	Duration Accident	Foreign	Lithium (Lithium)	PS		
400 MG (200						
Initial or Prolonged	Atrioventricular Block	Literature				
MG , 2 IN 1						
Other	Complete					
D)	12 YR					
	Blood Pressure Decreased		Rofecoxib			
	Blood Pressure Increased		(Rofecoxib)	SS		
590 MG (25						
	Drug Interaction					
MG, 2 IN 1 D)						
	Drug Level Above		Carbamazepine			
	Therapeutic		(Carbamazepine)	C		
	Dysarthria		Pipamperone			
	Extrapyramidal Disorder		(Pipamperone)	C		
	Fall		Zopliclone			
	Headache		(Zoplicone)	C		
	Kyphosis		Mirtazapine			
	Lordosis		(Mirtazapine)	C		
	Nausea					
	Pain In Extremity					
	Pancytopenia					
	Renal Impairment					
	Sinus Arrest					
	Sinus Bradycardia					
	Somnolence					

	Spinal Disorder
	Therapeutic Agent
	Toxicity
	Tremor
	Vomiting

Date:11/17/04ISR Number: 4503397-7Report Type:Expedited (15-DaCompany Report #PHFR2004GB04039
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Interaction	Consumer	Lithium	PS	Glaxosmithkline			
UNKNOWN								
	Renal Impairment		Voltarol	SS	Glaxosmithkline			
UNKNOWN								
	Therapeutic Agent							
	Toxicity							

Date:11/18/04ISR Number: 4505411-1Report Type:Direct Company Report #CTU 232388
Age:63 YR Gender:Male I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Confusional State
	Drug Level Above Therapeutic
	Gait Disturbance

		Medication Error Treatment Noncompliance Tremor	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
				Lithium	PS		
				Phenytoin	C		
				Mirtazapine	C		
				Escitalopram	C		
				Tiagabine	C		
				Topiramate	C		
				Gabapentin	C		
				Donepezil	C		

Date:11/18/04ISR Number: 4507109-2Report Type:Expedited (15-DaCompany Report #B0349845A
Age:50 YR Gender: I/FU:I

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Death		Antipsychotic Drug Level Above Therapeutic	Literature Health Professional	Lithium Salt (Formulation Unknown) (Lithium Salt)	PS		ORAL
ORAL							

Date:11/18/04ISR Number: 4507112-2Report Type:Expedited (15-DaCompany Report #B0349846A
Age:51 YR Gender: I/FU:I

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Death		Antipsychotic Drug Level Above Therapeutic	Literature Health Professional	Lithium Salt (Formulation Unknown) (Lithium Salt)	PS		ORAL
ORAL							

Date:11/18/04ISR Number: 4507118-3Report Type:Expedited (15-DaCompany Report #B0349848A
Age:58 YR Gender: I/FU:I

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Death		Antipsychotic Drug Level	Literature	Lithium Salt			

	Above Therapeutic Completed Suicide Drug Screen Positive	Health Professional	(Formulation Unknown) (Lithium Salt)	PS		ORAL	ORAL
			Nortriptyline (Formulation Unknown) (Nortriptyline)	SS		ORAL	ORAL
			Citalopram (Formulation Unknown) (Citalopram)	SS		ORAL	ORAL

Date:11/18/04ISR Number: 4507132-8Report Type:Expedited (15-DaCompany Report #B0349828A
Age:41 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardio-Respiratory Arrest Completed Suicide	Literature Health Professional	Paroxetine Hydrochloride (Formulation Unknown) (Generic) (Paroxetine Lithium Salt	PS		ORAL	ORAL	

			(Formulation Unknown) (Lithium Salt)	SS		ORAL	ORAL

Date:11/18/04ISR Number: 4507139-0Report Type:Expedited (15-DaCompany Report #B0349847A
Age:51 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Death	Antipsychotic Drug Level Above Therapeutic Completed Suicide	Literature Health Professional	Lithium Salt (Formulation Unknown) (Lithium Salt)	PS		ORAL	ORAL

Date:11/18/04ISR Number: 4507606-XReport Type:Expedited (15-DaCompany Report #B0349608A
Age:26 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Required Intervention to Prevent Permanent Impairment/Damage	Confusional State Disturbance In Attention Drug Interaction Dysphoria Lethargy Mania Skin Disorder Therapeutic Agent Toxicity	Foreign Literature Health Professional	Lithium Salt (Generic) (Lithium Salt) Lamictal (Lamotrigine) Risperidone (Risperidone) Topiramate (Topiramate) Valproate Sodium Clonazepam	PS SS SS SS C C			PER DAY 75 MG

Date:11/18/04ISR Number: 4507703-9Report Type:Expedited (15-DaCompany Report #B0349849A
Age:21 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Death	Cardio-Respiratory Arrest Completed Suicide	Literature Health	Lithium Salt (Formulation				

		Professional	Unknown) (Lithium Salt)	PS		ORAL
ORAL						
			Olanzapine (Olanzapine)	SS		ORAL
ORAL						
			Venlafaxine Hydrochloride (Venlafaxine Hydrochloride)	SS		ORAL
ORAL						

Date:11/18/04ISR Number: 4507705-2Report Type:Expedited (15-DaCompany Report #B0349850A
Age:25 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Completed Suicide	Literature Health Professional	Lithium Salt (Formulation Unknown)	PS		ORAL
ORAL						
			Tramadol Hydrochloride (Tramadol Hydrochloride)	SS		ORAL
ORAL						
			Paracetamol (Acetaminophen)	SS		ORAL
ORAL						

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/18/04ISR Number: 4507707-6Report Type:Expedited (15-DaCompany Report #B0349851A
Age:30 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Literature	Lithium Salt					
		Health Professional	(Formulation Unknown) (Lithium Salt)	PS		ORAL	ORAL	
			Verapamil (Verapamil)	SS		ORAL	ORAL	
			Perphenazine (Perphenazine)	SS		ORAL	ORAL	

Date:11/18/04ISR Number: 4507708-8Report Type:Expedited (15-DaCompany Report #B0349852A
Age:25 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Literature	Lithium Salt					
		Health Professional	(Formulation Unknown) (Lithium Salt)	PS		ORAL	ORAL	
			Clonazepam (Clonazepam)	SS		ORAL	ORAL	

Date:11/19/04ISR Number: 4505748-6Report Type:Expedited (15-DaCompany Report #JP-GLAXOSMITHKLINE-B0225660A
Age:65 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Alanine Aminotransferase Increased		Lithium Carbonate	PS	Glaxosmithkline	ORAL	200MG per day	8 YR
			Levomepromazine	SS		ORAL	10MG per day	8 YR
	Ammonia Increased		Phenobarbitone	SS				
INTRAMUSCULAR							3	DAY

		Anorexia			Chlorpromazine	C	Glaxosmithkline		ORAL
25MG per day	8	YR							
		Aspartate Aminotransferase Increased Blood Alkaline Phosphatase Increased Blood Creatine Phosphokinase Increased Coma Convulsion Creutzfeldt-Jakob Disease Depressed Level Of Consciousness Diarrhoea Electrocardiogram T Wave Inversion Electroencephalogram Abnormal Encephalopathy Gait Disturbance Gamma-Glutamyltransferase Increased Hyporeflexia Hypotonia Memory Impairment Myoclonus Visual Disturbance							

Date:11/19/04ISR Number: 4505751-6Report Type:Expedited (15-DaCompany Report #JP-GLAXOSMITHKLINE-B0324744A
Age:65 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Alanine Aminotransferase		Lithium Carbonate	PS	Glaxosmithkline			
UNKNOWN							200MG Per day	
Initial or Prolonged	Increased		Levopromazine	SS				
UNKNOWN							10MG Per day	
Other	Ammonia Abnormal		Phenobarbitone	SS				
INTRAMUSCULAR							200MG Per day	2 DAY
	Anorexia		Chlorpromazine	C	Glaxosmithkline			
UNKNOWN							25MG Per day	
	Aspartate Aminotransferase Increased							
	Blood Alkaline Phosphatase Increased							
	Blood Creatine Phosphokinase Increased							
	Coma							
	Convulsion							
	Diarrhoea							
	Electrocardiogram T Wave Inversion							
	Gait Disturbance							
	Hyporeflexia							
	Hypotonia							
	Medication Error							
	Memory Impairment							
	Myoclonus							
	Therapeutic Agent Toxicity							
	Visual Disturbance							

Date:11/19/04ISR Number: 4505979-5Report Type:Expedited (15-DaCompany Report #PHBS2004JP15202
Age:66 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Convulsion	Health Professional	Ludiomil	PS	Novartis Sector: Pharma	ORAL	25 mg/d	
Initial or Prolonged	Depressed Level Of Consciousness		Lithium Carbonate	SS		ORAL	400 mg/d	

	Mania		Loxoprofen	SS		ORAL 180 mg/d
	Parkinsonism		Fluvoxamine Maleate	C		ORAL 75 mg/d
	Therapeutic Agent Toxicity					

Date:11/19/04ISR Number: 4507368-6Report Type:Expedited (15-DaCompany Report #04-11-1603
Age:40 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Hospitalization - Initial or Prolonged	Dehydration Infection Therapeutic Agent Toxicity Urinary Tract Infection	Health Professional Other	Clozapine - Ivax Pharmaceuticals, Inc. Tablets	PS	Ivax Pharmaceuticals, Inc.	ORAL 25-250MG QD
			Lithium Unknown	SS		ORAL

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/22/04ISR Number: 4506679-8Report Type:Expedited (15-DaCompany Report #US-MERCK-0404USA02196
Age:47 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Agitation		Vioxx	PS	Merck & Co., Inc	ORAL		
Hospitalization -	Anaemia		Altace	SS		ORAL		
Initial or Prolonged	Coordination Abnormal		Aspirin	SS		ORAL		
	Depression		Peg-Intron	SS				
SUBCUTANEOUS							40	DAY
	Drug Level Increased		Lithium Carbonate	SS				
UNKNOWN								
	Drug Toxicity		Lithium Carbonate	SS				
UNKNOWN								
	Haematocrit Decreased		Rebetol	SS		ORAL		
40 DAY								
	Jaundice		Geodon	C		ORAL		
	Mental Status Changes		Zyprexa	C		ORAL		
	Therapeutic Agent		Lexapro	C		ORAL		
	Toxicity		Protonix	C		ORAL		
			Neurontin	C		ORAL		
			Clonazepam	C		ORAL		
			Hydrocodone/Apap	C		ORAL		
			Phenergan Tablets/Suppositories	C		ORAL		

Date:11/22/04ISR Number: 4507058-XReport Type:Expedited (15-DaCompany Report #US-MERCK-0411USA03084
Age:51 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Asthenia		Zocor	PS	Merck & Co., Inc	ORAL		
	Diarrhoea		Combivir	SS		ORAL		
	Drug Interaction		Lithium Carbonate	SS		ORAL		
	Nausea		Zyprexa	SS				
UNKNOWN								
	Therapeutic Agent		Bactrim	SS				
UNKNOWN								
	Toxicity		Sustiva	SS				
UNKNOWN								
	Vomiting		Concerta	SS				
UNKNOWN								

Date:11/22/04ISR Number: 4510323-3Report Type:Direct Company Report #USP 56953
Age:18 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Medication Error		Lithium 300 Mg Er	PS	Barr	TABLET		
	Overdose							

Date:11/22/04ISR Number: 4510436-6Report Type:Expedited (15-DaCompany Report #KII-2004-0013986
Age:45 YR Gender:Male I/FU:I

Outcome	PT
Other	Acidosis
	Blood Alkaline Phosphatase Increased
	Blood Bicarbonate Decreased
	Blood Chloride Increased
	Blood Magnesium Increased
	Blood Pressure Systolic Increased
	Chest Pain
	Cough
	Diabetes Insipidus
	Hypokalaemia
	Multiple Drug Overdose

	Pco2 Decreased Po2 Decreased Somnolence	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	White Blood Cell Count Increased	Study Health Professional Other	Oxycodone Hydrochloride (Similar To Nda 20-553)(Oxycodone Hydrochloride)	PS		ORAL	ORAL
			Olanzapine(Olanzapine)	SS		ORAL	ORAL
			Gabapentin(Gabapentin)	SS		ORAL	ORAL
			Sertraline (Sertraline)	SS		ORAL	ORAL
			Benzodiazepine Derivatives()	SS		ORAL	ORAL
			Lithium (Lithium)	SS		ORAL	ORAL

Date:11/23/04ISR Number: 4507767-2Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20041102397
Age:53 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Anticonvulsant Drug Level		Risperdal	PS		OROPHARINGEAL	1 tablet
	Below Therapeutic		Risperdal	SS		OROPHARINGEAL	2 tablets
	Antipsychotic Drug Level		Risperdal	SS		OROPHARINGEAL	
	Above Therapeutic		Risperdal	SS		OROPHARINGEAL	
	Blood Creatine		Risperdal	SS		OROPHARINGEAL	
	Phosphokinase Mb		Quilonum Retard	SS			
	Increased		Quilonum Retard	SS			

1 tablet	Csf Oligoclonal Band	Quilonum Retard	SS
1 tablet	Present	Quilonum Retard	SS
OROPHARINGEAL	Dehydration	Ergenyl	SS
OROPHARINGEAL	Electrocardiogram Qt	Ergenyl	SS
OROPHARINGEAL	Corrected Interval	Ergenyl	SS
OROPHARINGEAL	Prolonged	Ergenyl	SS
OROPHARINGEAL	Extrapyramidal Disorder	Ergenyl	SS
OROPHARINGEAL	Eyelid Oedema	Ergenyl	SS
OROPHARINGEAL	Fall	Ergenyl	SS
OROPHARINGEAL	Hepatitis	Quilonum Retard	SS
2.5 tablets	Infection	Quilonum Retard	SS
2.5 tablets	Nephropathy Toxic	Quilonum Retard	SS
1.5 tablets		Quilonum Retard	SS
2 tablets		Haldol	SS
OROPHARINGEAL		Risperdal	SS
OROPHARINGEAL		Risperdal	SS
OROPHARINGEAL		Risperdal	SS
OROPHARINGEAL		Haldol	C
INTRAMUSCULAR		Taxilan	C
OROPHARINGEAL		Taxilan	C
OROPHARINGEAL		Diazepam	C
OROPHARINGEAL		Diazepam	C
OROPHARINGEAL		Diazepam	C
OROPHARINGEAL		Diazepam	C
OROPHARINGEAL		Diazepam	C
OROPHARINGEAL		Benalapril	C
OROPHARINGEAL			

OROPHARINGEAL

OROPHARINGEAL

OROPHARINGEAL

1 tablet

Benalapril	C
Thyronajod	C
Thyronajod	C
Kalinor	C
Hydrochlorothiazide	C

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/23/04ISR Number: 4511310-1Report Type:Direct Company Report #CTU 232824
Age:70 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Confusional State		Lithium	PS		ORAL	300 MG TID	
Required Intervention to Prevent Permanent Impairment/Damage	Therapeutic Agent						ORAL	
	Toxicity		Citalopram Hydrobromide	C				
			Temazepam	C				
			Trazodone Hcl	C				
			Alprazolam	C				
			Gabapentin (Neurontin)	C				
			Ferrous Gluconate	C				
			Nitroglycerin Patch	C				
			Asprin	C				
			Albuterol/Ipratropium Inhl	C				

Date:11/23/04ISR Number: 4511661-0Report Type:Direct Company Report #CTU 232840
Age:54 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Antipsychotic Drug Level Increased		Lithium	PS		ORAL	450 MG BID	
	Asthenia		Disulfiram	C				
	Blood Creatinine Increased		Benztropine	C				
			Nifedipine	C				
	Dehydration		Glucovance	C				
	Diarrhoea		Benazepril	C				
	Dysarthria		Haloperidol	C				
	Haemodialysis		Risperidone	C				
	Loss Of Consciousness		Atorvastatin	C				
	Pain		Hydrochlorothiazide	C				

Date:11/23/04ISR Number: 4511922-5Report Type:Expedited (15-DaCompany Report #2004-BP-11414RO
Age:57 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Consumer	Lithium Carbonate	PS		ORAL	300 MG BID	
	Drowning						(300 MG, 2 IN	
	Intervertebral Disc						1 D), PO	
	Operation		Dexamethasone					
	Psychotic Disorder		(Dexamethasone)	SS		ORAL	TAPER: 32,	
							16, 8, 4MG	
							OVER 4 D	
							(4MG), PO	
			Sonata (Zaleplon)	C				
			Ambien (Zolpidem Tartrate)	C				

Date:11/23/04ISR Number: 4512025-6Report Type:Expedited (15-DaCompany Report #2004UW23235
Age:60 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Dizziness	Health	Seroquel	PS			75 MG	
	Fall	Professional	Lamictal Glaxo Wellcome	SS	Glaxo Wellcome	ORAL	100 MG PO	
			Lithium Salt	SS			900 MG	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/23/04ISR Number: 4512070-0Report Type:Expedited (15-DaCompany Report #2004079254
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Magnesium Decreased	Health Professional	Geodon (Ziprasidone)	PS				
	Blood Potassium Decreased		Lithium (Lithium)	SS				
Other	Cardiomyopathy		Fluconazole (Fluconazole0	SS				
	Electrocardiogram Qt Corrected Interval Prolonged							
	Electrocardiogram St-T Change							
	Electrolyte Imbalance							
	Therapeutic Agent Toxicity							
	Torsade De Pointes							

Date:11/24/04ISR Number: 4509711-0Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20041102397
Age:53 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anticonvulsant Drug Level		Risperdal	PS		OROPHARINGEAL		
	Below Therapeutic		Risperdal	SS		OROPHARINGEAL		
	Antipsychotic Drug Level		Risperdal	SS		OROPHARINGEAL		
	Above Therapeutic		Risperdal	SS		OROPHARINGEAL		
	Blood Creatine		Risperdal	SS		OROPHARINGEAL		
	Phosphokinase Mb		Quilonum Retard	SS			1 tablet	
	Increased		Quilonum Retard	SS			2 tablets	
	Csf Oligoclonal Band		Quilonum Retard	SS			1 tablet	
	Present		Quilonum Retard	SS			1 tablet	
	Dehydration		Ergenyl	SS		OROPHARINGEAL		
	Electrocardiogram Qt		Ergenyl	SS		OROPHARINGEAL		

OROPHARINGEAL	Corrected Interval	Ergenyl	SS
OROPHARINGEAL	Prolonged	Ergenyl	SS
OROPHARINGEAL	Extrapyramidal Disorder	Ergenyl	SS
OROPHARINGEAL	Eyelid Oedema	Ergenyl	SS
OROPHARINGEAL	Fall	Ergenyl	SS
2.5 tablets	Hepatitis	Quilonum Retard	SS
2.5 tablets	Infection	Quilonum Retard	SS
1.5 tablets	Lumbar Puncture Abnormal	Quilonum Retard	SS
2 tablets	Nephropathy Toxic	Quilonum Retard	SS
OROPHARINGEAL		Haldol	SS
OROPHARINGEAL		Risperdal	SS
OROPHARINGEAL		Risperdal	SS
OROPHARINGEAL		Risperdal	SS
INTRAMUSCULAR		Haldol	C
OROPHARINGEAL		Taxilan	C
OROPHARINGEAL		Taxilan	C
OROPHARINGEAL		Diazepam	C
OROPHARINGEAL		Diazepam	C
OROPHARINGEAL		Diazepam	C
OROPHARINGEAL		Diazepam	C
OROPHARINGEAL		Diazepam	C
OROPHARINGEAL		Benalapril	C
OROPHARINGEAL		Benalapril	C
OROPHARINGEAL		Thyronajod	C
OROPHARINGEAL		Thyronajod	C
OROPHARINGEAL		Kalinor	C
1 tablet		Hydrochlorothiazide	C

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/24/04ISR Number: 4509837-1Report Type:Expedited (15-DaCompany Report #PHBS2004JP15202
Age:66 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abnormal Behaviour		Ludiomil	PS	Novartis Sector: Pharma	ORAL	25 mg/d	
	Antipsychotic Drug Level Above Therapeutic		Ludiomil	SS	Novartis Sector: Pharma	ORAL	12.5-25 mg/day	
	Apathy		Lithium Carbonate	SS		ORAL	400 mg/d	
	Blood Creatinine Increased		Loxoprofen	SS		ORAL	180 mg/d	
	Blood Thyroid Stimulating Hormone Increased		Fluvoxamine Maleate	C		ORAL	75 mg/d	
	Blood Urea Increased		Phenobarbital	C			180 mg/day	
	Bradykinesia		Zonisamide	C			200 mg/day	
	Cerebellar Atrophy							
	Cerebellar Syndrome							
	Convulsion							
	Dementia							
	Depressed Level Of Consciousness							
	Depression							
	Difficulty In Walking							
	Disorientation							
	Disturbance In Attention							
	Drug Interaction							
	Dysstasia							
	Electroencephalogram Abnormal							
	Hypothyroidism							
	Insomnia							
	Mania							
	Masked Facies							
	Memory Impairment							
	Muscle Rigidity							
	Nuclear Magnetic Resonance Imaging Brain Abnormal							
	Parkinsonism							

	Postoperative Infection
	Somnolence
	Therapeutic Agent
	Toxicity
	Tremor

Date:11/24/04ISR Number: 4511761-5Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20041102397
Age:53 YR Gender:Male I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Alanine Aminotransferase Increased
	Aspartate Aminotransferase Increased
	Blood Creatine Phosphokinase Mb Increased
	Dehydration
	Drug Level Decreased
	Electrocardiogram Abnormal
	Electrocardiogram Qt

Corrected Interval Prolonged Extrapyramidal Disorder Eyelid Oedema	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Fall		Risperdal	PS		OROPHARINGEAL	
Hepatitis		Risperdal	SS		OROPHARINGEAL	
Infection		Risperdal	SS		OROPHARINGEAL	
Nephropathy Toxic		Risperdal	SS		OROPHARINGEAL	
Oedema Peripheral		Risperdal	SS		OROPHARINGEAL	
Qrs Axis Abnormal		Quilonum Retard	SS		1 tablet	
		Quilonum Retard	SS		2 tablets	
		Quilonum Retard	SS		1 tablet	
		Quilonum Retard	SS		1 tablet	
		Ergenyl	SS		OROPHARINGEAL	
		Ergenyl	SS		OROPHARINGEAL	
		Ergenyl	SS		OROPHARINGEAL	
		Ergenyl	SS		OROPHARINGEAL	
		Ergenyl	SS		OROPHARINGEAL	
		Ergenyl	SS		OROPHARINGEAL	
		Ergenyl	SS		OROPHARINGEAL	
		Quilonum Retard	SS		2.5 tablets	
		Quilonum Retard	SS		2.5 tablets	
		Quilonum Retard	SS		1.5 tablets	
		Quilonum Retard	SS		2 tablets	
		Haldol	SS		OROPHARINGEAL	

			Risperdal	SS		
OROPHARINGEAL						
			Risperdal	SS		
OROPHARINGEAL						
			Risperdal	SS		
OROPHARINGEAL						
			Haldol	C		
INTRAMUSCULAR						
			Taxilan	C		
OROPHARINGEAL						
			Taxilan	C		
OROPHARINGEAL						
			Diazepam	C		
OROPHARINGEAL						
			Diazepam	C		
OROPHARINGEAL						
			Diazepam	C		
OROPHARINGEAL						
			Diazepam	C		
OROPHARINGEAL						
			Diazepam	C		
OROPHARINGEAL						
			Benalapril	C		
OROPHARINGEAL						
			Benalapril	C		
OROPHARINGEAL						
			Thyronajod	C		
OROPHARINGEAL						
			Thyronajod	C		
OROPHARINGEAL						
			Kalinor	C		
1 tablet						
			Hydrochlorothiazide	C		

Date:11/24/04ISR Number: 4514142-3Report Type:Expedited (15-DaCompany Report #2004AP05725
Age:40 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Dry Mouth	Foreign	Omeprazole	PS		ORAL	40 MG DAILY	
Initial or Prolonged	Dysphagia	Health					PO	
	Oesophageal Candidiasis	Professional	Benztropine Mesylate	SS		ORAL	2 MG DAILY PO	
	Reflux Oesophagitis	Other	Lithium Carbonate	SS		ORAL	750 MG DAILY	
							PO	
			Thyroxine Sodium	SS		ORAL	1 DF DAILY PO	

	Amisulpride	SS	ORAL
800 MG DAILY			
PO			
	Imipramine Hydrochloride	SS	ORAL
200 MG DAILY			
PO			

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/26/04ISR Number: 4514664-5Report Type:Expedited (15-DaCompany Report #S04-FRA-04095-01
Age:40 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Asphyxia	Foreign	Seropram (Citalopram Hydrobromide)	PS				
	Drug Interaction	Health	Teralithe (Lithium Carbonate)	SS				
	Drug Screen Positive	Professional	Prothiaden (Dosulepin)	SS				
	Foreign Body Trauma	Other	Nordazepam	C				
	Hepatic Steatosis							
	Myocardial Fibrosis							
	Overdose							
	Pulmonary Embolism							
	Pulmonary Oedema							

Date:11/26/04ISR Number: 4515369-7Report Type:Expedited (15-DaCompany Report #2004093169
Age:55 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blood Sodium Decreased	Consumer	Geodon (Ziprasidone)	PS		ORAL	80 MG (40 MG, 2 IN 1 D), ORAL	
	Bruxism							
	Fatigue							
	Loss Of Consciousness		Lithium (Lithium)	SS		ORAL	ORAL	
	Road Traffic Accident		Diazepam (Diazepam)	C				
	Somnolence		Oxcarbazepine (Oxcarbazepine)	C				
	Speech Disorder		Metformin Hydrochloride (Metformin Hydrochloride)	C				
	Tongue Biting		Glipizide (Glipizide)	C				
	Tongue Disorder		Pantoprazole (Pantoprazole)	C				
	Tremor		Trihexyphenidyl (Trihexyphenidyl)	C				
			Procyclidine Hydrochloride (Procyclidine Hydrochloride)	C				

Novolin 20/80 (Insulin Human, Insulin Isophane, Human Biosynthetic)	C
Acetylsalicylic Acid (Acetylsalicylic Acid)	C

Date:11/26/04ISR Number: 4515470-8Report Type:Expedited (15-DaCompany Report #2004092981
Age:55 YR Gender:Male I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Back Pain
Other	Delusion Of Grandeur
	Depression
	Drug Interaction
	Flight Of Ideas
	Haemodialysis
	Hyperkinesia
	Logorrhoea
	Male Sexual Dysfunction

		Mania Movement Disorder Pain	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
		Rhabdomyolysis Sleep Disorder	Foreign Literature	Lipitor(Atorvastatin)	PS		ORAL
ORAL							
			Health Professional	Lithium (Lithium Carbonate) (Lithium)	SS		ORAL
600 MG ORAL							
				Chlorpromazine Hydrochloride (Chlorpromazine Hydrochloride)	SS		ORAL
125 MG ORAL							
				Antipsychotics (Antipsychotics)	SS		
				All Other Therapeutic Products (All Other Therapeutic Products)	SS		
				Valproate Sodium (Valproate Sodium)	C		
				Levomepromazine Maleate(Levomepromaz ine Maleate)	C		
				Olanzapine (Olanzapine)	C		
				Clonazepam (Clonazepam)	C		
				Risperidone (Risperidone)	C		

Date:12/01/04ISR Number: 4515462-9Report Type:Expedited (15-DaCompany Report #PHBS2004JP15202
Age:66 YR Gender:Male I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Abnormal Behaviour Apathy Blood Creatinine Increased Blood Thyroid Stimulating Hormone Increased Blood Urea Increased

Bradykinesia
Cerebellar Syndrome
Convulsion
Dementia
Depressed Level Of Consciousness
Difficulty In Walking
Disorientation
Disturbance In Attention
Drug Interaction
Dysstasia
Electroencephalogram Abnormal
Hypothyroidism
Insomnia
Mania
Masked Facies
Memory Impairment
Muscle Rigidity

	Nuclear Magnetic Resonance Imaging Brain Abnormal Parkinsonism Somnolence Therapeutic Agent Toxicity Tremor	Report Source	Product Maprotiline Hydrochloride Lithium Carbonate Loxoprofen Maprotiline Hydrochloride Fluvoxamine Maleate Phenobarbital Zonisamide	Role PS SS SS SS C C C	Manufacturer Novartis Sector: Pharma Novartis Sector: Pharma	Route ORAL ORAL ORAL ORAL ORAL
Dose 25 mg/d 400 mg/d 180 mg/d 12.5-25 mg/day 75 mg/d 180 mg/day 200 mg/day	Duration					

Date:12/01/04ISR Number: 4518702-5Report Type:Expedited (15-DaCompany Report #FRWYE227123NOV04
Age:76 YR Gender:Female I/FU:I

Outcome Hospitalization - Initial or Prolonged Other	PT Akinesia Antipsychotic Drug Level Above Therapeutic Confusional State Drug Interaction Electrocardiogram Repolarisation Abnormality Hypertension Myoclonus Systolic Hypertension	Report Source Foreign Health Professional Other	Product Effexor (Venlafaxine Hydrochloride, Tablet, 0) Teralithe (Lithium Carbonate, , 0) Imovane (Zopiclone) Levothyrox (Levothyroxine Sodium)	Role PS SS C C	Manufacturer	Route ORAL ORAL
Dose 100 MG DAILY AND THEN 150 MG DAILY ORAL SEE IMAGE	Duration					

	Tachycardia					
	Tremor					
	Vertigo					

Date:12/02/04ISR Number: 4518398-2Report Type:Expedited (15-DaCompany Report #FRWYE227123NOV04
Age:76 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Akinesia	Health Professional	Effexor (Venlafaxine Hydrochloride					
Other	Antipsychotic Drug Level Above Therapeutic	Other	Tablet)	PS		ORAL	100 MG DAILY	
	Confusional State						AND THYEN 150	
	Drug Interaction						MG DAILY	
	Electrocardiogram Repolarisation Abnormality		Teralithe (Lithium Carbonate)	SS		ORAL	SEE IMAGE	
	Myoclonus		Imovane (Zopiclone)	C				
	Systolic Hypertension		Levothyrox (Levothyroxine Sodium)	C				
	Tachycardia							
	Tremor							
	Vertigo							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/02/04ISR Number: 4533910-5Report Type:Periodic Company Report #269121
Age:41 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Cognitive Disorder	Consumer	Valium (Diazepam)	PS		ORAL		
	Dizziness		Klonopin					
	Drug Withdrawal Syndrome		(Clonazepam)	SS		ORAL		
	Libido Decreased		Lithium (Lithium					
	Sexual Dysfunction		Nos)	SS				

Date:12/03/04ISR Number: 4518295-2Report Type:Expedited (15-DaCompany Report #FR-ABBOTT-04P-056-0275099-00
Age:48 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Agitation		Depakote Tablets	PS		ORAL		
Hospitalization -	Anorexia		Depakote Tablets	SS				
Initial or Prolonged	Aphasia		Lithium Carbonate	SS		ORAL		
	Blood Creatinine		Olanzapine	SS		ORAL		
	Increased		Olanzapine	SS				
	Blood Glucose Increased							
	Confusional State							
	Disturbance In Attention							
	General Physical Health							
	Deterioration							
	Hypernatraemia							
	Mutism							
	Nephrogenic Diabetes							
	Insipidus							
	Pyrexia							
	Tremor							
	Urinary Incontinence							

Date:12/03/04ISR Number: 4520447-2Report Type:Expedited (15-DaCompany Report #2004-BP-11825RO
Age:51 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Drug Level Decreased	Consumer	Lithium Carbonate					
Initial or Prolonged	Mania		Capsules Usp, 300 Mg					

	Pharmaceutical Product	(Lithium Carbonate)	PS	ORAL

1500 MG QHS
Complaint
(300 MG, 5 IN

1 D), PO

	Seroquel (Quetiapine Fumarate)	C
	Synthroid (Levothyroxine Sodium)	C
	Iron (Iron)	C
	Multivitamins (Multivitamins)	C

Date:12/03/04ISR Number: 4520508-8Report Type:Expedited (15-DaCompany Report #2004009355
Age: Gender:Male I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Abdominal Pain
Other	Cardiac Disorder
	Chest Pain
	Chills
	Condition Aggravated

	Drug Tolerance Decreased Erectile Dysfunction Facial Pain Feeling Cold General Physical Health Deterioration Gingival Pain Glossodynia Neck Pain Oesophageal Spasm Pain In Jaw Sleep Disorder Tooth Abscess Tremor	Report Source Consumer Health Professional	Product Neurontin (Gabapentin) Lipitor (Atorvastatin) Lithium (Lithium) (Lithium) Naproxen (Naproxen) Rofecoxib (Rofecoxib) Amoxicillin (Amoxicillin) All Other Therapeutic Products (All Other Therapeutic Products) Levothyroxine Sodium (Levothyroxine Sodium) Vitamins (Vitamins) Diltiazem Hydrochloride (Diltiazem Hydrochloride)	Role PS SS SS SS SS C C C C	Manufacturer	Route ORAL ORAL ORAL

Dose Duration
1800 MG (TID), ORAL
20 MG (DAILY), ORAL
1000 MG (BID), ORAL

Date:12/03/04ISR Number: 4521102-5Report Type:Expedited (15-DaCompany Report #FRWYE227123NOV04
Age:76 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - Initial or Prolonged	Akinesia Antipsychotic Drug Level	Health Professional	Effexor (Venlafaxine Hydrochloride,			

Dose Duration

Other	Above Therapeutic	Other	Tablet, 0)	PS		ORAL
50 MG 3X PER						
	Anxiety					
1 DAY						
	Confusional State		Tertraline (Lithium			
	Drug Interaction		Carbonate,, 0)	SS		ORAL
SEE IMAGE						
	Electrocardiogram		Imovane (Zopiclone)	C		
	Repolarisation		Levothyrox			
	Abnormality		(Levothyroxine			
	Hypomania		Sodium)	C		
	Myoclonus					
	Panic Attack					
	Systolic Hypertension					
	Tachycardia					
	Tremor					
	Vertigo					

Date:12/06/04ISR Number: 4519331-XReport Type:Expedited (15-DaCompany Report #JP-GLAXOSMITHKLINE-B0358923A
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Serotonin Syndrome		Paxil	PS	Glaxosmithkline	ORAL
40MG Per day 17 WK						
Initial or Prolonged			Limas	SS	Glaxosmithkline	ORAL
400MG Per day						

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/06/04ISR Number: 4520434-4Report Type:Expedited (15-DaCompany Report #FRWYE227123NOV04
Age:76 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged Other	Akinesia Antipsychotic Drug Level Above Therapeutic Confusional State Drug Interaction Electrocardiogram Repolarisation Abnormality Myoclonus Systolic Hypertension Tachycardia Tremor Vertigo	Foreign Health Professional Other	Effexor (Venlafaxine Hydrochloride, Tablet, 0) Teralithe (Lithium Carbonate, , 0) Imovane (Zopiclone) Levothyrox (Levothyroxine Sodium)	PS SS C C		ORAL ORAL	50 MG 3X PER 1 DAY SEE IMAGE

Date:12/06/04ISR Number: 4520904-9Report Type:Expedited (15-DaCompany Report #L04-USA-07403-33
Age:58 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Death	Completed Suicide Intentional Misuse	Literature Health Professional	Citalopram (Citalopram) Lithium (Lithium) Nortriptyline	PS SS SS			

Date:12/06/04ISR Number: 4520982-7Report Type:Expedited (15-DaCompany Report #2003033768
Age:80 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Death Hospitalization - Initial or Prolonged	Bipolar I Disorder Blood Calcium Increased Blood Creatinine Increased	Foreign Health Professional	Lithium (Lithium) Glibenclamide (Glibenclamide) Metformin	PS SS		ORAL ORAL	ORAL

	Condition Aggravated	Hydrochloride	
	Hyperglycaemia	(Metformin	
	Hypoglycaemia	Hydrochloride)	C
	Non-Hodgkin'S Lymphoma	Dipyridamole	
	Overdose	(Dipyridamole)	C
	Therapeutic Agent	Furosemide	
	Toxicity	(Furosemide)	C
		Cyanocobalamin	
		(Cyanocobalamin)	C
		Morphine (Morphine)	C

Date:12/07/04ISR Number: 4519767-7Report Type:Expedited (15-DaCompany Report #PHRM2004FR03234
Age:58 YR Gender:Female I/FU:F

Outcome	PT
Hospitalization -	Anorexia
Initial or Prolonged	Antipsychotic Drug Level
	Above Therapeutic
	Balance Disorder
	Confusional State
	Disorientation
	Disturbance In Attention
	Drug Interaction
	Dysarthria

	Medical Diet						
	Tremor						
	Vertigo	Report Source	Product	Role	Manufacturer	Route	Dose Duration
			Trileptal	PS	Novartis Sector: Pharma	ORAL	UNK, UNK
			Mepronizine	SS			
			Teralithe	SS		ORAL	600 mg daily
			Seresta	C			
			Soprol	C			

Date:12/07/04ISR Number: 4519928-7Report Type:Expedited (15-DaCompany Report #GB-ROCHE-387448
Age:15 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Agitation		Clonazepam	PS	Roche	ORAL	47 DAY
Initial or Prolonged	Blood Potassium Decreased		Clozaril	SS		ORAL	68 DAY
	Blood Pressure Decreased		Lithium	SS		ORAL	
	Blood Urea Decreased						
	Fatigue						
	Grand Mal Convulsion						
	Malaise						
	Mycoplasma Infection						
	Psychotic Disorder						
	Therapeutic Agent						
	Toxicity						
	Viral Infection						

Date:12/07/04ISR Number: 4521973-2Report Type:Direct Company Report #CTU 233813
Age:47 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Antipsychotic Drug Level Increased		Lithium 450mg	PS		ORAL	450MG AMHS ORAL

Date:12/09/04ISR Number: 4522354-8Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-B0314536A
Age:30 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Cerebral Atrophy		Lithium	PS	Glaxosmithkline		450MG Twice per day	
	Confusional State							
	Delirium		Risperidone	SS			UNKNOWN	
	Delusion		Olanzapine	C			UNKNOWN	
	Hallucination		Divalproex	C				
	Hallucination, Auditory							
	Hypertension							
	Hyperthermia							
	Insomnia							
	Muscle Contractions Involuntary							
	Muscle Rigidity							
	Neuroleptic Malignant Syndrome							
	Speech Disorder							
	Tachycardia							
	Tremor							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/09/04ISR Number: 4524065-1Report Type:Expedited (15-DaCompany Report #2004014761
Age:58 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Hospitalization -	Alanine Aminotransferase Increased	Foreign Health	Lipitor (Atorvastatin)	PS		ORAL	10 MG (1 IN 1 D), ORAL	Initial or Prolonged
Other	Anuria	Professional						
	Blood Cholesterol Increased		Valproate Sodium (Valproate Sodium)	SS		ORAL	800 MG (1 IN 1 D), ORAL	
	Blood Glucose Increased							
	Blood Triglycerides Increased		Lithium Carbonate (Lithium Carbonate)	SS		ORAL	600 MG (1 IN 1 D), ORAL	
	Differential White Blood Cell Count Abnormal		Levomepromazine (Levomepromazine)	SS		ORAL	25 MG (1 IN 1 D), ORAL	
	Disease Recurrence							
	Drug Interaction							
	Gamma-Glutamyltransferase Increased		Chlorpromazine (Chlorpromazine)	SS		ORAL	125 MG (1 IN 1 D), ORAL	
	Haemodialysis							
	Movement Disorder		Risperidone (Risperidone)	C				
	Overdose		Flunitrazepam (Flunitrazepam)	C				
	Renal Failure Acute		Zopiclone (Zopiclone)	C				
	Rhabdomyolysis		Estazolam (Estazolam)	C				
	Sensory Loss		Etizolam (Etizolam)	C				
	White Blood Cell Count Increased		Olanzapine (Olanzapine)	C				
			Clonazepam (Clonazepam)	C				
			Senna Leaf (Senna Leaf)	C				
			Amlodipine Besilate (Amlodipine					

Besilate)	C
Maprotiline Hydrochloride (Maprotiline Hydrochloride)	C
Sulpiride (Sulpiride)	C
Vegetamin (Chlorpromazine Hydrochloride, Phenobarbital, Promethazine	C
Magnesium Oxide (Magnesium Oxide)	C
Nitrazepam (Nitrazepam)	C
Bethanechol Chloride (Bethanechol Chloride)	C
Clonazepam (Clonazepam)	C
Beclometasone Dipropionate (Beclometasone Dipropionate)	C
Fenoterol	

Hydrobromide (Fenoterol Hydrobromide)	C
Latanoprost (Latanoprost)	C

Date:12/13/04ISR Number: 4525399-7Report Type:Expedited (15-DaCompany Report #PHFR2004GB03786
Age:15 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agitation		Lithium	PS	Glaxosmithkline	UNKNOWN	1400MG per day	
	Blood Potassium Decreased							
	Blood Pressure Decreased		Clozaril	SS		ORAL	200MG per day	68 DAY
	Blood Urea Decreased		Clonazepam	SS		ORAL	2MG per day	47 DAY
	C-Reactive Protein Increased							
	Fatigue							
	Grand Mal Convulsion							
	Malaise							
	Mycoplasma Infection							
	Neutrophil Count Decreased							
	Platelet Count Increased							
	Psychotic Disorder							
	Pyrexia							
	Rebound Effect							
	Red Blood Cell Sedimentation Rate Increased							
	Therapeutic Agent Toxicity							
	Viral Infection							
	White Blood Cell Count Decreased							

Date:12/13/04ISR Number: 4526681-XReport Type:Expedited (15-DaCompany Report #04US000538
Age:10 YR Gender:Male I/FU:I

Outcome	PT

Hospitalization - Initial or Prolonged	Abdominal Pain
Other	Antipsychotic Drug Level Below Therapeutic
	Atrioventricular Block First Degree
	Conduction Disorder
	Diarrhoea
	Disorientation
	Dizziness
	Electrocardiogram Qrs Complex Prolonged
	Hypotension
	Mania
	Oral Intake Reduced
	Pallor
	Therapeutic Agent Toxicity
	Ventricular Extrasystoles
	Ventricular Tachycardia
	Vomiting
	White Blood Cell Count

		Increased					
			Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
			Literature	Lithium Carbonate			
			Health	(Lithium Carbonate)			
			Professional	Tablet	PS		
600 MG, BID							
				Methylphenidate	C		
				Escitalopram	C		
				Oxacarbazine	C		
				Depakote (Valproate Semisodium)	C		
				Levothyroxine	C		
				Clonidine	C		

Date:12/13/04ISR Number: 4526734-6Report Type:Expedited (15-DaCompany Report #2004101239
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization -	Bone Disorder	Consumer	Geodon (Ziprasidone)	PS		
SEE IMAGE						
Initial or Prolonged	Dyspepsia		Lithium (Lithium)	SS		ORAL
ORAL						
	Oesophageal Pain					
	Pollakiuria					
	Stress					
	Tooth Disorder					

Date:12/14/04ISR Number: 4528959-2Report Type:Expedited (15-DaCompany Report #B0358690A
Age:53 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization -	Abnormal Behaviour	Literature	Lithium Salt			
Initial or Prolonged	Agitation	Health	(Formulation			
	Ammonia Increased	Professional	Unknown) (Lithium			
	Anaemia Macrocytic		Salt)	PS		
300 MG/ TWICE						
	Circadian Rhythm Sleep					
PER DAY						
	Disorder		Carbamazepine	C		

	Cognitive Disorder	Phenytoin	C
	Condition Aggravated	Quetiapine	C
	Confusional State	Fluticasone	
	Delirium	Propionate	C
	Disorientation		
	Electroencephalogram		
	Abnormal		
	Hallucination		
	Mania		
	Nervous System Disorder		
	Therapeutic Agent		
	Toxicity		
	Thrombocytopenia		

Date:12/15/04ISR Number: 4530067-1Report Type:Expedited (15-DaCompany Report #2004105159
Age: Gender:Female I/FU:I

Outcome	PT
Other	Fatigue
	Gynaecomastia
	Haemodialysis
	Hepatic Function Abnormal
	Hyperhidrosis

Pneumonia

		Report Source	Product	Role	Manufacturer	Route	Dose	Duration
		Health Professional	Lithium (Lithium)	PS				
			Zoloft (Sertraline)	SS		ORAL	200 MG (100 MG, 2 IN 1 D), ORAL	
			Valproate Semisodium (Valproate Semisodium)	SS				

Date:12/15/04ISR Number: 4530181-0Report Type:Direct Company Report #CTU 234389
Age:58 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Disability Required Intervention to Prevent Permanent Impairment/Damage	Abasia Arrhythmia Asthenia Balance Disorder Blood Pressure Increased Dysarthria Nephrogenic Diabetes Insipidus Polyuria Renal Failure Acute Tremor		Lithium 450mg Er Ritalin Glucotrol Diovan Ditropan Xl Centrum Mvi Kcl Zyprex Lipitor Effexor Femhrt	PS C C C C C C C C C C		ORAL	450MG ER BID-1,2- ORAL	

Date:12/16/04ISR Number: 4528685-XReport Type:Expedited (15-DaCompany Report #CA-JNJFOC-20041005317
Age:26 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Hospitalization - Initial or Prolonged	Bipolar Disorder Confusional State		Topamax Topamax	PS SS				

Initial or Prolonged	Disturbance In Attention		
on Day 39			
Other	Drug Interaction		
posthospitali			
	Lethargy		
zation.			
	Mania	Topamax	SS
Dose started			
	Refusal Of Treatment By		
on Day 32			
	Patient		
posthospitali			
	Therapeutic Agent		
zation.			
	Toxicity	Valproate	C
		Clonazepam	C
		Lithium	I
Dose started			
on Day 19			
posthospitali			
zation.			
		Lithium	I
Dose started			
on Day 8			
posthospitali			
zation.			
		Lithium	I

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/16/04ISR Number: 4531458-5Report Type:Expedited (15-DaCompany Report #PERC20040072
Age:31 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Blood Ph Decreased	Literature	Percocet	PS		ORAL	PO	
Life-Threatening	Coma	Health	Clonidine	SS		ORAL	PO	
Hospitalization - Initial or Prolonged	Completed Suicide	Professional	Benzodiazepine	SS		ORAL		
	Hepatic Failure		Hydromorphone	SS		ORAL	PO	
Required Intervention to Prevent Permanent Impairment/Damage	Hepatotoxicity		Lithium	SS		ORAL	PO	
	Intentional Misuse							
	International Normalised Ratio Increased							
	Loss Of Consciousness							

Date:12/17/04ISR Number: 4531984-9Report Type:Expedited (15-DaCompany Report #02100-JPN-04-0336
Age:73 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Hepatic Function Abnormal	Health	Cilostazol, Ticlopidine Hydrochloride, Lithium Carbonate	PS		ORAL	200 MG; ORAL	1 WK
	Renal Failure Acute	Professional	Ticlopidine Hydrochloride	SS		ORAL	200 MG; ORAL	31 DAY
			Lithium Carbonate	SS		ORAL	NI; ORAL	

Date:12/20/04ISR Number: 4536543-XReport Type:Expedited (15-DaCompany Report #2004079254
Age:28 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Agitation	Health	Geodon (Ziprasidone)	PS		ORAL	80 MG (2 IN 1	

Initial or Prolonged D), ORAL	Anaemia	Professional				
Other	Blood Magnesium Decreased		Fluconazole			
	Blood Potassium Decreased		(Fluconazole)	SS		ORAL 100 MG (1 IN
	Bradycardia					1 D), ORAL
	Candiduria		Lithium Carbonate			
	Electrocardiogram Qt		(Lithium Carbonate)	SS		
	Corrected Interval		Escitalopram			
	Prolonged		(Escitalopram)	SS		ORAL 15 MG, 1 IN 1
	Electrolyte Imbalance					D, ORAL
	Myocardial Infarction		Topiramate			
	Myocardial Ischaemia		(Topiramate)	SS		ORAL 100 MG, 1 IN
	Therapeutic Agent					1 D, ORAL
	Toxicity		Loratadine			
	Torsade De Pointes		(Loratadine)	SS		ORAL 10 MG, 1 IN 1
	Urinary Tract Infection					D, ORAL
	Ventricular Tachycardia		Lansoprazole (Lansoprazole)	C		
			All Other Therapeutic Products (All Other Therapeutic Products)	C		
			Clonazepam (Clonazepam)	C		
			Olanzapine (Olanzapine)	C		
			Levetiracetam (Levetiracetam)	C		
			Ciprofloxacin			

			(Ciprofloxacin)	C		
			Trazodone (Trazodone)	C		
			Metoprolol (Metoprolol)	C		
			Levothyroxine Sodium (Levothyroxine Sodium)	C		
			Prednisone (Prednisone)	C		

Date:12/20/04ISR Number: 4536596-9Report Type:Expedited (15-DaCompany Report #2004108025
Age:59 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain Upper Depression	Consumer	Phenelzine Sulfate (Phenelzine Sulfate)	PS		ORAL	15 MG, ORAL	
	Dizziness		Lithium (Lithium)	SS		ORAL	ORAL	
	Drug Ineffective Drug Withdrawal Syndrome Feeling Abnormal Feeling Jittery Headache Lethargy Somnolence		Xanax Xr (Alprazolam) All Other Therapeutic Products (All Other Therapeutic Products)	C C				

Date:12/21/04ISR Number: 4533283-8Report Type:Expedited (15-DaCompany Report #PHBS2004US16877
Age:54 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Neutropenia Obstructive Uropathy Renal Failure Acute White Blood Cell Count Decreased		Clozapine Lithium Divalproex Sodium	PS SS SS	Novartis Sector: Pharma			

Date:12/21/04ISR Number: 4537851-9Report Type:Expedited (15-DaCompany Report #MK200412-0146-1
Age:25 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Death	Completed Suicide	Literature	Tramadol			
	Multiple Drug Overdose	Health	Hydrochloride	PS		
		Professional	Lithium	SS		
			Tramadol/Acetaminoph			
			en	SS		

Date:12/21/04ISR Number: 4537876-3Report Type:Expedited (15-DaCompany Report #MK200412-0167-1
Age:58 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Death	Completed Suicide	Literature	Pamelor	PS		
	Multiple Drug Overdose	Health	Lithium	SS		
		Professional	Citalopram	SS		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/21/04ISR Number: 4538076-3Report Type:Expedited (15-DaCompany Report #2003033768
Age:80 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Bipolar I Disorder	Foreign	Lithium (Lithium)	PS		ORAL		
Hospitalization - Initial or Prolonged	Blood Calcium Increased Blood Creatinine Increased Condition Aggravated Hyperglycaemia Hypoglycaemia Non-Hodgkin'S Lymphoma Overdose Therapeutic Agent Toxicity	Health Professional	Glibenclamide (Glibenclamide) Metformin Hydrochloride (Metformin Hydrochloride) Dipyridamole (Dipyridamole) Furosemide (Furosemide) Cyanocobalamin (Cyanocobalamin) Morphine (Morphine)	SS C C C C		ORAL		

Date:12/22/04ISR Number: 4539058-8Report Type:Expedited (15-DaCompany Report #2004009355
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Abdominal Pain Back Pain Chest Pain Erectile Dysfunction Facial Pain Feeling Cold Gastrooesophageal Reflux Disease Gingival Pain Glossodynia Hypersomnia Irritability Nasopharyngitis	Consumer Health Professional	Neurontin (Gabapentin) Lipitor (Atorvastatin) Lithium (Lithium) (Lithium) Naproxen (Naproxen) Rofecoxib (Rofecoxib) Amoxicillin	PS SS SS SS		ORAL ORAL	1800 MG (600 MG, 3 IN 1 D), ORAL 20 MG (DAILY), ORAL	

	Neck Pain	(Amoxicillin)	SS	ORAL 1000 MG
	Nervous System Disorder			(BID), ORAL
	Oesophageal Spasm	Levothyroxine Sodium		
	Pain In Jaw	(Levothyroxine		
	Sleep Disorder	Sodium)	C	
	Somnolence	Vitamins (Vitamins)	C	
	Tooth Abscess	Diltiazem		
	Treatment Noncompliance	Hydrochloride		
	Tremor	(Diltiazem		
		Hydrochloride)	C	

Date:12/23/04ISR Number: 4536873-1Report Type:Expedited (15-DaCompany Report #JP-GLAXOSMITHKLINE-B0358923A
Age:74 YR Gender:Female I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	C-Reactive Protein Increased
	Dehydration
	Depressed Level Of Consciousness
	Diarrhoea
	Drug Level Increased
	Fall
	Hyperhidrosis

		Hyperreflexia Incontinence Pyrexia	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
		Serotonin Syndrome		Paxil	PS	Glaxosmithkline	ORAL
		Tremor		Limas	SS	Glaxosmithkline	ORAL
		White Blood Cells Urine Positive					

Date:12/27/04ISR Number: 4539173-9Report Type:Direct Company Report #CTU 235129E
Age:15 YR Gender:Female I/FU:I

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Hospitalization - Initial or Prolonged		Abdominal Pain Asthenia Hepatic Enzyme Increased Vomiting		Strattera Lithium	PS SS		

Date:12/28/04ISR Number: 4541026-7Report Type:Expedited (15-DaCompany Report #B0358561A
Age:45 YR Gender:Female I/FU:I

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Other		Cataract Corneal Pigmentation Extrapyramidal Disorder	Foreign Literature Health Professional	Thorazine (Formulation Unknown) (Chlorpromazine Hcl)	PS		
300 MG / PER DAY	25 YR						
				Lithium Carbonate (Formulation Unknown)(Generic) (Lithium Carbonate)	SS		
300 MG /TWICE PER DAY							
				Haloperidol	C		
				Trifluoperazine Hcl	C		

Date:12/30/04ISR Number: 4543311-1Report Type:Direct Company Report #CTU 235417
Age:53 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product		Role	Manufacturer	Route	Dose	Duration
Other	Sinus Bradycardia		Lithium	300 Mg	PS		ORAL	300 MG	

AMHS ORAL

Date:12/30/04ISR Number: 4544291-5Report Type:Expedited (15-DaCompany Report #DSA_25509_2004
Age:86 YR Gender:Female I/FU:I

Outcome	PT
Death	Aphasia
Hospitalization - Initial or Prolonged	Confusional State
	Depressed Level Of Consciousness
	Drug Interaction
	Dysarthria
	Extrapyramidal Disorder
	General Physical Health Deterioration
	Heart Rate Decreased
	Hemiparesis
	Protein Total Increased

	Renal Failure Somnolence						
	Therapeutic Agent	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Toxicity	Foreign	Enalapril-Hctz	PS		ORAL	1 TAB Q DAY
		Health					PO
		Professional	Lithium Carbonate	SS		ORAL	375 MG Q DAY
		Other					PO
			Lercanidipine	C			
			Omeprazole	C			
			Piribedil	C			
			Zopiclone	C			

Date:12/30/04ISR Number: 4544299-XReport Type:Expedited (15-DaCompany Report #DSA_24535_2004
Age:79 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Circulatory Collapse	Foreign	Teveten-Hct	PS			
	Clostridium Colitis	Health	Teveten /Sch/	SS		ORAL	600 MG PO
Disability	Hypercalcaemia	Professional	Teveten /Sch/	SS		ORAL	600 MG PO
	Ischaemic Stroke	Other	Lithicarb	SS		ORAL	250 MG Q DAY
	Salivary Hypersecretion						PO
	Therapeutic Agent		Actonel	SS		ORAL	70 MG QWK PO
	Toxicity		Caltrate	SS		ORAL	600 MG Q DAY
							PO
			Norvasc /Den/	C			
			Risperidone	C			

Date:12/30/04ISR Number: 4549256-5Report Type:Periodic Company Report #04-05-0777
Age:47 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Leukopenia Neutrophil Count Decreased	Health Professional Other	Clozapine Tablets - Ivax Pharmaceuticals, Inc.	PS	Ivax Pharmaceuticals, Inc.	ORAL	300MG QD	
			Eskalith	SS			450MG QHS	

Date:12/30/04ISR Number: 4554335-2Report Type:Periodic Company Report #04-07-1026
Age:48 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Disorientation Dizziness	Health Professional Other	Clozapine Tablets - Ivax Pharmaceuticals, Inc.	PS	Ivax Pharmaceuticals, Inc.	ORAL	250 MG QD	
			Lithium Unknown	SS			ORAL	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/03/05ISR Number: 4545060-2Report Type:Expedited (15-DaCompany Report #2004196601CH
Age:61 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Hospitalization -	Abdominal Distension Anaemia	Foreign Health	Luvox (Fluvoxamine Maleate)	PS		ORAL	800 MG	Initial or Prolonged (SINGLE),
	Bowel Sounds Abnormal	Professional						
	Bradycardia					ORAL		
	Coma Gastritis Haemorrhagic		Tolterodine (Tolterodine)	SS		ORAL	14 MG	(SINGLE),
	Haematemesis							
	Haemodialysis					ORAL		
	Hypotension Hypoxia		Ponstan (Mefenamic Acid)	SS			1800 MG	(SINGLE)
	Myoclonus							
	Oedema Peripheral Petechiae		Lithium Carbonate (Lithium Carbonate)	SS		ORAL	400 MG	(SINGLE),
	Pitting Oedema							
	Renal Failure Acute					ORAL		
	Serotonin Syndrome Suicide Attempt Tachycardia Tachypnoea		Clorazepate Dipotassium (Clorazepate Dipotassium)	SS		ORAL	25 MG	(SINGLE),
	Thrombocytopenia					ORAL		
			Flurazepam Hydrochloride (Flurazepam Hydrochloride)	SS		ORAL	1800 MG	(SINGLE),

ORAL							
			Propranolol (Propranolol)	SS		ORAL	300 MG
(SINGLE),							
ORAL							
			Tramadol Hydrochloride (Tramadol Hydrochloride)	SS		ORAL	4500 MG
(SINGLE),							
ORAL							
			Clotiapine (Clotiapine)	C		ORAL	4000 MG
(SINGLE),							
ORAL							

Date:01/03/05ISR Number: 4545711-2Report Type:Direct Company Report #CTU 235548
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Coordination Abnormal Lethargy Tremor		Lithium 300 Mg/ 60 Mg	PS		ORAL	300 MG PO QAM, 600 MG PO QPM	5 YR

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/04/05ISR Number: 4544173-9Report Type:Expedited (15-DaCompany Report #PHBS2004JP15202
Age:66 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abnormal Behaviour		Ludiomil	PS	Novartis Sector: Pharma	ORAL	25 mg/d	
	Apathy							
	Blood Creatinine		Lithium Carbonate	SS		ORAL	400 mg/d	
	Increased		Loxoprofen	SS		ORAL	180 mg/d	
	Blood Thyroid Stimulating Hormone Increased		Ludiomil	SS	Novartis Sector: Pharma	ORAL	12.5-25 mg/day	
	Blood Urea Increased							
	Bradykinesia		Fluvoxamine Maleate	C		ORAL	75 mg/d	
	Cerebellar Syndrome		Phenobarbital	C			180 mg/day	
	Convulsion		Zonisamide	C			200 mg/day	
	Dementia							
	Depressed Level Of Consciousness							
	Difficulty In Walking							
	Disorientation							
	Disturbance In Attention							
	Drug Interaction							
	Dysstasia							
	Electroencephalogram Abnormal							
	Hypothyroidism							
	Insomnia							
	Mania							
	Masked Facies							
	Memory Impairment							
	Muscle Rigidity							
	Nuclear Magnetic Resonance Imaging Brain Abnormal							
	Parkinsonism							
	Somnolence							
	Therapeutic Agent Toxicity							
	Tremor							

Date:01/05/05ISR Number: 4546902-7Report Type:Expedited (15-DaCompany Report #B0361964A
Age:58 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Depressed Level Of Consciousness	Foreign Literature	Lithium Carbonate (Generic)	PS				
	Disorientation	Health Professional Other	Haloperidol	C				
	Drug Level Changed		Lorazepam	C				
	Dysarthria		Biperiden	C				
	Dyskinesia		Methotrimeprazine	C				
	Encephalopathy		Captopril	C				
	Haemodialysis		Fluvastatin Sodium	C				
	Incoherent		Allopurinol	C				
	Neurotoxicity		Frusemide	C				
	Somnolence		Nimodipine	C				
	Therapeutic Agent Toxicity							
	Urinary Tract Infection							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/07/05ISR Number: 4547428-7Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0372364A
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Renal Failure		Eskalith	PS	Glaxosmithkline	ORAL	300MG Per day	10 YR

Date:01/10/05ISR Number: 4566202-9Report Type:Direct Company Report #CTU 236070
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Aggression		Lithobid (Generic)	PS			300 Q AM 450	
	Pharmaceutical Product						Q PM	
	Complaint							

Date:01/12/05ISR Number: 4550661-1Report Type:Expedited (15-DaCompany Report #FR-ABBOTT-04P-056-0275099-00
Age:48 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Agitation		Depakote Tablets	PS		ORAL		
Hospitalization -	Anorexia		Depakote Tablets	SS				
Initial or Prolonged	Aphasia		Lithium Carbonate	SS		ORAL		
	Blood Creatinine		Olanzapine	SS		ORAL		
	Increased		Olanzapine	SS				
	Blood Glucose Increased							
	Confusional State							
	Disturbance In Attention							
	General Physical Health							
	Deterioration							
	Hypernatraemia							
	Mutism							
	Nephrogenic Diabetes							
	Insipidus							
	Polydipsia							
	Polyuria							
	Pyrexia							
	Tremor							
	Urinary Incontinence							

Date:01/13/05ISR Number: 4551792-2Report Type:Expedited (15-DaCompany Report #2005000542
Age:18 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Ill-Defined Disorder		Quilonum Retard	PS	Glaxosmithkline	ORAL	9450MG Single	
	Intentional Misuse						dose	
	Overdose		Risperdal	SS		ORAL	17.5MG Single	
	Somnolence						dose	
	Suicide Attempt		Trileptal	SS		ORAL	11550MG	
							Single dose	
			Cipralex	SS		ORAL	350MG Single	
							dose	

Date:01/14/05ISR Number: 4553164-3Report Type:Expedited (15-DaCompany Report #DE-GLAXOSMITHKLINE-D0037311A
Age:65 YR Gender:Female I/FU:F

Outcome	PT
Other	Alanine Aminotransferase Increased
	Angioneurotic Oedema

		Anticonvulsant Drug Level Above Therapeutic					
		Aspartate	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
		Aminotransferase		Elmendos	PS	Glaxosmithkline	ORAL
		Increased		Lamictal	SS	Glaxosmithkline	ORAL
		Blood Alkaline		Quilonum Retard	SS	Glaxosmithkline	ORAL
450MG Twice							
		Phosphatase Increased					
per day							
		Blood Calcium Increased		Saroten Retard	C	Glaxosmithkline	ORAL
		Blood Immunoglobulin E		Climopax	C		ORAL
		Increased					
		Breast Cancer					
		C-Reactive Protein					
		Increased					
		Drug Level Decreased					
		Dry Mouth					
		Haematocrit Increased					
		Hepatic Enzyme Increased					
		Hypertension					
		Hypothyroidism					
		Mean Cell Volume					
		Increased					
		Oedema					
		Rash					
		Red Blood Cell Count					
		Increased					
		Skin Disorder					
		Skin Ulcer					
		Urinary Incontinence					
		Weight Increased					

Date:01/14/05ISR Number: 4556089-2Report Type:Expedited (15-DaCompany Report #2004092981
Age:54 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization -	Alanine Aminotransferase	Foreign	Lipitor			
Initial or Prolonged	Increased	Literature	(Atorvastatin)	PS		ORAL
ORAL						
Other	Aspartate	Health	Lithium (Lithium			
	Aminotransferase	Professional	Carbonate) (Lithium)	SS		ORAL
600 MG, ORAL						
	Increased		Chlorpromazine			

	Blood Urea Increased	Hydrochloride		
	Delusion Of Grandeur	(Chlorpromazine		
	Depressed Level Of	Hydrochloride)	SS	ORAL
125 MG, ORAL				
	Consciousness	Valproate Sodium		
	Depression	(Valproate Sodium)	SS	ORAL
ORAL				
	Disease Recurrence	Levomepromazine		
	Drug Interaction	Maleate		
	Erectile Dysfunction	(Levomepromazine		
	Flight Of Ideas	Maleate)	SS	ORAL
ORAL				
	Haemodialysis	Olanzapine		
	Hyperkinesia	(Olanzapine)	C	
	Logorrhoea	Clonazepam		
	Mental Disorder	(Clonazepam)	C	
	Movement Disorder	Risperidone		
	Pain	(Risperidone)	C	
	Rhabdomyolysis			
	Sleep Disorder			
	White Blood Cell Count Increased			

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/18/05ISR Number: 4554310-8Report Type:Expedited (15-DaCompany Report #8836
Age:69 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Amnesia		Paroxetine	PS	Glaxosmithkline		UNKNOWN	2TAB per day
Initial or Prolonged	Arrhythmia		Clomipramine					
	Difficulty In Walking		Hydrochloride	SS			UNKNOWN	6TAB per day
	Drug Level Increased		Lithicarb	SS	Glaxosmithkline		2.5TAB per day	
	Fall							
	Gait Disturbance		Lipitor	C			UNKNOWN	1TAB per day
	Pernicious Anaemia							
	Tremor							
	Urinary Tract Infection							

Date:01/18/05ISR Number: 4554778-7Report Type:Expedited (15-DaCompany Report #2005000765
Age:72 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Confusional State		Quilonum Retard	PS	Glaxosmithkline	ORAL	675MG Per day	
Initial or Prolonged	Electrocardiogram Qt							
	Prolonged							
	Somnolence							

Date:01/18/05ISR Number: 4556552-4Report Type:Expedited (15-DaCompany Report #2004009355
Age: Gender:Male I/FU:F

Outcome	PT
Hospitalization -	Abdominal Pain
Initial or Prolonged	Accident
Other	Back Disorder
	Back Pain
	Blood Cholesterol Increased
	Chest Pain
	Chills

Condition Aggravated
Contusion
Disorientation
Drug Effect Decreased
Drug Ineffective
Drug Intolerance
Erectile Dysfunction
Facial Pain
Feeling Abnormal
Feeling Cold
Gastrooesophageal Reflux
Disease
Gingival Disorder
Glossodynia
Hostility
Hyporeflexia
Impaired Healing
Injury
Irritability
Neck Pain
Oesophageal Spasm
Sedation
Sleep Disorder
Somnolence
Tooth Abscess

Treatment Noncompliance Tremor Vertigo		Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
		Consumer Health	Neurontin (Gabapentin)	PS		ORAL
1800 MG (600 MG, 3 IN 1 D), ORAL		Professional				
			Lipitor (Atorvastatin)	SS		ORAL
20 MG (1 IN 1 D), ORAL						
			Lithium (Lithium) (Lithium)	SS		
			Naproxen (Naproxen) (Naproxen)	SS		
			Rofecoxib (Rofecoxib)	SS		
			Amoxicillin (Amoxicillin)	SS		ORAL
1000 MG (1 IN 2 D), ORAL						
			All Other Therapeutic Products (All Other Therapeutic Products)	C		
			Levothyroxine Sodium (Levothyroxine Sodium)	C		
			Vitamins (Vitamins)	C		
			Diltiazem Hydrochloride (Diltiazem Hydrochloride)	C		

Date:01/18/05ISR Number: 4557035-8Report Type:Expedited (15-DaCompany Report #04-0010-PO FOLLOW UP 2
Age:61 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Hospitalization - Initial or Prolonged	Anaemia Coma Gastric Ulcer	Foreign Health Professional	Ponstan (Mefenamic Acid) Pontel Nda 15-034	PS		ORAL	18G, ONCE, PO	
	Gastritis Haemorrhagic	Other	Lithium Carbonate	SS		ORAL	4000MG, ONCE, PO	
	Haematemesis							
	Haemodialysis Myoclonus		Fluvoxamine Malelate (Floxyfral)	SS		ORAL	800MG ONCE PO	
	Oedema Peripheral Overdose Packed Red Blood Cell		Clorazepate Dipotassium (Tranxillium)	SS		ORAL	250MG ONCE PO	
	Transfusion Renal Failure Acute		Clotiapine (Entumine)	SS		ORAL	4000MG ONCE PO	
	Serotonin Syndrome							
	Suicide Attempt Thrombocytopenia		Flurazepam Hydrochloride	SS		ORAL	1800MG ONCE PO	
			Tramadol Hydrochloride (Tramal)	SS		ORAL	450MG ONCE PO	
			Propranolol Hydrochloride (Inderal)	SS		ORAL	300MG ONCE PO	
			Luvox	C				

			Tolteradine	C			

Date:01/18/05ISR Number: 4557294-1Report Type:Expedited (15-DaCompany Report #2005003481
Age:26 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Condition Aggravated	Foreign	Lithium (Lithium)	PS				
	Confusional State	Literature	Topiramate (Topiramate)	SS				
	Disturbance In Attention	Health	Risperidone (Risperidone)	SS				
	Lethargy	Professional	Clonazepam (Clonazepam)	SS				
	Mania		Lamotrigine (Lamotrigine)	SS				
			Valproic Acid (Valproic Acid)	C				

Date:01/19/05ISR Number: 4555662-5Report Type:Expedited (15-DaCompany Report #PHBS2005CH00545
Age:62 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Contusion		Brinerdin	PS	Novartis Sector: Pharma	ORAL	1 tablet/day	
	Electrocardiogram Qt Prolonged		Flusol	SS		ORAL	40 mg/day	
	Face Injury		Lithiofor	SS		ORAL	1.5 tablet/day	12960MIN
	Feeling Abnormal							
	Hypokalaemia		Buspar	C		ORAL	20 mg/day	
	Syncope							

Date:01/19/05ISR Number: 4558578-3Report Type:Expedited (15-DaCompany Report #02100-JPN-04-0336
Age:73 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Arteritis Obliterans Dialysis Hepatic Function Abnormal Renal Failure Acute Stent Placement	Foreign Health Professional	Cilostazol Ticlopidine Hydrochloride Lithium Carbonate	PS SS SS		ORAL ORAL ORAL	200 MG 200 MG 400 MG	1 WK 43 DAY

Date:01/19/05ISR Number: 4582243-XReport Type:Periodic Company Report #2004-BP-03487RO
Age:22 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Toxicity Insomnia Tremor Weight Decreased	Consumer	Lithium Carbonate Capsules Usp, 300 Mg (Lithium Carbonate) Vivarin (Caffeine) Vitamins (Vitamins) Ortho Tri-Cyclen (Cilest)	PS C C C		ORAL	1200 MG/DAY (300 MG, 4 IN 1 D), PO	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/19/05ISR Number: 4582244-1Report Type:Periodic Company Report #2004-BP-05876RO
Age:72 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Therapeutic Agent Toxicity	Consumer	Lithium Carbonate Capsules Usp, 300 Mg (Lithium Carbonate)	PS		ORAL	600 MG (300 MG), PO	25 YR
			Pulmicort (Budesonide)	C				
			Albuterol (Salbutamol)	C				
			Miralax (Macrogol)	C				
			Theodur (Theophylline)	C				
			Ibuprofen (Ibuprofen)	C				
			Valium (Diazepam)	C				
			Aldactone (Spironolactone)	C				
			Lasix (Furosemide)	C				
			Stool Softener (Docusate Sodium)	C				
			Vitamins (Vitamins)	C				

Date:01/20/05ISR Number: 4560091-4Report Type:Direct Company Report #CTU 237306
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Abnormal Behaviour Pharmaceutical Product Complaint		Lithium Carbonate	PS				

Date:01/21/05ISR Number: 4558778-2Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0538064A
Age:20 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Other 4 MON	Bundle Branch Block Right		Lamictal	PS	Glaxosmithkline	ORAL
	Convulsion		Lithium	SS	Glaxosmithkline	ORAL
900MG per day						
	Electrocardiogram St-T Segment Abnormal Mood Altered Sinus Tachycardia					

Date:01/24/05ISR Number: 4559945-4Report Type:Expedited (15-DaCompany Report #C04-C-115
Age:28 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Therapeutic Agent Toxicity	Health Professional	Lithium Carbonate Capsules Usp 300 Mg	PS		
300 MG TID						
		Other	Clozapine - Ivax Pharmaceuticals, Inc.	SS	Ivax Pharmaceuticals, Inc.	ORAL
400 MG BID						
ORAL						
			Zantac	C		
			Haloperidol	C		
			Geodon	C		

			Ativan	C		

Date:01/24/05ISR Number: 4560790-4Report Type:Expedited (15-DaCompany Report #GBWYE037213SEP04
Age:60 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Interaction Haemoglobin Decreased Therapeutic Agent Toxicity	Health Professional	Efexor Xl (Venlafaxine Hydrochloride, Capsule, Extended Release)	PS		ORAL	225 MG 1X PER 1 DAY ORAL; 150 MG 1X PER 1 DAY ORAL	
			Priadel (Lithium Carbonate)	SS		ORAL	600 MG 1X PER 1 DAY ORAL	
			Olanzapine (Olanzapine)	C				
			Zopiclone (Zopiclone)	C				
			Nu-Seals Aspirin (Acetylsalicylic Acid)	C				
			Istin (Amlodipine Besilate)	C				
			Cardura Xl (Doxazosin Mesilate)	C				
			Atenolol (Atenolol)	C				

Date:01/24/05ISR Number: 4562312-0Report Type:Expedited (15-DaCompany Report #2005BI000681
Age:57 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Hospitalization -	Bedridden	Consumer	Avonex Lyophilized	PS			
INTRAMUSCULAR	30UG; QW; IM						
Initial or Prolonged	Depression		Avonex Liquid	SS			
INTRAMUSCULAR	30 UG; QW; IM						
	Dysphagia		Lithium Carbonate	SS			
	Gastrooesophageal Reflux Disease						
	Headache						
	Hemiplegia						
	Oral Intake Reduced						
	Progressive Multiple Sclerosis						
	Somnolence						
	Urinary Incontinence						
	Weight Decreased						

Date:01/24/05ISR Number: 4562340-5Report Type:Expedited (15-DaCompany Report #2004105231
Age:38 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Atrioventricular Block	Health	Geodon (Ziprasidone)	PS				
	First Degree	Professional	Lithium (Lithium)	SS		ORAL	1200 MG, ORAL	
	Electrocardiogram Pr Prolongation		Lamotrigine (Lamotrigine)	C				
	Sinus Bradycardia							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/26/05ISR Number: 4566525-3Report Type:Direct Company Report #CTU 238143
Age:79 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Akathisia		Lithium Carbonate 150mg Roxane	PS	Roxane	ORAL	150MG QAM & QHS	ORAL
	Dystonia							
	Fall							
			Risperidone 4mg Jannsen	SS	Jannsen	ORAL	7MG QHS	ORAL
			Acetaminophen	C				
			Albuterol	C				
			Aspirin	C				
			Atrovent	C				
			Diovan	C				
			Docusate	C				
			Flovent	C				
			Levothyroxine	C				
			Lipitor	C				
			Lorazepam	C				
			Mom	C				
			Phenytoin	C				
			Ranitidine	C				
			Bisacodyl	C				
			Maalox	C				

Date:01/26/05ISR Number: 4566695-7Report Type:Expedited (15-DaCompany Report #2004009355
Age: Gender:Male I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Abdominal Injury
Other	Abdominal Pain
	Accident
	Back Disorder
	Back Pain
	Blood Cholesterol Increased
	Body Temperature Decreased
	Cardiac Disorder

Chest Pain
Condition Aggravated
Contusion
Coordination Abnormal
Disorientation
Drug Ineffective
Drug Intolerance
Erectile Dysfunction
Facial Pain
Feeling Abnormal
Feeling Cold
Gastrointestinal Disorder
Gastrooesophageal Reflux
Disease
Gingival Pain
Glossodynia
Hostility
Hypersomnia
Hyporeflexia
Impaired Healing
Injury

Irritability Limb Injury Medication Error Movement Disorder Myalgia Neck Pain Oesophageal Spasm Overdose Pain In Jaw Post Procedural Pain Sedation Sleep Disorder Somnolence Tenderness Tooth Abscess Tremor Vertigo	Report Source Consumer Health Professional	Product Neurontin (Gabapentin) Lipitor (Atorvastatin) Lithium (Lithium) Naproxen (Naproxen) Amoxicillin (Amoxicillin) Rofecoxib (Rofecoxib) All Other Therapeutic Products (All Other Therapeutic Products) Levothyroxine Sodium (Levothyroxine Sodium) Vitamins (Vitamins) Diltiazem Hydrochloride (Diltiazem Hydrochloride)	Role PS SS SS SS SS C C C C	Manufacturer	Route ORAL ORAL ORAL	Dose Duration 1800 MG (600 MG, 3 IN 1 D), ORAL 20 MG (20 MG, 1 IN 1 D),ORAL 1000 MG (1 IN 2 D), ORAL

Date:01/28/05ISR Number: 4563440-6Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0510925A
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Urticaria		Wellbutrin	PS	Glaxosmithkline	ORAL		
			Lithium	SS	Glaxosmithkline			
			Bupropion Hydrochloride	C	Glaxosmithkline			

Date:01/28/05ISR Number: 4585778-9Report Type:Direct Company Report #CTU 238544
Age:57 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Confusional State		Lisinopril /Hctz					
	Dialysis		(Prev On 12.5 Mg					
Other	Diarrhoea		Hctz 3/2004)	PS			10 MG/ 12.5	
Required	Fluid Overload						MG DAILY	
Intervention to	Pulmonary Oedema		Lithium	SS			450 MG Q AM	
Prevent Permanent	Renal Failure						AND 900 MG Q	
Impairment/Damage	Therapeutic Agent						PM [CHRONIC]	
	Toxicity		Metformin	C				
			Felodipine	C				
			Trazodone	C				
			Clonazepam	C				
			Levobunolol Hydrochloride	C				
			Paxil	C				

Travoprost	C
Trazadone	C
Zolpidem	C
Mvi	C

Date:01/28/05ISR Number: 4695314-4Report Type:Direct Company Report #CTU 238516
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Abnormal Behaviour Therapeutic Response Unexpected With Drug Substitution		Lithium Carbonate	PS				

Date:01/31/05ISR Number: 4569772-XReport Type:Expedited (15-DaCompany Report #2004009355
Age: Gender:Male I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged Other	Abdominal Injury Abdominal Pain Accident Back Disorder Back Pain Blood Cholesterol Increased Chest Pain Contusion Coordination Abnormal Disorientation Drug Ineffective Drug Intolerance Erectile Dysfunction Facial Pain Feeling Cold Gastrooesophageal Reflux Disease Gingival Disorder Glossodynia Hostility Hypersomnia Hyporeflexia Impaired Healing

Injury
Irritability
Limb Injury
Medication Error
Mobility Decreased
Muscle Spasms
Myalgia
Neck Pain
Oesophageal Spasm
Pain In Extremity
Pain In Jaw
Sedation
Sleep Disorder
Somnolence
Tooth Abscess
Treatment Noncompliance
Tremor

Vertigo

		Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
		Consumer	Neurontin			
		Health	(Gabapentin)	PS		ORAL
1800 MG (600						
		Professional				
MG, 3 IN 1						
D), ORAL						
			Lipitor			
			(Atorvastatin)	SS		ORAL
20 MG (20 MG,						
1 IN 1 D),						
ORAL						
			Lithium (Lithium)			
			(Lithium)	SS		
			Naproxen (Naproxen)			
			(Naproxen)	SS		
			Amoxicillin			
			(Amoxicillin)			
			(Amoxicillin)	SS		ORAL
1000 MG (1 IN						
2 D), ORAL						
			Rofecoxib			
			(Rofecoxib)	SS		
			Levothyroxine			
			(Levothyroxine			
			Sodium)	C		
			Vitamins (Vitamins)	C		
			Diltiazem			
			Hydrochloride			
			(Diltiazem			
			Hydrochloride)	C		

Date:02/01/05ISR Number: 4567184-6Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0542858A
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization -	Mania		Lithium	PS	Glaxosmithkline	

Initial or Prolonged	Rash Therapeutic Agent Toxicity		Lamictal	SS	Glaxosmithkline	ORAL

Date:02/01/05ISR Number: 4567185-8Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0542859A
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Renal Disorder Therapeutic Agent Toxicity		Lithium Carbonate	PS	Glaxosmithkline			

Date:02/02/05ISR Number: 4568309-9Report Type:Expedited (15-DaCompany Report #DE-GLAXOSMITHKLINE-D0045778A
Age:33 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Suicide Attempt		Quilonum Retard	PS	Glaxosmithkline	ORAL	50TAB	Single
	Vomiting						dose	
			Thyronajod	SS		ORAL	1200MG	per day

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/02/05ISR Number: 4570203-4Report Type:Expedited (15-DaCompany Report #2005-BP-00701RO
Age:26 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Confusional State	Foreign	Lithium Carbonate					
	Disturbance In Attention	Literature	(Lithium Carbonate)	PS		ORAL	900 MG/DAY,	
	Dysphoria	Health					PO	
	Lethargy	Professional	Topiramate					
	Mania		(Topiramate)	SS		ORAL	75 MG/DAY, PO	
	Refusal Of Treatment By		Valproate (Valproate					
	Patient		Sodium)	C				
	Skin Disorder		Clonazepam					
	Therapeutic Agent		(Clonazepam)	C				
	Toxicity							
	Therapy Non-Responder							

Date:02/04/05ISR Number: 4574426-XReport Type:Expedited (15-DaCompany Report #2004101239
Age:43 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Bipolar Disorder	Consumer	Geodon (Ziprasidone)	PS				
PARENTERAL	SEE IMAGE							
Initial or Prolonged	Bone Disorder	Health	Lithium (Lithium)	SS		ORAL		
ORAL								
	Chest Pain	Professional						
	Disease Recurrence							
	Dyspepsia							
	Musculoskeletal Pain							
	Oesophageal Pain							
	Palpitations							
	Pollakiuria							
	Stress							
	Tooth Disorder							

Date:02/07/05ISR Number: 4572413-9Report Type:Expedited (15-DaCompany Report #A01200405023
Age:76 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Blood Calcium Increased		Lithium	PS	Glaxosmithkline	ORAL		
Hospitalization - Initial or Prolonged	Blood Creatinine Increased		Chlorpromazine	C	Glaxosmithkline	ORAL		
			Procyclidine	C	Glaxosmithkline			
UNKNOWN								
Other	Blood Urea Increased		Nitrazepam	C				
UNKNOWN								
	Clubbing		Zopiclone	C				
UNKNOWN								
	Dehydration							
	Depressed Level Of Consciousness							
	Gastrointestinal Haemorrhage							
	Hypernatraemia							
	Hypoventilation							
	Lung Consolidation							
	Malaise							
	Nephrogenic Diabetes Insipidus							
	Pneumonia							
	Po2 Decreased							
	Renal Failure							
	Vomiting							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/07/05ISR Number: 4576252-4Report Type:Expedited (15-DaCompany Report #DSA_25708_2005
Age:32 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Activated Partial Thromboplastin Time Prolonged Alanine Aminotransferase Increased Aspartate Aminotransferase Increased Blood Amylase Increased Blood Chloride Increased Blood Creatine Phosphokinase Increased Blood Fibrinogen Increased C-Reactive Protein Increased Coma Diarrhoea Gamma-Glutamyltransferase Increased Overdose	Foreign Health Professional Other	Tavor Tavor Amineurin Chloral Hydrate Fluoxetine Hydrochloride Hypnorex - Slow Release Tramal Zolpidem	PS SS SS SS SS SS SS SS		ORAL ORAL ORAL ORAL ORAL ORAL ORAL ORAL	5.5 MG ONCE Initial or Prolonged PO 8 MG ONCE PO 150 MG ONCE PO 5000 MG ONCE PO 140 MG ONCE PO 18000 MG ONC EPO 8 TAB ONCE PO 130 MG ONCE PO

Date:02/07/05ISR Number: 4576343-8Report Type:Expedited (15-DaCompany Report #GBWYE386801FEB05
Age:39 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Interaction	Health	Advil (Ibuprofen, 0)	PS		ORAL	400 MG 3X PER	
	Drug Level Increased	Professional						1 DAY, ORAL 5 DAY
	Renal Impairment	Other	Lithium Carbonate (Lithium Carbonate, , 0)	SS		ORAL	1 G 1X PER 1	DAY, ORAL
			Olanzapine (Olanzapine)	C				
			Paroxetine (Paroxetine)	C				

Date:02/08/05ISR Number: 4576910-1Report Type:Expedited (15-DaCompany Report #05-02-0144
Age:57 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Therapeutic Agent Toxicity	Health Professional Other	Clozapine - Ivax Pharmaceuticals, Inc. Tablets	PS	Ivax Pharmaceuticals, Inc.	ORAL	50-550MG QD	ORAL
			Lithium	SS				

Date:02/08/05ISR Number: 4576913-7Report Type:Expedited (15-DaCompany Report #05-02-0149
Age:53 YR Gender:Male I/FU:I

Outcome	PT	Report Source
Hospitalization - Initial or Prolonged	Therapeutic Agent Toxicity	Health Professional

Other

			Product	Role	Manufacturer	Route
Dose	Duration					
			Clozapine - Ivax Pharmaceuticals, Inc. Tablets	PS	Ivax Pharmaceuticals, Inc.	ORAL
400-500MG QD						
ORAL						
			Lithium	SS		

Date:02/08/05ISR Number: 4576953-8Report Type:Expedited (15-DaCompany Report #2004009355
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization - Initial or Prolonged	Abdominal Pain Accident	Consumer Health	Neurontin (Gabapentin)	PS		ORAL
1800 MG (600 MG, 3 IN 1 D), ORAL						
Other	Back Disorder	Professional				
	Blood Cholesterol Increased		Lipitor 9atorvastatin)	SS		ORAL
20 MG (20 MG, 1 IN 1 D), ORAL						
	Chest Pain Condition Aggravated Contusion					
	Disorientation		Lithium (Lithium)	SS		
	Drug Effect Decreased		Naproxen (Naproxen)	SS		
	Erectile Dysfunction Facial Pain		Amoxicillin (Amoxicillin)	SS		ORAL
1000 MG (1 IN 2 D), ORAL						
	Feeling Cold Gastrooesophageal Reflux Disease		Rofecoxib (Rofecoxib)	SS		
	Gingival Pain Glossodynia Hostility		All Other Therapeutic Products(All Other			

	Hypersomnia	Therapeutic
	Hyporeflexia	Products0 C
	Impaired Healing	Levothyroxine Sodium
	Injury	(Levothyroxine
	Movement Disorder	Sodium) C
	Muscle Spasms	Vitamins (Vitamins0 C
	Myalgia	Diltiazem
	Oesophageal Spasm	Hydrochloride
	Overdose	(Dialtiazem
	Pain In Extremity	Hydrochloride) C
	Pain In Jaw	
	Sedation	
	Skeletal Injury	
	Sleep Disorder	
	Somnolence	
	Tenderness	
	Tooth Abscess	
	Tremor	
	Vertigo	

Date:02/08/05ISR Number: 4577418-XReport Type:Expedited (15-DaCompany Report #GBWYE386801FEB05
Age:39 YR Gender: I/FU:F

Outcome	PT
Other	Antipsychotic Drug Level Increased

	Drug Interaction Renal Impairment						
		Report Source	Product	Role	Manufacturer	Route	Dose Duration
		Health Professional Other	Advil (Ibuprofen)	PS		ORAL	400 MG 3 X PER 1 DAY, ORAL 5 DAY
			Lithium Carbonate (Lithium Carbonate)	SS		ORAL	1 G 1XPER 1 DAY, ORAL
			Olanzapine (Olanzapine)	C			
			Paroxetine (Paroxetine)	C			

Date:02/09/05ISR Number: 4575662-9Report Type:Expedited (15-DaCompany Report #DE-GLAXOSMITHKLINE-D0045821A
Age:65 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Drug Interaction Dystonia		Quilonum Retard Zeldox	PS SS	Glaxosmithkline		675MG per day UNKNOWN 80MG per day 14 DAY
	Extrapyramidal Disorder		Remergil	SS			UNKNOWN 30MG per day
	Gait Disturbance		Tavor	C			UNKNOWN .5MG per day 272 DAY
	Pleurothotonus						

Date:02/09/05ISR Number: 4577235-0Report Type:Expedited (15-DaCompany Report #2004AL000808
Age:53 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Death	Blood Creatine Phosphokinase Increased Blood Creatinine	Literature Health Professional	Chlorpromazine Hydrochloride Oral Concentrate Usp, 100				

Increased	Mg/Ml (Alpharma)	PS	Alpharma	ORAL	PO
Chills	Metoprolol	SS		ORAL	PO
Hyperhidrosis	Amphetamine	SS		ORAL	PO
Hypertension Hyperthermia Hypotension	Fluoxetine Oral Solution Usp, 20mg/5ml (Alpharma)	SS	Alpharma	ORAL	PO
Metabolic Acidosis Multiple Drug Overdose	Temazepam Capsules, 30 Mg (Purepac)	SS	Purepac	ORAL	PO
Pyrexia Tachycardia	Lovastatin Tablets Usp, 40 Mg (Purepac)	SS	Usp	ORAL	PO
Tremor	Carisoprodol	SS		ORAL	PO
	Morphine	SS		ORAL	PO
	Lithium	SS		ORAL	PO
	Levothyroxine	SS		ORAL	PO

Date:02/10/05ISR Number: 4579591-6Report Type:Expedited (15-DaCompany Report #2004AL000819
Age:25 YR Gender:Male I/FU:F

Outcome	PT
Death	Alanine Aminotransferase Increased
Hospitalization - Initial or Prolonged	Aspartate Aminotransferase Increased
	Aspiration
	Blood Ph Decreased
	Cardio-Respiratory Arrest

	Coma Completed Suicide Hypoxia	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Intentional Misuse	Literature	Clonazepam	PS	Purepac	ORAL	PO
	Lung Infiltration	Health	Lithium	SS		ORAL	PO
	Myocardial Infarction Pulmonary Embolism Tachycardia Therapy Non-Responder Wheezing	Professional					

Date:02/10/05ISR Number: 4579632-6Report Type:Expedited (15-DaCompany Report #NLWYE330811JAN05
Age:74 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Life-Threatening Hospitalization - Initial or Prolonged	Cardiac Failure	Health Professional	Efexor Xr (Venlafaxine Hydrochloride, Capsule, Extended Release, 0)	PS		ORAL	75 MG 1X PER 1 DAY, ORAL ; 75 MG 2X PER 1 DAY 14 DAY
			Lithium Carbonate (Lithium Carbonate, 0)	SS			600 MG 1X PER 1 DAY

Date:02/10/05ISR Number: 4579875-1Report Type:Expedited (15-DaCompany Report #2004AL000664
Age:40 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death Hospitalization - Initial or Prolonged	Cardiac Arrest Completed Suicide Nervous System Disorder Pneumonia Pupil Fixed Respiratory Arrest	Literature Health Professional	Carbamazepine Tablets, Usp, 200 Mg (Purepac) Clonazepam Tablets Usp, 2 Mg (Purepac) Quetiapine Chlordiazepoxide Acetaminophen/Hydrocodone Lithium	PS SS SS SS SS SS	Purepac Purepac	ORAL PO ORAL PO ORAL PO ORAL PO ORAL PO		

Date:02/11/05ISR Number: 4582521-4Report Type:Direct Company Report #CTU 240207
Age:54 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drooling Extrapyramidal Disorder		Risperdal Lithium	PS SS		ORAL	4 MG PO HS 300 M Q AM AND 600 MG Q AM	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/11/05ISR Number: 4584126-8Report Type:Expedited (15-DaCompany Report #2005-124999-NL
Age:61 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Level Increased		Mirtazapine	PS		ORAL	30 MG QD , ORAL	
	Therapeutic Agent							
	Toxicity		Lithium	SS		ORAL	800 MG QD ; ORAL	
			Flupentixol	C				
			Olanzapine	C				

Date:02/14/05ISR Number: 4580525-9Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0498203A
Age:28 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Asthenia		Lamictal	PS	Glaxosmithkline	ORAL	25MG Alternate days	
	Drug Level Fluctuating							
	Nausea							
	Tremor		Lithium	SS	Glaxosmithkline			
			Depakote	C				

Date:02/14/05ISR Number: 4580727-1Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0511457A
Age:32 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Contusion		Lamictal	PS	Glaxosmithkline	ORAL	200MG Per day	6 MON
	Hypothyroidism		Lithium	SS	Glaxosmithkline			
	Rash		Klonopin	C			UNKNOWN	
	Thrombocytopenia		Zoloft	C		ORAL	50MG Per day	

Date:02/14/05ISR Number: 4580802-1Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0513560A
Age: Gender: I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Interaction		Lamictal	PS	Glaxosmithkline	ORAL	400MG	Unknown
	Tremor		Zyprexa	SS			UNKNOWN	
			Lithium	SS	Glaxosmithkline		UNKNOWN	

Date:02/14/05ISR Number: 4580927-0Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0516257A
Age:50 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Mania		Lamictal	PS	Glaxosmithkline	ORAL	200MG Per day	MON
			Lithium	SS	Glaxosmithkline	ORAL		
			Lexapro	C		ORAL	10MG Per day	

Date:02/14/05ISR Number: 4580943-9Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0516622A
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Blood Creatinine Increased		Lamictal	PS	Glaxosmithkline	ORAL		
	Tremor		Lithium	SS	Glaxosmithkline			

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/14/05ISR Number: 4581363-3Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0528567A
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Ineffective		Lamictal	PS	Glaxosmithkline	ORAL		
			Eskalith	SS	Glaxosmithkline	ORAL		
			Wellbutrin	SS	Glaxosmithkline	ORAL		
			Parnate	SS	Glaxosmithkline	ORAL		

Date:02/14/05ISR Number: 4581673-XReport Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0537297A
Age:42 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Asthenia		Lamictal	PS	Glaxosmithkline	ORAL	150MG At night	
			Lithium	SS	Glaxosmithkline		900MG At night	

Date:02/14/05ISR Number: 4581928-9Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0506231A
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Ineffective		Lamictal	PS	Glaxosmithkline	ORAL	100MG Per day	3 MON
	Ear Pruritus		Lithium	SS	Glaxosmithkline		3	MON
			Prozac	SS			3	MON
			Alprazolam	C				
			Ambien	C				

Date:02/15/05ISR Number: 4584735-6Report Type:Expedited (15-DaCompany Report #C04-C-049
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Pharmaceutical Product	Health	Lithium Carbonate					
	Complaint	Professional	Capsules, Usp 300 Mg	PS				
	Stool Analysis Abnormal							

Date:02/15/05ISR Number: 4587544-7Report Type:Expedited (15-DaCompany Report #C02-C-003
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Irritability	Consumer	Lithium Carbonate	PS	Usp		1	MON
	Pharmaceutical Product							
	Complaint							

Date:02/15/05ISR Number: 4587545-9Report Type:Expedited (15-DaCompany Report #C02-T-062
Age: Gender: I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Chest Pain	Consumer	Lithium Carbonate	PS	Usp			
	Drug Hypersensitivity	Other						
	Dyspnoea							
	Rash							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/15/05ISR Number: 4587556-3Report Type:Expedited (15-DaCompany Report #C03-C-029
Age: Gender: I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Antipsychotic Drug Level Increased	Health Professional	Lithium Carbonate	PS				
			Lithium Carbonate Capsules, Usp 300 Mg	SS				

Date:02/15/05ISR Number: 4587570-8Report Type:Expedited (15-DaCompany Report #C02-C-002
Age:29 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Disturbance In Attention	Consumer	Lithium	PS	Usp		13	YR
	Drug Ineffective Feeling Jittery Mania Reading Disorder	Health Professional	Xanax (Alprazolam)	C				

Date:02/15/05ISR Number: 4587599-XReport Type:Expedited (15-DaCompany Report #C03-C-029_02
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Antipsychotic Drug Level Increased	Health Professional	Lithium Carbonate Capsules, Usp 300 Mg	PS				
			Lithium Carbonate Capsules, Usp 300 Mg	SS				

Date:02/16/05ISR Number: 4589262-8Report Type:Expedited (15-DaCompany Report #2004-BP-11825RO
Age:51 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Effect Decreased Drug Level Decreased Mania	Consumer	Lithium Carbonate (Lithium Carbonate)	PS	Usp	ORAL	1500 MG	QHS

	Pharmaceutical Product						
(300 MG, 5 IN							
	Complaint						
1 D), PO							
			Seroquel (Quetiapine Fumarate)	C			
			Synthroid (Levothyroxine Sodium)	C			
			Iron (Iron)	C			
			Multivitamins (Multivitamins)	C			

Date:02/16/05ISR Number: 4589555-4Report Type:Expedited (15-DaCompany Report #A015018
Age:43 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Affective Disorder	Foreign	Viagra (Sildenafil)	PS		ORAL	100 MG (1 IN	
Initial or Prolonged	Condition Aggravated	Literature					1 D), ORAL	
	Depression	Health	Lithium (Lithium)	SS		ORAL	ORAL	
	Drug Interaction	Professional	Dosulepin (Dosulepin)	C				
	Elevated Mood		Flupentixol (Flupentixol)	C				
	Erectile Dysfunction							
	Mania							
	Paranoia							
	Suicidal Ideation							

Date:02/17/05ISR Number: 4585265-8Report Type:Expedited (15-DaCompany Report #AU-JNJFOC-20040501168
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - OROPHARINGEAL	Coordination Abnormal		Risperidone	PS				
Initial or Prolonged	Csf Pressure Increased							
Other	Depression							
	Headache		Risperidone	SS		OROPHARINGEAL		
	Hypomania		Lithium Carbonate	SS		OROPHARINGEAL		
	Hypothyroidism		Risperidone	SS		OROPHARINGEAL		
	Intervertebral Disc Protrusion							
	Intracranial Pressure		Antitriptyline	C		OROPHARINGEAL		
	Increased		Metformin	C		OROPHARINGEAL		
	Papilloedema							
	Retinal Haemorrhage							
	Therapeutic Response Decreased							

Hospitalization - stopped for a few days for dechallenge
Initial or Prolonged re-started after dechallenge

Date:02/18/05ISR Number: 4590994-6Report Type:Expedited (15-DaCompany Report #2005AP01123
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Diabetes Insipidus	Foreign	Seroquel	PS		ORAL	200 MG DAILY	
	Drug Level Increased	Health Professional Other						
	Renal Failure Acute		Lithium Carbonate	SS		ORAL	500 MG DAILY	
			Ostelin	C				
			Nexium	C				

PO
PO

			Metoprolol	C		
			Oxazepam	C		
			Venlafaxine	C		

Date:02/23/05ISR Number: 4589815-7Report Type:Expedited (15-DaCompany Report #DE-GLAXOSMITHKLINE-D0045934A
Age:61 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Asthenia		Quilonum Retard	PS	Glaxosmithkline			
UNKNOWN							2TAB	per day
Initial or Prolonged	Cerebral Infarction		Seroxat	SS	Glaxosmithkline			
UNKNOWN							40MG	per day
	Hypoaesthesia		Truxal	SS				
UNKNOWN							45MG	per day
	Muscular Weakness		Plavix	SS				
UNKNOWN							75MG	per day
	Speech Disorder		Dogmatil	C				
UNKNOWN							400MG	per day
			Sortis	C				
UNKNOWN							20MG	per day
			Ranitidin	C	Glaxosmithkline			
UNKNOWN							300MG	per day
			Dehydro Sanol Tri	C				
UNKNOWN							1CAP	per day

Date:02/24/05ISR Number: 4590577-8Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0370903A
Age:57 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Arrhythmia		Lithium	PS	Glaxosmithkline			
UNKNOWN							500MG	per day
	Cardiac Disorder		Olanzapine	SS				
UNKNOWN							20MG	per day
	Mitral Valve Prolapse		Levomepromazine	SS				
UNKNOWN							200MG	per day
	Sudden Death		Tropatepine	SS				
UNKNOWN							10MG	per day
	Ventricular Hypertrophy		Clomipramine	SS				
UNKNOWN							75MG	per day

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/24/05ISR Number: 4590598-5Report Type:Expedited (15-DaCompany Report #2005002950
Age:36 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Fatigue Hypotension		Quilonum Retard	PS	Glaxosmithkline	ORAL	450MG See dosage text	1 DAY
Other	Intentional Misuse Suicide Attempt		Zodurat	SS		ORAL	7.5MG See dosage text	1 DAY

Date:02/24/05ISR Number: 4591221-6Report Type:Direct Company Report #CTU 241350
Age:18 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Dysarthria Exophthalmos		Eskalith - Cr -450 Mg	PS			675 MG DAILY	
	Feeling Abnormal		Klonopin 1 Mg	SS			1.5 MG BID	
	Mydriasis Sedation							

Date:02/24/05ISR Number: 4594978-3Report Type:Expedited (15-DaCompany Report #GXKR2003GB00639
Age:64 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Interaction Drug Level Increased	Foreign Health	Trimethoprim Lithium(Lithium)	PS SS		ORAL	600 MG, QD, ORAL	
	Drug Toxicity	Professional						
		Other	Metformin (Metformin) Perindopril (Perindopril) Repaglinide (Repaglinide)	C C C				

				Lithium Carbonate (Lithium Carbonate)	C		

Date:02/24/05ISR Number: 4595630-0Report Type:Expedited (15-DaCompany Report #2005-125347-NL
Age:61 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain Upper	Foreign	Mirtazapine	PS			15 MG/30 MG	
	Blood Amylase Increased	Health Professional Other	Olanzapine	SS			2.5 MG	2 WK
	Lipase Increased		Venlafaxine Hydrochloride	SS			75 MG/150 MG	3 WK
			Lithium Carbonate	SS			DF/2 DF/1	
							DF/1.5 DF	13 DAY
			Reboxetine	SS			4 MG	3 DAY
			Zoplicone	C				
			Lorazepam	C				

Date:02/24/05ISR Number: 4596263-2Report Type:Expedited (15-DaCompany Report #2005AC00283
Age:74 YR Gender:Female I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Agitation
	Antipsychotic Drug Level Above Therapeutic
	Apathy
	Blood Creatinine

Increased Confusional State Dehydration Drug Interaction	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Drug Level Above Therapeutic	Foreign Literature	Lisinopril	PS		ORAL	20 MG DAILY
Dysarthria	Health	Lisinopril	SS		ORAL	PO 30 MG DAILY
Nervous System Disorder	Professional					PO
Neurotoxicity	Other	Irbesartan	SS			300 MG DAILY
Oliguria		Risperidone	SS			0.25 MG BID
Overdose		Lithium	SS			250 MG TID
Somnolence		Escitalopram	SS			10 MG DAILY
Therapeutic Agent		Levomepromazine	SS			6.25 MG DAILY
Toxicity		Spironolactone	SS			50 MG DAILY
Tremor		Furosemide	SS			30 MG DAILY
		Dexetimide	C			
		Lormetazepam	C			
		Metformin	C			
		Repaglinide	C			

Date:02/25/05ISR Number: 4596122-5Report Type:Expedited (15-DaCompany Report #2005-DE-00533GD
Age:21 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Bipolar I Disorder Communication Disorder	Literature	Sertraline (Sertraline)	PS			200 MG, QHS
	Drug Effect Decreased Drug Resistance		Lithium (Lithium Carbonate)	SS			1650 MG, QD
	Mania Paraesthesia		Quetiapine (Quetiapine)	SS			200 MG, QHS

	Skin Reaction		Clonazepam				
	Suicidal Ideation		(Clonazepam)	SS			
2 MG, QID							
	Treatment Noncompliance		Ziprasidone				
			(Ziprasidone)	SS			
80 MG, QHS							
			Verapamil				
			(Verapamil)	SS			
160 MG, BID							

Date:02/25/05ISR Number: 4596917-8Report Type:Expedited (15-DaCompany Report #2005-BP-02559RO
Age:24 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hypomania	Foreign	Lithium Carbonate					
	Leukocytosis	Literature	(Lithium Carbonate)	PS		ORAL		
SEE IMAGE, PO							97	DAY
	Platelet Count Decreased	Health	Thioridazine					
	Productive Cough	Professional	(Thioridazine)	C				
			Chlorpromazine					
			(Chlorpromazine)	C				

Date:02/28/05ISR Number: 4592917-2Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0545940A
Age:60 YR Gender:Female I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Blood Potassium Abnormal
	Cognitive Disorder
	Depressive Symptom
	Hypernatraemia
	Hypothyroidism
	Leukocytosis
	Psychomotor Retardation

Renal Failure

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
			Lamictal	PS	Glaxosmithkline	ORAL	6	MON
			Depakote	SS			500MG per day	
			Lithium	SS	Glaxosmithkline			
			Effexor	C			225MG per day	
			Multiple Medications	C				
			Clonazepam	C			.5MG At night	
			Abilify	C				

Date:02/28/05ISR Number: 4592922-6Report Type:Expedited (15-DaCompany Report #04-11-1603
Age:40 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Dehydration		Lithium	PS	Glaxosmithkline		UNKNOWN	
Initial or Prolonged	Infection		Clozapine	SS		ORAL		
	Therapeutic Agent Toxicity							
	Urinary Tract Infection							

Date:02/28/05ISR Number: 4597602-9Report Type:Direct Company Report #CTU 241588
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Mental Status Changes		Lithium Carbonate	PS		ORAL	600 MG BID	
Initial or Prolonged							ORAL	
			Olanzapine	C				
			Aripiprazole	C				
			Diphenhydramine	C				
			Terazosin	C				
			Asa	C				
			Kcl	C				

			Metformin	C		

Date:03/01/05ISR Number: 4594076-9Report Type:Expedited (15-DaCompany Report #DE-BRISTOL-MYERS SQUIBB COMPANY-12874905
Age:46 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Confusional State		Glucophage	PS	Bristol-Myers Squibb Company		
	Delirium						
	Disorientation		Hypnorex	I			
	Drug Interaction		Convulex	I			
	Restlessness		Ciatyl-Z	I			
			Novonorm	I			
			Haldol	I			15mg 15-Oct-2003 to 28-Oct-2003, 20mg
			Leponex	I			
			Tavor	I			

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/01/05ISR Number: 4594187-8Report Type:Expedited (15-DaCompany Report #2005003330
Age:48 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Abuser		Quilonum Retard	PS	Glaxosmithkline	ORAL		
	Somnolence		Rohypnol	SS		ORAL		
			Taxilan	SS		ORAL		

Date:03/01/05ISR Number: 4597188-9Report Type:Expedited (15-DaCompany Report #DEWYE443221FEB05
Age:61 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain Upper	Study	Trevilor (Venlafaxine Hydrochloride, Tablet, 0)	PS			SEE IMAGE	21 DAY
	Blood Amylase Increased		Edronax (Reboxetine, , 0)	SS			4 MG PER DAY;	3 DAY
	Lipase Increased		Quilonum - Slow Release (Lithium Carbonate, , 0)	SS			SEE IMAGE	6 DAY
			Zyprexa (Olanzapine, , 0)	SS			2.5 MG PER DAY;	14 DAY
			Remergil (Mirtazapine, , 0)	SS			30 MG PER DAY;	7 DAY
			.	C			SEC	
			.	C				
			.	C				
			.	C				
			.	C				

Date:03/02/05ISR Number: 4595947-XReport Type:Expedited (15-DaCompany Report #DE-JNJFOC-20050204773
Age:60 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Cerebellar Syndrome		Topamax	PS				
	Coordination Abnormal		Topamax	SS				
	Dizziness		Ergenyl	SS				
UNKNOWN								
	Fall		Zyprexa	SS				
UNKNOWN								
	Gait Disturbance		Jatrosom N	SS				
UNKNOWN								
			Hypnorex	SS				
UNKNOWN								
			Tavor	SS				
UNKNOWN								
			Tavor	SS				
UNKNOWN								
			Mpa	SS				
UNKNOWN								
			Magnesium	SS				
UNKNOWN								
			Estraderm	SS				
UNKNOWN								

Date:03/02/05ISR Number: 4596711-8Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0547760A
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blood Glucose Increased		Eskalith	PS	Glaxosmithkline	ORAL	450MG Twice	
	Hepatic Enzyme Increased						per day	
	Platelet Count Decreased		Seroquel	C				
			Lexapro	C				
			Insulin Lantus	C				
			Cozaar	C				

				Amaryl	C		
				Actos	C		

Date:03/02/05ISR Number: 4596748-9Report Type:Expedited (15-DaCompany Report #DE-NOVOPROD-242418
Age:46 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Delirium		Novonorm	PS	Novo Nordisk A/S	ORAL	1 mg, qd	41760MIN
	Drug Interaction		Hypnorex	SS			1000 mg, qd	10080MIN
			Convulex "Byk Gulden"	SS			900 mg, qd	5760 MIN
			Glucophage "Abic"	SS			850 mg, qd	12960MIN
			Ciatyl-Z	SS			75 mg, qd	5760 MIN
			Ciatyl-Z	SS			25 mg, qd	1440 MIN
			Haldol "Janssen"	C			15 mg, qd	18720MIN
			Leponex "Novartis"	C			150 mg, qd	15840MIN
			Tavor	C			3 mg, qd	21600MIN
			Haldol "Janssen"	C			20 mg, qd	1440 MIN
			Haldol "Janssen"	C			10 mg, qd	1440 MIN

Date:03/07/05ISR Number: 4600240-2Report Type:Expedited (15-DaCompany Report #05-02-0144
Age:57 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Pneumonia		Lithium	PS	Glaxosmithkline	ORAL	1800MG per day	28 DAY
	Therapeutic Agent							
	Toxicity		Clozapine	SS		ORAL	550MG Per day	

			Effexor Xr	C		ORAL
			Depakote	C		ORAL

3000MG Per

day

Date:03/07/05ISR Number: 4600247-5Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0548378A
Age:21 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Other	Condition Aggravated		Eskalith Cr	PS	Glaxosmithkline	ORAL	900MG per day
	Mania						

Date:03/07/05ISR Number: 4600277-3Report Type:Expedited (15-DaCompany Report #DE-GLAXOSMITHKLINE-D0046044A
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Drug Interaction		Trizivir	PS	Glaxosmithkline	ORAL	2TAB per day
Initial or Prolonged	Drug Level Below Therapeutic		Lithium	SS	Glaxosmithkline	ORAL	
	Drug Level Decreased						
	Psychotic Disorder						

Date:03/07/05ISR Number: 4602477-5Report Type:Expedited (15-DaCompany Report #2005035202
Age:21 YR Gender:Female I/FU:I

Outcome	PT
Hospitalization -	Bipolar I Disorder
Initial or Prolonged	Condition Aggravated
	Drug Ineffective
	Drug Resistance

	Mania Paraesthesia Speech Disorder	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Suicidal Ideation Treatment Noncompliance	Literature Health Professional	Ziprasidone (Caps) (Ziprasidone)	PS			20 MG (20 MG, 1 IN 1 D)
			Sertraline (Sertraline)	SS			200 MG (QHS)
			Lithium (Lithium)	SS			1200 MG (QD)
			Clonazepam (Clonazepam)	SS			2 MG (QID)
			Fluoxetine (Fluoxetine)	SS			
			Topiramate (Topiramate)	SS			
			Quetiapine (Quetiapine)	C			
			Lamotrigine (Lamotrigine)	C			
			Oxcarbazepine (Oxcarbazepine)	C			
			Verapamil (Verapamil)	C			
			Citalopram (Citalopram)	C			

Date:03/07/05ISR Number: 4602515-XReport Type:Expedited (15-DaCompany Report #2005036751
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged Other	Drug Interaction Drug Level Above Therapeutic Dysarthria Facial Bones Fracture Fall Gait Disturbance Laceration	Consumer	Lithium (Lithium) Carbamazepine (Carbamazepine) Terbinafine Hydrochloride Atorvastatin Paracetamol Zolpidem Tartrate	PS SS C C C C			

	Quadriplegia		Rofecoxib	C		

Date:03/07/05ISR Number: 4602936-5Report Type:Expedited (15-DaCompany Report #2005035266
Age:63 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anuria Drug Interaction Haemodialysis Neuroleptic Malignant Syndrome Renal Failure Acute Rhabdomyolysis	Foreign Health Professional	Lithium (Lithium) Lorazepam (Lorazepam) Trazodone Hydrochloride (Trazodone Hydrochloride) Ziprasidone (Caps) (Ziprasidone) Haloperidol (Haloperidol) Donepezil Hydrochloride (Donepezil Hydrochloride)	PS SS SS SS SS SS		ORAL	675 MG 6 MG, ORAL 400 MG 80 MG 6 MG 10 MG (1 IN 1	

D)

			Quetiapine Fumarate (Quetiapine Fumarate)	SS			
400 MG							
			Olanzapine (Olanzapine)	SS			
20 MG							

Date:03/07/05ISR Number: 4602962-6Report Type:Expedited (15-DaCompany Report #B0370903A
Age:57 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Arrhythmia	Foreign	Lithium Salt (Generic) (Lithium Salt)	PS				
	Cardiac Disorder	Literature	Olanzapine (Olanzapine)	SS				
	Mitral Valve Prolapse	Health	Methotrimeprazine (Methotrimeprazine)	SS				
	Sudden Death	Professional	Tropatepine Hydrochloride (Tropatepine Hydrochloride)	SS				
	Ventricular Hypertrophy		Clomipramine Hcl (Clomipramine Hcl)	SS				

Date:03/08/05ISR Number: 4601367-1Report Type:Expedited (15-DaCompany Report #200511752GDDC
Age:65 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Interaction		Ketek	PS	Aventis Pharmaceuticals Inc.	ORAL		
Other	Metabolic Encephalopathy							
	Therapeutic Agent Toxicity		Lithane	SS				

Date:03/08/05ISR Number: 4601645-6Report Type:Expedited (15-DaCompany Report #DE-GLAXOSMITHKLINE-D0045037A
Age:48 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Interaction Weight Increased		Quilonum Retard	PS	Glaxosmithkline	ORAL	1150MG per day	4 YR
			Leponex	SS		ORAL	75MG per day	4 YR
			Seroxat	C	Glaxosmithkline	ORAL	40MG per day	
			Lamictal	C	Glaxosmithkline		UNKNOWN	
			Zeldox	C			UNKNOWN	

Date:03/08/05ISR Number: 4601646-8Report Type:Expedited (15-DaCompany Report #DE-GLAXOSMITHKLINE-D0045136A
Age:48 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Consciousness Fluctuating Delirium Disorientation Drug Interaction Hallucination Hallucinations, Mixed Sedation Somnolence		Quilonum Retard Leponex Belladonna Herb Diazepam Orfiril Haldol	PS SS SS C C C	Glaxosmithkline	ORAL ORAL ORAL ORAL ORAL ORAL	450MG Per day 20DROP Per day 35 DAY	21 DAY

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/08/05ISR Number: 4601648-1Report Type:Expedited (15-DaCompany Report #DE-GLAXOSMITHKLINE-D0046061A
Age:37 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Interaction		Quilonum Retard	PS	Glaxosmithkline	ORAL	2TAB per day	
	Oedema Peripheral		Remergil	SS				
UNKNOWN							30MG per day	15 DAY

Date:03/08/05ISR Number: 4601649-3Report Type:Expedited (15-DaCompany Report #DE-GLAXOSMITHKLINE-D0046073A
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Depressed Level Of		Quilonum Retard	PS	Glaxosmithkline		UNKNOWN	
Initial or Prolonged	Consciousness		Quilonum	SS	Glaxosmithkline		UNKNOWN	
	Drug Level Increased		Paracetamol	SS	Glaxosmithkline	ORAL		
	Overdose							
	Therapeutic Agent							
	Toxicity							

Date:03/08/05ISR Number: 4601650-XReport Type:Expedited (15-DaCompany Report #2005003866
Age:61 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Blood Glucose Decreased		Quilonum Retard	PS	Glaxosmithkline	ORAL	450MG Twice	
Initial or Prolonged	Bowel Sounds Abnormal						per day	
	Convulsion		Leponex	SS		ORAL	25MG per day	
	Myalgia							
	Myoclonus							
	Somnolence							

Date:03/09/05ISR Number: 4602881-5Report Type:Expedited (15-DaCompany Report #ES-GLAXOSMITHKLINE-B0372711A
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Convulsion Hypernatraemia Metabolic Encephalopathy Myoclonus Renal Disorder Stupor Thinking Abnormal		Lithium Carbonate	PS	Glaxosmithkline		UNKNOWN	

Date:03/10/05ISR Number: 4603958-0Report Type:Expedited (15-DaCompany Report #2005002060
Age:75 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Atrial Fibrillation Confusional State Psychotic Disorder Somnolence Tachyarrhythmia		Quilonum Retard	PS	Glaxosmithkline	ORAL	1TAB Twice per day	

Date:03/10/05ISR Number: 4607067-6Report Type:Expedited (15-DaCompany Report #B0373014B
Age: Gender:Female I/FU:I

Outcome
Required
Intervention to

Prevent Permanent
Impairment/Damage

	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Bradycardia Neonatal	Literature	Lithium Salt					
	Congenital Anomaly	Health	(Lithium Salt)	PS				
TRANSPLACENTAL							TWICE PER DAY	
	Drug Exposure During	Professional						
/ TRANSPLACEN							6	MON
	Pregnancy		Semisodium Valproate	C				
	Dysphagia		Inhaler	C				
	Feeding Disorder							
	Hypokinesia Neonatal							
	Hypotonia							
	Micrognathia							
	Neonatal Tachypnoea							
	Poor Sucking Reflex							
	Temperature Regulation							
	Disorder							
	Therapeutic Agent							
	Toxicity							
	Tricuspid Valve							
	Incompetence							

Date:03/11/05ISR Number: 4606418-6Report Type:Expedited (15-DaCompany Report #CH-MERCK-0310CHE00016
Age:68 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Atrioventricular Block		Vioxx	PS	Merck & Co., Inc	ORAL		
							8	DAY
Hospitalization -	Complete		Lithium Carbonate	SS		ORAL		
							12	YR
Initial or Prolonged	Blood Creatinine		Lithium Carbonate	SS		ORAL		
	Increased		Carbamazepine	SS		ORAL		
	Blood Pressure Increased		Carbamazepine	SS		ORAL		
							12	YR
	Bradycardia		Pipamperone					
	Drug Interaction		Hydrochloride	C		ORAL		
							6	YR
	Drug Level Increased		Mirtazapine	C		ORAL		
							3	MON
	Drug Toxicity		Zopiclone	C		ORAL		
	Dysarthria							
	Electrocardiogram							

Abnormal
Electrocardiogram T Wave
Inversion
Extrapyramidal Disorder
Feeling Abnormal
Headache
Hypotension
Kyphosis
Lordosis
Malaise
Osteochondrosis
Pancytopenia
Renal Impairment
Sinus Arrest
Sinus Bradycardia
Somnolence
Spinal Osteoarthritis
Therapeutic Agent
Toxicity
Tremor
Vomiting

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/11/05ISR Number: 4608608-5Report Type:Expedited (15-DaCompany Report #B0373536A
Age:68 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Diabetes Insipidus Hyperparathyroidism Hypothyroidism Parathyroid Tumour Benign Sick Sinus Syndrome	Foreign Literature Health Professional	Lithium Salt (Formulation Unknown) (Lithium Salt) (Generic)	PS			30	YR

Date:03/14/05ISR Number: 4609176-4Report Type:Expedited (15-DaCompany Report #DSA_25986_2005
Age:60 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Cerebellar Syndrome	Foreign	Tavor	PS		ORAL	3 MG PO	
	Depressed Level Of Consciousness	Health Professional	Tavor	SS		ORAL	2.5 MG PO	
			Ergenyl "Labaz"	SS	Labaz	ORAL	800 MG PO	
	Drug Interaction	Other	Hypnorex	SS		ORAL	2 TAB PO; A	FEW MONTHS
			Jatrosom N	SS		ORAL	40 MG PO; A	FEW MONTHS
			Jatrosom N	SS		ORAL	30 MG PO	
			Topamax	SS		ORAL	25 MG PO	
			Topamax	SS		ORAL	50 MG PO	
			Mpa	C				
			Magnesium	C				
			Estraderm Tts	C				

Date:03/14/05ISR Number: 4609647-0Report Type:Direct Company Report #CTU 243086
Age:35 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abasia Abnormal Behaviour Blood Potassium Increased Haemodialysis Lethargy Renal Failure Acute Therapeutic Agent Toxicity		Eskalith 450 Mg Sk-Beecham	PS	Sk-Beecham	ORAL	450MG/900MG AM/PM ORAL	

Date:03/15/05ISR Number: 4608485-2Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0549462A
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Interaction Ill-Defined Disorder		Wellbutrin Sr Lithium Cogentin Klonopin Trazodone Prolixin Seroquel	PS SS SS SS SS SS SS	Glaxosmithkline Glaxosmithkline	ORAL		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/15/05ISR Number: 4608497-9Report Type:Expedited (15-DaCompany Report #2005004461
Age:39 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Asthenopia		Quilonum Retard	PS	Glaxosmithkline	ORAL	6TAB Single	
	Dizziness						dose	1 DAY
	Intentional Misuse		Risperdal	SS		ORAL	20TAB Single	
	Suicide Attempt						dose	

Date:03/15/05ISR Number: 4611431-9Report Type:Direct Company Report #CTU 243211
Age:50 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Pruritus		Lithium	PS				

Date:03/15/05ISR Number: 4613230-0Report Type:Expedited (15-DaCompany Report #2005042524
Age:21 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Anencephaly	Foreign	Lithium (Lithium)	PS		ORAL	900 MG, ORAL	
	Drug Exposure During Pregnancy	Literature Health Professional	Haloperidol (Haloperidol)	SS				
	Drug Ineffective							
	Neuroleptic Malignant Syndrome							
	Refusal Of Treatment By Patient							
	Retroplacental Haematoma							
	Spine Malformation							
	Ultrasound Antenatal Screen Abnormal							

Date:03/15/05ISR Number: 4613231-2Report Type:Expedited (15-DaCompany Report #2005042143
Age: Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Congenital Anomaly	Anencephaly	Foreign	Lithium (Lithium)	PS				
	Complications Of Maternal Exposure To Therapeutic Drugs	Literature Health Professional	Haloperidol (Haloperidol)	SS				
	Foetal Disorder							
	Small For Dates Baby							
	Spinal Disorder							

Date:03/15/05ISR Number: 4614085-0Report Type:Expedited (15-DaCompany Report #2005035202
Age:21 YR Gender:Female I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Bipolar I Disorder
	Condition Aggravated
	Drug Ineffective
	Drug Resistance
	Major Depression
	Mania
	Mood Swings
	Paraesthesia
	Psychotic Disorder
	Skin Reaction

	Speech Disorder Suicidal Ideation Treatment Noncompliance	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Weight Increased	Literature	Ziprasidone (Caps) (Ziprasidone)	PS		ORAL	20 MG (20 MG, 1 IN 1 D),
			Sertrline (Sertraline)	SS		ORAL	200 MG (QHS),
			Lithium (Lithium)	SS			1200 MG (QD),
			Clonazepam (Clonazepam)	SS			2 MG (QID),
			Fluoxetine (Fluoxetine)	SS			ML
			Topiramate (Topiramate)	SS			
			Risperidone (Risperidone)	C			
			Valproate Semisodium (Valproate Semisodium)	C			
			Quetiapine (Quetiapine)	C			
			Lamotrigine (Lamotrigine)	C			
			Oxcarbazepine (Oxcarbazepine)	C			
			Verapamil (Verapamil)	C			
			Citalopram (Citalopram)	C			

Date:03/16/05ISR Number: 4613885-0Report Type:Expedited (15-DaCompany Report #6012939
Age:62 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration

Hospitalization - Initial or Prolonged	Liver Disorder Transaminases Increased		Health Professional Other	Euthyrox (Levothyroxine Sodium) 125 MCG	PS			
SEE IMAGE	69 DAY			Hypnorex (Lithium Carbonate)	SS			
SEE IMAGE	60 DAY			Amineurin (Amitriptyline Hydrochloride)	SS			
SEE IMAGE	27 DAY			Tavor (Lorazepam)	SS			
SEE IMAGE	1 DAY			Truxal (Chlorporthixene Hydrochloride) 20 MG	SS			
SEE IMAGE	1 DAY			Lasix (Furosemide)	SS			

Date:03/17/05ISR Number: 4611610-0Report Type:Expedited (15-DaCompany Report #DE-GLAXOSMITHKLINE-D0045935A
Age:61 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain Upper		Quilonum Retard	PS	Glaxosmithkline		UNKNOWN	
	Blood Amylase Increased		Remergil	SS			UNKNOWN	8 DAY
	Lipase Increased		Zyprexa	SS			UNKNOWN	2.5MG per day 14 DAY
			Trevilor	SS			UNKNOWN	22 DAY

				Edronax	SS		
UNKNOWN	4MG per day	3	DAY				
				Tavor	C		
UNKNOWN							
				Ximovan	C		
UNKNOWN	7.5MG per day	12	DAY				

Date:03/17/05ISR Number: 4615675-1Report Type:Expedited (15-DaCompany Report #KII-2005-0015464
Age:67 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Flushing Intentional Misuse Oxygen Saturation Decreased Rash Respiratory Rate Decreased Somnolence Vomiting	Study Health Professional Other	Oxycontin Tablets (Oxycodone Hydrochloride) Cr Tablet	PS		ORAL	SEE TEXT, ORAL	
			Acetaminophen W/Oxycodone (Paracetamol, Oxycodone Hydrochloride)	SS		ORAL	SEE TEXT, ORAL	
			Lithium (Lithium)	SS		ORAL	ORAL	

Date:03/17/05ISR Number: 4619028-1Report Type:Direct Company Report #CTU 243516
Age:60 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Hospitalization - Initial or Prolonged	Blood Creatinine Increased Blood Urea Increased Confusional State Dehydration		Lithium Carbonate 450 Mg	PS		ORAL	450 MG ORAL	BID
			Hydrochlorithiazide 25 Mg	SS		ORAL	25 MG	DAILY

	Dialysis
ORAL	
	Dizziness
	Hypovolaemia
	Myoclonus
	Nephrogenic Diabetes
	Insipidus
	Therapeutic Agent
	Toxicity

Date:03/18/05ISR Number: 4616430-9Report Type:Expedited (15-DaCompany Report #L04-USA-07403-33
Age:28 YR Gender:Male I/FU:F

Outcome	PT
Death	Abdominal Pain
	Acidosis
	Blood Pressure Systolic Increased
	Blood Sodium Decreased
	Cardio-Respiratory Arrest
	Completed Suicide
	Confusional State
	Convulsion
	Diarrhoea
	Drug Screen Positive
	General Physical Health Deterioration
	Haemodialysis
	Hypotension

		Intentional Misuse Mental Status Changes Obstructive Airways	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
		Disorder Renal Failure	Literature Health Professional	Citalopram (Citalopram) Lithium (Lithium) Nortriptiline Paroxetine Valsartan Hydrochlorothiazide Gabapentin Levothyroxine	PS SS SS C C C C C		

Date:03/18/05ISR Number: 4616556-XReport Type:Expedited (15-DaCompany Report #L04-USA-07403-18
Age:40 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Blood Pressure Abnormal Completed Suicide Intentional Misuse Mydriasis Pneumonia Pupil Fixed	Literature Health Professional	Carbamazepine Clonazepam Hydrocodone W/Acetaminophen Chlordiazepoxide Lithium Quetiapine	PS SS SS SS SS SS		

Date:03/21/05ISR Number: 4616906-4Report Type:Expedited (15-DaCompany Report #2005035736
Age:63 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Anuria Body Temperature	Foreign Health	Zeldox (Capsules) (Ziprasidone)	PS		ORAL
80 MG (1 IN 1						
Other	Increased	Professional				
D), ORAL						
	Catatonia		Aricept (Donepezil)	SS		ORAL
10 MG (1 IN 1						
	Chills					
D), ORAL						
	Delirium		Lithium Acetate			

	Diarrhoea		(Lithium Acetate)	SS		
675 MG (1 IN						
	Drug Interaction					
1 D)						
	Haemodialysis		Trazaodne			
	Neuroleptic Malignant		(Trazadone)	SS		
400 MG (1 IN						
	Syndrome					
1 D)						
	Renal Failure Acute		Haloperidol			
	Rhabdomyolysis		(Haloperidol)	SS		ORAL
6 MG (1 IN 1						
D), ORAL						
			Lorazepam			
			(Lorazepam)	SS		ORAL
6 MG (1 IN 1						
D), ORAL						
			Quetiapone Fumarte (Quetiapine Fumarate)	C		
			Olanzapine (Olanzapine)	C		

Date:03/21/05ISR Number: 4619722-2Report Type:Direct Company Report #CTU 243823
Age:42 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Disability	Blindness		Haldol	PS		
	Medication Error		Lithuim	SS		

				Prolixin	SS		
				Seroquel	SS		
				..	C		
				..	C		

Date:03/22/05ISR Number: 4614765-7Report Type:Expedited (15-DaCompany Report #IE-BRISTOL-MYERS SQUIBB COMPANY-12648671
Age:72 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dry Mouth		Lipostat	PS	Bristol-Myers Squibb Company	ORAL	10	DAY
	Salivary Hypersecretion							
	Therapy Non-Responder		Lithium	SS		ORAL	10	YR
			Innovace	C		ORAL	3	YR
			Nu-Seals Aspirin	C			3	YR

Date:03/22/05ISR Number: 4615142-5Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0550434A
Age:53 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Depressed Level Of Consciousness		Eskalith Cr	PS	Glaxosmithkline	ORAL	900MG Twice per day	15 DAY
	Drug Level Increased		Lithium	SS	Glaxosmithkline	ORAL	900MG Twice per day	
	Hypoglycaemia							
	Mental Status Changes		Glucophage	C				
	Urinary Tract Infection		Glipizide	C				
			Effexor	C				
			Risperdal	C				
			Synthroid	C	Glaxosmithkline			
			Allegra	C				
			Desyrel	C				
			Nadolol	C				
			Prinivil	C				

Date:03/22/05ISR Number: 4615571-XReport Type:Expedited (15-DaCompany Report #BE-MERCK-0503USA02984
Age:74 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agitation		Prinivil	PS	Merck & Co., Inc	ORAL		
	Apathy		Lithium Carbonate	SS				UNKNOWN
	Blood Creatinine		Escitalopram Oxalate	SS				UNKNOWN
	Increased		Levomepromazine	SS				UNKNOWN
	Confusional State		Irbesartan	SS				UNKNOWN
	Creatinine Renal		Spironolactone	SS				UNKNOWN
	Clearance Decreased		Dexetimide	SS				UNKNOWN
	Dehydration		Furosemide	SS				UNKNOWN
	Diarrhoea		Lormetazepam	C				UNKNOWN
	Drug Interaction		Metformin	C				UNKNOWN
	Dysarthria		Repaglinide	C				UNKNOWN
	Lethargy							
	Motor Dysfunction							
	Oliguria							
	Performance Status Decreased							
	Somnolence							
	Therapeutic Agent Toxicity							
	Tremor							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/22/05ISR Number: 4617599-2Report Type:Expedited (15-DaCompany Report #MOBN20050001
Age:43 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardiomegaly	Literature	Molindone 50 Mg					
	Circulatory Collapse	Health	Unknown	PS		ORAL	100 MG BID PO	
	Completed Suicide	Professional	Lithium	SS		ORAL	PO	
	Hypertension							
	Hypothyroidism							
	Intentional Misuse							
	Pyelonephritis Chronic							

Date:03/23/05ISR Number: 4618857-8Report Type:Expedited (15-DaCompany Report #2005044232
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Alopecia	Consumer	Neurontin					
	Antipsychotic Drug Level Increased		(Gabapentin)	PS		ORAL	800 MG (1 D), ORAL	
	Bipolar Disorder		Lithium (Lithium)	SS				
	Bladder Prolapse		Cyclobenzaprine (Cyclobenzaprine)	C				
	Breath Odour		Thyroid (Thyroid)	C				
	Dental Necrosis		All Other Therapeutic Products (All Other Therapeutic Products)	C				
	Drug Ineffective		Clonazepam (Clonazepam)	C				
	Hypoaesthesia		Rosiglitazone Maleate (Rosiglitazone Maleate)	C				
	Medication Error		Naproxen (Naproxen)	C				
	Panic Attack		Simvastatin (Simvastatin)	C				
	Tooth Discolouration							
	Tooth Loss							

Date:03/23/05ISR Number: 4618902-XReport Type:Expedited (15-DaCompany Report #MOBN20050001
Age:43 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardiomegaly	Literature	Molindone 50 Mg	PS		ORAL	100 MG BID PO	
	Circulatory Collapse	Health	Lithium	SS		ORAL	PO	
	Completed Suicide	Professional						
	Drug Toxicity							
	Hypertension							
	Hypothyroidism							
	Intentional Misuse							
	Pyelonephritis Chronic							

Date:03/23/05ISR Number: 4620056-0Report Type:Direct Company Report #CTU 244078
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Tremor		Lithium 300mg	PS		ORAL	300MG AMHS	

ORAL

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/23/05ISR Number: 4620059-6Report Type:Direct Company Report #CTU 244079
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product		Role	Manufacturer	Route	Dose	Duration
Other	Tremor		Lithium	300mg	PS		ORAL	300MG	AMHS
								ORAL	

Date:03/23/05ISR Number: 4620068-7Report Type:Direct Company Report #CTU 244083
Age:51 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product		Role	Manufacturer	Route	Dose	Duration
Other	Drug Interaction		Chlorpromazine	100 Mg	PS		ORAL	QD	ORAL
			Lithium	300 Mg	SS		ORAL	1200MG	QD
								ORAL	

Date:03/24/05ISR Number: 4617606-7Report Type:Expedited (15-DaCompany Report #US-MERCK-0503USA03482
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Adverse Event		Cogentin	PS	Merck & Co., Inc	ORAL	UNKNOWN	
	Drug Interaction		Wellbutrin Sr	SS				
			Lithium Carbonate	SS		ORAL	UNKNOWN	
			Klonopin	SS				
			Trazodone Hydrochloride	SS			UNKNOWN	
			Seroquel	SS			UNKNOWN	
			Prolixin	SS			UNKNOWN	

Date:03/25/05ISR Number: 4619476-XReport Type:Expedited (15-DaCompany Report #US-JNJFOC-20050106806
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Abnormal Dreams		Risperdal	PS		OROPHARINGEAL		
Initial or Prolonged	Amnesia		Lithium	SS		OROPHARINGEAL		
	Confusional State		Lithium	SS		OROPHARINGEAL		
	Dehydration		Klonapin	C		OROPHARINGEAL		
	Nasopharyngitis		Effexor Xl	C				
	Nightmare		Topamax	C				
	Therapeutic Agent Toxicity							
	Urinary Tract Infection							

Date:03/29/05ISR Number: 4621856-3Report Type:Expedited (15-DaCompany Report #FR-BRISTOL-MYERS SQUIBB COMPANY-12903332
Age:62 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Hypercalcaemia		Vasten	PS	Bristol-Myers Squibb Company	ORAL		
Hospitalization -	Hyperparathyroidism							
Initial or Prolonged	Nephrogenic Diabetes Insipidus		Teralithe	SS		ORAL		
			Tercian	SS		ORAL	5	DAY
			Loxen	SS		ORAL	5	DAY
			Tranxene	SS		ORAL	4	DAY
			Levothyrox	C		ORAL		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/29/05ISR Number: 4621918-0Report Type:Expedited (15-DaCompany Report #DE-GLAXOSMITHKLINE-D0046073A
Age:64 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Asterixis		Quilonum Retard	PS	Glaxosmithkline	UNKNOWN	1TAB Twice per day	
	Delirium							
	Depressed Level Of Consciousness		Paracetamol	SS	Glaxosmithkline	ORAL	10G per day	
	Drug Abuser							
	Drug Level Increased							
	Haemodialysis							
	Overdose							
	Somnolence							
	Therapeutic Agent Toxicity							

Date:03/29/05ISR Number: 4621934-9Report Type:Expedited (15-DaCompany Report #US-BRISTOL-MYERS SQUIBB COMPANY-12908679
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Interaction		Trazodone Hcl	PS	Apothecon			
			Prolixin	I	Apothecon			
			Wellbutrin Sr	I				
			Lithium	I		ORAL		
			Benztropine Mesylate	I				
			Clonazepam	I				
			Quetiapine Fumarate	I				

Date:03/29/05ISR Number: 4622106-4Report Type:Expedited (15-DaCompany Report #2004009355
Age: Gender:Male I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Abdominal Injury
	Abdominal Pain
Other	Back Disorder
	Blood Cholesterol Increased
	Chest Pain

Contusion
Coordination Abnormal
Difficulty In Walking
Disorientation
Drug Ineffective
Erectile Dysfunction
Facial Pain
Feeling Cold
Gastrooesophageal Reflux
Disease
General Physical Health
Deterioration
Glossodynia
Hostility
Hyporeflexia
Impaired Healing
Injury
Irritability
Limb Injury
Movement Disorder
Muscle Spasms
Myalgia

	Neck Pain Oesophageal Spasm Pain In Extremity Pain In Jaw Road Traffic Accident Sedation Sleep Disorder Somnolence Tenderness Tooth Abscess Tremor Vertigo	Report Source Consumer Health Professional	Product Neurontin (Gabapentin) Lipitor (Atorvastatin) Lithium (Lithium) (Lithium) Naproxen (Naproxen) Amoxicillin (Amoxicillin) (Amoxicillin) Rofecoxib (Rofecoxib) Levothyroxine Sodium (Levothyroxine Sodium) Vitamins (Vitamins) Diltiazem Hydrochloride (Diltiazem Hydrochloride)	Role PS SS SS SS SS C C C	Manufacturer	Route ORAL ORAL ORAL
Dose	Duration					
1800 MG (600 MG, 3 IN 1 D), ORAL 20 MG (20 MG, 1 IN 1 D), ORAL 1000 MG (1 IN 2 D), ORAL						

Date:03/29/05ISR Number: 4623237-5Report Type:Expedited (15-DaCompany Report #2005-BP-04789RO
Age:54 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization - Initial or Prolonged	Amnesia Dehydration	Health Professional	Lithium Carbonate Capsules Usp, 300 Mg			

	Depressed Level Of		(Lithium Carbonate)	PS		ORAL
900 MG TID						
	Consciousness					
(300 MG), PO						
	Influenza					
	Nasopharyngitis					
	Therapeutic Agent					
	Toxicity					

Date:03/30/05ISR Number: 4622842-XReport Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0550491A
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Multiple Drug Overdose		Lithium	PS	Glaxosmithkline	
	Overdose		Lamictal	SS	Glaxosmithkline	ORAL
			Unspecified Medication	SS		

Date:03/30/05ISR Number: 4622962-XReport Type:Expedited (15-DaCompany Report #PHNR2005AU00572
Age:67 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Drug Interaction		Clozaril	PS	Novartis Sector: Pharma	
	Drug Level Increased					
12 - 700						
mg/day 1705 DAY						

				Clozaril	SS	Novartis Sector: Pharma	
12 mg, QD							
				Lithium	SS		
				Celebrex	SS		
				Sertraline	SS		

Date:03/30/05ISR Number: 4623447-7Report Type:Expedited (15-DaCompany Report #2005042524
Age:21 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Neuroleptic Malignant Syndrome	Foreign Literature	Lithium (Lithium) Haloperidol	PS		ORAL	900 MG, ORAL	
	Retroplacental Haematoma	Health	(Haloperidol)	SS				
	Unintended Pregnancy	Professional						

Date:03/30/05ISR Number: 4624293-0Report Type:Direct Company Report #CTU 244786
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Drug Ineffective		Lithium Er (Generic)					
Other	Gastrointestinal Disorder		300mg	PS			300 MG ONCE A	
	Gastrooesophageal Reflux Disease						DAY [OVER PAST 10 YEARS]	10 YR

Date:03/30/05ISR Number: 4625707-2Report Type:Expedited (15-DaCompany Report #2005042143
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Congenital Anomaly	Anencephaly	Foreign	Lithium (Lithium)	PS				
	Congenital Spinal Cord Anomaly	Literature Health	Haloperidol (Haloperidol)	SS				

	Drug Exposure During Pregnancy	Professional
	Retroplacental Haematoma	

Date:03/30/05ISR Number: 4626831-0Report Type:Expedited (15-DaCompany Report #B0373535A
Age:56 YR Gender:Female I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Activities Of Daily Living Impaired
	Agitation
	Blood Calcium Increased
	Blood Parathyroid Hormone Increased
	Confusional State
	Delirium
	Difficulty In Walking
	Drug Toxicity
	Fall
	Hyperthyroidism
	Polydipsia
	Polyuria
	Psoriasis
	Respiratory Failure
	Restlessness

	Skin Turgor Decreased					
	Speech Disorder					
	Sputum Retention	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
		Foreign	Lithium Salt			
		Literature	(Formulation			
		Health	Unknown) (Generic)			
		Professional	(Lithium Salt)	PS		
30 YR						

Date:03/31/05ISR Number: 4627220-5Report Type:Expedited (15-DaCompany Report #2005UW04517
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization -	Drug Interaction	Health	Seroquel	PS		
Initial or Prolonged		Professional	Wellbutrin - Slow			
			Release	SS		
			Lithium	SS		
			Cogentin	SS		
			Klonopin	SS		
			Trazodone	SS		
			Prolixin	SS		

Date:04/04/05ISR Number: 4626344-6Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0552174A
Age:54 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization -	Amnesia		Lithium Carbonate	PS	Glaxosmithkline	ORAL
900MG Three						
Initial or Prolonged	Dehydration					
times per day						
	Depressed Level Of		Risperdal	C		
	Consciousness		Klonopin	C		
	Influenza					
	Nasopharyngitis					
	Therapeutic Agent					
	Toxicity					

Date:04/04/05ISR Number: 4626363-XReport Type:Expedited (15-DaCompany Report #IE-GLAXOSMITHKLINE-B0376280A
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Balance Disorder		Lamictal	PS	Glaxosmithkline		2	MON
	Coordination Abnormal		Lithium	SS	Glaxosmithkline			YR
	Dizziness							
	Dysarthria							
	Extrapyramidal Disorder							
	Hypertonia							
	Tremor							

Date:04/04/05ISR Number: 4626372-0Report Type:Expedited (15-DaCompany Report #BE-BRISTOL-MYERS SQUIBB COMPANY-12907242
Age:74 YR Gender:Female I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Apathy
	Confusional State
	Dehydration
	Diarrhoea
	Drug Interaction
	Dysarthria
	Lethargy

	Oliguria						
	Therapeutic Agent Toxicity	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Tremor		Lithium Carbonate	PS			
			Levomepromazine	SS			
			Spironolactone	SS			
			Furosemide	SS			
			Escitalopram	SS			
			Lormetazepam	C			
			Repaglinide	C			
			Metformin Hcl	C	Bristol-Myers Squibb Company		
			Irbesartan	I	Bristol-Myers Squibb Company		
			Prinivil	I		ORAL	
			Risperidone	I			

Date:04/04/05ISR Number: 4629280-4Report Type:Direct Company Report #CTU 245146
Age:53 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Life-Threatening	Blood Glucose Decreased		Eskalith Cr 450 Mg	PS			900 MG BID
Hospitalization - Initial or Prolonged	Depressed Level Of Consciousness		Lisinopril 5 Mg	C			5 MG QD
	Drug Interaction						
	Drug Level Increased						
	Encephalopathy						
	Mental Status Changes						
	Movement Disorder						
	Urinary Tract Infection						

Date:04/04/05ISR Number: 4629349-4Report Type:Expedited (15-DaCompany Report #B0375015A
Age:65 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Death	Conjunctival Hyperaemia	Foreign	Lithium Carbonate				
	Contusion	Literature	(Lithium Carbonate)				
	Excoriation	Health	(Generic)	PS			

	Neuroleptic Malignant Syndrome Serotonin Syndrome Tryptase Increased	Professional	Clomipramine Hcl (Clomipramine Hcl) Fluvoxamine (Fluvoxamine) Methotrimeprazine (Methotrimeprazine)	SS SS SS

Date:04/05/05ISR Number: 4626980-7Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20050106806
Age: Gender:Male I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Abnormal Dreams Amnesia Confusional State Dehydration Drug Interaction Nasopharyngitis Nightmare Therapeutic Agent Toxicity

Urinary Tract Infection

		Report Source	Product	Role	Manufacturer	Route	Dose	Duration
			Risperdal	PS			OROPHARINGEAL	
			Lithium	SS			OROPHARINGEAL	
			Lithium	SS			OROPHARINGEAL	
			Klonapin	C			OROPHARINGEAL	
			Effexor Xl	C				
			Topamax	C				

Date:04/05/05ISR Number: 4627170-4Report Type:Expedited (15-DaCompany Report #2005002950
Age:36 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Fatigue Hypotension		Quilonum Retard	PS	Glaxosmithkline	ORAL	450MG See dosage text	1 DAY
Other	Intentional Misuse Suicide Attempt		Zodurat	SS		ORAL	7.5MG See dosage text	1 DAY

Date:04/05/05ISR Number: 4627297-7Report Type:Expedited (15-DaCompany Report #US-BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.-2005-
BAge:54 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Amnesia Dehydration General Physical Health Deterioration Malaise Nasopharyngitis		Lithium Carbonate Capsules Usp, 300 Mg	PS	Roxane Laboratories, Inc.	ORAL	1800 mg/day	
	Therapeutic Agent		Lithium Carbonate Capsules Usp, 300 Mg Topamax	SS C	Roxane Laboratories, Inc.	ORAL	300 mg bid	

	Toxicity		Effexor	C		ORAL
			Synthroid	C		ORAL

Date:04/05/05ISR Number: 4629335-4Report Type:Expedited (15-DaCompany Report #2005-BP-04789RO
Age:54 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Amnesia Dehydration Depressed Level Of Consciousness Drug Level Above Therapeutic Influenza Nasopharyngitis Therapeutic Agent Toxicity	Health Professional	Lithium Carbonate Capsules Usp, 300 Mg (Lithium Carbonate) Topamax (Topiramate) Effexor (Venlafaxine Hydrochloride) Synthroid (Levothyroxine Sodium)	PS C C C		ORAL	1800 MG/DAY (300 MG) PO	

Date:04/06/05ISR Number: 4628094-9Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0536505A
Age:29 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Anaemia Nephritis Interstitial Renal Failure Chronic		Lamictal Lithium Topamax Seroquel	PS SS C C	Glaxosmithkline Glaxosmithkline	ORAL	UNKNOWN UNKNOWN UNKNOWN	3 YR 100NG At night

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/06/05ISR Number: 4628134-7Report Type:Expedited (15-DaCompany Report #2005005884
Age:43 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Intentional Misuse		Quilonum Retard	PS	Glaxosmithkline	ORAL	9000MG Single	
	Mydriasis							
	Somnolence		Zyprexa	SS		ORAL	75MG Single	
	Suicide Attempt							
			Doxepin	SS		ORAL	2000MG Single	
			Ibuprofen	SS	Glaxosmithkline	ORAL	6000MG Single	
			Lorazepam	SS		ORAL	10TAB Single	
			Pipamperon	SS		ORAL	400MG Single	
			Alcohol	SS		ORAL		

Date:04/07/05ISR Number: 4629134-3Report Type:Expedited (15-DaCompany Report #200511752GDDC
Age:65 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Amnesia		Ketek	PS	Aventis Pharmaceuticals Inc.	ORAL		
Other	Confusional State							
	Drug Interaction		Lithane	SS				
	Metabolic Encephalopathy							
	Speech Disorder							
	Therapeutic Agent Toxicity							

Date:04/08/05ISR Number: 4630106-3Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0550434A
Age:53 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Depressed Level Of Consciousness		Eskalith Cr	PS	Glaxosmithkline	ORAL	900MG Twice per day	15 DAY
Other	Drug Level Increased		Lithium	SS	Glaxosmithkline	ORAL	900MG Twice per day	
	Hypoglycaemia							
	Mental Status Changes		Glucophage	C				
	Urinary Tract Infection		Glipizide	C				
			Effexor	C				
			Risperdal	C				
			Synthroid	C	Glaxosmithkline			
			Allegra	C				
			Desyrel	C				
			Nadolol	C				
			Prinivil	C		ORAL	5MG Per day	5 DAY
			Prinivil	C		ORAL	10MG Per day	2 DAY

Date:04/08/05ISR Number: 4630755-2Report Type:Expedited (15-DaCompany Report #US-ROCHE-400153
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Interaction		Klonopin	PS	Roche		UNKNOWN	
			Wellbutrin Sr	I		ORAL		
			Lithium Salt	I			UNKNOWN	
			Cogentin	I			UNKNOWN	
			Trazodone	I	Roche		UNKNOWN	
			Prolixin	I			UNKNOWN	

			Seroquel	I			
UNKNOWN							

Date:04/11/05ISR Number: 4632378-8Report Type:Expedited (15-DaCompany Report #SE-GLAXOSMITHKLINE-B0375995A
Age:48 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Depression		Lamictal	PS	Glaxosmithkline	ORAL	25MG Unknown	8 MON
Initial or Prolonged	Drug Interaction		Lithium	SS	Glaxosmithkline	ORAL	40MG per day	1 DAY
	Mania							

Date:04/11/05ISR Number: 4635063-1Report Type:Expedited (15-DaCompany Report #A001-002-006453
Age:63 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Balance Disorder	Health	Aricept (Donepezil					
Initial or Prolonged	Depressed Level Of	Professional	Hydrochloride)	PS		ORAL	SEE MAGE	
	Consciousness		Lithium (Lithium)	SS		ORAL	ORAL	
	Dizziness		Statin					
	Drug Interaction		(?Lipitor/Atorvastat					
	Therapeutic Agent		in)	C				
	Toxicity							

Date:04/12/05ISR Number: 4633104-9Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0545940A
Age:60 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Blood Potassium Abnormal		Lamictal	PS	Glaxosmithkline	ORAL	6 MON	
Initial or Prolonged	Bradyphrenia		Depakote	SS		ORAL	500MG Unknown	
Other	Depressive Symptom		Lithium	SS	Glaxosmithkline			
	Drug Interaction		Effexor	C			225MG per day	

	Hypernatraemia		Multiple Medications	C		
	Hypothyroidism		Clonazepam	C		
.5MG At night						
	Leukocytosis		Abilify	C		
	Renal Failure					

Date:04/13/05ISR Number: 4634095-7Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0553380A
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Accidental Overdose		Eskalith Cr	PS	Glaxosmithkline	ORAL	450MG Twice
Initial or Prolonged	Drug Level Increased						per day
	Insomnia		Lithium Sr	SS	Glaxosmithkline	ORAL	450MG Twice
	Weight Increased						per day
			Sleeping Pills	C			
			Synthroid	C	Glaxosmithkline		
			Water Pill	C			

Date:04/13/05ISR Number: 4634159-8Report Type:Expedited (15-DaCompany Report #JP-SOLVAY-00305001107
Age:65 YR Gender:Female I/FU:I

Outcome	PT
Death	Chills
	Hyperhidrosis
	Hyperreflexia
	Hyperthermia
	Mental Status Changes

	Myoclonus Neuroleptic Malignant Syndrome	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Restlessness		Fluvoxamine	PS			UNKNOWN Daily dose:
	Rhabdomyolysis						unknown
	Tremor		Clomipramine	SS			UNKNOWN Daily dose:
							unknown
			Lithium	SS			UNKNOWN Daily dose:
							unknown
			Levomepromazine	SS			UNKNOWN Daily dose:
							unknown

Date:04/13/05ISR Number: 4635795-5Report Type:Expedited (15-DaCompany Report #B0376118A
Age:15 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	Benign Intracranial Hypertension Eye Pain Headache Hypoaesthesia Musculoskeletal Stiffness Paraesthesia Sleep Disorder Due To General Medical Condition, Insomnia Type Vision Blurred	Literature Health Professional	Lithium Salt (Lithium Salt) Minocycline (Minocycline) Quetiapine	PS SS C			75 MG/TWICE PER DAY

Date:04/13/05ISR Number: 4635855-9Report Type:Expedited (15-DaCompany Report #KII-2005-0015822
Age:47 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Bowel Sounds Abnormal Confusional State Coordination Abnormal Lethargy	Study Health Professional Other	Oxycontin Tablets (Oxycodone Hydrochloride) Cr Tablet	PS		ORAL		
	Mental Status Changes Multiple Drug Overdose Pupil Fixed		Hydrocodone W/Acetaminophen (Paracetamol, Hydrocodone Bitartrate)	SS		ORAL		
			Benzodiazepine Derivatives ()	SS		ORAL		
			Lithium (Lithium)	SS		ORAL		
			Antiepileptics	C				
			Ssri	C				
			Antipsychotics	C				

Date:04/14/05ISR Number: 4634922-3Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20050106806
Age: Gender:Male I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Amnesia Confusional State Dehydration Myocardial Infarction Nasopharyngitis Nightmare

	Therapeutic Agent Toxicity Urinary Tract Infection	Report Source	Product	Role	Manufacturer	Route	Dose Duration
			Risperdal	PS		OROPHARINGEAL	
			Risperdal	SS		OROPHARINGEAL	one dose
			Lithium	SS		OROPHARINGEAL	
			Lithium	SS		OROPHARINGEAL	
			Klonapin	C		OROPHARINGEAL	
			Effexor Xl	C			
			Topamax	C			

Date:04/15/05ISR Number: 4638608-0Report Type:Direct Company Report #CTU 246307
Age:60 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Bipolar Disorder Dementia		Thiothixene	PS	Sandos	ORAL	5 MG PO ONE QHS 60 DAY
Other	Hepatic Failure Renal Failure		Lithium Carbonate	SS	Barr	ORAL	300MG PO ONCE BID 60 DAY

Date:04/18/05ISR Number: 4637642-4Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-B0376785A
Age:46 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Bradycardia		Lithium	PS	Glaxosmithkline		UNKNOWN 261 DAY
Initial or Prolonged	Drug Interaction		Lisinopril	SS			UNKNOWN 20MG Per day 78 DAY
	Drug Level Below		Fosinopril	C			20MG In the

	Therapeutic		
morning			
	Salivary Hypersecretion	Haloperidol	C
10MG Twice			
	Sedation		
per day			
	Therapeutic Agent	Benztropine	C
1MG Twice per			
	Toxicity		
day			
	Tremor	Olanzapine	C
20MG At night			
		Clonazepam	C
1MG Twice per			
day			
		Divalproex Sodium	C
1250MG Per			
day			
		Simvastatin	C
10MG At night			
		Atenolol	C
100MG In the			
morning			
		Sodium Valproate	C

Date:04/18/05ISR Number: 4637664-3Report Type:Expedited (15-DaCompany Report #DE-GLAXOSMITHKLINE-D0046106A
Age:75 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Chills		Quilonum Retard	PS	Glaxosmithkline	ORAL	225MG per day	73 DAY
Initial or Prolonged	Masked Facies		Zyprexa	SS		ORAL	53 DAY	
	Parkinsonian Gait		Molsidomin	C		ORAL	8MG per day	
	Parkinsonism		Isdn Ass	C C	Glaxosmithkline	ORAL	100MG per day	
			Zocor	C		ORAL	20MG per day	267 DAY
			Propra Ratiopharm	C		ORAL	30MG per day	292 DAY
			Favistan	C		ORAL	1TAB per day	278 DAY
			Seroquel	C			UNKNOWN	

Leponex C

UNKNOWN

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/18/05ISR Number: 4639254-5Report Type:Expedited (15-DaCompany Report #2005UW05644
Age:43 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Life-Threatening	Aortic Stenosis	Study	Lithium	PS		ORAL	600 MG DAILY
Hospitalization -	Arrhythmia	Health					PO
Initial or Prolonged	Atrioventricular Block	Professional	Placebo	SS		ORAL	400 MG DAILY
	Complete						PO
	Bradycardia		Tylenol	SS		ORAL	2500 MG DAILY
	Cardiac Murmur						PO
	Dizziness		Tylenol Pm	SS		ORAL	1500 MG HS PO
	Loss Of Consciousness		Aspirin	SS		ORAL	975 MG DAILY
	Mitral Valve Incompetence						PO
	Syncope		Aleve /00256202	SS		ORAL	1200 MG DAILY
							PO

Date:04/19/05ISR Number: 4639121-7Report Type:Expedited (15-DaCompany Report #US-MERCK-0504USA01869
Age:46 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Blood Creatinine		Prinivil	PS	Merck & Co., Inc	ORAL	78 DAY
Initial or Prolonged	Increased		Lithium Gluconate	SS		ORAL	70 DAY
	Blood Potassium Increased		Lithium Gluconate	SS		ORAL	113 DAY
	Bradycardia		Lithium Gluconate	SS		ORAL	78 DAY
	Drug Interaction		Fosinopril Sodium	C		ORAL	
	Salivary Hypersecretion		Haloperidol	C			UNKNOWN

	Therapeutic Agent		Benztropine Mesylate	C		
UNKNOWN						
	Toxicity		Olanzapine	C		
UNKNOWN						
			Clonazepam	C		
UNKNOWN						
			Divalproex Sodium	C		
UNKNOWN						
			Zocor	C		ORAL
			Atenolol	C		
UNKNOWN						

Date:04/19/05ISR Number: 4640635-4Report Type:Expedited (15-DaCompany Report #2005055604
Age:65 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Conjunctival Hyperaemia	Foreign	Lithium (Lithium)	PS		
Hospitalization -	Contusion	Literature	Clomipramine			
Initial or Prolonged	Excoriation	Health	Hydrochloride			
Other	Petechiae	Professional	(Clomipramine			
	Serotonin Syndrome		Hydrochloride)	SS		
			Fluvoxamine Maleate			
			(Fluvoxamine			
			Maleate)	SS		
			Levomepromazine			
			(Levomepromazine)	SS		

Date:04/19/05ISR Number: 4641022-5Report Type:Direct Company Report #CTU 246563
Age:48 YR Gender:Male I/FU:I

Outcome	PT
Death	Abasia
	Arrhythmia
	Asthenia
	Cardio-Respiratory Arrest
	Confusional State
	Fluid Intake Reduced
	Lethargy

	Morbid Thoughts Oral Intake Reduced Tremor	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
			Lithium Carbonate 450 Mg Cr	PS		
450 MG BY MOUTH TWICE DAILY 10 YR						
			Furosemide	C		
			Asa	C		
			Levothyroxine	C		
			Omeprazole	C		
			Metocarbamol	C		
			Fioricet	C		
			Orlistat	C		
			Citalopram	C		
			Clonazepam	C		
			Tramadol	C		
			Ziprasidone	C		

Date:04/19/05ISR Number: 4641227-3Report Type:Direct Company Report #CTU 246589
Age:57 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Acute Myocardial Infarction		Lithium 300 Mg	PS		
1 CAPSULE THREE TIMES A DAY						
	Dehydration					
	Drug Interaction		Aspirin	C		
	Drug Toxicity		Ciprofloxacin	C		
	Hypothyroidism		Clindamycin	C		
	Renal Impairment		Clopidogrel	C		
			Vicodin	C		
			Hydrochlorothiazide	C		
			Levothyroxine	C		
			Lisinopril	C		
			Metformin	C		
			Metoprolol	C		
			Omeprazole	C		

			Spironolactone	C			

Date:04/20/05ISR Number: 4640295-2Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0501612A
Age:64 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Bradycardia		Eskalith	PS	Glaxosmithkline	ORAL	450MG Twice	
	Dizziness						per day	4 YR
	Dyspnoea		Paxil	C	Glaxosmithkline			
			Synthroid	C	Glaxosmithkline			

Date:04/20/05ISR Number: 4640296-4Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0502181A
Age: YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Haematuria		Eskalith	PS	Glaxosmithkline	ORAL	450MG Twice	
	Ketonuria						per day	6 WK
	Pollakiuria		Risperdal	C				
	Proteinuria							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/20/05ISR Number: 4640297-6Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0502369A
Age: YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Interaction		Eskalith	PS	Glaxosmithkline	ORAL	20	YR
	Drug Level Increased		Lisinopril	SS				

Date:04/20/05ISR Number: 4640298-8Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0507917A
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Sedation		Eskalith	PS	Glaxosmithkline	ORAL	450MG Per day	
			Lithium Carbonate	C	Glaxosmithkline			

Date:04/20/05ISR Number: 4640299-XReport Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0509247A
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Insomnia		Eskalith	PS	Glaxosmithkline	ORAL		
			Trileptal	C				
			Neurontin	C				

Date:04/20/05ISR Number: 4640300-3Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0509449A
Age:67 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Tinnitus		Eskalith	PS	Glaxosmithkline	ORAL	450MG Per day	15 YR

Date:04/20/05ISR Number: 4640301-5Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0510748A
Age:16 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Alopecia		Eskalith	PS	Glaxosmithkline	ORAL	225MG Twice per day	6 WK

Date:04/20/05ISR Number: 4640302-7Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0512616A
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Depressed Mood		Eskalith	PS	Glaxosmithkline	ORAL	450MG Three times per day	14 YR
	Drug Level Increased							
	Pharmaceutical Product Complaint							
	Tremor							
	Vision Blurred							

Date:04/20/05ISR Number: 4640303-9Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0513487A
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Tremor		Eskalith	PS	Glaxosmithkline	ORAL	900MG Per day	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/20/05ISR Number: 4640304-0Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0513603A
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Dehydration		Eskalith	PS	Glaxosmithkline	ORAL	1300MG	
	Diarrhoea							Unknown
			No Concurrent Medication	C				

Date:04/20/05ISR Number: 4640305-2Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0514513A
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Diarrhoea		Eskalith	PS	Glaxosmithkline	ORAL	10	YR
	Tinnitus		Thyroid Medication	C				

Date:04/20/05ISR Number: 4640306-4Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0514857A
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Pharyngolaryngeal Pain		Eskalith	PS	Glaxosmithkline	ORAL	450MG Per day	2 WK
	Swollen Tongue		Vaseretic	C				
			Vasotec	C				
			Potassium	C				
			Allopurinol	C	Glaxosmithkline			
			Glucophage	C				
			Pavulon	C				
			Vitamins	C				

Date:04/20/05ISR Number: 4640307-6Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0518080A
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Other	Dyspepsia		Eskalith	PS	Glaxosmithkline	ORAL
300MG Per day 5 YR						
	Goitre		Lithium Carbonate	SS	Glaxosmithkline	
15 YR						
	Psoriasis		Neurontin	C		
			Diovan	C		
			Humalog	C		
			Lantus	C		
			Tricor	C		
			Avandia	C	Glaxosmithkline	
			Lipitor	C		
			Metoprolol	C		
			Aspirin	C	Glaxosmithkline	

Date:04/20/05ISR Number: 4640308-8Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0519202A
Age:12 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
	Blood Thyroid Stimulating		Eskalith	PS	Glaxosmithkline	ORAL
150MG Twice						
	Hormone Increased					
per day						
	Thyroxine Free Increased		No Concurrent			
			Medication	C		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/20/05ISR Number: 4640309-XReport Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0520099A
Age:45 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Antipsychotic Drug Level		Eskalith	PS	Glaxosmithkline	ORAL	900MG At	
	Below Therapeutic						night	
			Risperdal	C				
			Cogentin	C				

Date:04/20/05ISR Number: 4640311-8Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0520305A
Age:47 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Diarrhoea		Eskalith	PS	Glaxosmithkline	ORAL		
	Nausea							

Date:04/20/05ISR Number: 4640312-XReport Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0521666A
Age:68 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Creatinine Renal		Eskalith	PS	Glaxosmithkline	ORAL	450MG Twice	
	Clearance Decreased						per day	15 YR

Date:04/20/05ISR Number: 4640313-1Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0521827A
Age:62 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Haemorrhage Urinary Tract		Eskalith	PS	Glaxosmithkline	ORAL	450MG Twice	
	Medication Error						per day	2 WK
	Visual Disturbance		Toprol	C				
			Nexium	C				

Lipitor	C		
Aspirin	C	Glaxosmithkline	
Multivitamin	C		

Date:04/20/05ISR Number: 4640314-3Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0528127A
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Tinnitus		Eskalith	PS	Glaxosmithkline	ORAL	450MG Per day	
	Tremor							

Date:04/20/05ISR Number: 4640315-5Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0530337A
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Dizziness		Eskalith Cr	PS	Glaxosmithkline	ORAL	450MG Unknown	
	Nausea							
	Pharmaceutical Product Complaint							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/20/05ISR Number: 4640316-7Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0530626A
Age:65 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Alopecia		Eskalith	PS	Glaxosmithkline	ORAL	6	WK
	Hypotrichosis		Wellbutrin	SS	Glaxosmithkline	ORAL	300MG Per day	6 WK
			Wellbutrin	SS	Glaxosmithkline	ORAL	100MG Four times per day	5 YR
			Humibid	C				
			Robaxin	C				
			Ultram	C				
			Neurontin	C				
			Valium	C				

Date:04/20/05ISR Number: 4640317-9Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0530910A
Age:63 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Tremor		Eskalith	PS	Glaxosmithkline	ORAL	600MG Twice per day	4 YR
			Glucophage	C				
			Lisinopril	C			UNKNOWN	
			Levothyroxin	C	Glaxosmithkline		UNKNOWN	
			Aspirin	C	Glaxosmithkline			
			Multivitamins	C				

Date:04/20/05ISR Number: 4640318-0Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0531334A
Age:63 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Influenza Like Illness		Lithium Carbonate	PS	Glaxosmithkline	ORAL	450MG Per day	2 DAY

Somnolence

Date:04/20/05ISR Number: 4640319-2Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0532543A
Age:50 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Alopecia		Eskalith	PS	Glaxosmithkline	ORAL	450MG Twice per day	3 WK
			Doxepin	C				
			Zyprexa	C				

Date:04/20/05ISR Number: 4640320-9Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0534149A
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Diarrhoea		Eskalith	PS	Glaxosmithkline	ORAL	450MG Twice per day	
			Metronidazole	C	Glaxosmithkline			
			Zyprexa	C				
			Cytomel	C	Glaxosmithkline			

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/20/05ISR Number: 4640321-0Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0535382A
Age:47 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Affect Lability		Eskalith	PS	Glaxosmithkline	ORAL	450MG Three	
	Drug Ineffective						times per day	18 YR
	Pharmaceutical Product		Ibuprofen	C	Glaxosmithkline			
	Complaint							
	Tremor							

Date:04/20/05ISR Number: 4640322-2Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0538842A
Age:91 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Fall		Eskalith	PS	Glaxosmithkline	ORAL	450MG Per day	1 YR
	Injury		Synthroid	C	Glaxosmithkline			

Date:04/20/05ISR Number: 4640323-4Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0541561A
Age:37 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Pruritus		Eskalith	PS	Glaxosmithkline	ORAL	450MG Per day	1 YR
			Prozac	C				
			Clonazepam	C				
			Geodon	C				

Date:04/20/05ISR Number: 4640324-6Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0543275A
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Depression		Lithium Carbonate	PS	Glaxosmithkline	ORAL		YR
	Feeling Abnormal							

Ill-Defined Disorder
Laziness

Date:04/20/05ISR Number: 4640326-XReport Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0543955A
Age:54 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Bipolar Disorder		Eskalith Cr	PS	Glaxosmithkline	ORAL	450MG Twice per day	13 YR
			Lithium Carbonate	SS	Glaxosmithkline	ORAL	300MG In the morning	
			Depakote Er	C				
			Vitamin C	C	Glaxosmithkline			
			Electrolyte Supplements	C				

Date:04/20/05ISR Number: 4640327-1Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0544236A
Age:54 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Stool Analysis Abnormal		Eskalith	PS	Glaxosmithkline	ORAL	450MG At night	YR
			Depakote Er	C				
UNKNOWN							250MG Twice per day	
			Lithium	C	Glaxosmithkline			

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/20/05ISR Number: 4640350-7Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0503524A
Age: YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Dysgeusia		Eskalith	PS	Glaxosmithkline	ORAL	1200MG per	
	Headache						day	
	Overdose		Prozac	C				
			Skelaxin	C				
			Synthroid	C	Glaxosmithkline			
			Ibuprofen	C	Glaxosmithkline			
			Vistaril	C				

Date:04/20/05ISR Number: 4640351-9Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0504306A
Age:66 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Level Fluctuating		Lithium Carbonate	PS	Glaxosmithkline	ORAL	600MG Twice	
							per day	15 YR
			Atenolol	C				
			Norvasc	C				
			Accupril	C				
			Atarax	C				

Date:04/20/05ISR Number: 4640352-0Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0510727A
Age:43 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Alopecia		Eskalith	PS	Glaxosmithkline	ORAL	300MG	
	Weight Increased						Variable dose	35 YR
			Aciphex	C				
			Aspirin	C	Glaxosmithkline			
			Vitamin B12	C	Glaxosmithkline			
			Vitamin B1	C				
			Vitamin C	C	Glaxosmithkline			

Date:04/20/05ISR Number: 4640354-4Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0513157A
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Somnolence		Lithium	PS	Glaxosmithkline			
			Valium	SS				

10MG Three

times per day

Date:04/20/05ISR Number: 4640355-6Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0514499A
Age:31 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Therapeutic Agent		Eskalith Cr	PS	Glaxosmithkline	ORAL	1350MG per	
Hospitalization -	Toxicity						day	
Initial or Prolonged			Loxapine	C		ORAL	75MG At night	
Other			Serzone	C		ORAL	600MG per day	
			Albuterol	C	Glaxosmithkline		RESPIRATORY	
							(INHALATION)	
			Seroquel	C			300MG At	
							night	
			Lisinopril	C				
			Cogentin	C			1MG Per day	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/20/05ISR Number: 4640356-8Report Type:Periodic Company Report #04-07-1026
Age:48 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Disorientation		Lithium	PS	Glaxosmithkline	ORAL	250MG Per day	
	Dizziness		Clozapine	SS		ORAL		

Date:04/20/05ISR Number: 4640357-XReport Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0521925A
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Weight Increased		Lithium	PS	Glaxosmithkline			

Date:04/20/05ISR Number: 4640358-1Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0521926A
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Affective Disorder		Lithium	PS	Glaxosmithkline		7 YR	
	Depression							
	Sedation							

Date:04/20/05ISR Number: 4640359-3Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0523758A
Age:56 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Burning Sensation		Eskalith	PS	Glaxosmithkline	ORAL	900MG Per day	
	Diarrhoea		Eskalith Cr	SS	Glaxosmithkline	ORAL	450MG Per day	10 MON
	Dry Eye		Ativan	C				
	Dry Mouth		Prozac	C				
	Dry Skin		Ambien	C				
	Erythema Of Eyelid							
	Eye Irritation							
	Oral Discomfort							

	Tremor					
	Weight Decreased					
	Weight Increased					

Date:04/20/05ISR Number: 4640360-XReport Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0524515A
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
	Drug Interaction		Eskalith	PS	Glaxosmithkline	
	Drug Level Increased		Bactrim	SS	Glaxosmithkline	
			Ibuprofen	C	Glaxosmithkline	

Date:04/20/05ISR Number: 4640361-1Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0525174A
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
	Adverse Event		Lithium	PS	Glaxosmithkline	
UNKNOWN						

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/20/05ISR Number: 4640362-3Report Type:Periodic Company Report #165540
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Sluggishness		Lithium	PS	Glaxosmithkline		UNKNOWN	
			Zyprexa	SS				

Date:04/20/05ISR Number: 4640363-5Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0531742A
Age:40 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Alopecia		Eskalith	PS	Glaxosmithkline	ORAL	450MG Twice per day	3 WK
			Zyprexa	C				

Date:04/20/05ISR Number: 4640364-7Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0532072A
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Blood Creatinine Increased		Eskalith	PS	Glaxosmithkline		UNKNOWN	

Date:04/20/05ISR Number: 4640365-9Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0536856A
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Weight Increased		Lithium Carbonate	PS	Glaxosmithkline			

Date:04/20/05ISR Number: 4640366-0Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0538321A
Age:33 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Tremor		Lithium Carbonate	PS	Glaxosmithkline	ORAL	300MG Four times per day	

Date:04/20/05ISR Number: 4640367-2Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0538574A
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Renal Impairment		Eskalith	PS	Glaxosmithkline			

Date:04/20/05ISR Number: 4640368-4Report Type:Periodic Company Report #200400706425
Age:56 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Hypotrichosis		Lithium	PS	Glaxosmithkline	ORAL	600MG Per day	30 YR
			Risperdal	SS		ORAL	4MG Per day	YR
			Synthroid	C	Glaxosmithkline	ORAL	.125MG Per day	
			Novolog	C			SUBCUTANEOUS	
			Lantus	C			SUBCUTANEOUS	15UD Per day
			Premarin	C		ORAL	.3MG Per day	
			Clonopin	C		ORAL	2MG Per day	
			Novolin N	C			SUBCUTANEOUS	5UD Per day

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/20/05ISR Number: 4640370-2Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0541555A
Age:13 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Mood Swings		Eskalith	PS	Glaxosmithkline	ORAL		
	Oedema		Clonidine	C				

Date:04/20/05ISR Number: 4640371-4Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0544256A
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Antipsychotic Drug Level		Eskalith	PS	Glaxosmithkline	ORAL	1350MG	
	Below Therapeutic							Unknown
	Drug Ineffective		Lamictal	C	Glaxosmithkline	ORAL		
			Hypoglycaemic Medication	C		ORAL		

Date:04/20/05ISR Number: 4640372-6Report Type:Periodic Company Report #05-02-0149
Age:53 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Therapeutic Agent		Lithium	PS	Glaxosmithkline			UNKNOWN
	Toxicity		Clozapine	SS		ORAL		

Date:04/20/05ISR Number: 4641744-6Report Type:Expedited (15-DaCompany Report #MK200504-0060-1
Age:65 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardiomyopathy	Foreign	Anafranil 25mg					
	Conjunctival Hyperaemia	Literature	Capsules	PS				ANTIDEPRESSAN T
	Excoriation							
	Hyperthermia		Fluvoxamine	SS				

	Neuroleptic Malignant Syndrome Petechiae Serotonin Syndrome Tryptase Increased		Lithium Levomepromazine	SS SS

Date:04/21/05ISR Number: 4640976-0Report Type:Expedited (15-DaCompany Report #TR-BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.-2005-
DAge: 32GD Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Abortion Induced		Lithium	PS	Roxane Laboratories, Inc.			

Date:04/21/05ISR Number: 4641503-4Report Type:Expedited (15-DaCompany Report #GBWYE514718MAR05
Age:77 YR Gender:Male I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Abdominal Pain Alanine Aminotransferase Increased Blood Alkaline Phosphatase Increased Gamma-Glutamyltransferase Abnormal Intestinal Obstruction

	Liver Function Test Abnormal Transaminases Increased	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
			Lithium	PS	Glaxosmithkline	
UNKNOWN	600MG Per day					
			Efexor Xl	SS		
UNKNOWN						
			Mirtazapine	SS		
UNKNOWN	60MG Unknown					
			Olanzapine	SS		
UNKNOWN	102 WK					
			Efexor	C		
37.5MG Per day						

Date:04/21/05ISR Number: 4641915-9Report Type:Expedited (15-DaCompany Report #2005056057
Age:63 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization - Initial or Prolonged	Balance Disorder	Consumer	Lithium (Lithium)	PS		ORAL
ORAL						
10 MG (5 MG, 2 IN 1 D), ORAL	Depressed Level Of Consciousness		Aricept (Donepezil)	SS		ORAL
	Dizziness					
	Drug Interaction Therapeutic Agent Toxicity		Hmg Coa Reductase Inhibitors (Hmg Coa Reductase Inhibitors)	C		

Date:04/21/05ISR Number: 4642998-2Report Type:Expedited (15-DaCompany Report #2005-DE-01332GD
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Other Required	Abortion Induced Drug Exposure During	Foreign Literature	Lithium (Lithium Carbonate)	PS		
NR						

Intervention to Prevent Permanent Impairment/Damage	Pregnancy					

Date:04/21/05ISR Number: 4643369-5Report Type:Expedited (15-DaCompany Report #2004059901
Age:50 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Acute Respiratory Failure	Consumer	Neurontin					
Hospitalization - Initial or Prolonged	Agitation		(Gabapentin)	PS				
Other	Anxiety		Xanax Tablet					
	Aortic Injury		(Alprazolam)	SS		ORAL	4 MG (1 MG, 4	
	Completed Suicide						IN 1 D), ORAL	
	Haemothorax		Lithium (Lithium)	SS		ORAL	600 MG (300	
	Lung Injury						MG, 2 IN 1	
	Overdose						D), ORAL	
	Pain		Fluoxetine					
	Pubic Rami Fracture		Hydrochloride					
	Rib Fracture		(Fluoxetine					
	Suicidal Ideation		Hydrochloride)	SS		ORAL	20 MG (20 MG,	
	Suicide Attempt						1 IN 1 D),	
							ORAL	
			Lorazepam					
			(Lorazepam)	SS				
			Zolpidem Tartrate					
			(Zolpidem Tartrate)	SS		ORAL	10 MG (10 MG,	
							1 IN 1 D),	
							ORAL	
			Temazepam					

			(Temazepam)	C			
			Diazepam (Diazepam)	C			
			Olanzapine (Olanzapine)	C			

Date:04/22/05ISR Number: 4644495-7Report Type:Direct Company Report #CTU 246845
Age:42 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Diabetes Insipidus		Lithium Er	PS			ONE Q AM & TWO HS	

Date:04/22/05ISR Number: 4645061-XReport Type:Expedited (15-DaCompany Report #2005047808
Age:42 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Abortion Induced Drug Exposure During Pregnancy	Health Professional	Diflucan Tablets (Fluconazole)	PS		ORAL	450 MG (DAILY), ORAL	
	Pregnancy Trisomy 21		Prednisone (Prednisone)	SS			20 MG (DAILY)	
			Amoxicillin (Amoxicillin)	SS			1500 MG (500 MG, TID)	
			Bactrim (Sulfamethoxazole, Trimethoprim)	SS			1000 MG (500 MG, BID)	
			Salmeterol Xinafoate (Salmeterol Xinafoate)	SS			RESPIRATORY	

(INHALATION)	2 PUFFS TWICE DAILY, INHALATION	Fluticasone Propionate (Fluticasone Propionate)	SS
RESPIRATORY			
(INHALATION)	2 PUFFS ONE DAILY, INHALATION	Salbutamol (Salbutamol)	SS
RESPIRATORY			
(INHALATION)	PRN, INHALATION	Loratadine (Loratadine)	SS
PRN		Lithium (Lithium)	SS
600 MG (DAILY)		Clorazepate Dipotassum (Clorazepate Dipotassium)	SS
PRN			

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/25/05ISR Number: 4644159-XReport Type:Expedited (15-DaCompany Report #PHFR2005GB01418
Age:47 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Drug Level Increased		Lithium	PS	Glaxosmithkline			UNKNOWN
Initial or Prolonged	Renal Failure Therapeutic Agent Toxicity		Clozaril	SS		ORAL		

Date:04/25/05ISR Number: 4644494-5Report Type:Direct Company Report #CTU 247052
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Nausea Pharmaceutical Product Complaint		Lithobid	PS				

Date:04/25/05ISR Number: 4644530-6Report Type:Direct Company Report #CTU 247025
Age:42 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Erythema		Lithium 300 Mg Qam &					
Initial or Prolonged	Swelling Face		600mg Hs	PS				
300 MG QAM &								
600MG HS <								
1 MONTH							1	MON
			Tegretol 200mg Bid	SS		ORAL		
200 MG PO BID								
< 1 MONTH							1	MON
			Abilify	C				

Date:04/25/05ISR Number: 4645770-2Report Type:Expedited (15-DaCompany Report #2005047687
Age: Gender:Unknown I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Congenital Anomaly	Abortion Induced Drug Exposure During Pregnancy Trisomy 21	Health Professional	Diflucan Tablets (Fluconazole)	PS			450 MG (DAILY)	
			Prednisone (Prednisone)	SS			20 MG DAILY	
			Amoxicillin (Amoxicillin)	SS			1500 MG (500 MG, TID)	
			Bactrim (Sulfamethoxazole, Trimethoprim)	SS			1000 MG (500 MG, BID)	
			Salmeterol Xinafoate (Salmeterol Xinafoate)	SS			RESPIRATORY (INHALATION)	2 PUFFS, TWICE DAILY, INHALATION
			Fluticasone Propionate (Fluticasone Propionate)	SS			RESPIRATORY (INHALATION)	2 PUFFS, ONCE DAILY, INHALATION
			Salbutamol					

			(Salbutamol)	SS			
AS NEEDED							
			Loratadine (Loratadine)	SS			
AS NEEDED							
			Lithium (Lithium)	SS			
600 MG							
(DAILY)							
			Clorazepate Dipotassium (Clorazepate Dipotassium)	SS			
AS NEEDED							

Date:04/26/05ISR Number: 4644752-4Report Type:Expedited (15-DaCompany Report #200511350FR
Age:73 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agitation		Amarel	PS	Aventis Pharmaceuticals Inc.	ORAL		
	Asthenia							
	Blood Creatinine Decreased		Teralithe	SS		ORAL		
			Fluorouracile	SS				
	Confusional State		Levothyrox	SS		ORAL		
	Depressed Level Of Consciousness		Mopral	SS		ORAL		
			Diffu K	SS		ORAL		
	Disorientation		Forlax	C		ORAL		
	Extrapyramidal Disorder		Spasfon	C				
	Fall		Tardyferon	C		ORAL		
	General Physical Health Deterioration							
	Haemoglobin Decreased							
	Muscle Rigidity							
	Somnolence							
	Tremor							
	Vomiting							

Date:04/26/05ISR Number: 4645205-XReport Type:Expedited (15-DaCompany Report #05-03-0532
Age:14 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Hospitalization - UNKNOWN	Aggression	Lithium	PS	Glaxosmithkline	
Initial or Prolonged UNKNOWN	Blood Creatine	Haldol	SS		
Other	Phosphokinase Increased Body Temperature Increased Confusional State Drooling Drug Interaction Dyspnoea Neuroleptic Malignant Syndrome	Clozapine	SS		ORAL

Date:04/26/05ISR Number: 4647273-8Report Type:Expedited (15-DaCompany Report #2005059988
Age:35 YR Gender:Female I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Antipsychotic Drug Level Below Therapeutic Depression Fatigue General Physical Health Deterioration Malaise

		Self-Medication Sleep Disorder Weight Increased	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
			Consumer	Geodon (Ziprasidone)	PS		
UNKNOWN	UNKNOWN						
				Lithium (Lithium)	SS		
UNKNOWN	UNKNOWN						
				Trazodone (Trazodone)	SS		
UNKNOWN	UNKNOWN						
				Escitalopram (Escitalopram)	SS		
UNKNOWN	UNKNOWN						
				Topiramate (Topiramate)	SS		
UNKNOWN	UNKNOWN						
				Lorazepam (Lorazepam)	C		

Date:04/26/05ISR Number: 4647885-1Report Type:Expedited (15-DaCompany Report #MET-US-05-00016
Age:50 YR Gender:Female I/FU:F

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Life-Threatening Other		Blood Pressure Decreased Bradyphrenia Cardiomegaly Constipation	Health Professional Company Representative	Fortamet (Metformin Hcl) Extended-Release (Tablets)	PS		ORAL
1000 MG PO QD							
		Coronary Artery Insufficiency Drug Abuser Emotional Disorder Gastrooesophageal Reflux Disease Haemoglobin Decreased Nail Tinea Overdose Renal Failure Acute Therapeutic Agent Toxicity Tinea Pedis Urinary Tract Infection		Lithium Unspecified Psychiatric Medications	SS C		

Date:04/27/05ISR Number: 4646738-2Report Type:Expedited (15-DaCompany Report #211004-05
Age:75 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agitation Confusional State Coordination Abnormal Drug Level Increased		Quilonorm Retard Paracetamol	PS C	Glaxosmithkline Glaxosmithkline	ORAL ORAL	12.2MMOL Twice per day 1G Four times per day	

Date:04/28/05ISR Number: 4647858-9Report Type:Expedited (15-DaCompany Report #251103-12
Age:45 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Seborrhoeic Dermatitis		Quilonorm Retard Efexor Temesta	PS C C	Glaxosmithkline	ORAL ORAL ORAL		13 DAY

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/28/05ISR Number: 4647860-7Report Type:Expedited (15-DaCompany Report #B0379354A
Age:71 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Level Increased		Quilonorm Retard	PS	Glaxosmithkline	ORAL	1.5U Per day	11 MON
	Myoclonus		Celecoxib	SS		ORAL	200MG Twice per day	
	Personality Disorder							
	Polydipsia		Hydrochlorothiazide + Irbesartan	SS		ORAL		
	Tremor		Aspirin	C	Glaxosmithkline	ORAL	100MG Per day	
			Propranolol Hydrochloride	C		ORAL	20MG Twice per day	7 DAY
			Simvastatin	C		ORAL	20MG Per day	
			Trimipramine Maleate	C		ORAL	75MG Per day	5 MON
			Oxazepam	C		ORAL	15MG Unknown	
			Tizanidine Hydrochloride	C		ORAL	4MG Per day	
			Gabapentin	C		ORAL	300MG Twice per day	
			Tramadol Hydrochloride	C			100MG As required	
			Phlebodril	C		ORAL	1U Per day	

Date:04/28/05ISR Number: 4647862-0Report Type:Expedited (15-DaCompany Report #B0379398A
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Condition Aggravated		Quilonorm Retard	PS	Glaxosmithkline	ORAL	675MG per day	
	Scrotal Pain		St Johns Wort	SS		ORAL		

Date:04/28/05ISR Number: 4647863-2Report Type:Expedited (15-DaCompany Report #B0379412A
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Unknown Disability	Coordination Abnormal Delirium Drug Interaction Gait Disturbance		Quilonorm Retard Tranylcypromine Sulphate + Trifluoperazine Hydrochloride	PS SS	Glaxosmithkline Glaxosmithkline	ORAL ORAL	12.2MMOL 70MG per day	YR 1 YR
			Dexamphetamine	SS	Glaxosmithkline	ORAL	5MG Unknown	2 YR
			Levothyroxine + Liothyronine	SS		ORAL		YR
			Alprazolam	SS		ORAL	4MG per day	YR

Date:04/28/05ISR Number: 4650275-9Report Type:Expedited (15-DaCompany Report #KII-2005-0016091
Age:27 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Drug Abuser Heart Rate Increased Self-Medication	Study Health Professional Other	Oxycontin Tablets (Oxycodone Hydrochloride) Cr Tablet	PS		ORAL	ORAL	
			Lithium (Lithium)	SS		ORAL	ORAL	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/29/05ISR Number: 4649102-5Report Type:Expedited (15-DaCompany Report #CH-GLAXOSMITHKLINE-B0269841A
Age:58 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Akathisia		Deroxat	PS	Glaxosmithkline	ORAL	20MG Per day	3 YR
	Disorientation		Reductil	SS		ORAL	15MG Per day	56 DAY
	Drug Interaction		Quilonorm	SS	Glaxosmithkline	ORAL	665MG Per day	3 YR
	Hyperhidrosis		Eltroxin	C	Glaxosmithkline	ORAL	.05MG Per day	6 YR
	Hyperreflexia							
	Serotonin Syndrome							
	Tremor							
	Vertigo							

Date:04/29/05ISR Number: 4649135-9Report Type:Expedited (15-DaCompany Report #2003-4292
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Catatonia		Quilonorm Retard	PS	Glaxosmithkline	ORAL	450MG Unknown	MON
	Drug Interaction		Norvasc	SS		ORAL	5MG Unknown	7 DAY
	Hypertonia		Surmontil	SS		ORAL	25MG per day	41 DAY
			Seropram	SS		ORAL	20MG Unknown	48 DAY
			Seresta	C		ORAL	22.5MG per day	MON
			Triatec Comp	C		ORAL	MON	
			Nexium	C		ORAL	40MG per day	MON
			Insulin Mixtard	C			SUBCUTANEOUS	MON

Date:04/29/05ISR Number: 4649137-2Report Type:Expedited (15-DaCompany Report #200303260
Age:62 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Aggression		Quilonorm Retard	PS	Glaxosmithkline	ORAL	1350MG per day	
	Blood Thyroid Stimulating Hormone Decreased		Edronax	C		ORAL	8MG	Unknown
	Hyperthyroidism		Seropram	C		ORAL	30MG	Unknown
			Temesta	C		ORAL	1.25MG	Unknown

Date:04/29/05ISR Number: 4649138-4Report Type:Expedited (15-DaCompany Report #B0379470A
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agitation		Quilonorm Retard	PS	Glaxosmithkline	ORAL	12.5MMOL	
	Drug Interaction							
Unknown	Drug Level Increased		Rofecoxib	SS		ORAL	50MG	Unknown
	Therapeutic Agent		Diclofenac	SS		ORAL	50MG	Unknown
	Toxicity Tremor		Hydrochlorothiazide + Losartan Potassium	SS		ORAL	75MG	per day
			Clomipramine	C		ORAL	75MG	per day
			Maprotilin	C		ORAL	10MG	per day
			Bisoprolol	C		ORAL	10MG	per day
			Amlodipine	C		ORAL	10MG	per day
			Phenprocoumon	C		ORAL		
			Nadroparin	C	Glaxosmithkline	SUBCUTANEOUS	.6ML	per day
			Esomeprazole	C		ORAL	10MG	per day
			Losartan	C		ORAL	50MG	per day

15 YR
15 DAY
DAY

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/29/05ISR Number: 4649139-6Report Type:Expedited (15-DaCompany Report #B0379502A
Age:72 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Level Increased		Quilonorm	PS	Glaxosmithkline	ORAL	450MG per day	YR
	Grand Mal Convulsion		Amiloride + Hydrochlorothiazide	C		ORAL	50MG per day	
	Parkinsonism							
	Stupor		Maprotilin	C		ORAL	75MG per day	
			Tamsulosin	C		ORAL	400MG per day	

Date:04/29/05ISR Number: 4649331-0Report Type:Expedited (15-DaCompany Report #US-ABBOTT-05P-163-0298039-00
Age:60 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Potassium Abnormal		Depakote 500mg	PS		ORAL	3	MON
	Cognitive Disorder		Lithium Salt	SS			UNKNOWN	
Other	Drug Interaction		Venlafaxine Hydrochloride	C				
	Hypernatraemia		Abilify	C				
	Leukocytosis		Unknown Medication	C				
	Neurological Examination Abnormal		Unknown Medication	C				
	White Blood Cell Count Increased		Clonazepam	C				
			Lamotrigine	I			UNKNOWN	

Date:05/02/05ISR Number: 4651462-6Report Type:Expedited (15-DaCompany Report #2005059988
Age:35 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Alcohol Use	Consumer	Geodon (Ziprasidone)	PS				
	Depression		Lithium (Lithium)	SS				
	Drug Interaction		Trazodone (Trazodone)	SS				
	Drug Level Decreased		Escitalopram					
	Fatigue							

	General Physical Health		(Escitalopram)	SS			
	Deterioration		Topiramate				
	Malaise		(Topiramate)	SS			
	Pharmaceutical Product		Lorazepam				
	Complaint		(Lorazepam)	C			
	Self-Medication						
	Sleep Disorder						
	Weight Increased						

Date:05/02/05ISR Number: 4652050-8Report Type:Expedited (15-DaCompany Report #2003034801
Age:52 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Death	Anger	Health	Geodon (Ziprasidone)	PS		ORAL	ORAL
Hospitalization - Initial or Prolonged	Chest Pain	Professional	Lithium (Lithium)	SS		ORAL	900 MG (2 IN 1 D), ORAL
	Depressed Level Of	Company					
Other	Consciousness	Representative	Bupropion Hydrochloride (Bupropion Hydrochloride)	C			
	Diabetic Hyperglycaemic Coma		Anti-Diabetics (Anti-Diabetics)	C			
	Dizziness						
	Glucose Tolerance Impaired						
	Hepatitis C						

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/02/05ISR Number: 4652732-8Report Type:Expedited (15-DaCompany Report #2005UW05644
Age:43 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Aortic Stenosis	Study	Lithium	PS		ORAL	600 MG DAILY	
Hospitalization - Initial or Prolonged	Atrioventricular Block Complete	Health Professional	Tylenol	SS		ORAL	2500 MG DAILY	
	Bradycardia						PO	
	Drug Interaction		Tylenol Pm	SS		ORAL	1500 MG HS PO	
	Mitral Valve Incompetence		Aspirin	SS		ORAL	975 MG DAILY	
							PO	
			Aleve /00256202/	SS		ORAL	1200 MG DAILY	
							PO	
			Placebo	SS		ORAL	400 MG DAILY	
							PO	

Date:05/03/05ISR Number: 4650794-5Report Type:Expedited (15-DaCompany Report #CH-GLAXOSMITHKLINE-B0296700A
Age:64 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Blood Creatinine		Quilonorm	PS	Glaxosmithkline	ORAL	13 YR	
	Increased		Clozapine	SS		ORAL	150MG Per day	YR
	Nephritis Interstitial							
	Nephropathy Toxic							
	Renal Failure Chronic							
	Renal Interstitial Fibrosis							
	Tubulointerstitial Nephritis							

Date:05/03/05ISR Number: 4650795-7Report Type:Expedited (15-DaCompany Report #CH-GLAXOSMITHKLINE-B0305947A
Age:44 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Arrhythmia		Lithium Carbonate	PS	Glaxosmithkline			
	Depressed Level Of Consciousness		Clozapine	SS				
			Sodium Valproate	SS				
	Electroencephalogram Abnormal		Lorazepam	SS				
			Laxative	C				
	Hyperventilation							
	Overdose							
	Somnolence							
	Transient Ischaemic Attack							

Date:05/03/05ISR Number: 4650808-2Report Type:Expedited (15-DaCompany Report #2004-10868
Age:42 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blood Creatinine Increased		Quilonorm Retard	PS	Glaxosmithkline	ORAL	450MG Twice per day	
	Haemoglobin Increased		Efexor	C		ORAL	112.5MG Twice per day	
	Nephrogenic Diabetes Insipidus							
	Urine Sodium Decreased							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/03/05ISR Number: 4650809-4Report Type:Expedited (15-DaCompany Report #080305-02
Age:53 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Coordination Abnormal		Quilonorm Retard	PS	Glaxosmithkline	ORAL		
	Dizziness		Carbamazepine	SS		ORAL		15 DAY
	Drug Interaction		Quetiapine	SS		ORAL	50MG per day	
	Drug Level Increased		Fluvoxamine	SS		ORAL	200MG per day	
	Gait Disturbance							
	Posture Abnormal							

Date:05/03/05ISR Number: 4650810-0Report Type:Expedited (15-DaCompany Report #251103-13
Age:77 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Apathy		Quilonorm	PS	Glaxosmithkline	ORAL		11 DAY
	Asthenia		Calcimagon	C	Glaxosmithkline			
	Muscle Twitching		Efexor	C				
	Poisoning		Remeron	C				
	Speech Disorder		Reniten	C				
			Tenormin	C				
			Zyprexa	C				

Date:05/03/05ISR Number: 4650811-2Report Type:Expedited (15-DaCompany Report #2004-0480
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Coordination Abnormal		Quilonorm Retard	PS	Glaxosmithkline	ORAL	450MG Per day	MON
	Drug Interaction		Brufen	SS	Glaxosmithkline	ORAL	400MG Unknown	MON
	Dysarthria		Aleve	SS		ORAL		MON
	Renal Failure Acute		Seroquel	SS		ORAL	25MG Per day	MON
			Novalgine	C				

Buscopan	C		
Demetrin	C		
Panadol	C	Glaxosmithkline	
Solatran	C	Glaxosmithkline	
Xanax	C		

Date:05/03/05ISR Number: 4650812-4Report Type:Expedited (15-DaCompany Report #2004-3165
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Diabetes Insipidus		Quilonorm Retard	PS	Glaxosmithkline	ORAL	450MG Twice	
Initial or Prolonged	Diarrhoea						per day	14 YR
Disability	Extrapyramidal Disorder		Allopurinol	C	Glaxosmithkline	ORAL	300MG See	
	Hypercalcaemia						dosage text	YR
	Hyperglycaemia		Levothyroxine	C	Glaxosmithkline	ORAL	6	YR
	Hypothyroidism		Inderal	C		ORAL	10MG See	
	Mental Impairment						dosage text	10 YR
	Renal Failure Chronic							
	Tremor							

Date:05/03/05ISR Number: 4650814-8Report Type:Expedited (15-DaCompany Report #2002-0356
Age: Gender:Male I/FU:I

Outcome	PT
Life-Threatening	Drug Interaction
	Hypothermia

		Miosis Stupor					
			Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
				Lithium	PS	Glaxosmithkline	ORAL
1	DAY						
				Clozapine	SS		ORAL
1	DAY						
				Metformin	C		ORAL
1700MG per							
day		MON					
				Acetylsalicylsaure	C	Glaxosmithkline	ORAL
MON							
				Alendronate	C		ORAL
MON							
				Calcium + Vitamin D	C		ORAL
500MG per day		MON					
				Lactitol	C		ORAL
20ML per day		MON					
				Latanoprost	C		
SUBCONJUNCTIVAL			MON				
				Amiodarone	C		ORAL
MON							
				Nitroglycerin	C	Glaxosmithkline	
TRANSDERMAL			MON				

Date:05/03/05ISR Number: 4650932-4Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0554927A
Age:35 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization -	Activities Of Daily		Phazyme Ultra			
Initial or Prolonged	Living Impaired		Strength Softgels	PS	Glaxosmithkline	ORAL
Disability	Amnesia		Vioxx	SS		ORAL
	Cerebrovascular Accident		Lithium	SS	Glaxosmithkline	ORAL
2200MG Per						
	Coma					
day						
	Dialysis		Ibuprofen	SS	Glaxosmithkline	ORAL
	Difficulty In Walking		Bextra	SS		ORAL
	Hallucination		Multi Vitamin	C		ORAL
	Hemiplegia		Vitamin C	C	Glaxosmithkline	ORAL
	Influenza		Acidophilus	C		ORAL
	Malaise		Garlic	C		ORAL

	Renal Failure	Vitamin E	C		ORAL
	Speech Disorder	Neurontin	C		ORAL
2400MG Per day					
		Celebrex	C		ORAL
400MG Per day					
		Prilosec	C	Glaxosmithkline	ORAL
		Singular	C		ORAL
10MG Per day					
		Claritin	C		ORAL
		Imitrex	C	Glaxosmithkline	ORAL
		Buspar	C		ORAL
		Sleeping Tablets (Unspecified)	C		ORAL
		Colace	C		ORAL
		Effexor	C		ORAL
		Pulmicort RESPIRATORY (INHALATION)	C		
		Albuterol RESPIRATORY (INHALATION)	C	Glaxosmithkline	
		Serevent RESPIRATORY (INHALATION)	C	Glaxosmithkline	
		Atrovent RESPIRATORY (INHALATION)	C	Glaxosmithkline	
		Aspirin	C	Glaxosmithkline	ORAL

Date:05/03/05ISR Number: 4651137-3Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20050106806
Age: Gender:Male I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Abnormal Dreams
	Amnesia

	Confusional State						
	Dehydration						
	Drug Interaction	Report Source	Product	Role	Manufacturer	Route	
Dose	Duration						
	Malaise		Risperdal	PS			
OROPHARINGEAL							
	Myocardial Infarction		Risperdal	SS			
OROPHARINGEAL							
	Nasopharyngitis		Lithium	SS			
OROPHARINGEAL							
	Nightmare		Lithium	SS			
OROPHARINGEAL							
	Pneumonia		Risperdal	SS			
OROPHARINGEAL	one dose						
	Therapeutic Agent		Klonapin	C			
OROPHARINGEAL							
	Toxicity		Effexor Xl	C			
	Tremor		Topamax	C			
	Urinary Tract Infection						

Date:05/03/05ISR Number: 4655081-7Report Type:Expedited (15-DaCompany Report #2005AC00647
Age:59 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Required	Drug Interaction	Foreign	Seroquel	PS		ORAL
200 MG DAILY						
Intervention to	Tardive Dyskinesia	Health				
PO						
Prevent Permanent		Professional	Seroquel	SS		ORAL
400 MG DAILY						
Impairment/Damage		Other				
PO						
			Zyprexa	SS		
			Lithium	SS		

Date:05/04/05ISR Number: 4652349-5Report Type:Expedited (15-DaCompany Report #B0379603 B0379603A
Age:60 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Life-Threatening	Abdominal Distension		Quilonorm Retard	PS	Glaxosmithkline	ORAL
28	MON					

	Oedema
	Testicular Swelling

Date:05/04/05ISR Number: 4652353-7Report Type:Expedited (15-DaCompany Report #2003-4284
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Hypernatraemia		Lithium Carbonate	PS	Glaxosmithkline	ORAL	20	YR
Initial or Prolonged	Nephrogenic Diabetes		Aspirin Cardio	C	Glaxosmithkline	ORAL	100MG per day	
	Insipidus		Beloc Zok	C		ORAL	100MG per day	
			Eltroxin	C	Glaxosmithkline	ORAL	.05MG per day	
			Aricept	C		ORAL	10MG per day	
			Lactulose	C		ORAL		
			Calcimagon	C	Glaxosmithkline	ORAL		

Date:05/04/05ISR Number: 4653724-5Report Type:Expedited (15-DaCompany Report #KII-2005-0016206
Age:37 YR Gender:Female I/FU:I

Outcome	PT
Hospitalization -	Alcohol Use
Initial or Prolonged	Apnoea
Other	Blood Glucose Increased
	Blood Ph Decreased
	Blood Pressure Decreased
	Coma
	Drug Abuser
	Electrocardiogram Qrs
	Complex Prolonged

		Electrocardiogram Qt Corrected Interval Prolonged					
		Loss Of Consciousness	Study	Oxycontin Tablets (Oxycodone Hydrochloride) Cr Tablet	PS		ORAL
		Multiple Drug Overdose	Health Professional				
		Somnolence	Other				
ORAL							
				Acetaminophen W/Oxycodone (Paracetamol, Oxycodone Hydrochloride)	SS		ORAL
ORAL							
				Aspirin With Carisoprodol ()	SS		ORAL
ORAL							
				Diphenhydramine (Diphenhydramine)	SS		ORAL
ORAL							
				Antipsychotics()	SS		ORAL
ORAL							
				Alcohol (Ethanol)	SS		
				Marijuana (Cannabis)	SS		

Date:05/04/05ISR Number: 4654629-6Report Type:Direct Company Report #CTU 247731
Age:46 YR Gender:Male I/FU:I

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Other		Drug Interaction		Cymbalta (Duloxeline) 30 Mg Caps By Lilly	PS	Lilly	ORAL
		Muscle Twitching					
		Myoclonus					
CYMBALTA 30 MG DAILY PO							
				Lithobid Sr (Lithium) 300 Mg Tabs By Solvay	SS	Solvay	
LITHOBID SR 900 MG BEDT							

Date:05/04/05ISR Number: 4654962-8Report Type:Expedited (15-DaCompany Report #KII-2005-0016357
Age:36 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Heart Rate Increased	Study	Morphine Sulfate (Similar To Nda 19-516)(Morphine Sulfate) Other	PS		ORAL	ORAL	
Other	Intentional Misuse	Health Professional Other						
	Multiple Drug Overdose							
	Oxygen Saturation Decreased		Trazodone (Trazodone)	SS		ORAL	ORAL	
	Poor Quality Drug Administered		Thiazides	SS		ORAL	ORAL	
	Somnolence		Niacin (Nicotinic Acid)	SS		ORAL	ORAL	
	Tearfulness		Beta Blocking Agents	SS		ORAL	ORAL	
	Toxicologic Test Abnormal		Proton Pump (Inhibitor)	SS		ORAL	ORAL	

Date:05/06/05ISR Number: 4655235-XReport Type:Expedited (15-DaCompany Report #2005-UK-00095
Age:18 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Gingival Oedema		Lithium Carbonate	PS	Glaxosmithkline	UNKNOWN		
	Syncope		Univer Meningococcal Polysaccharide	SS		UNKNOWN		

Vaccine Group C SS Glaxosmithkline
UNKNOWN 1 DAY

Date:05/06/05ISR Number: 4656922-XReport Type:Expedited (15-DaCompany Report #05US000682
Age:46 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Creatinine Increased	Literature	Lithium Carbonate					
	Blood Potassium Increased	Health Professional	(Lithium Carbonate)Tablet	PS			SEE IMAGE	
	Bradycardia		Fosinopril					
	Salivary Hypersecretion		(Fosinopril)	C				
	Sedation		Lisinopril					
	Therapeutic Agent Toxicity		(Lisinopril)	C				
	Treatment Noncompliance		Haloperidol					
	Tremor		(Haloperidol)	C				
			Benztropine	C				
			Olanzapine					
			(Olanzapine)	C				
			Clonazepam					
			(Clonazepam)	C				
			Divalproex Sodium (Valproate					
			Semisodium)	C				
			Simvastatin					
			(Simvastatin)	C				
			Atenolol (Atenolol)	C				

Date:05/09/05ISR Number: 4658663-1Report Type:Expedited (15-DaCompany Report #S05-USA-02250-01
Age:30 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Condition Aggravated	Consumer	Lexapro					
Hospitalization -	Depression		(Escitalopram)	PS		ORAL	20 MG QD PO	
Initial or Prolonged	Drug Ineffective		Lithium	SS			600 MG QD	
	Mania		Lamictal					
	Multiple Drug Overdose		(Lamotrigine)	SS			50 MG BID	
	Personality Change		Abilify					

	Suicide Attempt		(Aripiprazole)	SS		
15 MG QD						
	Weight Increased		Seroquel (Quetiapine Fumarate)	SS		
			Trazodone	SS		

Date:05/10/05ISR Number: 4657952-4Report Type:Expedited (15-DaCompany Report #2005SE02665
Age:58 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Akathisia		Blopress	PS	Astrazeneca Pharmaceuticals	ORAL		
	Tremor		Lithiofor	SS		ORAL		
			Fluox-Basan	SS		ORAL		
			Remeron	SS		ORAL		
			Truxal	SS		ORAL		
			Thrombace Neo	C		ORAL		
			Simcora	C		ORAL		
			Estrofem	C		ORAL		
			Eltroxin	C		ORAL		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/11/05ISR Number: 4659006-XReport Type:Expedited (15-DaCompany Report #05-03-0532
Age:14 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Aggression		Lithium Sr	PS	Glaxosmithkline	ORAL	300MG Three	
Hospitalization -	Blood Creatine						times per day	7 DAY
Initial or Prolonged	Phosphokinase Increased		Lithium Citrate	SS		ORAL	300MG per day	118 DAY
Other	Body Temperature		Haloperidol	SS			INTRAMUSCULAR	10MG Weekly
	Increased		Clozapine	SS		ORAL	12 DAY	
	Confusional State		Benztropine	C		ORAL	2MG Twice per	
	Developmental						day	
	Coordination Disorder		Ddavp	C		ORAL	.2MG At night	
	Difficulty In Walking		Guanfacine	C		ORAL	1MG Three	
	Drooling						times per day	
	Drug Interaction		Synthroid	C	Glaxosmithkline	ORAL	50MCG In the	
	Dysphagia						morning	
	Dyspnoea		Valproic Acid	C		ORAL	500MG Three	
	Eating Disorder						times per day	
	Hyperventilation		Docusate Sodium	C		ORAL	100MG Twice	
	Lethargy						per day	
	Neuroleptic Malignant		Diphenhydramine	C			INTRAMUSCULAR	
	Syndrome		Lorazepam	C			INTRAMUSCULAR	2MG Weekly
	Somnolence		Trileptal	C		ORAL	300MG Three	
	Unresponsive To Verbal						times per day	21 DAY
	Stimuli		Risperdal	C				

	Urinary Incontinence		Bromocriptine	C			
2.5MG Three							
	White Blood Cell Count						
times per day							
	Increased						

Date:05/11/05ISR Number: 4661971-1Report Type:Direct Company Report #CTU 248301
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Antipsychotic Drug Level		Lithium 300 Mg					
Initial or Prolonged	Increased		Capsules	PS				
300 MG QAM,								
Other	Asthenia							
600 MG QPM	26 MON							
	Chest Discomfort							
	Dehydration							
	Hypercalcaemia							
	Mental Status Changes							

Date:05/13/05ISR Number: 4661799-2Report Type:Expedited (15-DaCompany Report #2005UW07199
Age:30 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Abnormal Behaviour		Seroquel	PS	Zeneca			
Hospitalization -	Depression				Pharmaceutical	ORAL		
3 YR								
Initial or Prolonged	Drug Ineffective		Lexapro	SS		ORAL		
	Intentional Misuse		Lithium	SS				
	Mania		Lamictal	SS				
	Multiple Drug Overdose		Abilify	SS				
	Personality Change		Trazodone	SS				
3 YR								
	Social Avoidant Behaviour							
	Suicide Attempt							
	Weight Increased							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/16/05ISR Number: 4663811-3Report Type:Expedited (15-DaCompany Report #2005068728
Age:64 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Abdominal Distension	Consumer	Celebrex (Celecoxib)	PS				
Hospitalization -	Aggression		Bextra (Valdecoxib)	SS				
Initial or Prolonged	Antidepressant Drug Level Increased		Lithium	SS			20 MG (20 MG, 1 IN 1 D)	
	Dementia		Olanzapine	SS				
	Difficulty In Walking		Asasantin (Acetylsalicylic Acid, Dipyridamole)	C				
	Drug Effect Decreased		Fosinopril Sodium	C				
	Dyskinesia		Valproate Semisodium	C				
	Erythema		Levothyroxine Sodium	C				
	Helicobacter Infection		Potassium	C				
	Myocardial Infarction		Quetiapine Fumarate	C				
	Pruritus Generalised		Atenolol	C				
			Metformin Hydrochloride	C				
			Minoxidil	C				
			Fosinopril Sodium	C				
			Furosemide	C				
			Simvastatin	C				
			Rosiglitazone Maleate	C				

Date:05/16/05ISR Number: 4664542-6Report Type:Direct Company Report #CTU 248689
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Mental Status Changes		Lithium 600mg	PS		ORAL	600MG PO BID	
Initial or Prolonged			Seroquel	C				
			Depakote Er	C				

Date:05/17/05ISR Number: 4663499-1Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0554390A
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Renal Failure		Eskalith Cr	PS	Glaxosmithkline	ORAL	34 YR	
	Speech Disorder		Synthroid	C	Glaxosmithkline			
	Suicide Attempt		Cymbalta	C				
	Tremor		Xanax	C				
			Prevacid	C				
			Protonix	C			INTRAVENOUS	
			Nexium	C				

Date:05/17/05ISR Number: 4663502-9Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0558030A
Age:30 YR Gender:Female I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Antisocial Behaviour
	Depression
	Drug Ineffective
	Intentional Misuse
	Mania
	Overdose
	Personality Change
	Suicidal Ideation

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Suicide Attempt Weight Increased							
			Lamictal	PS	Glaxosmithkline	ORAL	UNKNOWN	600MG Per day
			Lithium	SS	Glaxosmithkline			
			Lexapro	SS		ORAL	20MG Per day	
			Abilify	SS			UNKNOWN	15MG Per day
			Seroquel	SS			UNKNOWN	
			Trazodone	SS			UNKNOWN	

Date:05/17/05ISR Number: 4664895-9Report Type:Direct Company Report #CTU 248814
Age:48 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Pollakiuria		Lithium	PS				

Date:05/17/05ISR Number: 4664950-3Report Type:Direct Company Report #CTU 248777
Age:47 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hyponatraemia Renal Failure Acute		Lithium	PS				

Date:05/17/05ISR Number: 4665185-0Report Type:Expedited (15-DaCompany Report #B0380465A
Age:42 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Basedow'S Disease Hypothyroidism	Foreign Literature Health Professional	Lithium Salt (Lithium Salt) (Generic)	PS			20	YR

Date:05/17/05ISR Number: 4665187-4Report Type:Expedited (15-DaCompany Report #B0380467A
Age:47 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Basedow'S Disease Hypothyroidism	Foreign Literature Health Professional	Lithium Salt (Lithium Salt) (Generic)	PS				18 YR

Date:05/17/05ISR Number: 4665188-6Report Type:Expedited (15-DaCompany Report #B0380470A
Age:50 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Basedow'S Disease	Foreign Literature Health Professional	Lithium Salt (Lithium Salt) (Generic)	PS				4 YR

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/17/05ISR Number: 4665190-4Report Type:Expedited (15-DaCompany Report #B0380471A
Age:51 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hyperthyroidism	Foreign	Lithium Salt					
	Toxic Nodular Goitre	Literature	(Lithium Salt)					
		Health	(Generic)	PS				5 YR
		Professional						

Date:05/17/05ISR Number: 4665965-1Report Type:Direct Company Report #CTU 248899
Age:60 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Creatinine Increased		Lithium Carbonate 350mg	PS		ORAL	350MG	TID
	Granuloma					ORAL		
	Hypercalcaemia		Lasix	C				
	Parathyroid Disorder							
	Polyuria							
	Renal Failure Acute							

Date:05/18/05ISR Number: 4664592-XReport Type:Expedited (15-DaCompany Report #A01200502770
Age:65 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Renal Failure Chronic		Lithium Carbonate	PS	Glaxosmithkline			UNKNOWN
			Clozaril	C				UNKNOWN
			Sodium Valproate	C				UNKNOWN

Date:05/18/05ISR Number: 4665435-0Report Type:Direct Company Report #CTU 248996
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Speech Disorder		Lithium Carbonate	PS				

Date:05/18/05ISR Number: 4668557-3Report Type:Expedited (15-DaCompany Report #D0045611A
Age:72 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Confusional State Depressed Level Of Consciousness Dysarthria Electrocardiogram Qt Prolonged Muscle Contractions Involuntary Myoclonus Somnolence Therapeutic Agent Toxicity Ventricular Arrhythmia	Foreign Health Professional	Eskalith Tablet (Lithium Carbonate)	PS		ORAL	675 MG/PER DAY/ORAL	

Date:05/19/05ISR Number: 4668516-0Report Type:Expedited (15-DaCompany Report #2005-01660
Age:30 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other Required Intervention to Prevent Permanent Impairment/Damage	Depression Drug Ineffective Intentional Misuse Mania Multiple Drug Overdose Off Label Use Personality Change Suicide Attempt Weight Increased	Consumer Other	Trazodone Hydrochloride (Watson Laboratories)(Trazodone Hydrochloride)	PS	Watson Laboratories	ORAL		
			Lexapro (Escitalopram)	SS		ORAL	20 MG, DAILY,	ORAL
			Lithium (Lithium)	SS		ORAL	600 MG,	DAILY, ORAL
			Lamictal "Glaxo Welcome"	SS	Glaxo Welcome	ORAL	50 MG, BID,	ORAL
			Ariprazole (Apirprazole)	SS		ORAL	15 MG, DAILY,	ORAL
			Seroquel (Quetiapine Fumarate)	SS		ORAL		ORAL

Date:05/19/05ISR Number: 4668524-XReport Type:Expedited (15-DaCompany Report #B0380472A
Age:44 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Basedow'S Disease Hyperthyroidism	Foreign Literature Health Professional	Lithium Salt (Formulation Unknown) (Generic) (Lithium Salt)	PS				17 YR

Date:05/20/05ISR Number: 4667785-0Report Type:Expedited (15-DaCompany Report #JP-GLAXOSMITHKLINE-B0381033A
Age:43 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Hypersensitivity		Paxil	PS	Glaxosmithkline	ORAL	6	WK
			Meilax	SS		ORAL	4	WK
			Limas	SS	Glaxosmithkline	ORAL	5	WK

Date:05/20/05ISR Number: 4670158-8Report Type:Expedited (15-DaCompany Report #2005061102
Age:88 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Rash	Consumer	Bextra (Valdecoxib)	PS		ORAL	20 MG (20 MG, 1 IN 1 D),	
	Skin Discolouration	Health						
	Skin Haemorrhage	Professional						
	Skin Laceration		Nsaid'S (Nsaid'S)	SS				
			Multivitamins (Mutivitamins)	C				

Date:05/23/05ISR Number: 4672856-9Report Type:Expedited (15-DaCompany Report #2005-BP-07788RO
Age:46 YR Gender:Male I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Bradycardia
	Drug Level Below Therapeutic

		Hypomania Salivary Hypersecretion Sedation	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
		Therapeutic Agent Toxicity	Literature Health	Lithium Carbonate (Lithium Carbonate)	PS		ORAL
300 MG QHS							
		Treatment Noncompliance	Professional				
(300 MG) PO							
		Tremor		Lisinopril (Lisinopril)	SS		ORAL
20 MG QD PO							
				Fosinopril	C		
				Haloperidol	C		
				Benztropine (Benztropine Mesilate)	C		
				Olanzapine	C		
				Clonazepam	C		
				Divalproex Sodium (Valproate Semisodium)	C		
				Simvastatin	C		
				Atenolol	C		

Date:05/23/05ISR Number: 4672916-2Report Type:Expedited (15-DaCompany Report #2005073197
Age:60 YR Gender:Male I/FU:I

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Other		Liver Function Test	Health	Geodon (Ziprasidone)	PS		
160 MG 980							
		Abnormal	Professional				
MG, 2 IN 1							
		Neuroleptic Malignant	Company				
D),							
		Syndrome	Representative	Lithium (Lithium)	SS		
		Pneumonia		Quetiapine (Quetiapine)	SS		

Date:05/23/05ISR Number: 4673576-7Report Type:Expedited (15-DaCompany Report #2005072701
Age:63 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Balance Disorder	Health	Lithium (Lithium)	PS		ORAL		
Initial or Prolonged	Depressed Level Of Consciousness	Professional	Aricept (Donepezil)	SS		ORAL	10 MG (1 IN 1 D), ORAL	
	Dizziness		Lipitor					
	Therapeutic Agent Toxicity		(Atorvastatin)	C				

Date:05/24/05ISR Number: 4672574-7Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0559748A
Age:23 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Hypothyroidism		Eskalith	PS	Glaxosmithkline	ORAL		
Initial or Prolonged	Intentional Misuse		Lexapro	C				
	Suicidal Ideation		Depakote	C				

Date:05/24/05ISR Number: 4672575-9Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0559750A
Age:41 YR Gender:Male I/FU:I

Outcome
Life-Threatening
Hospitalization -

Initial or Prolonged
Disability
Other

	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Anger		Eskalith	PS	Glaxosmithkline	ORAL	450MG Twice	
	Crying						per day	3 WK
	Depression		Paxil	SS	Glaxosmithkline	ORAL	20MG Per day	9 YR
	Poisoning		Wellbutrin Xl	SS	Glaxosmithkline	ORAL	150MG Per day	2 WK
	Psychotic Disorder		Seroquel	SS			UNKNOWN	
	Suicide Attempt		Risperdal	C				
			Klonopin	C				

Date:05/24/05ISR Number: 4672587-5Report Type:Expedited (15-DaCompany Report #AU-GLAXOSMITHKLINE-B0377981A
Age:62 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Insomnia		Quilonum Sr	PS	Glaxosmithkline	ORAL	900MG At	
	Therapeutic Agent						night	
	Toxicity		Telmisartan	C	Glaxosmithkline	ORAL		
	Tremor		Thyroxine	C	Glaxosmithkline	ORAL		
			Olanzapine	C		ORAL		

Date:05/24/05ISR Number: 4672608-XReport Type:Expedited (15-DaCompany Report #2005009412
Age:23 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Fatigue		Quilonum Retard	PS	Glaxosmithkline	ORAL	9000MG Single	
	Intentional Misuse						dose	
	Suicide Attempt		Paracetamol	SS	Glaxosmithkline	ORAL	15000MG	
							Single dose	

			Tavor	SS		ORAL

20MG Single

dose

Date:05/24/05ISR Number: 4672793-XReport Type:Expedited (15-DaCompany Report #US-BRISTOL-MYERS SQUIBB COMPANY-12965893
Age:30 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Depression		Abilify	PS	Otsuka			
Hospitalization -	Drug Ineffective				Pharmaceutical			
Initial or Prolonged	Intentional Misuse				Company, Ltd.			
	Mania		Trazodone Hcl	SS	Apothecon			
	Suicide Attempt		Lexapro	SS		ORAL		
	Weight Increased		Lithium	SS				
			Lamictal	SS				
			Seroquel	SS				

Date:05/24/05ISR Number: 4673318-5Report Type:Direct Company Report #CTU 249364
Age:56 YR Gender:Female I/FU:I

Outcome	PT
Hospitalization -	Activities Of Daily
Initial or Prolonged	Living Impaired
	Anorexia
	Balance Disorder
	Bronchitis
	Confusional State
	Disturbance In Attention
	Dizziness

		Electrocardiogram T Wave Amplitude Decreased					
		Mental Status Changes	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
		Personality Change		Lithium Carbonate			
		Polydipsia		900 Mg At Bedtime	PS		
900 MG AT							
		Renal Failure Acute					
BEDTIME							
		Somnolence		B12 Injections	C		
		Therapeutic Agent		Rosiglitazone	C		
		Toxicity		Hydrochlorothiazide	C		
				Terazosin	C		

Date:05/24/05ISR Number: 4674103-0Report Type:Direct Company Report #CTU 249389
Age:61 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Required	Agitation		Lithium	PS		
Intervention to	Autonomic Nervous System		Haldoperidol	SS		
Prevent Permanent	Imbalance		Lisinopril	SS		
Impairment/Damage	Bradycardia		Risperidone	SS		
	Confusional State					
	Decreased Appetite					
	Diarrhoea					
	Dyskinesia					
	Dystonia					
	Faeces Discoloured					
	Fatigue					
	Heart Rate Increased					
	Hypernatraemia					
	Memory Impairment					
	Mental Status Changes					
	Nephrogenic Diabetes Insipidus					
	Tardive Dyskinesia					
	Therapeutic Agent Toxicity					
	Tremor					
	Verbigeration					

Date:05/25/05ISR Number: 4673120-4Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20050503672
Age:77 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Interaction		Risperdal	PS				
OROPHARINGEAL								
	Extrapyramidal Disorder		Risperdal	SS				
OROPHARINGEAL								
	Parkinson'S Disease		Remergil	C				
OROPHARINGEAL								
			Nortrilen	C				
OROPHARINGEAL								
			Nortrilen	C				
OROPHARINGEAL								
			Tavor	C				
OROPHARINGEAL								
			Hypnorex	I				
OROPHARINGEAL								

Date:05/25/05ISR Number: 4674066-8Report Type:Expedited (15-DaCompany Report #KII-2005-0016638
Age:56 YR Gender:Female I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Agitation
	Alanine Aminotransferase Increased
Other	Anion Gap Increased

		Aspartate Aminotransferase Increased	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
		Blood Amylase Increased	Study	Oxycontin Tablets			
		Blood Bicarbonate Decreased	Health Professional	(Oxycodone Hydrocholride) Cr			
		Blood Creatine Phosphokinase Increased	Other	Tablet	PS		
		Blood Creatine Phosphokinase Mb Increased		Gabapentin (Gabapentin)	SS		
		Blood Creatinine Increased		Metaxalone (Metaxalone)	SS		
		Blood Glucose Increased		Orubal	SS		
		Blood Lactate Dehydrogenase Increased		Zolpidem	SS		
		Blood Ph Decreased		Clonazepam(Clonazepam)	SS		
		Blood Potassium Increased		Modafinil(Modafinil)	SS		
		Blood Urea Increased		Oral Antidiabetics	SS		
		Coma		Biguanides	SS		
		Drug Screen Positive		Niacin (Nicotinic Acid)	SS		
		Haemodialysis		Ace Inhibitor	SS		
		Haemoglobin Decreased		Lidocaine (Lidocaine)	SS		
		Lipase Increased		Thiazides	SS		
		Prothrombin Time Prolonged		Ssri	SS		
		Renal Function Test Abnormal		Antidepressants	SS		
				Antihistamines For Systemic Use	SS		
				Antibiotics	SS		
				Monistat(Miconazole Nitrate)	SS		
				Norethindrone (Norethisterone)	SS		
				Albuterol Sulfate(Salbutamol Sulfate)	SS		
				Terbutaline And Other Beta-2 Agonist	SS		
				Warfarin (Warfarin)	SS		
				Fentanyl (Fentanyl)	SS		
				Rhinocort Aqua (Budesonide)	SS		
				Ethanol(Ethanol)	SS		
1	WK						

Date:05/26/05ISR Number: 4674231-XReport Type:Expedited (15-DaCompany Report #PHNR2005AU00572
Age:67 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Interaction Drug Level Increased Sedation		Clozaril	PS	Novartis Sector: Pharma		12 - 700 mg/day	1806 DAY
			Clozaril	SS	Novartis Sector: Pharma		12 mg, QD	
			Lithium	SS				
			Celebrex	SS				
			Sertraline	SS				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/26/05ISR Number: 4675225-0Report Type:Expedited (15-DaCompany Report #B0380662A
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Congenital Anomaly	Anencephaly Drug Exposure During Pregnancy	Foreign Literature Health Professional	Lithium Salt (Lithium Salt) (Generic)	PS			TRANSPLACENTAL 900MG/ DAY/ TRANSPLACENTARY	PER
			Folic Acid (Folic Acid)	SS			TRANSPLACENTAL TRANSPLACENTARY	8 WK
			Calcium Salt (Calcium Salt)	SS			TRANSPLACENTAL TRANSPLACENTARY	
			Iron Supplements (Iron Supplements)	SS			TRANSPLACENTAL TRANSPLACENTARY	

Date:05/26/05ISR Number: 4676657-7Report Type:Expedited (15-DaCompany Report #2004059901
Age:50 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death Hospitalization - Initial or Prolonged Other	Acute Respiratory Failure Agitation Anxiety Aortic Injury Completed Suicide Haemothorax	Consumer	Neurontin (Gabapentin)	PS				
			Xanax Tablet (Alprazolam)	SS		ORAL	4 MG (1 MG, 4 IN 1 D), ORAL	
			Lithium (Lithium)	SS		ORAL	600 MG (300	

Lung Injury				
Major Depression				
Multiple Drug Overdose	Fluoxetine Hydrochloride (Fluoxetine Hydrochloride)	SS		20 MG (20 MG, 1 IN 1 D), ORAL
Pain				
Pelvic Fracture				
Polytraumatism				
Rib Fracture				
Suicidal Ideation				
Suicide Attempt	Lorazepam (Lorazepam)	SS		
	Zolpidem Tartrate (Zolpidem Tartrate)	SS		10 MG (10 MG, 1 IN 1 D), ORAL
	Temazepam (Temazepam)	C		
	Diazepam (Diazepam)	C		
	Olanzapine (Olanzapine)	C		

Date:05/26/05ISR Number: 4676950-8Report Type:Expedited (15-DaCompany Report #2004079254
Age:28 YR Gender:Female I/FU:F

Outcome
Hospitalization -
Initial or Prolonged
Other
Required
Intervention to
Prevent Permanent

Impairment/Damage

PT
Abdominal Tenderness
Activated Partial
Thromboplastin Time
Prolonged
Aggression
Agitation
Ammonia Abnormal
Anaemia
Anxiety
Bacterial Infection
Blood Chloride Decreased
Blood Creatine
Phosphokinase Increased
Blood Creatine
Phosphokinase Mb
Increased
Blood Creatinine
Increased
Blood Magnesium Decreased
Blood Sodium Decreased
Blood Urea Increased
Candidiasis
Cardiomegaly
Central Line Infection
Cholelithiasis
Confusional State
Contusion
Decreased Appetite
Delirium
Dialysis
Disorientation
Ecchymosis
Ejection Fraction
Decreased
Electrocardiogram St
Segment Abnormal
Electrocardiogram T Wave
Abnormal
Electrocardiogram T Wave
Biphasic
Electrolyte Imbalance
Eye Injury
Gallop Rhythm Present
Headache

Heparin-Induced
Thrombocytopenia
Hypokalaemia
Incoherent
Lupus Nephritis
Mental Status Changes
Migraine
Mucosal Dryness
Pain
Platelet Count Decreased
Proteinuria
Prothrombin Time
Prolonged
Pyrexia

	Renal Failure Sepsis Skin Striae	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Somnolence	Health	Geodon (Ziprasidone)	PS		ORAL	240 MG (120
	Therapeutic Agent	Professional					MG, 2 IN 1
	Toxicity						D), ORAL
	Tooth Disorder Torsade De Pointes		Fluconazole (Fluconazole)	SS		ORAL	100 MG (1 IN
	Treatment Noncompliance						1 D), ORAL
	Tremor Tricuspid Valve		Claritin (Loratadine)	SS		ORAL	10 MG, 1 IN 1
	Incompetence						D, ORAL
	Urinary Casts Urinary Tract Infection		Lithobid (Lithium Carbonate)	SS		ORAL	1200 MG (600
	Urine Ketone Body Present						MG, 2 IN 1
	Urine Leukocyte Esterase						D), ORAL
	Positive Ventricular Extrasystoles		Lexapro (Escitalopram)	SS		ORAL	15 MG, 1 IN 1
	Vomiting						D, ORAL
	White Blood Cells Urine		Topiramate (Topiramate)	SS		ORAL	100 MG, 1 IN
							1 D, ORAL
			Prednisone (Prednisone)	C			
			Vancomycin (Vancomycin)	C			
			Tylenol (Paracetamol)	C			
			Heparin (Heparin)	C			
			Excedrin (Caffeine, Paracetamol)	C			

Aspirin (Acetylsalicylic Acid)	C
Protonix (Pantoprazole)	C
Prevacid (Lansoprazole)	C
Klonopin (Clonazepam)	C
Zyprexa (Olanzapine)	C
Keppra (Levetiracetam)	C
Ciprofloxacin (Ciprofloxacin)	C
Trazodone (Trazodone)	C
Metoprolol (Metoprolol)	C
Synthroid (Levothyroxine Sodium)	C
Diflucan (Fluconazole)	C
Lactaid (Tilactase)	C
Prozac (Fluoxetine Hydrochloride)	C
Ferrous Sulfate (Ferrous Sulfate)	C
Clonazepam	

				(Clonazepam)	C		
				Simethicone (Simethicone)	C		
				Naltrexone (Naltrexone)	C		
				Abilify (Aripiprazole)	C		
				Plaquenil (Hydroxychloroquine Phosphate)	C		
				Fioricet (Butalbital, Caffeine, Paracetamol)	C		

Date:05/26/05ISR Number: 4677355-6Report Type:Expedited (15-DaCompany Report #HQWYE828520MAY05
Age:34 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Interaction	Foreign	Efexor (Venlafaxine Hydrochloride,					
Other	Dyskinesia	Health Professional	Tablet)	PS		ORAL	SEE IMAGE	45 DAY
			Quilonorm Retard (Lithium Carbonate,)	SS		ORAL	SEE IMAGE	2 DAY
			Seroquel (Quetiapine,)	SS		ORAL	SEE IMAGE	5 DAY

Date:05/26/05ISR Number: 4677475-6Report Type:Direct Company Report #CTU 249684
Age:61 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Fall		Lithium Carbonate					
	Therapeutic Agent Toxicity		Eskalith Glaxosmithkline Antimanic	PS	Glaxosmithkline	ORAL	300 MG PO BID	
			Baclofen	C				
			Bupropion	C				

				Clonazepam	C		
				Metoprolol	C		
				Nitroglycerin	C		
				Olanzapine	C		

Date:05/27/05ISR Number: 4676643-7Report Type:Expedited (15-DaCompany Report #US-ROCHE-405250
Age:43 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Aphasia		Klonopin	PS	Roche	ORAL		
	Confusional State		Gabitril	I		ORAL	AT BEDTIME	1 WK
	Delusion		Gabitril	I		ORAL	AT BEDTIME	
	Disorientation		Lithium	I		ORAL		
	Drug Interaction		Trileptal	I		ORAL		
	Sedation		Seroquel	I		ORAL		
			Clozaril	I		ORAL		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/27/05ISR Number: 4676885-0Report Type:Expedited (15-DaCompany Report #2005073197
Age:60 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Liver Function Test	Health	Geodon (Ziprasidone)	PS			160 MG (80 MG, 2 IN 1 D)	
	Abnormal	Professional						
	Neuroleptic Malignant Syndrome	Company Representative	Lithium (Lithium)	SS				
	Pneumonia		Quetiapine (Quetiapine)	SS				
	Unevaluable Event							

Date:05/27/05ISR Number: 4678232-7Report Type:Expedited (15-DaCompany Report #2005075840
Age:35 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	Consumer	Lithium (Lithium)	PS		ORAL	2200 MG, ORAL	
			Bextra (Valdecoxib)	SS		ORAL	ORAL	
Disability	Amnesia		Ibuprofen	SS		ORAL	ORAL	
	Cerebrovascular Accident		Vioxx (Rofecoxib)	SS		ORAL	ORAL	
	Coma		Phazyme (Diastase, Pancreatin, Pepsin, Simeticone)	SS		ORAL	ORAL	
	Dialysis							
	Difficulty In Walking							
	Hallucination		Multivitamins	C				
	Hemiplegia		Ascorbic Acid	C				
	Influenza		Acidophilus (Lactobacillus Adicophilus)	C				
	Renal Failure							
	Speech Disorder		Garlic	C				
			Vitamin E	C				
			Neurontin (Gabapentin)	C				
			Celebrex (Celecoxib)	C				
			Prilosec (Omeprazole)	C				
			Montelukast Sodium	C				
			Claritin					

(Loratadine)	C
Imitrex (Sumatriptan Succinate)	C
Buspar (Buspirone Hydrochloride)	C
All Other Therapeutic Products	C
Colace (Docusate Sodium)	C
Effexor (Venlafaxine Hydrochloride)	C
Pulmicort (Budenoside)	C
Albuterol (Salbutamol)	C
Serevent (Salmeterol Xinafoate)	C
Atrovent (Ipratropium Bromide)	C
Aspirin (Acetylsalicylic Acid)	C

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/31/05ISR Number: 4677684-6Report Type:Expedited (15-DaCompany Report #US-MERCK-0505USA02439
Age:35 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Disability	Activities Of Daily Living Impaired		Vioxx	PS	Merck & Co., Inc	ORAL		
	Amnesia		Simethicone	SS		ORAL		
	Arthritis		Lithium Sulfate	SS		ORAL		
	Cerebrovascular Accident		Bextra	SS		ORAL		
	Coma		Ibuprofen	SS		ORAL		
	Dialysis		Vitamins (Unspecified)	C				UNKNOWN
	Difficulty In Walking		Ascorbic Acid	C				UNKNOWN
	Hallucination		Acidophilus	C				UNKNOWN
	Hemiplegia		Garlic Extract	C				UNKNOWN
	Influenza		Vitamin E	C				UNKNOWN
	Malaise		Gabapentin	C				UNKNOWN
	Renal Failure		Celebrex	C				UNKNOWN
	Speech Disorder		Omeprazole	C				UNKNOWN
			Singulair	C				UNKNOWN
			Loratadine	C				UNKNOWN
			Sumatriptan Succinate	C				UNKNOWN
			Buspirone Hydrochloride	C				UNKNOWN
			[Therapy Unspecified]	C				UNKNOWN
			Aspirin	C				UNKNOWN
			Ipratropium Bromide	C				UNKNOWN
			Docusate Sodium	C				UNKNOWN
			Venlafaxine					

	Hydrochloride	C
UNKNOWN		
	Budesonide	C
UNKNOWN		
	Albuterol Sulfate	C
UNKNOWN		
	Salmeterol Xinafoate	C
UNKNOWN		

Date:05/31/05ISR Number: 4677909-7Report Type:Expedited (15-DaCompany Report #2005003330
Age:48 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Abuser		Quilonum Retard	PS	Glaxosmithkline	ORAL		
	Gait Disturbance		Rohypnol	SS		ORAL		
	Somnolence		Taxilan	SS		ORAL		

Date:05/31/05ISR Number: 4677959-0Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20050507184
Age: Gender:Male I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Activities Of Daily Living Impaired
Disability	Amnesia
	Cerebrovascular Accident
	Coma
	Dialysis
	Difficulty In Walking
	Drug Interaction
	Hallucination
	Hemiplegia
	Influenza
	Malaise
	Renal Failure

Speech Disorder

Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Ibuprofen	PS				
	Phazyme	SS			OROPHARINGEAL	
	Phazyme	SS			OROPHARINGEAL	
	Phazyme	SS			OROPHARINGEAL	
	Vioxx	SS			OROPHARINGEAL	
	Phazyme	SS			OROPHARINGEAL	
	Multivitamins	C				
	Multivitamins	C				
	Multivitamins	C				
	Imitrex	C				
	Claritin	C				
	Prilosec	C				
	Celebrex	C				
	Neurontin	C				
	Vitamin E	C				
	Garlic	C				
	Acidophilus	C				
	Ascorbic Acid	C				
	Singulair	C				
	Aspirin	C				
	Atrovent	C				
	Serevent	C				
	Albuterol	C				
	Pulmicort	C				
	Effexor	C				
	Colace	C				
	Sleeping Tablets	C				
	Buspar	C				
	Multivitamins	C				
	Multivitamins	C				
	Multivitamins	C				
	Multivitamins	C				
	Multivitamins	C				
	Lithium	I			OROPHARINGEAL	
	-Bextra	I			OROPHARINGEAL	

Date:05/31/05ISR Number: 4678009-2Report Type:Expedited (15-DaCompany Report #2005GB00966
Age:76 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Disability	Cerebrovascular Disorder		Quetiapine	PS	Zeneca Pharmaceutical	ORAL		
	Drug Interaction							
	Drug Level Increased		Bendrofluazide	C		ORAL		
	Gastroenteritis		Omeprazole	C		ORAL		
	Therapeutic Agent Toxicity		Tamsulosin	C		ORAL		
			Lorazepam	C		ORAL		
			Priadel	I		ORAL		
			Priadel	I		ORAL	22	DAY

Date:05/31/05ISR Number: 4679707-7Report Type:Expedited (15-DaCompany Report #2005073197
Age:60 YR Gender:Male I/FU:F

Outcome	PT
Other	Confusional State
	Liver Function Test Abnormal

	Neuroleptic Malignant Syndrome						
	Pneumonia	Report Source	Product	Role	Manufacturer	Route	Dose Duration
		Health Professional	Geodon (Ziprasidone)	PS			160 MG (80 MG, 2 IN 1 D)
		Company Representative	Lithium (Lithium)	SS			
			Quetiapine (Quetiapine)	SS			

Date:05/31/05ISR Number: 4680111-6Report Type:Expedited (15-DaCompany Report #2005077556
Age:42 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Other	Akathisia	Foreign	Lithium (Lithium)	PS		ORAL	800 MG (1 IN 1 D), ORAL
	Drug Interaction	Literature					
	Potentiation	Health Professional	Risperidone (Risperidone)	SS		ORAL	5 MG, ORAL
	Dyskinesia						
	Extrapyramidal Disorder						

Date:06/01/05ISR Number: 4678259-5Report Type:Expedited (15-DaCompany Report #200511752GDDC
Age:65 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Amnesia		Ketek	PS	Aventis Pharmaceuticals Inc.	ORAL	
Other	Antipsychotic Drug Level Above Therapeutic		Lithane	SS			
	Blood Creatinine Increased		Altace	C			
	Confusional State		Synthroid	C			
	Drug Interaction		Advair	C			
	Metabolic Encephalopathy						
	Speech Disorder						
	Therapeutic Agent Toxicity						

Date:06/01/05ISR Number: 4680767-8Report Type:Direct Company Report #CTU 250097
Age:46 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Adverse Drug Reaction		Lithium Slow Release Tabs 300 Mg Able Laboratories	PS	Able Laboratories	ORAL	300 MG 1	

AM./2 PM ORAL

Date:06/01/05ISR Number: 4681095-7Report Type:Expedited (15-DaCompany Report #2005044232
Age:56 YR Gender:Female I/FU:F

Outcome	PT
Other	Alopecia
	Antipsychotic Drug Level Above Therapeutic
	Bladder Prolapse
	Breath Odour
	Drug Ineffective
	Dysgeusia
	Gangrene
	Hypoaesthesia

	Inadequate Analgesia Nausea Panic Attack	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Pharmaceutical Product Complaint Tooth Discolouration	Consumer	Neurontin (Gabapentin)	PS		ORAL	800 MG (1 D), ORAL
	Tooth Loss		Lithium (Lithium)	SS			
			Cyclobenzaprine (Cyclobenzaprine)	C			
			Thyroid (Thyroid)	C			
			All Other Therapeutic Product (All Other Therapeutic Products)	C			
			Clonazepam (Clonazepam)	C			
			Avandia (Rosiglitazone Maleate)	C			
			Naproxen (Naproxen)	C			
			Zocor (Simvastatin)	C			

Date:06/02/05ISR Number: 4679362-6Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0560600A
Age:53 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Life-Threatening Hospitalization - Initial or Prolonged Other	Intentional Misuse		Eskalith Zyprexa Beer	PS SS SS	Glaxosmithkline	ORAL	300MG Per day

Date:06/02/05ISR Number: 4681773-XReport Type:Expedited (15-DaCompany Report #2005080856
Age:45 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Disability	Dysphoria	Literature	Sertraline				

	Hypomania	Health	(Sertraline)	PS
	Initial Insomnia	Professional	Lithium (Lithium)	SS
	Irritability			
	Middle Insomnia			
	Mood Swings			
	Sleep Disorder			

Date:06/03/05ISR Number: 4681091-XReport Type:Expedited (15-DaCompany Report #DE-GLAXOSMITHKLINE-D0046723A
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Drug Interaction		Quilonum Retard	PS	Glaxosmithkline	ORAL	2TAB per day	
Initial or Prolonged	Drug Level Increased		Ass	SS	Glaxosmithkline		UNKNOWN	100MG Per day

Date:06/03/05ISR Number: 4683476-4Report Type:Direct Company Report #CTU 250327
Age:40 YR Gender:Female I/FU:I

Outcome	PT
Other	Drug Intolerance
	Stomach Discomfort

	Therapeutic Response Unexpected With Drug Substitution	Report Source	Product	Role	Manufacturer	Route	Dose Duration
			Lithium 300 Mg 3 @ Hs	PS		ORAL	PO @ HS
			Synthroid	C			
			Protonix	C			

Date:06/06/05ISR Number: 4682829-8Report Type:Expedited (15-DaCompany Report #2005GB01020
Age:76 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Cerebrovascular Accident		Quetiapine	PS	Zeneca Pharmaceutical	ORAL	UNKNOWN
	Confusional State						
Disability	Drug Interaction		Omeprazole	C			UNKNOWN
	Facial Paresis		Prostap	C			UNKNOWN
	Gastroenteritis		Tamsulosin	C			UNKNOWN
	Hemiparesis		Lorazepam	C			UNKNOWN
			Zopiclone	C			UNKNOWN
			Priadel	I		ORAL	INCREASED TO 600MG
			Priadel	I		ORAL	INCREASED FROM 400MG
			Bendrofluazide	I			UNKNOWN

Date:06/06/05ISR Number: 4683290-XReport Type:Direct Company Report #CTU 250357
Age:9 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration

Other Required Intervention to Prevent Permanent Impairment/Damage	Abnormal Behaviour Aggression Depression Hallucination, Auditory Hostility Mania Pharmaceutical Product Complaint Regressive Behaviour Thinking Abnormal Verbal Abuse		Lithium Carbonate 300 Mg Able Laboratories	PS	Able Laboratories	ORAL 1 3 TIMES A DAY ORAL

Date:06/06/05ISR Number: 4686386-1Report Type:Expedited (15-DaCompany Report #2005079018
Age:74 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Hospitalization - Initial or Prolonged	Blood Creatine Abnormal Confusional State Diarrhoea Drug Interaction Drug Toxicity Dysarthria Glasgow Coma Scale Abnormal Lethargy Nervous System Disorder Tremor	Foreign Literature Health Professional Other	Lithium (Lithium) Levomepromazine (Levomepromazine) Lisinopril (Lisinopril) Risperidone (Risperidone) Escitalopram (Escitalopram)	PS SS SS SS SS		750 MG (250 MG, 3 IN 1 D), 6.25 MG, 30 MG, 0.5 MG (0.25 MG, 2 IN 1 D), 10 MG,

			Irbesartan (Irbesartan)	SS			300 MG,
			Lormetazepam (Lormetazepam)	C			
			Metformin (Metformin)	C			
			Furosemide (Furosemide)	C			
			Repaglinide (Repaglinide)	C			
			Spironolactone (Spironolactone)	C			

Date:06/06/05ISR Number: 4686969-9Report Type:Expedited (15-DaCompany Report #2005079018
Age:74 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Creatine Increased	Foreign	Lithium (Lithium)	PS			750 MG (250 MG, 3 IN 1 D)	
	Creatinine Renal Clearance Increased	Literature						
	Drug Interaction	Health Professional	Levomepromazine (Levomeromazine)	SS			6.25 MG	
	Glasgow Coma Scale Abnormal		Lisinopril (Lisinopril)	SS			30 MG	
	Neurological Symptom		Risperidone (Risperidone)	SS			0.5 MG (0.25 MG, 2 IN 1 D)	
	Therapeutic Agent Toxicity							
			Escitalopram (Escitalopram)	SS			10 MG	
			Irbesartan (Irbesartan)	SS			300 MG	
			Lormetazepam (Lormetazepam)	C				
			Metformin (Metformin)	C				
			Furosemide					

9furosemide)	C	
Repaglinide (Repaglinide)	C	
Spironolactone (Spironolactone)	C	

Date:06/07/05ISR Number: 4684148-2Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0560946A
Age:65 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blood Pressure		Eskalith	PS	Glaxosmithkline	ORAL	300MG Three	
	Inadequately Controlled						times per day	40 YR
	Blood Pressure Systolic		Atenolol	SS				
	Increased		Flonase	C	Glaxosmithkline			
	Dizziness		Singulair	C				
	Headache							
	Loss Of Consciousness							
	Somnolence							
	Weight Increased							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/08/05ISR Number: 4686961-4Report Type:Expedited (15-DaCompany Report #B0382926A
Age:74 YR Gender:Female I/FU:U

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agitation	Foreign	Lithium Salt (Formulation Unknown) (Generic) (Lithium Salt)	PS			250 MG / THREE TIMES PER DAY /	SEE DOSAGE TEXT
	Apathy	Literature						
	Confusional State	Health Professional						
	Dehydration							
	Diarrhoea							
	Drug Interaction							
	Dysarthria		Lisinopril (Formulation Unknown) (Lisionpril)	SS				
	Lethargy							
	Neurotoxicity							
	Oliguria							
	Somnolence		Irbesartan (Formulation Unknown) (Irbesartan)	SS				
	Therapeutic Agent Toxicity							
	Tremor							
			Risperidone (Formulation Unknown) (Rispedridone)	SS				
			Citalopram (Formulation Unknown) (Citalopram)	SS				
			Methotrimeprazine (Formulation Unknown) (Methotrimeprazine)	SS				
			Lormetazepam	C				
			Metformin Hydrochloride	C				
			Repaglinide	C				
			Frusemide	C				
			Spironolactone	C				
			Dexetimide	C				

Date:06/08/05ISR Number: 4686966-3Report Type:Expedited (15-DaCompany Report #B0379891A
Age:19 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain Balance Disorder Chills Coordination Abnormal Diarrhoea Dizziness Dysaesthesia Headache Hyperhidrosis Hypersomnia Intentional Misuse Intentional Self-Injury Overdose Scotoma Therapeutic Agent Toxicity Vision Blurred Visual Disturbance Vomiting	Foreign Literature Health Professional	Lithium Carbonate (Formulation Unknwn) (Generic) (Lithium Carbonate)	PS		ORAL ORAL		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/08/05ISR Number: 4687401-1Report Type:Expedited (15-DaCompany Report #2005073197
Age:60 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Acute Coronary Syndrome	Health	Geodon (Ziprasidone)	PS			160 MG (80 MG, 2 IN 1 D),	
	Neuroleptic Malignant Syndrome	Professional Company						
	Pneumonia	Representative	Lithium (Lithium)	SS				
			Quetiapine (Quetiapine)	SS				

Date:06/08/05ISR Number: 4687669-1Report Type:Direct Company Report #CTU 250648
Age:57 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Activities Of Daily Living Impaired		Lithium Carbonate 300 Mg (Able Laboratories)	PS	Able Laboratories		IMPRINT ON LITHIUM CARBONATE "A 270"	
	Bipolar I Disorder							
	Condition Aggravated							
	Depression							
	Drug Level Decreased							
	Mood Altered							
	Pharmaceutical Product Complaint							
	Somnolence							

Date:06/09/05ISR Number: 4688750-3Report Type:Direct Company Report #CTU 250865
Age:40 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Pharmaceutical Product Complaint		Lithium 300 Mg Three @Hs	PS		ORAL	PO @ HS	

	Stomach Discomfort		Synthroid	C		
			Protonix	C		

Date:06/10/05ISR Number: 4687911-7Report Type:Expedited (15-DaCompany Report #CA-GLAXOSMITHKLINE-A0561854A
Age:40 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Aggression		Paxil	PS	Glaxosmithkline	ORAL	20MG	Unknown
	Alcohol Problem		Lithium	SS	Glaxosmithkline		UNKNOWN	
	Amnesia							
	Anxiety							
	Condition Aggravated							
	Depersonalisation							
	Depression							
	Disturbance In Attention							
	Emotional Disorder							
	Mood Swings							
	Suicidal Ideation							

Date:06/13/05ISR Number: 4688821-1Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0562115A
Age:46 YR Gender:Female I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Constipation
	Fatigue
	Thirst

		Treatment Noncompliance					
		Tremor					
		Vision Blurred	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
				Lithium Carbonate	PS	Glaxosmithkline	ORAL
				Clonazepam	C		

Date:06/14/05ISR Number: 4691880-3Report Type:Direct Company Report #CTU 251164
Age:54 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Other	Depression		Lithium Carbonate Er			
	Mood Altered		300 Mg Mfr: Able			
	Pharmaceutical Product		Laboratories -			
	Complaint		Imprint "A 283" On			
	Therapeutic Response		Tablet	PS	Able Laboratories	
1 EVERY DAY						
	Unexpected With Drug		Lamictal	C		
	Substitution		Lotensin	C		
			Synthroid	C		
			Tiazac	C		
			Diovan	C		
			Advair	C		
			Zyrtec	C		

Date:06/14/05ISR Number: 4691920-1Report Type:Direct Company Report #CTU 251136
Age:53 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization -	Asthenia		Fosinopril	PS		ORAL
10 MG PO QD						
Initial or Prolonged	Bradycardia		Lithium	SS		ORAL
300 MG PO BID						
	Electrocardiogram					
600 MG Q HS						
	Abnormal					
	Hyperkalaemia					
	Hyponatraemia					
	Mental Impairment					
	Speech Disorder					

Date:06/14/05ISR Number: 4692205-XReport Type:Expedited (15-DaCompany Report #2005079018
Age:74 YR Gender:Female I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Agitation
	Apathy
	Blood Creatinine Increased
	Condition Aggravated
	Confusional State
	Creatinine Renal Clearance Increased
	Dehydration
	Diarrhoea
	Drug Interaction
	Dysarthria
	Glasgow Coma Scale Abnormal
	Lethargy
	Nervous System Disorder
	Neurotoxicity
	Oliguria

	Therapeutic Agent Toxicity Tremor	Report Source	Product	Role	Manufacturer	Route	Dose Duration
		Foreign	Lithium (Lithium)	PS			750 MG (250 MG, 3 IN 1 D)
		Literature					
		Health Professional	Levomepromazine (Levomepromazine)	SS			6.25 MG
			Lisinopril (Lisinopril)	SS			30 MG
			Risperidone (Risperidone)	SS			0.5 MG (0.25 MG, 2 IN 1 D)
			Escitalopram (Escitalopram)	SS			10 MG
			Irbesartan (Irbesartan)	SS			300 MG
			Lormetazepam	C			
			Metformin	C			
			Furosemide	C			
			Repaglinide	C			
			Spironolactone	C			

Date:06/15/05ISR Number: 4690231-8Report Type:Expedited (15-DaCompany Report #FR-ROCHE-406545
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Hospitalization - Initial or Prolonged	Drug Exposure During Pregnancy		Rivotril	PS	Roche	
	Foetal Macrosomia		Rivotril	SS	Roche	
	Somnolence Neonatal		Teralithe	SS		
			Teralithe	SS		
			Teralithe	SS		
			Largactil	SS		
			Largactil	SS		
			Largactil	SS		

			Largactil	SS		
AFTER THE						
BIRTH.						
			Akineton Retard	SS		
			Akineton Retard	SS		
64 DAY						
			Risperdal	C		
			Haldol	C		

Date:06/15/05ISR Number: 4690421-4Report Type:Expedited (15-DaCompany Report #2005UW08382
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Interaction Headache		Seroquel	PS	Zeneca Pharmaceutical	ORAL		
			Lithium	I				

Date:06/15/05ISR Number: 4690642-0Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0562426A
Age:45 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Haemolytic Anaemia		Lithium Carbonate	PS	Glaxosmithkline			
			Lamictal	SS	Glaxosmithkline	ORAL		
22 MON								
			Prozac	C				
			Prednisone	C				
			Remeron	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/15/05ISR Number: 4691400-3Report Type:Expedited (15-DaCompany Report #C05-C-102
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Depression Mood Altered Sluggishness Therapy Non-Responder	Consumer Health Professional	Lithium Carbonate Capsules Usp 300 Mg	PS			300 MG, AM, 600 MG PM	

Date:06/15/05ISR Number: 4693022-7Report Type:Expedited (15-DaCompany Report #2005044232
Age:56 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Alopecia Bladder Prolapse Breath Odour Drug Ineffective Drug Level Increased Dysgeusia Gangrene Hair Disorder Hypoaesthesia Malaise Panic Attack Pharmaceutical Product Complaint Tooth Discolouration Tooth Loss	Consumer	Neurontin (Gabapentin) Lithium (Lithium) Cyclobenzaprine (Cyclobenzaprine) Thyroid (Thyroid) Clonazepam (Clonazepam) Avandia (Rosiglitazone Maleate) Naproxen (Naproxen) Zocor (Simvastatin)	PS SS C C C C C		ORAL	800 MG (1 D), ORAL	

Date:06/16/05ISR Number: 4692038-4Report Type:Direct Company Report #CTU 251348
Age:51 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Arrhythmia Bradycardia		Lithium Carbonate 300mg	PS		ORAL	300 MG	QHS

	Drug Toxicity					
ORAL						
	Hypermagnesaemia		Milk Of Magnesia	SS		ORAL
30 ML BID						
	Hypotension					
PRN ORAL						
	Nodal Rhythm					

Date:06/16/05ISR Number: 4693797-7Report Type:Expedited (15-DaCompany Report #2005-06-0411
Age:60 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Disability	Bipolar I Disorder	Foreign	Interferon Alpha			
Other	Cerebrovascular Disorder	Literature	(Like			
	Drug Ineffective	Health	Intron A)	PS		
	Foot Amputation	Professional	Lithium	SS		
	Gangrene		Hydroxyurea	C		
	Impaired Healing					
	Lacunar Infarction					
	Pulmonary Hypertension					
	Skin Ulcer					
	Vasculitis					

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/16/05ISR Number: 4695739-7Report Type:Direct Company Report #CTU 251304
Age:54 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Abnormal Behaviour		Lithium Carbonate					
Hospitalization -	Drug Dose Omission		300 Mg Caabl Able					
Initial or Prolonged	Drug Level Increased		Labs	PS	Caabl Able Labs		2 CAPS ,	
Disability	Fatigue						TWICE A DAY	
047							20	YR

Date:06/17/05ISR Number: 4693102-6Report Type:Expedited (15-DaCompany Report #200511992FR
Age:75 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Abdominal Pain		Lasilix	PS	Aventis			
Initial or Prolonged	Impaired Gastric Emptying				Pharmaceuticals Inc.	ORAL		
	Intestinal Obstruction		Teralithe	SS		ORAL		
			Motilyo	SS		ORAL		
			Risperdal	SS		ORAL		
			Mopral	C		ORAL		

Date:06/20/05ISR Number: 4694291-XReport Type:Expedited (15-DaCompany Report #FR-ABBOTT-05P-056-0301988-00
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Foetal Heart Rate		Akineton	PS				
Initial or Prolonged	Abnormal		Chlorpromazine	SS				
Other	Macrosomia		Clonazepam	SS				
	Somnolence		Lithium	SS				

Date:06/20/05ISR Number: 4694300-8Report Type:Expedited (15-DaCompany Report #FR-ABBOTT-05P-056-0302380-00
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Hospitalization - Initial or Prolonged	Abortion Bipolar I Disorder Weight Increased	Akineton	PS	ORAL
		Chlorpromazine Hydrochloride	SS	ORAL
		Chlorpromazine Hydrochloride	SS	
		Chlorpromazine Hydrochloride	SS	
		Chlorpromazine Hydrochloride	SS	
		Clonazepam	SS	ORAL
		Clonazepam	SS	
		Clonazepam	SS	
		Clonazepam	SS	
		Lithium Carbonate	SS	ORAL
		Lithium Carbonate	SS	
		Lithium Carbonate	SS	
		Lithium Carbonate	SS	
		Risperidone	C	
		Haloperidol	C	
		Haloperidol	C	
		Zopiclone	C	
		Bromocriptine Mesilate	C	

One half

capsule 1 DAY

		Naproxen	C	

1 DAY

			Hydroxyzine Hydrochloride	C		

Date:06/20/05ISR Number: 4694665-7Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0563187A
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Convulsion		Eskalith	PS	Glaxosmithkline	ORAL		
	Road Traffic Accident		Wellbutrin	SS	Glaxosmithkline	ORAL	300MG Per day	1 MON
			Unknown	C				

Date:06/20/05ISR Number: 4694667-0Report Type:Expedited (15-DaCompany Report #JP-GLAXOSMITHKLINE-B0358923A
Age:74 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	C-Reactive Protein Increased		Paxil	PS	Glaxosmithkline	ORAL		
	Dehydration		Limas	SS	Glaxosmithkline	ORAL		
	Depressed Level Of Consciousness							
	Diarrhoea							
	Fall							
	Hyperhidrosis							
	Hyperreflexia							
	Incontinence							
	Pyrexia							
	Serotonin Syndrome							
	Tremor							
	White Blood Cells Urine Positive							

Date:06/20/05ISR Number: 4694686-4Report Type:Expedited (15-DaCompany Report #AT-GLAXOSMITHKLINE-B0384595A
Age:29 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Back Pain		Quilonorm Retard	PS	Glaxosmithkline	ORAL	17	DAY

	Pulmonary Embolism	Zuclopenthixol	C	ORAL
5 DAY				
	Shoulder Pain	Risperdal	C	
UNKNOWN				
		Lovenox	C	
17 DAY				
		Depakine Chrono	C	ORAL
17 DAY				
		Temesta	C	ORAL
2.5MG per day 1 DAY				

Date:06/20/05ISR Number: 4694703-1Report Type:Expedited (15-DaCompany Report #PHBS2004BR07756
Age:51 YR Gender:Male I/FU:F

Outcome	PT
Hospitalization -	Amnesia
Initial or Prolonged	Arthropathy
Other	Coordination Abnormal
	Delusion
	Disturbance In Attention
	Hypertension
	Increased Appetite
	Myoclonus
	Pneumonia
	Schizophrenia
	Thrombosis

Venous Insufficiency
Weight Decreased
Weight Increased

Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Leponex	PS	Novartis Sector: Pharma	ORAL	300 mg/d	
	Leponex	SS	Novartis Sector: Pharma	ORAL	500 mg/d	
	Leponex	SS	Novartis Sector: Pharma	ORAL	600 mg/d	
	Leponex	SS	Novartis Sector: Pharma	ORAL	400 mg/d	
	Lithium	SS			UNKNOWN	600 mg/d
	Lithium	SS			UNKNOWN	300 mg/d
	Geodon	C				
	Aluminium Hydroxide	C			UNKNOWN	
	Norvasc	C		ORAL	15 mg/d	
	Moduretic	C		ORAL	50 mg, Q48H	
	Omeprazole	C			UNKNOWN	
	Ketoprofen	C				
	Magnesium Hydroxide	C			UNKNOWN	
	Folic Acid	C		ORAL	5 mg/d	
	Valproic Acid	C		ORAL	2000 mg/d	
	Exelon	C		ORAL	6 mg, BID	
	Haloperidol	C			UNKNOWN	

Date:06/20/05ISR Number: 4695481-2Report Type:Direct Company Report #CTU 251516
Age:47 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agitation Antipsychotic Drug Level Increased Blood Creatinine Increased Confusional State Dialysis Mental Status Changes		Lithium Hctz/Lisinopril 12.5/20mg	300mg PS SS		ORAL ORAL	600MG 12.5/20MG	BID QD

Date:06/20/05ISR Number: 4696050-0Report Type:Expedited (15-DaCompany Report #B0384309A
Age:52 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Cognitive Disorder Depression Polydipsia Polyuria Psychotic Disorder Therapeutic Agent Toxicity	Foreign Literature Health Professional	Lithium Salt (Formulation Unknown) (Lithium Salt)	PS			20	YR

Date:06/21/05ISR Number: 4697725-XReport Type:Direct Company Report #CTU 251624
Age:49 YR Gender:Male I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Coordination Abnormal Diarrhoea Dyskinesia Hyponatraemia

	Inappropriate Schedule Of Drug Administration Renal Impairment Therapeutic Agent Toxicity	Report Source	Product Lithium Carbonate , 300 Mg	Role PS	Manufacturer	Route ORAL

Dose Duration

2 CAP PO Q AM

, 3 CAP PO

QHS, 2 CAP PO

BID

Date:06/21/05ISR Number: 4697729-7Report Type:Direct Company Report #CTU 251649
Age:73 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Confusional State Somnolence Tremor		Lithium	PS		

Dose Duration

Date:06/22/05ISR Number: 4697216-6Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0563617A
Age:45 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - Initial or Prolonged	Brain Death Cardiac Failure Congestive Cardiomyopathy Coma Diabetes Mellitus Myocardial Infarction Therapeutic Agent Toxicity		Eskalith Antihypertensives	PS C	Glaxosmithkline	ORAL

Dose Duration

1 YR

Date:06/22/05ISR Number: 4699532-0Report Type:Expedited (15-DaCompany Report #B0383307A
Age:43 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Pressure Systolic Decreased	Foreign Literature	Lithium Carbonate (Generic) (Lithium Carbonate)	PS			1200 MG/ PER DAY	
	Body Temperature Increased	Health Professional						
	Depressed Level Of Consciousness		Risperidone	C				
	Diarrhoea		Carbamazepine	C				
	General Physical Health Deterioration		Frusemide	C				
	Heart Rate Increased		Amiloride	C				
	Nephrogenic Diabetes Insipidus							
	Pain In Extremity							
	Pneumonia Aspiration							
	Somnolence							
	Tongue Dry							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/23/05ISR Number: 4698179-XReport Type:Expedited (15-DaCompany Report #2005011715
Age:56 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Cold Sweat		Quilonum Retard	PS	Glaxosmithkline	ORAL		
	Halitosis		Alcohol	SS		ORAL		
	Intentional Misuse							
	Suicide Attempt							

Date:06/23/05ISR Number: 4698210-1Report Type:Expedited (15-DaCompany Report #FR-JNJFOC-20050602622
Age:75 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Abdominal Pain		Risperdal	PS				
OROPHARINGEAL								
Initial or Prolonged	Gastrointestinal		Motilyo	SS				
OROPHARINGEAL								
	Obstruction		Lasilix	SS				
OROPHARINGEAL								
	Impaired Gastric Emptying		Teralithe	SS				
OROPHARINGEAL								
			Teralithe	SS				
OROPHARINGEAL								
			Mopral	C				
UNKNOWN								

Date:06/23/05ISR Number: 4699162-0Report Type:Direct Company Report #CTU 251876
Age:62 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Dispensing Error		Lithium Citrate					
	Empyema		8meq/5ml Roxane					
	Medication Error		500ml	PS	Roxane	ORAL		
100 MG PO								
	Overdose							
DAILY								
	Pneumonia							

Date:06/23/05ISR Number: 4699163-2Report Type:Direct Company Report #CTU 251875
Age:50 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Dispensing Error Medication Error Overdose		Lithium Citrate 8meq/5ml 500ml Roxane	PS	Roxane		100ML IN AM AND QHS	

Date:06/24/05ISR Number: 4699333-3Report Type:Expedited (15-DaCompany Report #GB-GLAXOSMITHKLINE-B0384921A
Age:36 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death Hospitalization - Initial or Prolonged	Chest Pain Coronary Artery Disease Coronary Artery Dissection		Lithium	PS	Glaxosmithkline	ORAL	600MG Unknown	

Date:06/24/05ISR Number: 4699558-7Report Type:Expedited (15-DaCompany Report #2005UW09331
Age:54 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Glucose Fluctuation Blood Prolactin Increased Depression Lactation Disorder Weight Increased		Seroquel Lithium	PS SS	Zeneca Pharmaceutical	ORAL	75 MG QAM, 75 MG @ 1600, 100 MG HS	1 YR

Mellaril	C
Effexor Xr	C
Clonazepam	C
Ativan	C
Lopressor	C
Pariet	C
Pariet	C

Date:06/27/05ISR Number: 4700040-9Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0350706A
Age:41 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Bipolar I Disorder		Eskalith Cr	PS	Glaxosmithkline	ORAL	450MG See dosage text	
	Confusional State		Lithium Carbonate	SS	Glaxosmithkline	ORAL	UNKNOWN	15MG At night
	Depression							
	Drug Ineffective		Risperdal	C				
	Drug Level Decreased		Navane	C				
	Drug Level Increased		Cogentin	C			UNKNOWN	
	Dry Mouth							
	Dysgeusia							
	Hallucination, Auditory							
	Irritability							
	Libido Decreased							
	Mania							
	Periodontal Disease							
	Pollakiuria							
	Psychotic Disorder							
	Renal Impairment							
	Schizophrenia							
	Self-Injurious Ideation							
	Somnolence							
	Suicidal Ideation							
	Suicide Attempt							
	Therapeutic Agent							
	Toxicity							
	Thirst							
	Visual Disturbance							
	Vomiting							

Date:06/27/05ISR Number: 4701587-1Report Type:Expedited (15-DaCompany Report #L05-BEL-02196-01
Age:74 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agitation	Foreign	Escitalopram	PS		ORAL	10 MG QD PO	
	Apathy	Literature	Lithium	SS			250 MG TID	
	Blood Creatinine Increased	Health Professional	Levomepromazine	SS			6.25 MG QD	
	Dehydration	Other	Lisinopril	SS			30 MG QD	
	Drug Interaction		Lisinopril	SS			20 MG QD	
	Dysarthria		Irbesartan	SS			300 MG QD	
	Neurotoxicity		Spironolactone	SS			50 MG QD	
	Oliguria		Risperidone	SS			0.25 MG QD	
	Somnolence		Furosemide	C				
	Therapeutic Agent		Repaglinide	C				
	Toxicity		Metformin	C				
	Tremor		Lormetazepam	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/27/05ISR Number: 4702002-4Report Type:Expedited (15-DaCompany Report #2005-DE-02217GD
Age: Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dialysis	Literature	Lithium (Lithium					
Required	Overdose		Carbonate)	PS				
NR								
Intervention to	Renal Failure Acute							
Prevent Permanent								
Impairment/Damage								

Date:06/29/05ISR Number: 4703110-4Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0559784A
Age:54 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Cognitive Deterioration		Lithium Carbonate	PS	Glaxosmithkline	ORAL	300MG Twice	
Other	Coordination Abnormal							
per day								4 DAY
	Depressed Level Of		Seroquel	C		ORAL	150MG At	
	Consciousness							
night								
	Disorientation		Zoloft	C		ORAL	50MG Per day	
	Disturbance In Attention							
	Dysarthria							
	Lethargy							
	Nervous System Disorder							
	Therapeutic Agent							
	Toxicity							

Date:06/29/05ISR Number: 4703146-3Report Type:Expedited (15-DaCompany Report #MAI-01-101
Age:63 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Coordination Abnormal		Quilonum Retard	PS	Glaxosmithkline	ORAL	900MG per day	
Initial or Prolonged	Dysarthria		Tegretal	SS		ORAL	600MG per day	

	Fall		Zyprexa	SS		ORAL
20MG per day						
	Restlessness		Tavor	SS		ORAL
	Sedation		Diovan	C		ORAL
80MG per day						
			Natrilix	C		ORAL
1TAB per day						
			Actrapid	C		
UNKNOWN						

Date:06/29/05ISR Number: 4705714-1Report Type:Expedited (15-DaCompany Report #2005-BP-10622RO
Age:21 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Drug Exposure During	Foreign	Lithium Carbonate			
	Pregnancy	Literature	(Lithium Carbonate)	PS		ORAL
900 MG DAILY,						
	Retroplacental Haematoma	Health				
PO 2 YR						
	Unintended Pregnancy	Professional	Folic Acid (Folic Acid)	C		
			Calcium (Calcium)	C		
			Iron (Iron)	C		

Date:06/29/05ISR Number: 4705720-7Report Type:Expedited (15-DaCompany Report #2005-BP-10624RO
Age: Gender: I/FU:I

Outcome	PT
Congenital Anomaly	Anencephaly
	Drug Exposure During Pregnancy
	Foetal Disorder

	Spine Malformation Unintended Pregnancy						
		Report Source	Product	Role	Manufacturer	Route	Dose Duration
		Foreign Literature	Lithium Carbonate (Lithium Carbonate)	PS			
INTRA-UTERINE EXPOSURE TO	IN-UTERO	Health Professional					
900 MG/D X 8W, IU	8 WK						
			Folic Acid (Folic Acid)	C			
			Calcium (Calcium)	C			
			Iron (Iron)	C			

Date:06/29/05ISR Number: 4705727-XReport Type:Expedited (15-DaCompany Report #2005-BP-10433RO
Age:74 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Agitation Apathy	Foreign Literature	Lithium Carbonate (Lithium Carbonate)	PS		ORAL	250 MG TID, PO
	Blood Creatinine	Health Professional					
	Increased Confusional State		Escitalopram (Escitalopram)	SS		ORAL	10 MG/DAY, PO
	Dehydration Diarrhoea		Levomepromazine (Levomepromazine)	SS		ORAL	6.25 MG/DAY, PO
	Drug Interaction Dysarthria Lethargy		Lisinopril (Lisinopril)	SS			30 MG/DAY
	Oliguria Somnolence		Irbesartan (Irbesartan)	SS			300 MG/DAY
	Therapeutic Agent Toxicity		Furosemide (Furosemide)	SS			30 MG/DAY

	Tremor		Spironolactone (Spironolactone)	SS		
50 MG/DAY						
			Risperidone (Risperidone)	SS		
0.25 MG BID						
(2 IN 1 D)						
			Lormetazepam (Lormetazepam)	C		
			Metformin (Metformin)	C		
			Rapaglinide (Repaglinide)	C		

Date:07/05/05ISR Number: 4706482-XReport Type:Expedited (15-DaCompany Report #JP-GLAXOSMITHKLINE-B0384748A
Age:51 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Extrapyramidal Disorder		Paxil	PS	Glaxosmithkline	ORAL		
	Parkinsonism		Limas	SS	Glaxosmithkline	ORAL	600MG Per day	

Date:07/05/05ISR Number: 4709612-9Report Type:Expedited (15-DaCompany Report #B0384309A
Age:52 YR Gender:Female I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Asthenia
	Bipolar Ii Disorder
	Blood Chloride Increased
	Blood Creatine

		Phosphokinase Increased						
		Blood Creatinine Abnormal						
		Blood Osmolarity Abnormal						
		Blood Sodium Increased	Report Source	Product	Role	Manufacturer	Route	Dose
Duration								
		Cognitive Disorder	Foreign	Lithium Salt				
		Constricted Affect	Literature	(Generic)	PS			600 MG PER
		Coordination Abnormal	Health					DAY
20 YR								
		Dehydration	Professional	Sulpiride				
		Delirium	Other	(Formulation				
		Depressed Level Of		Unknown) (Sulpiride)	SS			SEE DOSAGE
		Consciousness						
TEXT	3 YR							
		Disorientation		Fluoxetine				
		Disturbance In Attention		(Formulation				
		Dysarthria		Unknown)				
		Extrapyramidal Disorder		(Fluoxetine)	SS			20 MG / PER
		Feeling Guilty						
DAY	4 YR							
		Hallucinations, Mixed		Proppranolol				
		Hyperlipidaemia		Hydrochloride	C			
		Hyperuricaemia		Lorazepam	C			
		Ideas Of Reference		Zotepine	C			
		Masked Facies		Estazolam	C			
		Memory Impairment		Dipyridamole	C			
		Mental Impairment		Aspirin	C			
		Nephrogenic Diabetes		Conjugated Estrogens	C			
		Insipidus		Benzbromarone	C			
		Polydipsia		Fluvastatin Sodium	C			
		Polyuria						
		Psychomotor Retardation						
		Self Esteem Decreased						
		Sleep Disorder						
		Somnolence						
		Speech Disorder						
		Suicide Attempt						
		Therapeutic Agent						
		Toxicity						
		Tremor						

Date:07/06/05ISR Number: 4708368-3Report Type:Expedited (15-DaCompany Report #KII-2005-0017206
Age:30 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Blood Ph Decreased	Study	Oxycontin					
Other	Coma	Health	Tablets(Oxycodone					
	Cough	Professional	Hydrochloride) Cr					
	Grand Mal Convulsion	Other	Tablet	PS		ORAL	ORAL	
	Pco2 Decreased		Lithium (Lithium)	SS		ORAL	ORAL	
	Po2 Decreased		Trazadone					
	Respiratory Arrest		(Trazodone)	SS		ORAL	ORAL	
			Ssri	SS		ORAL	ORAL	

Date:07/06/05ISR Number: 4709512-4Report Type:Direct Company Report #CTU 252631
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Nephrogenic Diabetes		Lithium	PS		ORAL	600 MG	QAM
Initial or Prolonged	Insipidus						ORAL	
			Lithium	SS		ORAL	900 MG	QHS
							ORAL	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/06/05ISR Number: 4709628-2Report Type:Direct Company Report #CTU 252648
Age:60 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Diarrhoea		Lithium Carbonate					
Hospitalization - Initial or Prolonged	Drug Toxicity		300mg	PS		ORAL	600MG	BID
Required Intervention to Prevent Permanent Impairment/Damage	Renal Failure Acute					ORAL		
			Albuterol	C				
			Aspirin	C				
			Carbamazepine	C				
			Fexofenadine	C				
			Lisinopril	C				
			Hydrochlorothiazide	C				
			Clonidine	C				
			Ibuprofen	C				
			Levothyroxine	C				
			Metoprolol	C				
			Multivitamins	C				
			Sildenafil	C				
			Simvastatin	C				

Date:07/07/05ISR Number: 4709038-8Report Type:Expedited (15-DaCompany Report #2005079018
Age:74 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agitation	Foreign	Lithium					
	Apathy	Literature	(Lithium)	PS		ORAL	750 MG (250	
	Confusional State	Health					MG, 3 IN 1 D)	
	Dehydration	Professional	Levomepromazine					
	Diarrhoea	Other						
	Drug Clearance Decreased		(Levomepromazine)	SS			6.25 MG	
	Drug Ineffective		Lisinopril					
	Drug Interaction							
	Dysarthria		(Lisinopril)	SS			30 MG	
	General Physical Health		Risperidone					
	Deterioration		(Risperidone)	SS			0.5 MG (0.25	

	Glasgow Coma Scale		
MG, 2 IN 1 D)			
	Abnormal	Escitalopram	
	Lethargy	(Escitalopram)	SS
10 MG			
	Neurological Symptom	Irbesartan	
	Neurotoxicity	(Irbesartan)	SS
300 MG			
	Oliguria	Lormetazepam	
	Overdose	(Lormetazepam)	C
	Renal Impairment	Metformin	
	Somnolence	(Metformin)	C
	Therapeutic Agent	Furosemide	
	Toxicity	(Furosemide)	C
	Tremor	Repaglinide	
		(Repaglinide)	C
		Spironolactone	
		(Spironolactone)	C

Date:07/07/05ISR Number: 4710635-4Report Type:Expedited (15-DaCompany Report #2005079018
Age:74 YR Gender:Female I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Agitation
	Apathy

	Blood Creatinine Increased					
	Confusional State	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
	Creatinine Renal	Foreign	Lithium (Lithium)	PS		
750 MG (250						
	Clearance Decreased	Literature				
MG, 3 IN 1 D)						
	Dehydration	Health	Levomepromazine			
	Diarrhoea	Professional	(Levomeprolazine)	SS		
6.25 MG						
	Drug Interaction		Lisinopril			
	Dysarthria		(Lisinopril)	SS		
30 MG						
	General Physical Health		Risperidone			
	Deterioration		(Risperidone)	SS		
0.5 MG (0.25						
	Glasgow Coma Scale					
MG, 2 IN 1 D)						
	Abnormal		Escitalopram			
	Lethargy		(Escitalopram)	SS		
10 MG						
	Neurotoxicity		Irbesartan			
	Oliguria		(Irbesartan)	SS		
300 MG						
	Overdose		Lormetazepam			
	Renal Impairment		(Lormetazepam)	C		
	Somnolence		Metformin			
	Therapeutic Agent		(Metformin)	C		
	Toxicity		Furosemide			
	Therapy Non-Responder		(Furosemide)	C		
	Tremor		Repaglinide			
			(Repaglinide)	C		
			Spironolactone			
			(Spironolactone)	C		

Date:07/08/05ISR Number: 4709446-5Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0565250A
Age:33 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Other	Hypertension		Bupropion	PS	Glaxosmithkline	
	Renal Failure		Lithium	SS	Glaxosmithkline	

Date:07/08/05ISR Number: 4710933-4Report Type:Expedited (15-DaCompany Report #B0386239A
Age:51 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hyperparathyroidism Primary Parathyroid Gland Enlargement Parathyroid Tumour Benign	Study Literature Health Professional	Lithium Salt (Lithium Salt)	PS				5 YR

Date:07/08/05ISR Number: 4710934-6Report Type:Expedited (15-DaCompany Report #B0386236A
Age:34 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hyperparathyroidism Primary Parathyroid Gland Enlargement Parathyroid Tumour Benign	Study Literature Health Professional	Lithium Salt (Lithium Salt)	PS				11 YR

Date:07/08/05ISR Number: 4710935-8Report Type:Expedited (15-DaCompany Report #B0386237A
Age:61 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hyperparathyroidism Primary Parathyroid Gland Enlargement Parathyroid Tumour Benign	Study Literature Health Professional	Lithium Salt (Lithium Salt)	PS				10 YR

Date:07/08/05ISR Number: 4710938-3Report Type:Expedited (15-DaCompany Report #B0386238A
Age:58 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hyperparathyroidism Primary Parathyroid Gland Enlargement Parathyroid Tumour Benign	Study Literature Health Professional	Lithium Salt (Lithium Salt)	PS				12 YR

Date:07/08/05ISR Number: 4710939-5Report Type:Expedited (15-DaCompany Report #B0386232A
Age:60 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hyperparathyroidism Primary Parathyroid Gland Enlargement Parathyroid Tumour Benign	Study Literature Health Professional	Lithium Salt (Lithium Salt)	PS				3 YR

Date:07/08/05ISR Number: 4710941-3Report Type:Expedited (15-DaCompany Report #B0386233A
Age:47 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Hospitalization - Initial or Prolonged	Hyperparathyroidism Primary Parathyroid Gland Enlargement Parathyroid Tumour Benign	Study Literature Health Professional	Lithium Salt (Lithium Salt)	PS			
10 YR							

Date:07/08/05ISR Number: 4710943-7Report Type:Expedited (15-DaCompany Report #B0386240A
Age:63 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hyperparathyroidism Primary Parathyroid Gland Enlargement Parathyroid Tumour Benign	Study Literature Health Professional	Lithiuim Salt (Lithium Salt)	PS				
9 YR								

Date:07/08/05ISR Number: 4710944-9Report Type:Expedited (15-DaCompany Report #B0386231A
Age:56 YR Gender:Female I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Hyperparathyroidism Primary Parathyroid Gland

		Enlargement Parathyroid Tumour Benign					
			Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
			Study Literature	Lithium Salt (Lithium Salt)	PS		
10	YR						
			Health Professional				

Date:07/08/05ISR Number: 4710947-4Report Type:Expedited (15-DaCompany Report #B0386230A
Age:61 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Hyperparathyroidism Primary Parathyroid Gland Enlargement	Study Literature Health Professional	Lithium Salt (Formulation Unknown) (Lithium Salt)	PS		
12 YR						
	Parathyroid Tumour Benign		Surgery (Formulation Unknown) (Surgery)	SS		

Date:07/08/05ISR Number: 4710948-6Report Type:Expedited (15-DaCompany Report #B0386235A
Age:66 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Hyperparathyroidism Primary Parathyroid Gland Enlargement	Study Literature Health Professional	Lithium Salt (Formulation Unknown) (Lithium Salt)	PS		
2 YR						
	Parathyroid Tumour Benign					

Date:07/08/05ISR Number: 4710949-8Report Type:Expedited (15-DaCompany Report #B0386229A
Age:59 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Hyperparathyroidism	Study	Lithium Salt			

Initial or Prolonged	Primary Parathyroid Gland Enlargement	Literature Health Professional	(Formulation Unknown) (Lithium Salt)	PS			
7 YR	Parathyroid Tumour Benign						

Date:07/08/05ISR Number: 4710950-4Report Type:Expedited (15-DaCompany Report #B0386234A
Age:58 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Hyperparathyroidism Primary Parathyroid Gland Enlargement	Study Literature Health Professional	Lithium Salt (Formulation Unknown) (Lithium Salt)	PS			
7 YR	Parathyroid Tumour Benign						

Date:07/08/05ISR Number: 4710951-6Report Type:Expedited (15-DaCompany Report #B0386226A
Age:66 YR Gender:Female I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Hyperparathyroidism Primary Parathyroid Gland

		Enlargement Parathyroid Tumour Benign Post Procedural Complication	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
			Study Literature Health Professional	Lithium Salt (Formulation Unknown) (Lithium Salt)	PS		
11	YR						

Date:07/08/05ISR Number: 4710953-XReport Type:Expedited (15-DaCompany Report #B0386227A
Age:57 YR Gender:Female I/FU:I

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Hospitalization - Initial or Prolonged		Hypercalcaemia Hyperparathyroidism Primary Parathyroid Gland	Study Literature Health Professional	Lithium Salt (Formulation Unknown) (Lithium Salt)	PS		
21	YR						
		Enlargement Parathyroid Tumour Benign Post Procedural Complication					

Date:07/08/05ISR Number: 4710954-1Report Type:Expedited (15-DaCompany Report #B0386228A
Age:74 YR Gender:Female I/FU:I

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Hospitalization - Initial or Prolonged		Hyperparathyroidism Primary Parathyroid Gland Enlargement	Study Literature Health Professional	Lithium Salt (Formulation Unknown) (Lithium Salt)	PS		
24	YR						
		Parathyroid Tumour Benign					

Date:07/08/05ISR Number: 4711155-3Report Type:Expedited (15-DaCompany Report #HQWYE953401JUL05
Age:62 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Akathisia	Health	Efexor Xr	PS		ORAL	STARTING DOSE	
	Coordination Abnormal	Professional					UNKNOWN ORAL	
	Drug Interaction						- SEE IMAGE	
	Impaired Driving Ability		Lithium (Lithium,)	SS		ORAL	UNKNOWN	
	Intention Tremor						DOSAGE,	
	Parkinson'S Disease						TABLET FORM	
							ORAL	
			Unspecified Beta Blocker (Unspecified Beta Blocker)	C				
			Unspecified Diuretic (Unspecified Diuretic)	C				
			Temazepam (Temazepam)	C				

Date:07/08/05ISR Number: 4711260-1Report Type:Expedited (15-DaCompany Report #2004009355
Age: Gender:Male I/FU:F

Outcome
Hospitalization -
Initial or Prolonged

Other

PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Abdominal Injury	Consumer	Neurontin					
Abdominal Pain	Health	(Gabapentin)	PS		ORAL	1800 MG (600 MG, 3 IN 1 D); ORAL	
Accident	Professional						
Agitation							
Back Disorder		Lipitor					
Blood Cholesterol Increased		(Atorvastatin)	SS		ORAL	20 (20MG, 1 IN 1 D); ORAL	
Cardiac Disorder		Lithium (Lithium)	SS				
Contusion		Naproxen (Naproxen)	SS				
Difficulty In Walking		Amoxicillin					
Disorientation		(Amoxicillin)	SS		ORAL	1000 MG (1 IN 2 D); ORAL	
Drug Intolerance							
Erectile Dysfunction		Rofecoxib					
Facial Pain		(Rofecoxib)	SS				
Feeling Abnormal		All Other					
Feeling Cold		Therapeutic Products	C				
Gastrooesophageal Reflux		Levothyroxine Sodium	C				
Disease		Vitamins (Vitamins)	C				
Gingival Disorder		Diltiazem					
Glossodynia		Hydrochloride	C				
Hostility							
Hypersomnia							
Hypokinesia							
Hyporeflexia							
Impaired Healing							
Injury							
Irritability							
Limb Injury							
Muscle Spasms							
Myalgia							
Neck Pain							
Oesophageal Spasm							
Overdose							
Pain In Extremity							
Pain In Jaw							
Sedation							

	Sleep Disorder
	Somnolence
	Tenderness
	Therapy Non-Responder
	Tooth Abscess
	Treatment Noncompliance
	Tremor
	Vertigo

Date:07/11/05ISR Number: 4711285-6Report Type:Expedited (15-DaCompany Report #C05-C-102
Age:58 YR Gender:Male I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Bradyphrenia
	Confusional State
	Cyclothymic Disorder
	Decreased Interest
	Depression
	Disturbance In Attention
	Drug Ineffective
	Feeling Abnormal

	Feelings Of Worthlessness						
	Hypokinesia						
	Impaired Self-Care	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Judgement Impaired	Consumer	Lithium Carbonate				
	Major Depression	Health	Capsules Usp 300 Mg	PS			300 MG AM,
	Mania	Professional					600 MG PM
	Medication Error		Risperdal	C			
	Memory Impairment		Ativan	C			
	Mood Altered						
	Pharmaceutical Product						
	Complaint						
	Psychomotor Retardation						
	Psychotic Disorder						
	Restlessness						
	Sluggishness						
	Suicidal Ideation						
	Therapy Non-Responder						

Date:07/11/05ISR Number: 4712015-4Report Type:Direct Company Report #CTU 252967
Age:15 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Abnormal Behaviour		Lithium-Controlled				
Initial or Prolonged	Affective Disorder		Release 450mg	PS		ORAL	450MG BID
	Attention						ORAL
	Deficit/Hyperactivity		Atomoxetine 80mg	SS		ORAL	80MG QAM
	Disorder						ORAL
	Catatonia						
	Confusional State						
	Cyclothymic Disorder						
	Delirium						
	Delusion						
	Disorientation						
	Drug Abuser						
	Drug Interaction						
	Drug Toxicity						
	Dyskinesia						

Grandiosity
Hallucination, Tactile
Hallucination, Visual
Insomnia
Irritability
Mental Status Changes
Neurotoxicity
Psychomotor Retardation
Sedation
Somatic Delusion
Speech Disorder
Tachycardia
Thinking Abnormal
Tremor
Weight Increased

Date:07/11/05ISR Number: 4712317-1Report Type:Expedited (15-DaCompany Report #2005095341
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Therapeutic Agent Toxicity	Health Professional	Lithium (Lithium)	PS				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/11/05ISR Number: 4712373-0Report Type:Expedited (15-DaCompany Report #A210937
Age:73 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Arachnoid Cyst	Consumer	Geodon (Ziprasidone)	PS		ORAL	40 MG (2 IN 1	
	Condition Aggravated	Health					D), ORAL	
	Constipation	Professional	Lithane (Lithium)	SS		ORAL	ORAL	
	Convulsion		Levoxyl (Levothyroxine Sodium)	C				
	Dry Mouth		Lipitor (Atorvastatin)	C				
	Dyskinesia		Hydrochlorothiazide/ Triamterene	C				
	Feeling Abnormal		Multivitamins	C				
	Heart Rate Irregular		Vitamin E (Tocopherol)	C				
	Insomnia		Glucosamine	C				
	Major Depression		Calcium	C				
	Muscle Twitching		Acetylsalicylic Acid	C				
	Parkinson'S Disease		Cenestin (Estrogens Conjugated)	C				
	Tachycardia							
	Tardive Dyskinesia							

Date:07/12/05ISR Number: 4712218-9Report Type:Expedited (15-DaCompany Report #PHBS2005BR09781
Age:55 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Glucose Increased		Leponex	PS	Novartis Sector: Pharma	ORAL	50 mg, BID	11520MIN
	Constipation							
	Convulsion		Leponex	SS	Novartis Sector: Pharma	ORAL	25 mg, BID	14400MIN
	Faecal Incontinence							
	Fall		Carbolitium	SS		ORAL	300 mg, QD	25920MIN
	Infection							
	Urinary Incontinence							
	White Blood Cell Count Increased							

Date:07/12/05ISR Number: 4712234-7Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0563617A
Age:45 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Brain Death		Eskalith	PS	Glaxosmithkline	ORAL	1	YR
	Cardiac Failure Congestive		Antihypertensives	C				
	Cardiomyopathy							
	Coma							
	Diabetes Mellitus							
	Myocardial Infarction							
	Renal Failure							
	Therapeutic Agent Toxicity							

Date:07/12/05ISR Number: 4712235-9Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0565045A
Age:32 YR Gender: I/FU:F

Outcome	PT
Other	Dissociation
	Drug Level Below Therapeutic

		Personality Change Suicidal Ideation					
			Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
				Lamictal	PS	Glaxosmithkline	ORAL
				Lithium	SS	Glaxosmithkline	
UNKNOWN							
				Paxil	C	Glaxosmithkline	ORAL
				Zyprexa	C		
UNKNOWN							
				Epival	C		
UNKNOWN							

Date:07/12/05ISR Number: 4712367-5Report Type:Expedited (15-DaCompany Report #B0238855A
Age:65 YR Gender:Female I/FU:I

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Hospitalization -		Akathisia	Foreign	Lithium Salt			
Initial or Prolonged		Dyskinesia	Literature	(Lithium Salt)	PS		
900 MG/PER							
		Mutism	Health				
DAY	1 WK						
		Parkinsonism	Professional				
		Pyrexia					

Date:07/13/05ISR Number: 4713304-XReport Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0565250A
Age:33 YR Gender:Female I/FU:F

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Other		Drug Exposure During		Lithium	PS	Glaxosmithkline	
		Pregnancy		Bupropion	SS	Glaxosmithkline	
		Hypertension					
		Pregnancy					
		Renal Failure					
		Renal Function Test					
		Abnormal					
		Renal Impairment					

Date:07/13/05ISR Number: 4713382-8Report Type:Expedited (15-DaCompany Report #BE-SANOFI-SYNTHELABO-N122176
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Antipsychotic Drug Level		Kayexalate	PS		ORAL	9	DAY
	Below Therapeutic		Depakine	C		ORAL	1800	mg
	Drug Interaction		Hygroton	C		ORAL	50	mg
	Inhibition		Amiloride	C		ORAL	20	mg 8 YR
	Hypomania		Haldol Decanoas	C			INTRAMUSCULAR	100 mg 11 YR
			Dominal	C		ORAL		
			Moduretic	C			UNKNOWN	20 mg
			Xanax	C		ORAL		
			Kemadrin	C		ORAL	UNK	
			Kayexalate	I		ORAL		
			Maniprex	I		ORAL	350	mg 19 YR
			Maniprex	I		ORAL	450	mg 1 YR

Date:07/13/05ISR Number: 4713880-7Report Type:Expedited (15-DaCompany Report #S05-USA-02250-01
Age:30 YR Gender:Female I/FU:F

Outcome	PT
Life-Threatening	Condition Aggravated
Hospitalization - Initial or Prolonged	Depression
	Drug Ineffective
	Mania

	Multiple Drug Overdose Personality Change Suicide Attempt	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Weight Increased	Consumer	Lexapro (Escitalopram)	PS		ORAL	20 MG QD PO
			Lithium	SS			600 MG QD
			Lamictal (Lamotrigine)	SS			50 MG BID
			Abilify (Aripiprazole)	SS			15 MG QD
			Seroquel (Quetiapine Fumarate)	SS			
			Trazodone	SS			

Date:07/13/05ISR Number: 4714929-8Report Type:Expedited (15-DaCompany Report #ERP05000098
Age:72 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Depression Drug Interaction Feeling Abnormal Mood Altered	Foreign Health Professional	Macrodantin (Nitrofurantoin Macrocrystals) Capsule	PS			
			Lithium (Lithium)	SS			
			Ferro-Gradumet/Aus/(Ferrous Sulfate)	C			

Date:07/13/05ISR Number: 4715556-9Report Type:Expedited (15-DaCompany Report #2005073197
Age:60 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Other	Liver Function Test Abnormal	Health Professional	Geodon (Ziprasidone)	PS			160 MG (80 MG, 2 IN 1 D)
	Neuroleptic Malignant Syndrome	Company Representative	Lithium (Lithium) Quetiapine	SS			

	Pneumonia		(Quetiapine)	SS		
	Pyrexia					

Date:07/15/05ISR Number: 4714913-4Report Type:Expedited (15-DaCompany Report #2005UW10111
Age:42 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hepatic Enzyme Increased		Seroquel	PS	Zeneca Pharmaceutical	ORAL		
	Intentional Misuse							
	Pancytopenia		Lithium	SS				
	White Blood Cell Count Decreased							

Date:07/15/05ISR Number: 4715083-9Report Type:Expedited (15-DaCompany Report #FR-SANOFI-SYNTHELABO-A02200501790
Age:67 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Asthenia		Stilnox	PS		ORAL	UNK	
	Orthostatic Hypotension		Teralithe	SS		ORAL		
	Vertigo		Risperdal	SS		ORAL		
			Levothyrox	C		ORAL		
			Titanoreine	C		RECTAL	UNK	
			Daflon	C		ORAL	1500 mg	4 DAY

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/15/05ISR Number: 4715173-0Report Type:Expedited (15-DaCompany Report #DE-GLAXOSMITHKLINE-D0047065A
Age:67 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Antipsychotic Drug Level Increased		Quilonum Retard	PS	Glaxosmithkline	ORAL	450MG Twice per day
	Gait Disturbance						

Date:07/15/05ISR Number: 4715665-4Report Type:Direct Company Report #CTU 253388
Age:53 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Agitation		Lithium	PS		ORAL	600 MG BID ORAL
	Antipsychotic Drug Level						
	Above Therapeutic		Enalapril	C			
	Contraindication To		Docusate	C			
	Medical Treatment		Simvastatin	C			
	Diabetes Insipidus		Perphenazine	C			
	Haemodialysis		Omeprazole	C			
	Hyperkalaemia		Glyburide	C			
	Mania		Aspirin	C			
	Nausea						
	Renal Failure Acute						
	Speech Disorder						
	Vomiting						

Date:07/18/05ISR Number: 4717797-3Report Type:Direct Company Report #CTU 253483
Age:74 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Agitation		Lithium Carbonate				
	Alcohol Use		300 Mg	PS		ORAL	300 MG TID
	Confusional State						ORAL
	Drug Toxicity						

Renal Failure Acute

Date:07/19/05ISR Number: 4717158-7Report Type:Expedited (15-DaCompany Report #A01200504369
Age:69 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Renal Failure Chronic		Lithium	PS	Glaxosmithkline			
UNKNOWN		YR						
			Clozaril	SS				
UNKNOWN								

Date:07/19/05ISR Number: 4717166-6Report Type:Expedited (15-DaCompany Report #DE-GLAXOSMITHKLINE-D0046723A
Age:70 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Drug Interaction		Quilonum Retard	PS	Glaxosmithkline	ORAL	1TAB Twice	
Initial or Prolonged	Renal Failure							
per day	19 YR							
	Therapeutic Agent		Ass	SS	Glaxosmithkline			
UNKNOWN	100MG Per day							
	Toxicity		Norvasc	C				
UNKNOWN	10MG per day							
			Sortis	C				
UNKNOWN	20MG per day							
			Delix	C				
UNKNOWN								
			Betablocker	C				
UNKNOWN								

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/19/05ISR Number: 4718766-XReport Type:Expedited (15-DaCompany Report #A109802
Age:45 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Required	Ageusia Agitation Akathisia Asthenia Cognitive Disorder Cogwheel Rigidity Contusion Coordination Abnormal Drug Ineffective Dysphagia Dystonia Extrapyramidal Disorder Fall Hallucination Hallucination, Auditory Hot Flush Hypertrophy Hypomania Incontinence Logorrhoea Movement Disorder Muscle Rigidity Muscle Spasms Muscle Twitching Myoclonus Neuroleptic Malignant Syndrome Oral Intake Reduced Parkinsonian Gait Restlessness Serotonin Syndrome Sleep Disorder Sleep Talking Tongue Discolouration Tongue Disorder Tremor	Health Professional	Geodon (Ziprasidone) Lithium (Lithium) Seroquel (Quetiapine Fumarate) Propranolol (Propranolol) Paxil (Paroxetine Hydrochloride) Nortriptyline (Nortriptyline) Thiamine (Thiamine) Folic Acid (Folic Acid) Clonazepam (Clonazepam) Benadryl	PS SS SS SS C C C C C		ORAL ORAL ORAL ORAL	40 MG (20 MG, 2 IN 1 D), 1200 MG, ORAL 200 MG, ORAL 60 MG, ORAL	

Date:07/20/05ISR Number: 4718543-XReport Type:Expedited (15-DaCompany Report #BE-SANOFI-SYNTHELABO-N122176
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Antipsychotic Drug Level		Kayexalate	PS		ORAL	9	DAY
	Below Therapeutic		Depakine	C		ORAL	1800	mg
	Drug Interaction		Hygroton	C		ORAL	50	mg
	Inhibition		Amiloride	C		ORAL	20	mg 8 YR
	Hypomania		Haldol Decanoas	C			INTRAMUSCULAR	100 mg 11 YR
			Dominal	C		ORAL		
			Moduretic	C			UNKNOWN	20 mg
			Xanax	C		ORAL		
			Kemadrin	C		ORAL	UNK	
			Kayexalate	I		ORAL		
			Maniprex	I		ORAL	350	mg 19 YR
			Maniprex	I		ORAL	450	mg 1 YR

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/20/05ISR Number: 4724391-7Report Type:Direct Company Report #CTU 253799
Age:71 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Antipsychotic Drug Level Increased Mental Status Changes		Lithium (Eskalith Cr 450 Mg) Daily	PS				

Date:07/21/05ISR Number: 4720724-6Report Type:Expedited (15-DaCompany Report #GB-GLAXOSMITHKLINE-B0360920A
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Anhedonia Anxiety		Paroxetine Hydrochloride	PS	Glaxosmithkline	UNKNOWN		
	Apathy		Lithium	SS	Glaxosmithkline			
	Depressed Mood		Thyroxine	C	Glaxosmithkline			
	Disturbance In Attention							
	Drug Withdrawal Syndrome							
	Fatigue							
	Hypoglycaemia							
	Irritability							
	Loss Of Libido							
	Memory Impairment							
	Middle Insomnia							
	Panic Reaction							
	Suicidal Ideation							
	Tearfulness							
	Tremor							
	Weight Increased							

Date:07/21/05ISR Number: 4723428-9Report Type:Direct Company Report #CTU 253888
Age:55 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product		Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Antipsychotic Drug Level Increased		Lithium	300 Mg	PS		ORAL	300 MG	TWICE DAILY

Mental Status Changes
ORAL

Date:07/21/05ISR Number: 4724405-4Report Type:Expedited (15-DaCompany Report #B0386190A
Age:75 YR Gender:Female I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Amnesia
	Balance Disorder
	Blood Thyroid Stimulating Hormone Increased
	Bradyphrenia
	Cognitive Disorder
	Dementia Alzheimer'S Type
	Disturbance In Attention
	Dysgraphia
	Fall
	Gait Disturbance
	General Physical Health Deterioration
	Hearing Impaired
	Memory Impairment
	Metabolic Disorder
	Mobility Decreased

	Motor Dysfunction Overdose Reading Disorder	Report Source	Product	Role	Manufacturer	Route Dose Duration
	Renal Impairment Therapeutic Agent	Foreign Literature	Lithium Salt (Lithium Salt)	PS		1 YR
	Toxicity Upper Limb Fracture	Health Professional	Beta-Blocker	C		

Date:07/21/05ISR Number: 4724406-6Report Type:Expedited (15-DaCompany Report #B0387470A
Age:32 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Hospitalization - Initial or Prolonged	Blood Pressure Systolic Increased Haemodialysis Intentional Misuse	Foreign Literature Health Professional	Lithium Carbonate Tablet-Controlled Release (Generic) (Lithium Carbonate)	PS		400 MG
	Overdose Therapeutic Agent Toxicity					

Date:07/22/05ISR Number: 4722867-XReport Type:Expedited (15-DaCompany Report #DE-GLAXOSMITHKLINE-D0047143A
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Life-Threatening	Accidental Overdose		Quilonum Retard	PS	Glaxosmithkline	ORAL 2700MG per
Hospitalization - Initial or Prolonged	Poisoning		Hypnorex	C	Glaxosmithkline	day ORAL 600MG per day

Date:07/25/05ISR Number: 4723801-9Report Type:Expedited (15-DaCompany Report #PHEH2005US08104
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration

Other	Anxiety		Trileptal	PS	Novartis Sector:	
	Hysterectomy				Pharma	ORAL
150 mg, QD						
	Panic Disorder		Xanax	SS		
10 mg, UNK						
	Renal Disorder		Sonata	SS		
	Vomiting		Haldol	SS		
10 mg, UNK						
			Serax	SS		
			Lithium	SS		
			Carbamazepine	SS		

Date:07/27/05ISR Number: 4725951-XReport Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0567574A
Age:53 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Other	Lung Neoplasm Malignant		Eskalith	PS	Glaxosmithkline	ORAL
750MG Per day	4 MON					
	Tremor		Seroquel	C		
			Effexor	C		
			Ativan	C		
			Cisplatin	C		
			Gemcitabine	C		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/27/05ISR Number: 4726375-1Report Type:Expedited (15-DaCompany Report #C05-T-128
Age:42 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Condition Aggravated	Consumer	Lithium Carbonate Er					
	Confusional State		Tablets, Usp 300 Mg	PS		ORAL	SEE IMAGE	
	Paranoia		Caffeine	SS				
	Sexual Dysfunction		Paxil	C				
			Risperdal	C				

Date:07/27/05ISR Number: 4727376-XReport Type:Direct Company Report #CTU 254543
Age:69 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Chest Pain		Lithium Carbonate	PS		ORAL	300 MG PO BID [CHRONIC SINE 198?]	
	Dehydration							
	Diarrhoea							
	Dizziness		Vit C	C				
	Drug Toxicity		Hctz	C				
	Orthostatic Hypotension		Lisinopril	C				
	Renal Failure Acute		Licarbonate	C				
	Tremor		Protonix	C				
			Prednisone	C				
			Lorazepam	C				
			Folic Acid	C				
			Sulindac	C				
			Remicade	C				

Date:07/28/05ISR Number: 4727265-0Report Type:Expedited (15-DaCompany Report #JP-GLAXOSMITHKLINE-B0384748A
Age:51 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Drug Interaction		Paxil	PS	Glaxosmithkline	ORAL	70	DAY
	Extrapyramidal Disorder		Limas	SS	Glaxosmithkline	ORAL	600MG Per day	121 DAY

	Parkinsonism	Lullan	SS	ORAL
9 DAY				
		Seroquel	SS	ORAL
8 DAY				
		Zyprexa	SS	ORAL

Date:07/29/05ISR Number: 4729370-1Report Type:Expedited (15-DaCompany Report #PHBS2005JP08966
Age:58 YR Gender:Male I/FU:F

Outcome	PT
Life-Threatening	Alanine Aminotransferase
Disability	Increased
	Aspartate
	Aminotransferase
	Increased
	Atrioventricular Block
	Complete
	Blood Alkaline
	Phosphatase Increased
	Blood Creatinine
	Increased
	Blood Glucose Increased
	Blood Potassium Increased
	Blood Urea Increased
	Cardiac Arrest
	Cardiac Pacemaker
	Insertion

		Circulatory Collapse Conduction Disorder Fall	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
		Feeling Abnormal Gamma-Glutamyltransferase		Tegretol	PS	Novartis Sector: Pharma	ORAL
200 mg, TID	8640 MIN						
		Increased		Limas	SS		ORAL
400 mg, TID	8640 MIN						
		Loss Of Consciousness		Lodopin	C		ORAL
90 mg/day	8640 MIN						
		Pulse Absent		Akineton	C		ORAL
4.5 mg/day	8640 MIN						
		White Blood Cell Count		Benzalin	C		ORAL
10 mg/day	8640 MIN						
		Increased					

Date:08/01/05ISR Number: 4732725-2Report Type:Direct Company Report #CTU 254919
Age:82 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product		Role	Manufacturer	Route
Dose	Duration						
Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Blood Creatinine Increased		Lithium	3.75 1 BEDTIME	PS		

Date:08/01/05ISR Number: 4732772-0Report Type:Expedited (15-DaCompany Report #S05-USA-03615-01
Age:35 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization - Initial or Prolonged	Delirium Tremens Dialysis	Health Professional	Campral (Acamprosate Calcium)	PS		ORAL
666 MG TID PO						
	Drug Interaction	Company Representative	Lithium	SS		
	Drug Level Above Therapeutic		Alcohol (Alcohol)	SS		
	Drug Toxicity					

Date:08/01/05ISR Number: 4735742-1Report Type:Direct Company Report #CTU 255059
Age:34 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Hospitalization - Initial or Prolonged	Dizziness Fatigue Nausea Therapeutic Agent Toxicity Tremor Weight Decreased		Lithium Sr	PS		ORAL	450 MG PO TID	

Date:08/02/05ISR Number: 4738148-4Report Type:Expedited (15-DaCompany Report #B0388220A
Age:36 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Automatism Complex Partial Seizures Convulsion Drug Interaction Major Depression	Foreign Literature Health Professional	Lithium Salt (Formulation Unknown) (Lithium Salt) Electroconvulsive Therapy (Formulation Unknown) (Electroconvulsive	PS				

			Therapy)	SS		
			Trazodone	C		
			Lorazepam	C		
			Thiopentone Sodium	C		

Date:08/02/05ISR Number: 4738149-6Report Type:Expedited (15-DaCompany Report #B0388221A
Age:62 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Blood Pressure Increased	Foreign	Lithium Salt			
	Chills	Literature	(Formulation			
	Cognitive Disorder	Health	Unknown) (Lithium			
	Disorientation	Professional	Salt)	PS		
	Heart Rate Increased		Electroconvulsive			
	Hyperreflexia		Therapy (Formulation			
	Leukocytosis		Unknown)			
	Major Depression		(Electroconvulsive			
	Muscle Rigidity		Therapy)	SS		
	Psychiatric Symptom		Carbamazepine	C		
	Psychomotor Retardation		Mirtazapine	C		
	Pyrexia		Thyroxine Sodium	C		
	Serotonin Syndrome		Enalapril	C		
	Therapy Non-Responder		Lorazepam	C		
			Thiopentone Sodium	C		

Date:08/02/05ISR Number: 4738150-2Report Type:Expedited (15-DaCompany Report #B0388222A
Age:79 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Anxiety	Foreign	Eskalith			
	Aphasia	Literature	(Formulation			
	Simple Partial Seizures	Health	Unknown) (Lithium			
		Professional	Carbonate)	PS		
			Electroconvulsive			
			Therapy (Formulation			
			Unknown)			
			(Electroconvulsive			
			Therapy)	SS		
			Trazodone	C		
			Enalapril	C		
			Hydrochlorothiazide	C		
			Thiopentone Sodium	C		

	Paroxetine Hydrochloride	C

Date:08/03/05ISR Number: 4733407-3Report Type:Expedited (15-DaCompany Report #PHBS2005JP08966
Age:58 YR Gender:Male I/FU:F

Outcome	PT
Life-Threatening	Alanine Aminotransferase Increased
Disability	Aspartate Aminotransferase Increased
	Atrioventricular Block Complete
	Blood Alkaline Phosphatase Increased
	Blood Creatinine

	Increased Blood Glucose Increased Blood Potassium Increased Blood Urea Increased	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Cardiac Arrest Cardiac Pacemaker		Tegretol	PS	Novartis Sector: Pharma	ORAL	200 mg, TID 8640 MIN
	Insertion		Limas	SS		ORAL	400 mg, TID 8640 MIN
	Circulatory Collapse		Lodopin	C		ORAL	90 mg/day 8640 MIN
	Conduction Disorder		Akineton	C		ORAL	4.5 mg/day 8640 MIN
	Fall		Benzalin	C		ORAL	10 mg/day 8640 MIN
	Feeling Abnormal Gamma-Glutamyltransferase Increased Loss Of Consciousness Pulse Absent White Blood Cell Count Increased		Pyrethia	C			

Date:08/03/05ISR Number: 4734225-2Report Type:Direct Company Report #CTU 255308
Age:58 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Laboratory Test Abnormal		Lithium	PS			900 MG TID

Date:08/04/05ISR Number: 4734454-8Report Type:Expedited (15-DaCompany Report #FR-ROCHE-411913
Age:67 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Disability	Peripheral Sensory Neuropathy		Rivotril	PS	Roche	ORAL	
			Effexor	SS		ORAL	
			Propranolol	SS	Roche	ORAL	60 DAY
			Theralene	SS		ORAL	
			Imovane	SS		ORAL	

Teralithe	SS	ORAL
L-Thyroxine	C	
Speciafoldine	C	
Atarax	C	
Stagid	C	
Novonorm	C	
Vastarel	C	
Trivastal	C	
Modopar	C	

Date:08/04/05ISR Number: 4734781-4Report Type:Expedited (15-DaCompany Report #DE-GLAXOSMITHKLINE-D0047099A
Age:69 YR Gender:Male I/FU:F

Outcome	PT
Life-Threatening	Accidental Overdose
Hospitalization -	Atrial Fibrillation
Initial or Prolonged	Coma
	Hypertension
	Nausea
	Pneumonia Aspiration
	Pulmonary Hypertension
	Sick Sinus Syndrome
	Therapeutic Agent
	Toxicity
	Tremor

Vomiting

Dose	Duration	Report Source	Product	Role	Manufacturer	Route
6TAB per day	6 DAY		Quilonum Retard	PS	Glaxosmithkline	ORAL
UNKNOWN	4 YR		Hypnorex	C	Glaxosmithkline	
UNKNOWN	5MG In the morning		Ramipril	C		
UNKNOWN	1MG In the morning		Risperidon	C		
UNKNOWN	750MG per day		Moclobemid	C		
10ML Twice per day			Orfiril	C		ORAL
UNKNOWN			Phenprocoumon	C		
UNKNOWN	100U Twice per day		Jodid	C		

Date:08/04/05ISR Number: 4734782-6Report Type:Expedited (15-DaCompany Report #DE-GLAXOSMITHKLINE-D0047143A
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Life-Threatening	Accidental Overdose		Quilonum Retard	PS	Glaxosmithkline	ORAL
2700MG per day						
Hospitalization - Initial or Prolonged	Poisoning		Hypnorex	C	Glaxosmithkline	ORAL
600MG per day						

Date:08/04/05ISR Number: 4735210-7Report Type:Expedited (15-DaCompany Report #2005068728
Age:64 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Abdominal Distension	Consumer	Celebrex					
Hospitalization - Initial or Prolonged	Aggression							
	Antipsychotic Drug Level Increased		(Celecoxib)	PS				
	Dementia		Bextra (Valdecoxib)	SS			20 MG (20 MG, 1 IN 1 D),	
	Difficulty In Walking							
	Drug Effect Decreased		Lithium (Lithium)	SS				
	Dyskinesia		Zyprexa (Olanzapine)	SS				
	Erythema		Aggrenox (Acetylsalicylic Acid, Dipyridamole)	C				
	Helicobacter Infection		Monopril (Fosinopril Sodium)	C				
	Myocardial Infarction		Depakote (Valproate Semisodium)	C				
	Pruritus Generalised		Synthroid (Levothyroxine Sodium)	C				
			Potassium (Potassium)	C				
			Seroquel (Quetiapine Fumarate)	C				
			Atenolol (Atenolol)	C				
			Glucophage (Metformin Hydrochloride)	C				
			Minoxidil (Minoxidil)	C				
			Monopril (Fosinopril					

Sodium)	C
Furosemide (Furosemide)	C
Zocor (Simvastatin)	C
Avandia (Rosiglitazone Maleate)	C

Date:08/04/05ISR Number: 4736511-9Report Type:Direct Company Report #CTU 255436
Age:72 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Antipsychotic Drug Level		Lithium	PS				
Hospitalization - Initial or Prolonged	Increased		Olanzapine	SS				
	Asthenia		Furosemide	SS				
Required Intervention to Prevent Permanent Impairment/Damage	Cardiac Pacemaker		Lisinopril	C				
	Insertion		Spironolactone	C				
	Dehydration		Atenolol	C				
	Dysarthria							
	Dyspnoea							
	Gait Disturbance							
	Heart Rate Decreased							
	Renal Failure Acute							
	Sinus Arrhythmia							
	Tremor							

Date:08/05/05ISR Number: 4735471-4Report Type:Expedited (15-DaCompany Report #2005AP04036
Age:70 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Interaction		Atacand	PS		ORAL		
	Dysarthria		Lithium Carbonate	SS		ORAL		
	Dyskinesia		Lithium Carbonate	SS		ORAL		
	Hypertonia		Celebrex	SS		ORAL		
	Muscle Rigidity		Aspirin	C				
	Therapeutic Agent		Hydroxocobalamin	C				
	Toxicity		Tegretol	C				
			Sertraline Hydrochloride	C				
			Zocor	C				
			Glyceryl Trinitrate	C				

			Azopt	C			

OPHTHALMIC

Date:08/09/05ISR Number: 4738046-6Report Type:Expedited (15-DaCompany Report #2005GB00966
Age:76 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Disability	Cerebrovascular Accident		Quetiapine	PS	Zeneca Pharmaceutical	ORAL		
	Cerebrovascular Disorder							
	Drug Interaction		Bendrofluazide	C		ORAL		
	Drug Level Increased		Omeprazole	C		ORAL		
	Therapeutic Agent		Tamsulosin	C		ORAL		
	Toxicity		Lorazepam	C		ORAL		
	Transient Ischaemic		Priadel	I		ORAL		
	Attack		Priadel	I		ORAL	22	DAY

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/10/05ISR Number: 4740685-3Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0546519A
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Abnormal Dreams		Lamictal	PS	Glaxosmithkline	ORAL		4 YR
	Adverse Event		Wellbutrin	SS	Glaxosmithkline			
	Hypnagogic Hallucination		Lithium	SS	Glaxosmithkline			
	Nightmare		Zoloft	C				
	Weight Increased							

Date:08/10/05ISR Number: 4740689-0Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0567574A
Age:53 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Interaction		Eskalith	PS	Glaxosmithkline	ORAL	750MG Per day	4 MON
	Tremor		Cisplatin	SS				
			Gemcitabine	SS				
			Seroquel	C				
			Effexor	C				
			Ativan	C				

Date:08/10/05ISR Number: 4741094-3Report Type:Expedited (15-DaCompany Report #US-ROCHE-405250
Age:43 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Aphasia		Klonopin	PS	Roche	ORAL		
	Confusional State		Gabitril	I		ORAL	AT BEDTIME	1 WK
	Coordination Abnormal		Gabitril	I		ORAL	AT BEDTIME	
	Delusion		Lithium	I		ORAL		
	Disorientation		Trileptal	I		ORAL		
	Drug Interaction		Seroquel	I		ORAL		
	Sedation		Clozaril	I		ORAL		

Date:08/11/05ISR Number: 4742814-4Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0569718A
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Diabetes Mellitus		Eskalith	PS	Glaxosmithkline	ORAL		YR
Initial or Prolonged	Renal Disorder		No Concurrent Medication	C				

Date:08/12/05ISR Number: 4743768-7Report Type:Expedited (15-DaCompany Report #DE-GLAXOSMITHKLINE-D0047275A
Age:35 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Intentional Misuse		Quilonum Retard	PS	Glaxosmithkline	ORAL		
	No Adverse Drug Effect							
	Suicide Attempt							

Date:08/15/05ISR Number: 4744834-2Report Type:Expedited (15-DaCompany Report #GB-GLAXOSMITHKLINE-B0359471A
Age: Gender:Female I/FU:F

Outcome	PT
Other	Abortion
	Anxiety
	Drug Withdrawal Syndrome
	Emotional Disorder

		Hypomania Insomnia Intentional Misuse	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
		Mood Swings		Seroxat	PS	Glaxosmithkline	
UNKNOWN		YR					
		Psychomotor Hyperactivity		Lithium	SS	Glaxosmithkline	ORAL
YR							
		Suicidal Ideation		Sodium Valproate	C		
UNKNOWN							
		Weight Increased		Carbamazepine	C		
UNKNOWN							
				Zopiclone	C		
UNKNOWN	3.75MG At						
night							

Date:08/16/05ISR Number: 4745915-XReport Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0565250A
Age:33 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Other	Drug Exposure During		Lithium	PS	Glaxosmithkline	
	Pregnancy		Bupropion	SS	Glaxosmithkline	
	Hypertension		Wellbutrin	SS	Glaxosmithkline	
300MG per day						
	Renal Failure		Lexapro	C		
30MG per day						
	Renal Function Test		Nortriptyline	C		
100MG Per day						
	Abnormal		Topamax	C		
150MG per day						
	Renal Impairment					

Date:08/16/05ISR Number: 4746030-1Report Type:Expedited (15-DaCompany Report #PHBS2005JP08966
Age:58 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Life-Threatening	Alanine Aminotransferase		Tegretol	PS	Novartis Sector:	
Disability	Increased				Pharma	ORAL
200 mg, TID	8640 MIN					

		Aspartate	Limas	SS	ORAL
400 mg, TID	8640 MIN				
		Aminotransferase	Lodopin	C	ORAL
90 mg/day	8640 MIN				
		Increased	Akineton	C	ORAL
4.5 mg/day	8640 MIN				
		Atrioventricular Block	Benzalin	C	ORAL
10 mg/day	8640 MIN				
		Complete	Pyrethia	C	
		Blood Alkaline			
		Phosphatase Increased			
		Blood Creatinine			
		Increased			
		Blood Glucose Increased			
		Blood Potassium Increased			
		Blood Urea Increased			
		Cardiac Arrest			
		Cardiac Pacemaker			
		Insertion			
		Circulatory Collapse			
		Conduction Disorder			
		Fall			
		Feeling Abnormal			
		Gamma-Glutamyltransferase			
		Increased			
		Loss Of Consciousness			
		Pulse Absent			
		White Blood Cell Count			
		Increased			

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/18/05ISR Number: 4747801-8Report Type:Expedited (15-DaCompany Report #2005AP04376
Age:39 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Granulocytopenia		Seroquel	PS	Zeneca			
Hospitalization -	Rash				Pharmaceutical	ORAL	48	DAY
Initial or Prolonged			Limas	SS		ORAL	48	DAY
			Hirnamin	C		ORAL		
			Silece	C		ORAL		
			Vegatamin A	C		ORAL		

Date:08/22/05ISR Number: 4749428-0Report Type:Expedited (15-DaCompany Report #JP-SOLVAY-00305002131
Age:17230 DYGender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Neuroleptic Malignant		Depromel 25	PS		ORAL	Daily dose:	
Initial or Prolonged	Syndrome						200	
							milligram(s)	52 DAY
			Limas	SS		ORAL	Daily dose:	
							200	
							milligram(s)	15 DAY
			Rize	C		ORAL	Daily dose: 1	
							dosage form	13 DAY
			Pl	C		ORAL	Daily dose:	
							unknown	
			Pabron	C				
UNKNOWN	Daily dose:						unknown	
			Betamac	C		ORAL	Daily dose:	

75

milligram(s) 52 DAY

Amoban C ORAL

Daily dose:

10

milligram(s) 15 DAY

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Summary report for FOI selections:

Selection by inexact search of active ingredient: LITHIUM_CARBONATE%

Selection by inexact search of Tradename/Verbatim: LITHIUM%

Total number of reports: 3,672

From: 01-NOV-1997 To: Present