Date:11/06/97ISR Number: 100000196Report Type:Expedited (15-DaCompany Report #97-10-0745
Age:40 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Heart Rate Decreased Hypotension	Consumer	Baclofen Tablets	PS	Zenith Goldine Pharm.	ORAL	10MG Q4-6HRS	
			Tylenol	C		ORAL		

Date:11/10/97ISR Number: 100000225Report Type:Expedited (15-DaCompany Report #97F--10891
Age:37 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agitation Clonic Convulsion Confusional State Hallucination Overdose	Foreign Health Professional Other	Lioresal	PS		ORAL	DAILY, ORAL	

Date:11/12/97ISR Number: 3000337-7Report Type:Expedited (15-DaCompany Report #970566
Age:35 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	Bradycardia Hypertonia Mydriasis Pulmonary Oedema Respiratory Arrest	Foreign Health Professional	Lioresal Inthrathecal (Balcofen Injection)	PS				DAY

Date:11/19/97ISR Number: 3038112-XReport Type:Periodic Company Report #97USA10819
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Paraesthesia Oral	Health	Lioresal Tablet	PS		ORAL	50 MG DAILY	
	Parosmia	Professional						

Date:11/19/97ISR Number: 3038114-3Report Type:Periodic Company Report #97USA10944
Age:42 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Urticaria	Consumer	Lioresal Tablet	PS		ORAL	20 MG, TID	6 YR

Date:11/19/97ISR Number: 3038117-9Report Type:Periodic Company Report #97USA11792
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Pulmonary Congestion	Health	Lioresal Tablet	PS		ORAL	PO	
		Professional						

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/19/97ISR Number: 3038120-9Report Type:Periodic Company Report #97USA11812
Age:16 MON Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Impaired Gastric Emptying	Health Professional	Lioresal Tablet	PS		ORAL		

Date:11/19/97ISR Number: 3038122-2Report Type:Periodic Company Report #96USA14950
Age:16 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Dizziness Nausea Vomiting	Health Professional	Baclofen Tablet	PS		ORAL		

Date:11/19/97ISR Number: 3038596-7Report Type:Periodic Company Report #96USA14306
Age:59 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Coordination Abnormal Dizziness Fatigue Hypoaesthesia Multiple Sclerosis Nausea Palpitations Sedation Vision Blurred	Health Professional	Lioresal Tablet	PS		ORAL	10 MG, TID	12 YR

Date:11/19/97ISR Number: 3038605-5Report Type:Periodic Company Report #96USA14623
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Abdominal Pain Dermatitis	Consumer	Lioresal Tablet	PS			20 MG, QID	2 YR

Dysgeusia
Insomnia
Nasal Congestion
Oedema Peripheral
Vision Blurred

Date:11/19/97ISR Number: 3038607-9Report Type:Periodic Company Report #96USA14953
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Alopecia	Health Professional	Lioresal Tablet	PS		ORAL	PO	

Date:11/19/97ISR Number: 3038608-0Report Type:Periodic Company Report #97USA10672
Age:40 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Confusional State	Health Professional	Lioresal Tablet	PS		ORAL	20 MG, TID	
	Hypertonia		Nortriptyline Tablet	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/19/97ISR Number: 3038611-0Report Type:Periodic Company Report #97USA10750
Age:42 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Urticaria	Health	Lioresal Tablet	PS		ORAL	20 MG, TID	6 YR
		Professional						

Date:12/03/97ISR Number: 3004006-9Report Type:Expedited (15-DaCompany Report #970568
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Blood Pressure Increased	Company	Lioresal Intrathecal	PS		INTRATHECAL	UNKNOWN	
	Cardiac Disorder	Representative				DOSE/FREQUENC		
	Faecaloma					Y;		
	Hyperthermia Malignant					INTRATHECAL		
	Hypertonia					ROUTE		
	Myocardial Infarction							
	Pyrexia							

Date:12/03/97ISR Number: 3006825-1Report Type:Direct Company Report #
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Bradycardia		Baclofen	PS		INTRAVENOUS	10 MG IV Q6	
Initial or Prolonged	Diplopia					HOURS		
Other	Lethargy							
	Mental Disorder							

Date:12/09/97ISR Number: 3006598-2Report Type:Direct Company Report #
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Condition Aggravated		Baclofen	PS			20MG -5/DAY	
	Drug Ineffective		Baclofen	SS			20MG -5/DAY	
	Hypertonia							

Date:12/24/97ISR Number: 3012858-1Report Type:Expedited (15-DaCompany Report #97F-10699
Age:19 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Leukopenia	Foreign	Lioresal	PS		ORAL	DAILY, ORAL	6 WK
Initial or Prolonged	Thrombocytopenia	Health	Methotrexate	C				
		Professional	Fraxiparine	C				

Date:12/24/97ISR Number: 3049149-9Report Type:Periodic Company Report #ZANA0319970300
Age:48 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hepatitis	Health	Zanaflex	PS		ORAL	PER ORAL	
	Pyrexia	Professional	Baclofen	SS				
	Sedation		Prozac	C				
			Wellbutrin	C				

Date:12/31/97ISR Number: 3013611-5Report Type:Expedited (15-DaCompany Report #97-10-0745
Age:40 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Heart Rate Decreased	Consumer	Baclofen	PS	Zenith Goldline			
Hospitalization -	Hypotension	Health			Pharm.	ORAL	10 MG Q4-6HRS	
Initial or Prolonged		Professional	Tylenol	C				

Date:01/02/98ISR Number: 3013617-6Report Type:Expedited (15-DaCompany Report #970579
Age:66 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required	Asthenia	Literature	Lioresal	PS				
INTRATHECAL							30.000MCG	
Intervention to	Coma	Health						
INTRATHECALLY								
Prevent Permanent	Diplopia	Professional						
Impairment/Damage	Dyspnoea							
	Hypotension							
	Medication Error							
	Overdose							
	Paralysis Flaccid							
	Vision Blurred							

Date:01/16/98ISR Number: 3016556-XReport Type:Expedited (15-DaCompany Report #98HQ-10019
Age:72 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Confusional State	Foreign	Lioresal	PS				
30MG DAILY								
Initial or Prolonged	Depressed Level Of	Literature	Hemodialysis	C				
	Consciousness	Health						
	Muscle Twitching	Professional						
	Urinary Incontinence							

Date:01/23/98ISR Number: 3018003-0Report Type:Expedited (15-DaCompany Report #970581
Age:68 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Accidental Overdose Dyspnoea	Foreign Health Professional	Lioresal	PS		INTRATHECAL		

Date:01/27/98ISR Number: 3020705-7Report Type:Expedited (15-DaCompany Report #970582
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Coma Overdose	Company Representative	Lioresal	PS		INTRATHECAL	INTRATHECAL	

Date:02/04/98ISR Number: 3024237-1Report Type:Direct Company Report #
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Medication Error	Health Professional	Baclofen	PS				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/06/98ISR Number: 3024846-XReport Type:Expedited (15-DaCompany Report #98J-10047
Age:31 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Depressed Level Of	Foreign	Lioresal	PS		ORAL	10 MG DAILY,	
	Consciousness	Health					ORAL	
	Hyponatraemia	Professional	Dantrolene	C				
	Inappropriate		Etizolam`	C				
	Antidiuretic Hormone		Carmellose Sodium					
	Secretion		Unknown	C				
			Pantethine	C				

Date:02/13/98ISR Number: 3063706-5Report Type:Direct Company Report #
Age:72 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Apnoea		Baclofen	PS			1300MCG/DAY	
	Coma						IT	
	Condition Aggravated							
	Hypertonia							
	Sedation							

Date:02/17/98ISR Number: 3029669-3Report Type:Expedited (15-DaCompany Report #98D--10123
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Haemorrhage	Foreign	Lioresal	PS		ORAL	10 MG TID	
Initial or Prolonged	Hepatic Cirrhosis	Health					ORAL	
	Varices Oesophageal	Professional	Non-Steroidal Anti-I	C				
		Other						

Date:02/20/98ISR Number: 3032698-7Report Type:Expedited (15-DaCompany Report #98GB-10084
Age:56 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blindness Transient	Foreign	Lioresal	PS		ORAL	10 MG, QID,	
	Vision Blurred	Health					ORAL	
		Professional	Ibuprofen	C				
		Other	Nifedipine	C				

Date:02/20/98ISR Number: 3032709-9Report Type:Expedited (15-DaCompany Report #98GB-10054
Age:52 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Convulsion	Foreign	Baclofen	PS		ORAL	DAILY, ORAL	
Initial or Prolonged	Hypothermia	Health	Tamoxifen	C				
	Respiratory Acidosis	Professional						
	Respiratory Arrest	Other						

Date:02/24/98ISR Number: 3036481-8Report Type:Expedited (15-DaCompany Report #970584
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Overdose	Foreign	Lioresal	PS			INTRATHECAL	
		Company Representative						

Date:02/24/98ISR Number: 3036483-1Report Type:Expedited (15-DaCompany Report #970581
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Accidental Overdose Depressed Level Of Consciousness Dyspnoea Renal Failure Acute	Foreign Health Professional	Lioresal Intrathecal	PS		INTRATHECAL	DAILY DOSE UNKNOWN AMOUNT INTRATHECAL	

Date:02/27/98ISR Number: 3037747-8Report Type:Expedited (15-DaCompany Report #98F--10125
Age:40 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Hepatic Enzyme Increased Hepatitis	Foreign Health Professional Other	Lioresal Corticoids	PS SS		ORAL ORAL	30 MG, DAILY, ORAL	2 YR

Date:02/27/98ISR Number: 3037749-1Report Type:Expedited (15-DaCompany Report #98F--10124
Age:67 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Alanine Aminotransferase Increased Aspartate Aminotransferase Increased Hepatitis	Foreign Health Professional Other	Lioresal Di-Antalvic Dafalgan	PS C C		ORAL	10 MG, BID, ORAL	11 DAY

Date:03/16/98ISR Number: 3056638-XReport 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	Crying	Health Professional	Topiramate	PS			50 MG AM, 25 MG PM	3-4 MONTHS
	Irritability							
	Oliguria							
			Glycopyrrolate	SS			1 MG PO,	3-4 MONTHS
			Baclofen	SS				

Date:03/17/98ISR Number: 3056245-9Report Type:Expedited (15-DaCompany Report #98GB-10188
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agitation	Foreign	Lioresal	PS		ORAL	DAILY, ORAL	
	Brain Stem Infarction	Health Professional	Sinemet	C				
	Fall		Bromocriptine	C				
		Other	Oxybutynin	C				

Date:03/26/98ISR Number: 3060584-5Report Type:Expedited (15-DaCompany Report #F/98/00616/CAS
Age:54 YR Gender:Female I/FU:I

Outcome
Life-Threatening
Required Intervention to

Prevent Permanent
Impairment/Damage

	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Multiple Sclerosis		Sandocal	PS		ORAL	1 G	ORAL
	Status Epilepticus		Lioresal	SS		ORAL	50 MG	ORAL
			Topalgic	SS		ORAL	200 MG	ORAL
			Senokot	C				
			Motilium	C				

Date:03/30/98ISR Number: 3068899-1Report Type:Expedited (15-DaCompany Report #980310-003010863
Age:54 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Amnesia	Foreign	Topalgic	PS		ORAL	200 MG, QD,	
Hospitalization -	Convulsion	Health					ORAL	
Initial or Prolonged	Crepitations	Professional	Senna	SS		ORAL	ORAL	
	Disorientation		Domperidone	SS		ORAL	40MG, QD,	
	Loss Of Consciousness						ORAL	
	Motor Dysfunction		Calcium Globionate	SS		ORAL	100MG, QD,	
	Multiple Sclerosis						ORAL	
	Salivary Hypersecretion		Baclofen	SS		ORAL	50 MG, QD,	
	Status Epilepticus						ORAL	

Date:04/01/98ISR Number: 3065060-1Report Type:Direct Company Report #
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Hospitalization -	Lethargy		Baclofen	PS		
INTRATHECAL 2000 MCG/ML						
Initial or Prolonged	Mental Impairment		Apap	C		
	Vomiting		Ibuprogen	C		

Date:04/06/98ISR Number: 3061250-2Report Type:Expedited (15-DaCompany Report #970589
Age:63 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Hyperhidrosis	Foreign	Lioresal	PS		
INTRAVENOUS 1200 MCQ/DAY;						
Initial or Prolonged	Muscle Spasms	Literature				
INTRATHECAL						
	Pyrexia	Health				
	Tachycardia	Professional				
	Tachypnoea					

Date:04/07/98ISR Number: 3060339-1Report Type:Expedited (15-DaCompany Report #98GB -10266
Age:37 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Agitation	Foreign	Baclofen	PS		ORAL
10 MG, TID,						
	Bronchospasm	Health				
ORAL 1 DAY						
	Disorientation	Professional				
	Loss Of Consciousness	Other				

Date:04/07/98ISR Number: 3063443-7Report Type:Expedited (15-DaCompany Report #970591
Age:54 YR Gender:Male I/FU:I

Outcome	PT	Report Source
Death	Death	Foreign
		Literature

		Health Professional				
			Product	Role	Manufacturer	Route
Dose	Duration					
			Lioresal	PS		
INTRATHECAL	(INJECTION)					

Date:04/07/98ISR Number: 3063444-9Report Type:Expedited (15-DaCompany Report #970590
Age:65 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization -	Hyperhidrosis	Foreign	Lioresal	PS		
INTRATHECAL	1100 MCG					
Initial or Prolonged	Muscle Spasms	Literature				
(INJECTION)/D						
	Pyrexia	Health				
AY						
	Tachycardia	Professional				
	Tachypnoea					

Date:04/09/98ISR Number: 3073686-4Report Type:Expedited (15-DaCompany Report #970592
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization -	Coma	Health	Lioresal	PS		
INTRATHECAL	2000 MCG/ML					
Initial or Prolonged	Medication Error	Professional				
INTRATHECAL						
Required	Overdose					
Intervention to						
Prevent Permanent						
Impairment/Damage						

Date:04/15/98ISR Number: 3065703-2Report Type:Expedited (15-DaCompany Report #98USA10515
Age:74 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					

Hospitalization - Initial or Prolonged	Small Intestinal Obstruction	Health Professional	Lioresal	PS		ORAL DAILY ORAL

Date:04/16/98ISR Number: 3070742-1Report Type:Expedited (15-DaCompany Report #970588
Age:21 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Haematemesis	Foreign	Lioresal	PS		INTRATHECAL	700 MCG/DAY,	
	Intestinal Functional Disorder Renal Impairment	Health Professional				INTRATHECAL		

Date:04/21/98ISR Number: 3065841-4Report Type:Expedited (15-DaCompany Report #98USA10556
Age:75 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Coma	Health	Lioresal	PS		ORAL	DAILY ORAL	
		Professional	Lescol	C				
			Atenolol	C				
			Ticlid	C				

Date:04/24/98ISR Number: 3068804-8Report Type:Expedited (15-DaCompany Report #98F--10306
Age:45 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Alanine Aminotransferase Increased Hepatic Necrosis Hepatitis	Foreign Health Professional	Lioresal	PS		ORAL	60 MG (TABLET), DAILY	9 WK

Date:04/28/98ISR Number: 3073283-0Report Type:Expedited (15-DaCompany Report #970584
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Overdose	Foreign Company Representative	Lioresal	PS				

Date:04/28/98ISR Number: 3073284-2Report Type:Expedited (15-DaCompany Report #970566
Age:35 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Bradycardia	Foreign	Lioresal	PS		INTRATHECAL	250MCG/DAY/IN	
Hospitalization - Initial or Prolonged	Coma Muscle Spasticity Mydriasis Pulmonary Oedema Respiratory Arrest Shock	Health Professional				TRATHECAL		

Date:04/30/98ISR Number: 3074373-9Report Type:Expedited (15-DaCompany Report #98F--10316
Age:46 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agitation Coma Pneumonia Aspiration Suicide Attempt	Foreign Health Professional Distributor Other	Lioresal	PS		ORAL	500 MG, ONCE,ORAL, TAB	

Date:04/30/98ISR Number: 3074374-0Report Type:Expedited (15-DaCompany Report #98USA10617
Age:80 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Confusional State Feeling Jittery Status Epilepticus Tongue Discolouration	Health Professional	Lioresal	PS		ORAL	5 MG, TID, ORAL, TAB	

Date:05/01/98ISR Number: 3073162-9Report Type:Direct Company Report #
Age:54 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Agitation Confusional State		Baclofen	PS			10 MG TID X 5 DAYS	

Date:05/05/98ISR Number: 3073588-3Report Type:Expedited (15-DaCompany Report #970588-1
Age:21 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Apallic Syndrome	Foreign	Lioresal	PS		INTRATHECAL	700 MCG/DAY,	
	Autonomic Neuropathy	Health				INTRATHECAL		
	Bladder Disorder	Professional						
	Gastrointestinal Disorder							
	Haematemesis							

Date:05/05/98ISR Number: 3073597-4Report Type:Expedited (15-DaCompany Report #98USA10515
Age:74 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Small Intestinal Obstruction	Health Professional	Lioresal	PS		ORAL (TABLET)	DAILY	

Date:05/15/98ISR Number: 3079236-0Report Type:Expedited (15-DaCompany Report #970597
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Accidental Overdose	Foreign Health	Lioresal	PS		INTRATHECAL	30 MG; 30 MG/30 ML	
	Disorientation							
	Drug Withdrawal Syndrome	Professional				INTRATHECAL		
	Hypotension							
	Medication Error							

Date:05/20/98ISR Number: 3080403-0Report Type:Direct Company Report #
Age:72 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Cerebrovascular Accident		Fluoxetine	PS			20 MG NG QD	
	Dystonia		Baclofen	SS			5-15 MG TID	
	Encephalopathy						NG	
	Hallucination							
	Hypertonia							
	Muscle Rigidity							
	Staring							
	Tremor							

Date:05/28/98ISR Number: 3084737-5Report Type:Expedited (15-DaCompany Report #98D-10328
Age:84 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Arrhythmia	Foreign	Lioresal	PS		ORAL	1 DF, BID,	
Life-Threatening	Atrial Flutter	Health					ORAL	
Hospitalization -	Phlebothrombosis	Professional	Euglucon N	SS		ORAL	3 DE, DAILY,	
Initial or Prolonged	Pneumonia						ORAL	
	Rash Erythematous		Adumbran	SS		ORAL	1 DF, DAILY,	
	Staphylococcal Sepsis						ORAL	
	Urinary Tract Infection		Heparin	SS			INTRAVENOUS	25000 I.E.
							DAILY	
							INTRAVENOUS	
			Sotalex	SS		ORAL	40 MG, DAILY,	
							ORAL	
			Sotalex	SS		ORAL	2 DF, DAILY	
							ORAL	
			Hypnomidate Ampoule	SS			10 MG, DAILY	

			Tramal Drops	SS		ORAL
15 DRP,						
DAILY, ORAL						
			Tambocor Ampoule	SS		
2 DF, DAILY						
			Novalgin Drops	SS		ORAL
30 DRP, DAILY						
ORAL						

Date:06/04/98ISR Number: 3090258-6Report Type:Direct Company Report #
Age:49 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Life-Threatening	Cardiac Arrest		Baclofen	PS		
INTRATHECAL INTRATHECAL						
Required	Coma					
10 MG						
Intervention to	Hypotension		Asa	C		
Prevent Permanent	Lethargy		Tylenol	C		
Impairment/Damage						

Date:06/04/98ISR Number: 3091096-0Report Type:Expedited (15-DaCompany Report #199811483HPD
Age:84 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Pneumonia	Foreign	Novalgin	PS		
Life-Threatening	Skin Disorder	Study	Euglucon N	SS		ORAL
2-1-0 U QD PO						
Hospitalization -	Staphylococcal Sepsis	Health	Azuglucon	SS		ORAL
2-1-0 U QD PO						
Initial or Prolonged	Stevens-Johnson Syndrome	Professional	Heparin	SS		
INTRAVENOUS 25000 IU/DAY						
	Toxic Epidermal					
IV						
	Necrolysis		Augmentan	SS		
			Tramal	SS		
			Adumbran	SS		
			Lioresal	SS		
			Tambocor	SS		

Sotalex	SS
Hypnomidate	SS
Sotalex Mite	SS
Dormicum	SS
Mono Embolex	C
Zantic	C
Acimethin	C
Novodigal	C
Glucobay	C
Digostada	C
Nizax	C

Date:06/11/98ISR Number: 3093410-9Report Type:Expedited (15-DaCompany Report #98USA10556
Age:75 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Coma	Health	Liorseal	PS		ORAL	DAILY, ORAL	
Hospitalization - Initial or Prolonged		Professional	Lescol Capsule	C				
			Atenolol Tablet	C				
Other			Ticlid Tablet	C				

Date:06/12/98ISR Number: 3093492-4Report Type:Expedited (15-DaCompany Report #970568
Age: Gender:Male I/FU:I

Outcome	PT
Death	Autonomic Neuropathy
	Faecaloma

		Hypertension Hypertonia Myocardial Infarction	Report Source	Product	Role	Manufacturer	Route	Dose
Duration								
		Pyrexia	Company	Lioresal Intrathecal	PS			
INTRATHECAL	UKNOWN	DOSE						
			Representative					

Date:06/24/98ISR Number: 3098110-7Report Type:Expedited (15-DaCompany Report #970600
Age: Gender:Male I/FU:I

Outcome		PT	Report Source	Product	Role	Manufacturer	Route	Dose
Duration								
		Unevaluable Event	Foreign Health Professional	Lioresal	PS			

Date:06/24/98ISR Number: 3098117-XReport Type:Expedited (15-DaCompany Report #98S--10034
Age:52 YR Gender:Male I/FU:I

Outcome		PT	Report Source	Product	Role	Manufacturer	Route	Dose
Duration								
Hospitalization -		Pruritus	Foreign	Lioresal	PS			
INTRATHECAL	338 MCG,							
Initial or Prolonged		Rash Generalised	Other					
DAILY,								
		Toxic Skin Eruption						
INTRATHECAL								
				Propavan	C			

Date:06/24/98ISR Number: 3098123-5Report Type:Expedited (15-DaCompany Report #970602
Age: Gender:Female I/FU:I

Outcome		PT	Report Source	Product	Role	Manufacturer	Route	Dose
Duration								
		Unevaluable Event	Foreign Consumer	Lioresal Intrathecal	PS			

Date:06/24/98ISR Number: 3098128-4Report Type:Expedited (15-DaCompany Report #98D--10348
Age:49 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Flushing	Foreign	Lioresal	PS		INTRATHECAL	500 MCG,	DAILY,
	Suicidal Ideation	Consumer						
		Other				INTRATHECAL	5	MON

Date:06/24/98ISR Number: 3098130-2Report Type:Expedited (15-DaCompany Report #98D--10348
Age:49 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Flushing	Foreign	Lioresal	PS		INTRATHECAL	DAILY,	
	Hypertonia	Consumer				INTRATHECAL	5	MON
Other	Pruritus							
	Suicidal Ideation							

Date:06/26/98ISR Number: 3098736-0Report Type:Direct Company Report #
Age:63 YR Gender:Female I/FU:I

Outcome	PT
Life-Threatening	Clonic Convulsion
	Depressed Level Of Consciousness
	Pain In Extremity

	Renal Failure Chronic Stupor Tachypnoea	Report Source	Product	Role	Manufacturer	Route Dose Duration
			Baclofen	PS		ORAL 10 MG PO 1700 AND 2300
			Isordil	C		
			Lepovir	C		
			Dorvil	C		
			Estrogen	C		
			Regulin	C		
			Ancef	C		

Date:06/29/98ISR Number: 3100132-4Report Type:Expedited (15-DaCompany Report #970606
Age:71 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Hospitalization -	Atrioventricular Block	Foreign	Lioresal	PS		INTRATHECAL 2000 MCG/DAY,
Initial or Prolonged	Complete	Health				INTRATHECAL 17 DAY
Required	Blood Pressure Decreased	Professional	Atropine	C		
Intervention to	Bradycardia		Diazepam	C		
Prevent Permanent	Drug Effect Decreased		Fentanyl	C		
Impairment/Damage	Muscle Spasms		Urapidil	C		
			Midazolam	C		
			Dopamine	C		
			Pancuronium	C		

Date:06/29/98ISR Number: 3100466-3Report Type:Expedited (15-DaCompany Report #970609
Age:41 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Hospitalization -	Condition Aggravated	Foreign	Lioresal	PS		INTRATHECAL 2000 MCG/DAY;
Initial or Prolonged	Drug Effect Decreased	Literature				INTRATHECAL
Required	Musculoskeletal Stiffness	Health	Pancuronium	C		
Intervention to	Sedation	Professional	Diazepam	C		

Prevent Permanent Impairment/Damage	Trismus		Flumanezil	C		

Date:06/29/98ISR Number: 3100467-5Report Type:Expedited (15-DaCompany Report #970608
Age:52 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Hypopnoea	Foreign	Lioresal	PS		INTRATHECAL 500 MCG/DAY,
	Sedation	Literature				INTRATHECAL
		Health Professional	Diazepam	C		
			Pancuronium	C		
			Flumazenil	C		

Date:06/29/98ISR Number: 3100468-7Report Type:Expedited (15-DaCompany Report #970607
Age:66 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Life-Threatening Required Intervention to Prevent Permanent Impairment/Damage	Drug Effect Decreased	Foreign	Lioresal	PS		INTRATHECAL VARIOUS;
	Hypotension	Literature				INTRATHECAL 54 DAY
		Health Professional	Midazolam	C		
			Pancuromium	C		
			Atropine	C		

				Dopamine	C	
				Diazepam	C	
				Flumazenil	C	

Date:06/29/98ISR Number: 3100948-4Report Type:Expedited (15-DaCompany Report #970605
Age:57 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Life-Threatening	Bradycardia	Foreign	Lioresal Intrathecal			
	Cardiac Arrest	Health	(Baclofen Injection)	PS		
INTRATHECAL 40 MG,	DAILY,					
	Electrocardiogram St	Professional				
INTRATHECAL 16 MON						
	Segment Elevation		Aspirin	C		
	Heart Rate Irregular		Glyceril Trinitrate	C		
	Hypotension		???	C		
	Hypothermia					
	Hypoventilation					
	Loss Of Consciousness					
	Medication Error					
	Myocardial Infarction					
	Respiratory Failure					

Date:06/29/98ISR Number: 3100951-4Report Type:Expedited (15-DaCompany Report #98GB-10607
Age:59 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Life-Threatening	Bradycardia	Foreign	Lioresal (Baclofen)	PS		
INTRATHECAL 40 MG DAILY						
	Cardio-Respiratory Arrest	Health				
INTRATHECAL 16 MON						
	Heart Rate Irregular	Professional	Aspirin	C		
	Hypotension		Glyceryl Trinitrate	C		
	Hypothermia		Amdur	C		
	Hypotonia		Fastin	C		
	Hypoventilation					
	Myocardial Infarction					
	Syncope					

Date:07/01/98ISR Number: 3100331-1Report Type:Expedited (15-DaCompany Report #98D-10374
Age:57 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Antinuclear Antibody Positive	Foreign Health	Tegretal (Carbamazepine)	PS		ORAL	600 MG, DAILY, ORAL	89 DAY
	Drug Toxicity	Professional						
	Hepatic Haemorrhage		Lioresal (Baclofen)	SS		ORAL	50 MG DAILY, ORAL	67 DAY
	Hepatic Necrosis							
	Hepatotoxicity		Jarsin Sugar-Coated	C				
	Liver Function Test Abnormal		Dytide H	C				

Date:07/07/98ISR Number: 3102583-0Report Type:Expedited (15-DaCompany Report #98F-10529
Age:40 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Coma	Foreign	Lioresal	PS		ORAL	2.5 MG, TID, ORAL	
	Hypoglycaemia	Health Professional	Pevaryl	SS		TOPICAL	TOPICAL/LOCAL	
			Zovirax	SS				
			Prozac	SS		ORAL	ORAL	

				Parenteral Nutrition Solution	C		

Date:07/07/98ISR Number: 3102790-7Report Type:Expedited (15-DaCompany Report #98USA10999
Age:54 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Pyrexia	Health Professional	Lioresal	PS		ORAL	DIALY, ORAL	

Date:07/16/98ISR Number: 3105955-3Report Type:Expedited (15-DaCompany Report #98I--10029
Age:15 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Dermatitis	Foreign	Lioresal	PS		ORAL	75 MG,DAILY, ORAL	
	Pyrexia	Health Professional	Tegretol	SS		ORAL	800 MG, DAILY, ORAL	
		Other	Vancomycin	SS		INTRAVENOUS	2G, DAILY	
			Heparin	C				
			Propranolol	C				

Date:07/17/98ISR Number: 3106161-9Report Type:Expedited (15-DaCompany Report #98F--10565
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Blood Creatine Phosphokinase Increased	Foreign	Lioresal	PS		ORAL	200 MG, ONCE, ORAL	
Hospitalization - Initial or Prolonged	Depressed Level Of Consciousness	Health Professional Other						

	Suicide Attempt					

Date:07/17/98ISR Number: 3106169-3Report Type:Expedited (15-DaCompany Report #970615
Age:4 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required	Hypertension	Health	Lioresal	PS			170MCG BOLUS,	
Intervention to	Medication Error	Professional					INTRATHECAL	
Prevent Permanent	Overdose							
Impairment/Damage								

Date:07/17/98ISR Number: 3108325-7Report Type:Direct Company Report #
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Amnesia		Baclofen	PS			5MG 4 X DAILY	
Initial or Prolonged	Confusional State		Famvir	C				
	Coordination Abnormal		Tenormin	C				
	Disorientation		Zestril	C				
	Hallucination		Prevacid	C				
	Movement Disorder							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/22/98ISR Number: 3108483-4Report Type:Expedited (15-DaCompany Report #98J-10271
Age:46 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Depressed Level Of Consciousness Respiratory Disorder	Foreign Health Professional	Lioresal	PS		ORAL	20 MG DAILY ORAL	

Date:07/27/98ISR Number: 3109297-1Report Type:Expedited (15-DaCompany Report #970617
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Condition Aggravated Hypertonia Procedural Site Reaction	Company Representative	Lioresal Intrathecal	PS		INTRATHECAL	APPROX. 2000MCG/DAY, INTRATHECAL	

Date:07/30/98ISR Number: 3111411-9Report Type:Expedited (15-DaCompany Report #970588-2
Age:21 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Bladder Disorder Haematemesis Intestinal Functional Disorder	Foreign Health Professional	Lioresal	PS		INTRATHECAL	700 MCG/DAY, INTRATHECAL	

Date:07/30/98ISR Number: 3111415-6Report Type:Expedited (15-DaCompany Report #970615-1
Age:4 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Required	Accidental Overdose	Health	Lioresal	PS		
INTRATHECAL 170 MCQ						
Intervention to	Hypotension	Professional				
BOLUS,						
Prevent Permanent	Respiratory Depression					
INTRATHECAL						
Impairment/Damage	Sedation					

Date:07/31/98ISR Number: 3111269-8Report Type:Expedited (15-DaCompany Report #98GB-10641
Age:15 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Hypothermia	Foreign	Baclofen	PS		ORAL	40 MG, DAILY,	
Initial or Prolonged		Health						
ORAL								
		Professional	Pro-Banthine	C				
			Cephradine	C				
			Prednisolone	C				
			Ranitidine	C				

Date:08/05/98ISR Number: 3115239-5Report Type:Expedited (15-DaCompany Report #98GB-10787
Age:49 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Liver Function Test	Foreign	Baclofen	PS		ORAL	25 MG DAILY,	
	Abnormal	Health						
ORAL								
		Professional						

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/05/98ISR Number: 3226195-3Report Type:Periodic Company Report #98-03-0039
Age:37 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blood Insulin Increased	Consumer	Baclofen - Zenith					
	Hepatic Function Abnormal		Goldline Pharm.					
	Hypoglycaemia		Tablets	PS		ORAL	60MG/DAY ORAL	
			Vicodin	C				
			Tenoretic	C				
			Cytotec	C				
			Naproxen	C				
			Tagamet	C				

Date:08/05/98ISR Number: 3226201-6Report Type:Periodic Company Report #97-10-0729
Age:61 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Muscular Weakness	Consumer	Baclofen - Zenith					
	Pollakiuria		Goldline Pharm.					
			Tablets	PS		ORAL	10MG 1/2QHS	
							ORAL	
			Prednisone Therapy	C				

Date:08/05/98ISR Number: 3226206-5Report Type:Periodic Company Report #97-12-0815
Age:30 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dizziness	Consumer	Baclofen - Zenith					
	Headache		Goldline Pharm.					
	Muscle Rigidity		Tablets	PS		ORAL	10MG BID ORAL	
	Muscle Spasms							
	Paraesthesia							
	Tremor							

Date:08/05/98ISR Number: 3226211-9Report Type:Periodic Company Report #98-04-0096
Age:37 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Heart Rate Increased	Consumer	Baclofen - Zenith					
	Paraesthesia		Goldline Pharm					
	Sedation		Tablets	PS		ORAL	40-60 MG/DAY	
	Sleep Apnoea Syndrome						ORAL	
			Paxil	C				
			Flexeril	C				
			Ambien	C				
			Morphine Sulfate	C				
			Clonidine Patch	C				

Date:08/05/98ISR Number: 3226215-6Report Type:Periodic Company Report #97-05-0385
Age:64 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Cerebrovascular Accident	Health	Baclofen - Zenith					
	Vomiting	Professional	Goldline Pharm.					
		Other	Tablets	PS		ORAL	5MG TID ORAL	
			Asa	C				
			Coumadin	C				
			Centrum	C				

				Zoloft	C		

Date:08/05/98ISR Number: 3226758-5Report Type:Periodic Company Report #98-01-0003
Age:49 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Asthenia	Consumer	Baclofen					
	Bladder Disorder	Other	Tablets-Zenith					
	Constipation		Goldline Pharm.	PS	Zenith Goldline			
	Hypersomnia				Pharm.	ORAL	20MG	TID ORAL
	Increased Appetite		Ms Contin	C				
	Muscle Spasms		Klonopin	C				
	Urinary Retention		Soma	C				
	Urinary Tract Disorder							
	Vision Blurred							

Date:08/05/98ISR Number: 3226759-7Report Type:Periodic Company Report #97-12-0818
Age:26 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Ineffective	Health Professional	Baclofen	PS	Zenith Goldline Pharm.	ORAL	20 MG 5/DAY	
		Other						
ORAL								
			Baclofen Capsules	SS		ORAL	20 MG 5/DAY	
ORAL								

Date:08/07/98ISR Number: 3114212-0Report Type:Expedited (15-DaCompany Report #970621
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Respiratory Depression	Foreign	Lioresal	PS				
	Sedation	Health Professional						

Date:08/07/98ISR Number: 3114361-7Report Type:Expedited (15-DaCompany Report #98D--10461
Age: Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Bradycardia Coma Hypotension Overdose Respiratory Depression	Foreign Health Professional Distributor	Lioresal	PS				

Date:08/14/98ISR Number: 3117305-7Report Type:Expedited (15-DaCompany Report #98J-10271
Age:46 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 Professional	Lioresal	PS		ORAL	20 MG DAILY	ORAL 4 DAY
	Haemodialysis Hypoaesthesia Lethargy Renal Failure Chronic Respiratory Disorder		Tegretol	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/16/98ISR Number: 3117258-1Report Type:Expedited (15-DaCompany Report #98F-10565
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Blood Creatine Phosphokinase Increased	Foreign Health Professional	Lioresal	PS		ORAL	200 MG ONCE	ORAL
	Depressed Level Of Consciousness Hypotonia Rhabdomyolysis Sedation Suicide Attempt							

Date:08/18/98ISR Number: 3118773-7Report Type:Expedited (15-DaCompany Report #FLUV001980094
Age:30 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Prothrombin Time Shortened		Floxyfral	PS		ORAL	PER ORAL	
			Sermion	SS		ORAL	PER ORAL	
			Lioresal	SS		ORAL	PER ORAL	
			Dantrium	SS		ORAL	3 DOSAGES DAILY	PER ORAL

Date:08/19/98ISR Number: 3118900-1Report Type:Expedited (15-DaCompany Report #99D-10374
Age:57 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Antinuclear Antibody Positive	Foreign Health	Tegretal	PS		ORAL	600 MG DAILY	ORAL 89 DAY

	Hepatic Haemorrhage	Professional	Lioresal	SS			ORAL 50 MG DAILY
	Hepatic Necrosis	Other					ORAL 67 DAY
	Liver Function Test Abnormal		Jarsin Sugar-Coated Tablet	C			
			Dytide H	C			

Date:08/20/98ISR Number: 3242793-5Report Type:Periodic Company Report #970545
Age:44 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Bradycardia	Foreign	Lioresal Intrathecal (Baclofen Injection)	PS			BOLUS DOSE OF 0.2 ML OF 500 MCG/ML
	Confusional State	Literature					
	Dyspnoea	Health					
	Hypertonia	Professional					
	Hypotonia						
	Sedation						

Date:08/20/98ISR Number: 3242797-2Report Type:Periodic Company Report #970546
Age:38 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Convulsion	Foreign	Lioresal Intrathecal (Baclofen Injection)	PS			100 MCG BOLUS DOSE
		Literature					
		Health					
		Professional					

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/20/98ISR Number: 3242806-0Report Type:Periodic Company Report #970547
Age: Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hypotonia	Literature Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS				

Date:08/20/98ISR Number: 3242810-2Report Type:Periodic Company Report #970548
Age: Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hypotonia	Literature Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS				

Date:08/20/98ISR Number: 3242813-8Report Type:Periodic Company Report #970549
Age: Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hypotonia	Literature Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS				

Date:08/20/98ISR Number: 3242815-1Report Type:Periodic Company Report #970550
Age: Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Urinary Retention	Literature Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS				

Date:08/20/98ISR Number: 3242817-5Report Type:Periodic Company Report #970551
Age: Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Urinary Retention	Literature Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		

Date:08/20/98ISR Number: 3242819-9Report Type:Periodic Company Report #970552
Age: Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Urinary Retention	Literature Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		

Date:08/20/98ISR Number: 3242820-5Report Type:Periodic Company Report #970553
Age: Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Dizziness Nausea Sedation	Literature Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/20/98ISR Number: 3242822-9Report Type:Periodic Company Report #970554
Age: Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Confusional State Hypotonia	Foreign Literature Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS				

Date:08/20/98ISR Number: 3242824-2Report Type:Periodic Company Report #970555
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Condition Aggravated Hypertonia	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS			390 MCG/DAY OF 2000 MCG/ML	

Date:08/20/98ISR Number: 3242826-6Report Type:Periodic Company Report #970556
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hypotonia	Company Representative	Lioresal Intrathecal (Baclofen Injection)	PS		INTRATHECAL	UNKNOWN;	

INTRATHECAL

Date:08/20/98ISR Number: 3242828-XReport Type:Periodic Company Report #970558
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Hypertonia	Foreign	Lioresal Intrathecal					

Initial or Prolonged Health (Baclofen Injection) PS
INTRATHECAL 250 MCG/DAY
Professional
INTRATHECAL

Date:08/20/98ISR Number: 3242829-1Report Type:Periodic Company Report #970562
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Urinary Incontinence	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		
INTRATHECAL UNKNOWN DOSE,						
INTRATHECAL						
DELIVERY						

Date:08/20/98ISR Number: 3242831-XReport Type:Periodic Company Report #970567
Age:4 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Convulsion	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		
INTRATHECAL 48 MCG						
INTRATHECAL						
BOLUS						

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/20/98ISR Number: 3242832-1Report Type:Periodic Company Report #970569
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Condition Aggravated Hypertonia	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		INTRATHECAL	105 MCG/DAY,	

INTRATHECAL

Date:08/20/98ISR Number: 3242833-3Report Type:Periodic Company Report #970570
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Condition Aggravated Hypertonia	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		INTRATHECAL	264 MCG/DAY,	

INTRATHECAL

Date:08/20/98ISR Number: 3242835-7Report Type:Periodic Company Report #970571
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Condition Aggravated Hypertonia	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		INTRATHECAL	638 MCG/DAY,	

INTRATHECAL

Date:08/20/98ISR Number: 3242837-0Report Type:Periodic Company Report #970572
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Condition Aggravated Hypertonia	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		INTRATHECAL	161 MCG/DAY,	

INTRATHECAL

Date:08/20/98ISR Number: 3242840-0Report Type:Periodic Company Report #970573
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hypertonia	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		INTRATHECAL	508 MCG/DAY,	

INTRATHECAL

Date:08/20/98ISR Number: 3249289-5Report Type:Periodic Company Report #970574
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hypertonia	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS			831 MCG/DAY,	

INTRATHECAL

Date:08/20/98ISR Number: 3249303-7Report Type:Periodic Company Report #970575
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Condition Aggravated Hypertonia	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS			830 MCG/DAY,	

INTRATHECAL

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/20/98ISR Number: 3249307-4Report Type:Periodic Company Report #970576
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Condition Aggravated Hypertonia	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS			260 MG/DAY,	INTRATHECAL

Date:08/20/98ISR Number: 3249311-6Report Type:Periodic Company Report #970577
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Sedation	Literature Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS			400 MCG/DAY,	INTRATHECAL

Date:08/20/98ISR Number: 3249353-0Report Type:Periodic Company Report #970578
Age:19 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Sedation	Literature Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS			200 MCG/DAY,	INTRATHECAL

Date:08/20/98ISR Number: 3249361-XReport Type:Periodic Company Report #970580
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hypertonia Pruritus	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS			500 MCG/DAY,	

Sedation
INTRATHECAL
Oral Baclofen, Dose Unknown C

Date:08/20/98ISR Number: 3249369-4Report Type:Periodic Company Report #970585
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hypotonia	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS			DOSE UNKNOWN, INTRATHECAL	ROUTE

Date:08/20/98ISR Number: 3249375-XReport Type:Periodic Company Report #970586
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hypotonia	Consumer	Lioresal Intrathecal (Baclofen Injection)	PS			UNK DOSE, INTRATHECAL	ROUTE

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/20/98ISR Number: 3249379-7Report Type:Periodic Company Report #970587
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hypotonia Urinary Incontinence	Study Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS			UNKNOWN DOSE; INTRATHECAL	ROUTE

Date:08/20/98ISR Number: 3249383-9Report Type:Periodic Company Report #970593
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hypotonia Vomiting	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS			330 MG BOLUS, INTRATHECAL	

Date:08/20/98ISR Number: 3249387-6Report Type:Periodic Company Report #970594
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Sedation	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS			UNKNOWN, INTRATHECAL	

Date:08/20/98ISR Number: 3249392-XReport Type:Periodic Company Report #970595
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Vomiting	Company	Lioresal Intrathecal					

Initial or Prolonged Representative (Baclofen Injection) PS
87, MCG/DAY,

INTRATHECAL

Date:08/20/98ISR Number: 3249395-5Report Type:Periodic Company Report #970596
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hypotonia Sedation	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS				

UNKNOWN DOSE;

INTRATHECAL

ROUTE

Date:08/20/98ISR Number: 3249398-0Report Type:Periodic Company Report #970598
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Convulsion	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS				

UNKNOWN DOSE;

INTRATHECAL

ROUTE

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/20/98ISR Number: 3249402-XReport Type:Periodic Company Report #970599
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hypotonia	Study Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		INTRATHECAL	UNKNOWN DOSE;	ROUTE

Date:08/20/98ISR Number: 3249405-5Report Type:Periodic Company Report #970601
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dyspnoea	Other	Lioresal Intrathecal (Baclofen Injection)	PS		INTRATHECAL	900 MG/DAY,	

Date:08/20/98ISR Number: 3249408-0Report Type:Periodic Company Report #970603
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Muscle Twitching	Other	Lioresal Intrathecal (Baclofen Injection)	PS		INTRATHECAL	2 MCG/HOUR,	

Date:08/20/98ISR Number: 3249414-6Report Type:Periodic Company Report #970604
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Condition Aggravated	Health	Lioresal Intrathecal					

	Hypertonia	Professional	(Baclofen Injection)	PS		

UNKNOWN DOSE,

INTRATHECAL

ROUTE

Date:08/20/98ISR Number: 3249417-1Report Type:Periodic Company Report #970610
Age: Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Medical Device	Foreign	Lioresal Intrathecal			
	Complication	Company	(Baclofen Injection)	PS		
		Representative				

Date:08/20/98ISR Number: 3249420-1Report Type:Periodic Company Report #970611
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Convulsion	Health	Lioresal Intrathecal			
		Professional	(Baclofen Injection)	PS		

UNKNOWN;

INTRATHECAL

Trazadone	C
Deserel	C
Depakote	C

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/20/98ISR Number: 3249423-7Report Type:Periodic Company Report #970612
Age:22 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Ineffective	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS			375 MCG BOLUS AT TRIAL	

Date:08/20/98ISR Number: 3249426-2Report Type:Periodic Company Report #970613
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Ejaculation Disorder Erectile Dysfunction	Foreign Literature Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS			UNKNOWN; INTRATHECAL	

Date:08/21/98ISR Number: 3120458-8Report Type:Expedited (15-DaCompany Report #98F--10715
Age:30 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Prothrombin Time Shortened	Foreign Health	Lioresal Sermion	PS SS		ORAL ORAL	DAILY ORAL 300 MG DAILY	4 WK 3 MON
		Professional	Dantrium Floxyfral	SS SS		ORAL ORAL	ORAL ORAL	

Date:09/02/98ISR Number: 3125871-0Report Type:Direct Company Report #
Age:64 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Ineffective		Baclofen	PS		ORAL	20 MG BID,	ORAL
			Tegretol	SS		ORAL	200 MG TID,	ORAL
			Oxycodone/Acetaminophen	C				
			Alendronate Sodium	C				
			Bisacodyl	C				

Date:09/09/98ISR Number: 3127343-6Report Type:Expedited (15-DaCompany Report #970623
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Confusional State	Health	Lioresal Intrathecal	PS		INTRATHECAL	INTRATHECAL	
Hospitalization - Initial or Prolonged	Convulsion	Professional				ROUTE		
	Drug Withdrawal Syndrome							
	Hypertension							
	Muscle Spasticity							

Date:09/11/98ISR Number: 3127618-0Report Type:Expedited (15-DaCompany Report #970626
Age: Gender:Male I/FU:I

Outcome
Required
Intervention to
Prevent Permanent

Impairment/Damage

	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Asthenia	Health	Lioresal	PS			DOSE,	
	Drug Withdrawal Syndrome	Professional					INTRATHECAL	
	Dyspnoea						DELIVERY	
	Hypertonia							
	Medication Error							
	Overdose							
	Paraesthesia							
	Pruritus							

Date:09/21/98ISR Number: 3133431-0Report Type:Expedited (15-DaCompany Report #98D--10461
Age:74 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Accidental Overdose	Foreign	Lioresal	PS				
Initial or Prolonged	Bradycardia	Health	Benzodiazepine	SS				
	Bradypnoea	Professional						
	Coma	Other						
	Drug Level Above							
	Therapeutic							
	Hypotension							
	Hypothermia							
	Respiratory Depression							

Date:09/25/98ISR Number: 3135394-0Report Type:Expedited (15-DaCompany Report #96-01870
Age:65 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Abdominal Pain	Study	Camptosar	PS			INTRAVENOUS	255 MG;
Initial or Prolonged	Asthenia	Health					INTRAVENOUS	
Other	Deep Vein Thrombosis	Professional	Adrucil	SS			INTRAVENOUS	1020 MG

Hyperbilirubinaemia

WEEKLY

Hypotension

INTRAVENOUS

Pulmonary Embolism

		Leucovorin	SS	
INTRAVENOUS	40 MG WEEKLY			
INTRAVENOUS				
		Baclofen	SS	ORAL
10 MILLIGRAMS				
TID ORAL				
		Amitriptyline	SS	ORAL
50 MILLIGRAMS				
ONCE DAILY				
ORAL				
		Prevacid	C	
		Propulsid	C	
		Carafate	C	
		Paxil	C	
		Megace	C	
		Prilosec	C	
		Axid	C	
		Advil	C	
		Duragesic Patch	C	
		Acyclovir	C	
		Indocin	C	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/28/98ISR Number: 3136190-0Report Type:Expedited (15-DaCompany Report #98USA11417
Age:49 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Abnormal Behaviour	Health	Baclofen	PS		ORAL	10MG TID	ORAL 2 DAY
Initial or Prolonged	Mental Impairment	Professional	Fosinopril	C				
	Tremor		Nifedipine Extended Release	C				

Date:09/29/98ISR Number: 3136285-1Report Type:Expedited (15-DaCompany Report #970628
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Coma	Health	Lioresal	PS			INTRATRACHEAL	229 MCG/DAY,
Initial or Prolonged	Dizziness	Professional					INTRATHECAL	
	Medication Error							

Date:10/02/98ISR Number: 3137390-6Report Type:Expedited (15-DaCompany Report #98--F10529
Age:41 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Coma	Foreign	Lioresal	PS		ORAL	2.5 MG, BID,	
	Hypoglycaemia	Health					ORAL	
	Medication Error	Professional	Pevaryl Spray					
		Other	(Econazole Nitrate)	SS			TOPICAL	TOPICAL/LOCAL
			Zovirax (Aciclovir)	SS				
			Prozac Drops(Fluoxetine)	SS		ORAL	10 DRP,	
							DAILY, ORAL	
			Parenteral Nutrition Solution(Parental					

			Nutrition)	SS		
PARENTERAL	PARENTERAL					

Date:10/02/98ISR Number: 3137393-1Report Type:Expedited (15-DaCompany Report #98GB-10868
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Liver Function Test Abnormal	Foreign Health Professional	Lioresal	PS		ORAL	10 MG, TID, ORAL	
		Other	Amitriptyline	C				
			Antibiotics	C				

Date:10/05/98ISR Number: 3138377-XReport Type:Expedited (15-DaCompany Report #970617
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Death	Company Representative	Lioresal	PS		INTRATHECAL	APPROX. 2000 MCG/DAY, INTRATHECAL	

Date:10/15/98ISR Number: 3142510-3Report Type:Expedited (15-DaCompany Report #98J-10368
Age:63 YR Gender:Male I/FU:I

Outcome	PT	Report Source
Hospitalization - Initial or Prolonged	Depressed Level Of Consciousness	Foreign Health Professional

Other

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
			Lioresal	PS		ORAL	10 MG, DAILY,	
						ORAL		2 DAY
			Landsen	C				
			Lendormin	C				

Date:10/22/98ISR Number: 3145451-0Report Type:Expedited (15-DaCompany Report #500691
Age:75 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Electroencephalogram	Foreign	Macrodantin	PS		ORAL	150 MG DAILY ; ORAL	
	Abnormal	Health						
	Epilepsy	Professional	Lioresal	SS		ORAL	20 MG DAILY ; ORAL	
	Loss Of Consciousness							
	Monoparesis		Lioresal	C				
	Movement Disorder							
	Tremor							
	Urinary Incontinence							

Date:10/27/98ISR Number: 3245512-1Report Type:Periodic Company Report #9830427
Age:44 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Ineffective	Consumer	Viagra Tablets	PS		ORAL	50.00 MG	
	Erectile Dysfunction							
							TOTAL:PRN:ORAL	
			Baclofen	SS		ORAL	ORAL	
			Betaseron	C				

			Amantidine	C		
			Desyrel	C		

Date:10/28/98ISR Number: 3148398-9Report Type:Expedited (15-DaCompany Report #R98-063
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Complications Of Maternal Exposure To Therapeutic Drugs Foetal Movements Decreased Intraventricular Haemorrhage Neonatal Premature Baby Small For Dates Baby	Health Professional	Baclofen	PS	Watson Laboratories Inc. Miami		TID	(28TH-29TH WEEK -30TH WEEK OF PREGNANCY)
			Hydrocortisone	C				
			Tylenol #3	C				

Date:11/04/98ISR Number: 3152136-3Report Type:Expedited (15-DaCompany Report #109/8697
Age:1 DY Gender:Female I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged Congenital Anomaly	Complications Of Maternal Exposure To Therapeutic Drugs Foetal Movements Decreased Intraventricular

	Haemorrhage Neonatal Premature Baby						
		Report Source	Product	Role	Manufacturer	Route	Dose Duration
		Health Professional	Cortef Baclofen	PS SS		ORAL	ORAL
		Company Representative	Tylenol With Codeine	SS			

Date:11/04/98ISR Number: 3152476-8Report Type:Expedited (15-DaCompany Report #98F--10882
Age:71 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Agitation Confusional State Convulsion	Foreign Health Professional Other	Lioresal	PS		ORAL	DAILY, ORAL

Date:11/04/98ISR Number: 3152478-1Report Type:Expedited (15-DaCompany Report #98HQ-10387
Age:71 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Abdominal Pain Cerebral Atrophy Cerebral Infarction Confusional State Difficulty In Walking Encephalopathy Hypotonia Muscular Weakness Neurological Symptom Sedation	Foreign Literature Health Professional Other	Baclofen Hemodialysis	PS C		ORAL	30 MG, DAILY, ORAL

Date:11/04/98ISR Number: 3152479-3Report Type:Expedited (15-DaCompany Report #98HQ-10388
Age:69 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Atrophy	Foreign	Baclofen	PS		ORAL	15 MG, DAILY,	
	Brain Stem Infarction	Literature					ORAL	
	Cheyne-Stokes Respiration	Health Professional	Hemodialysis	C				
	Coma	Other						
	Confusional State							

Date:11/09/98ISR Number: 3153742-2Report Type:Expedited (15-DaCompany Report #98-10-0239
Age:48 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Eye Disorder	Consumer	Baclofen	PS	Zenith Goldline Pharm.	ORAL	10 MG BID	
	Motor Dysfunction						ORAL	
	Paralysis		Darvocet-N 100	C				
			Meperidine Hydrochloride	C				

Date:11/09/98ISR Number: 3154503-0Report Type:Expedited (15-DaCompany Report #98F-10947
Age:34 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Coma Epilepsy	Foreign Health	Lioresal Tablet (Baclofen)	PS		ORAL	DAILY, ORAL	
	Hypertonia Overdose Status Epilepticus Suicide Attempt	Professional	Vastarel Tablet (Trimetazidine Dihydrochloride)	SS		ORAL	ORAL	

Date:11/09/98ISR Number: 3154708-9Report Type:Expedited (15-DaCompany Report #981104-107014347
Age: 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	Health Professional	Tylenol With Codeine #3	PS		INTRA-UTERINE	INTRAUTERINE	
	Drugs Intraventricular		Hydrocortisone Baclofen	SS SS		INTRA-UTERINE	INTRAUTERINE	
	Haemorrhage Neonatal Premature Baby							

Date:11/10/98ISR Number: 3155630-4Report Type:Expedited (15-DaCompany Report #500705
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Arrhythmia	Foreign	Dantrium	PS		ORAL	ORAL	
		Health Professional	Lioresal	SS				

Date:11/12/98ISR Number: 3157133-XReport Type:Expedited (15-DaCompany Report #98USA11651
Age:59 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Coma Dyspnoea Facial Palsy Hemiparesis Hypertension Tongue Oedema	Health Professional	Baclofen Procardia Capsule Compazine Tablet	PS C C		ORAL	DAILY ORAL	

Date:11/18/98ISR Number: 3160814-5Report Type:Expedited (15-DaCompany Report #98F--11010
Age:63 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Condition Aggravated Extrapyramidal Disorder Hemiplegia	Foreign Health Professional Other	Lioresal Mestinon Fonzylane Prozac Kardegic Glucor	PS SS SS SS SS SS		ORAL ORAL ORAL ORAL ORAL ORAL	15 MG, TID, ORAL 60 MG, DAILY, ORAL 600 MG, DAILY, ORAL 20 MG, DAILY, ORAL 300 MG, DAILY, ORAL 300 MG, DAILY, ORAL	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/18/98ISR Number: 3160815-7Report Type:Expedited (15-DaCompany Report #98--D11022
Age:12 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Electrolyte Imbalance	Foreign	Lioresal	PS			DAILY	
		Health Professional Other	Klistier	SS				

Date:11/20/98ISR Number: 3161642-7Report Type:Expedited (15-DaCompany Report #98USA11687
Age:79 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Aspiration	Health Professional	Baclofen	PS		ORAL	5 MG, TID, ORAL	
	Respiratory Failure							
	Sedation		Epogen Solution For Injecti	C				
			Prilosec	C				
			Trovan	C				

Date:11/23/98ISR Number: 3163511-5Report Type:Expedited (15-DaCompany Report #98USA11651
Age:59 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Asthenia	Health Professional	Baclofen	PS		ORAL	5 MG, TID, ORAL	24 HR
Hospitalization - Initial or Prolonged	Blood Pressure Increased							
	Coma		Prozac	C				
Disability	Dyspnoea		Catapres	C				
	Facial Palsy		Procardia Capsules	C				
	Hypotension		Erythromycin Solution For Infusion	C				
	Loss Of Consciousness							
	Nausea		Regular Insulin Suspension	C				
	Stridor							
	Tongue Oedema		Compazine Tablet	C				

Date:11/24/98ISR Number: 3163510-3Report Type:Expedited (15-DaCompany Report #98F-11034
Age:58 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Conduction Disorder	Foreign	Lioresal (Baclofen)	PS		ORAL	30 MG, DAILY, ORAL	
	Myocardial Infarction	Health						
	Ventricular Tachycardia	Professional	Tenormine (Atenolol)	SS		ORAL	ORAL	
			Dantrium (Dantrolene Sodium)	SS		ORAL	ORAL	
			Lexomil	C				
			Fonzylane	C				

Date:11/25/98ISR Number: 3164084-3Report Type:Direct Company Report #
Age:74 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Urinary Retention		Baclofen	PS				
			Insulin Reg Human	C				
			Acetaminophen/Codeine	C				
			Clindamycin	C				

Terazosin	C
Petrolatum	C
Camphor 0.5%/Menthol 0.5%	C
Cetirizine	C
Insulin Lente Human	C
Lansoprazole	C
Dorzolamide	C
Timolol	C
Ferrous Sulfate	C
Calcium Carbonate	C
Furosemide	C
Nitroglycerin	C
Bisacodyl	C
Albuterol	C
Acertaminophen	C
Hydroxyzine Hcl	C
Silver Sulfadiazine	C
Finasteride	C
Selenium Sulf	C
Petrolatum Hydrophilic	C
Neutrogena Soap	C
Ketoconazole	C
Casanthranol/Docusate	C
Aspirin Ec	C
Nifedipine (Adalat Cc)	C

Date:12/02/98ISR Number: 3165923-2Report Type:Expedited (15-DaCompany Report #98F--10947
Age:34 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Coma Hypertonia Overdose Pneumonia Aspiration Pregnancy Test Positive Status Epilepticus Suicide Attempt Therapeutic Agent	Foreign Health Professional Other	Lioresal Adalate	PS SS		ORAL ORAL	300 MG, ONCE 10 DF, ONCE	

	Toxicity					
	Vomiting					

Date:12/03/98ISR Number: 3166455-8Report Type:Expedited (15-DaCompany Report #98D--11022
Age:12 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Conversion Disorder	Foreign	Lioresal (Baclofen)	PS		ORAL	DAILY, ORAL	
	Electrolyte Imbalance	Health	Klistier (Travad					
	Fatigue	Professional	Phospate Enema)	SS		RECTAL	RECTAL	
	Gastrooesophageal Reflux Disease	Other						
	Hypernatraemia							
	Hypokalaemia							
	Metabolic Alkalosis							

Date:12/03/98ISR Number: 3166654-5Report Type:Expedited (15-DaCompany Report #500705
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Arrhythmia	Foreign	Dantrium	PS		ORAL	50MG DAILY	
	Myocardial Infarction	Health	Lioresal	SS		ORAL	30MG DAILY	
		Professional	Ditropan	C				
			Fonzylane	C				
			Lexomil	C				
			Lioresal	C				
			Tenormine	C				

Date:12/09/98ISR Number: 3168692-5Report Type:Expedited (15-DaCompany Report #R98-068
Age:49 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Convulsion	Consumer	Baclofen	PS	Watson Laboratories, Miami Div.		2 QID	
	Medication Error	Other						
			Amantidine	C				

Date:12/14/98ISR Number: 3170601-XReport Type:Expedited (15-DaCompany Report #970629
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Pyrexia	Health	Lioresal	PS		INTRATHECAL	INTRATHECAL ROUTE	
		Professional						

Date:12/14/98ISR Number: 3170602-1Report Type:Expedited (15-DaCompany Report #970630
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Death	Convulsion	Health	Lioresa	PS		
INTRATHECAL	INTRATHECAL					
		Professional				
ROUTE						

Date:12/17/98ISR Number: 3171745-9Report Type:Expedited (15-DaCompany Report #98CDN10565
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Respiratory Arrest	Foreign	Lioresal	PS		ORAL	7MG ONCE ORAL	
		Health Professional Other						

Date:12/21/98ISR Number: 3172394-9Report Type:Expedited (15-DaCompany Report #98F--11034
Age:58 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Conduction Disorder	Foreign	Lioresal (Baclofen)	PS		ORAL	30 MG DAILY	
	Left Ventricular Failure	Health				ORAL		
	Myocardial Infarction	Professional	Tenormine (Atenolol)	SS		ORAL	100 MG DAILY	
	Ventricular Tachycardia	Other				ORAL		
			Dantrium (Dantrolene Sodium)	SS		ORAL	50 MG DAILY	
						ORAL		
			Lexomil	C				
			Ditropan	C				
			Fonzylane	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/05/99ISR Number: 3176750-4Report 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	Sedation		Baclofen	PS			10MG QD	
			Procan Sr	C				
			Coumadin	C				
			Dig	C				
			Perd Colace	C				
			Premarine	C				
			Provera	C				
			Fosomax	C				
			Zantac	C				

Date:01/05/99ISR Number: 3192864-7Report Type:Expedited (15-DaCompany Report #ZANA0319990441
Age:1 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Rectal Prolapse	Foreign Health Professional Distributor	Ternelin (Tizanidine Hydrochloride)	PS		ORAL	PER ORAL	
			Lioresal (Baclofen)	SS				
			Phenobal	C				
			Erythromycin	C				
			Baktar	C				
			Biothree	C				
			Millact	C				
			Phenobal	C				
			Erythromycin	C				
			Baktar	C				
			Biothree	C				
			Millact	C				
			Mucodyne	C				
			Leftose	C				
			Bisolvone	C				
			Zaditen	C				

Date:01/07/99ISR Number: 3177760-3Report Type:Expedited (15-DaCompany Report #98-10-0239
Age:48 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Aphasia Bladder Disorder	Consumer	Baclofen	PS	Zenith Goldline Pharm.	ORAL	10MG BID ORAL	
	Eyelid Disorder		Darvocet-N	C				
	Faecal Incontinence		Arthotec	C				
	Feeling Abnormal							
	Hearing Impaired							
	Irritable Bowel Syndrome							
	Paralysis							

Date:01/07/99ISR Number: 3178238-3Report Type:Expedited (15-DaCompany Report #111395
Age:35 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Bilirubin Increased Cholestasis	Foreign Health	Rivotril (Clonazepam) 2.5					
	Jaundice	Professional	Mg/Ml	PS		ORAL	ORAL	
	Pruritus	Other	Azantac (Ranitidine)	SS		ORAL	DAILY ORAL	
			Di-Antalvic (Acetaminophen/Propo					

				xyphene Hydrochloride)	SS		ORAL
6 DOSE FORM DAILY ORAL							
				Imurel (Azathioprine)	SS		ORAL
2 DOSE DORM DIALY ORAL							
				Minidril (Ethinyl Estradiol/Levonorgestrel)	SS		ORAL
1 DOSE FORM DAILY ORAL							
				Lioresal (Baclofen) 10 Mg	SS		ORAL
30 MG DAILY ORAL							

Date:01/07/99ISR Number: 3179582-6Report Type:Expedited (15-DaCompany Report #98D-11022
Age:12 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Anorexia	Foreign	Lioresal	PS		ORAL	5MG DIALY	
	Electrolyte Imbalance	Health				ORAL		3 DAY
	Fatigue	Professional	Klistier (Travad					
	Hypernatraemia	Other	Phosphate Enema)	SS		RECTAL	1 DF, DAILY	
	Hypokalaemia					RECTAL		8 DAY
	Metabolic Alkalosis		Liskantin	C				
	Pyrexia		Tegretal	C				
			Rivotril	C				
			Antra	C				

Date:01/08/99ISR Number: 3179579-6Report Type:Expedited (15-DaCompany Report #99USA10012
Age:18 MON Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Nephrosclerosis Nephrotic Syndrome Scar	Health Professional	Lioresal Ibuprofen	PS SS		ORAL ORAL	DAILY	ORAL

Date:01/12/99ISR Number: 3180803-4Report Type:Expedited (15-DaCompany Report #99USA10012
Age:18 MON Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Cerebral Palsy Glomerulonephritis Hyperbilirubinaemia Kernicterus Nephrosclerosis Nephrotic Syndrome Scar	Health Professional	Lioresal Ibuprofen	PS SS		ORAL ORAL	20 MG, DAILY,	ORAL

Date:01/21/99ISR Number: 3203026-9Report Type:Expedited (15-DaCompany Report #98F-11092
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Ileus Paralytic	Foreign Health Professional	Lioresal (Baclofen) Solution For Injection	PS		INTRATHECAL	140 MCG DAILY	INTRATHECAL

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/21/99ISR Number: 3387083-5Report Type:Periodic Company Report #97USA11985
Age:54 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Liver Function Test Abnormal	Health Professional	Lioresal Tablet 10mg (Baclofen)	PS		ORAL	10 MG, TID,	
ORAL								4 DAY

Date:01/21/99ISR Number: 3387088-4Report Type:Periodic Company Report #97USA12197
Age:78 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Confusional State Sedation	Health Professional	Lioresal Tablet 10 Mg (Baclofen)	PS		ORAL	10 MG, QID,	
ORAL								
			Nitro	C				
			Diuretics	C				
			Potassium	C				

Date:01/21/99ISR Number: 3387091-4Report Type:Periodic Company Report #98USA10469
Age:54 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Nasal Oedema Parosmia	Health Professional	Lioresal Tablet 10 Mg (Baclofen)	PS		ORAL	10 MG, TID,	
ORAL								

Date:01/21/99ISR Number: 3387095-1Report Type:Periodic Company Report #98USA10780
Age:25 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

	Blood Prolactin Increased	Health Professional	Lioresal Tablet (Baclofen)	PS		ORAL

DAILY, ORAL

Date:01/21/99ISR Number: 3387097-5Report Type:Periodic Company Report #98USA10779
Age:55 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Abnormal Faeces	Health Professional	Lioresal Tablet 5mg (Baclofen)	PS		ORAL		

5 MG, TID,

ORAL

Date:01/21/99ISR Number: 3387100-2Report Type:Periodic Company Report #98USA10794
Age:23 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Dystonia	Health Professional	Lioresal Tablet (Baclofen)	PS		ORAL		
	Eye Movement Disorder							
	Hyperhidrosis							
	Pain							

DAILY, ORAL

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/21/99ISR Number: 3387102-6Report Type:Periodic Company Report #98USA11248
Age:72 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Pollakiuria	Consumer	Lioresal Tablet 20mg (Baclofen)	PS		ORAL	20 MG, QD,	ORAL
			Imipramine Tablet	C				
			Diflucan	C				
			Zantac	C				

Date:01/21/99ISR Number: 3387103-8Report Type:Periodic Company Report #98USA11305
Age:65 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Sedation	Health Professional	Lioresal Tablet 10 Mg (Baclofen)	PS			10 MG, BID,	ORAL

Date:01/21/99ISR Number: 3387107-5Report Type:Periodic Company Report #98USA11316
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Dystonia	Health Professional	Lioresal Tablet (Baclofen)	PS		ORAL	DAILY, ORAL	

Date:01/21/99ISR Number: 3387108-7Report Type:Periodic Company Report #98USA11326
Age:43 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Ineffective	Health	Lioresal Tablet					

	Loss Of Libido	Professional	(Baclofen)	PS			ORAL
DAILY, ORAL							
			Betaseron	C			

Date:01/21/99ISR Number: 3387111-7Report Type:Periodic Company Report #98USA11375
Age:23 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Liver Function Test Abnormal	Health Professional	Lioresal Tablet 20 Mg (Baclofen)	PS		ORAL	20 MG, TID, ORAL	
			Compazine Solution For Injection	C				
			Amitriptyline Tablet	C				
			Carafate Tablet	C				
			Zanaflex Tablet	C				
			Amitriptyline Tablet	C				
			Motrin Tablet	C				
			Ultram Tablet	C				

Date:01/21/99ISR Number: 3387112-9Report Type:Periodic Company Report #97USA12443
Age:48 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Hepatitis	Health Professional	Baclofen Tablet Unknown (Baclofen)	PS		ORAL	DAILY, ORAL	7 DAY
		Other	Tizanidine					

			Hydrochloride (Tizanidine Hydrochloride)	SS			ORAL
ORAL							
			Prozac	C			
			Wellbutrin	C			

Date:01/21/99ISR Number: 3387114-2Report Type:Periodic Company Report #98USA10706
Age:47 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Convulsion	Health	Baclofen Tablet					
	Hallucination	Professional	(Baclofen)	PS				
DAILY								
			Ditropan	C				

Date:01/21/99ISR Number: 3387117-8Report Type:Periodic Company Report #98USA10945
Age:6 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Haematuria	Health	Baclofen Tablet					
		Professional	(Baclofen)	PS				
DAILY, ORAL								

Date:01/21/99ISR Number: 3387120-8Report Type:Periodic Company Report #98USA11428
Age:52 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Nocturia	Health	Baclofen Tablet 20					
	Pollakiuria	Professional	Mg (Baclofen)	PS				
20 MG, TID,								
	Urinary Incontinence							
ORAL								
			Valium Tablet	C				
			Ditropan Tablet	C				
			Na	C				

Date:01/21/99ISR Number: 3387123-3Report Type:Periodic Company Report #98USA11708
Age:42 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Abnormal Behaviour	Health Professional	Baclofen Tablet (Baclofen)	PS		ORAL	DAILY, ORAL	
	Lethargy							
	Tongue Disorder		Remeron Tablet	C				
			Prilosec Tablet	C				
			Valium Tablet	C				

Date:01/22/99ISR Number: 3384582-7Report Type:Periodic Company Report #R98-017
Age:60 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Coordination Abnormal	Health Professional	Baclofen Tablets, (Strength Unknown) Watson, Miami	PS	Watson, Miami		1/2 (10 MG TID)	2 DAY
			Procardia Xl	C				
			Cardura	C				
			Zoloft	C				
			Leukeran	C				
			Nephrovit Qd	C				
			Quinidine	C				
			Ambien	C				

				Ticlid	C		

Date:01/22/99ISR Number: 3384588-8Report Type:Periodic Company Report #R98-024
Age:39 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Paraesthesia	Health Professional	Baclofen Tablets, 10 Mg, Watson Laboratories, Miami Div.	PS	Watson Laboratories, Miami Div.		10 MG TID	

Date:01/22/99ISR Number: 3384592-XReport Type:Periodic Company Report #R98-057
Age:46 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Ineffective	Consumer	Baclofen Tablets, 10 Mg, Watson Miami	PS	Watson Miami		QHS	
			Ridaura	C				
			Naprosyn	C				
			Seldane	C				
			Potassium	C				
			Methotrexate	C				
			Leucovorin	C				
			Oral Contraceptive (Ortho Novum 777)	C				
			Prednisone	C				

Date:01/22/99ISR Number: 3384594-3Report Type:Periodic Company Report #R98-065
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Dermatitis Hypoaesthesia	Consumer	Baclofen Tablets, 10 Mg, Watson Miami	PS	Watson Miami		1QAM, 1 NOON,	

1/2 QPM, 1/2

QHS

				Valium 80 Mg	C		
				Darvon-N	C		

Date:01/22/99ISR Number: 3384595-5Report Type:Periodic Company Report #R98-067
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
	Chronic Fatigue Syndrome	Health	Baclofen Tablets, 10			
	Epistaxis	Professional	Mg, Watson Miami	PS	Watson Miami	
1 OD (1/2						
	Eye Haemorrhage					
TAB)						
	Vaginal Haemorrhage		Chlortrimeton Qd	C		
			Entex	C		
			Berroca Plus	C		
			Qd V &C 500 Mg			
			(Ester-C) Qd	C		
			Locithin Qd	C		
			Vitamin E (Several			
			X/Week) Zinc Prn	C		
			Betacarotene (Prn)	C		
			Garlic (Prn)	C		
			Siberian Ginseng	C		

				Ginger Tea W/Licorice Root	C		

Date:01/25/99ISR Number: 3185447-6Report Type:Expedited (15-DaCompany Report #99USA10036
Age:46 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Accidental Overdose	Health	Baclofen	PS		ORAL	DAILY , ORAL
	Aggression	Professional					
	Drug Ineffective						
	Medication Error						

Date:01/25/99ISR Number: 3185448-8Report Type:Expedited (15-DaCompany Report #99USA10037
Age:40 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Gastrointestinal	Health	Lioresal	PS		ORAL	10 MG , Q8H, ORAL
	Obstruction	Professional					
	Peritonitis		Dilantin	C			
	Sepsis		Synthroid	C			

Date:01/26/99ISR Number: 3194364-7Report Type:Periodic Company Report #9830427
Age:44 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Other	Drug Ineffective	Consumer	Viagra Tablets	PS		ORAL	50 MG TOTAL
	Erectile Dysfunction	Health					PRN ORAL
		Professional	Baclofen	SS		ORAL	ORAL
			Betaseron	C			
			Amantidine	C			
			Desyrel	C			

Date:01/27/99ISR Number: 3186838-XReport Type:Expedited (15-DaCompany Report #B043818
Age:40 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Epilepsy	Foreign	Videx	PS		ORAL	300 MG QD	
		Health Professional	Baclofen	SS		ORAL	30 MG QD	
		Other	Bactrim Forte	C				
			Viracept	C				
			Viramune	C				
			..	C				
			..	C				
			..	C				
			..	C				
			..	C				

Date:01/28/99ISR Number: 3187763-0Report Type:Expedited (15-DaCompany Report #R98-068
Age:49 YR Gender:Female I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Appetite Disorder
	Convulsion
	Difficulty In Walking
	Disturbance In Attention

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Medication Error Nausea Sedation	Consumer Other	Baclofen	PS	Watson Labs, Miami Div.		2 QID TABLETS	
			Amantidine	C				

Date:01/29/99ISR Number: 3188604-8Report Type:Expedited (15-DaCompany Report #98J-10423
Age:12 MON Gender: I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Rectal Prolapse	Foreign	Lioresal Unknown (Baclofen)	PS		ORAL	5 MG, DAILY, ORAL	
			Ternelin Unknown (Tizanidine)	SS		ORAL	1 MG, DAILY, ORAL	

Date:01/29/99ISR Number: 3199029-3Report Type:Periodic Company Report #990637
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hypotonia Paraesthesia Spinal Disorder	Consumer	Lioresal Intrathecal (Baclofen Injection)	PS		INTRATHECAL	140 MCG/DAY	

Date:02/01/99ISR Number: 3188925-9Report Type:Direct Company Report #
Age:47 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Hospitalization -	Respiratory Distress	Health	Baclofen	PS		
INTRATHECAL IT						
Initial or Prolonged	Vomiting	Professional				

Date:02/08/99ISR Number: 3198526-4Report Type:Direct Company Report #
Age:51 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Coordination Abnormal		Baclofen 10mg	PS		ORAL	10MG PO	
Initial or Prolonged	Dysarthria		Humulin L	C				
	Insomnia		Colace Qd	C				
	Sedation		Niferex Forte	C				
	Tremor		Ecasa	C				
			Coumadin	C				
			Nephrocaps	C				
			Nahco3	C				
			Phoslo	C				
			Catapress	C				
			Synthroid	C				

Date:02/16/99ISR Number: 3199725-8Report Type:Expedited (15-DaCompany Report #99F-10094
Age:35 YR Gender:Female I/FU:I

Outcome	PT
Hospitalization -	Blood Bilirubin Increased
Initial or Prolonged	Hepatic Function Abnormal
	Hepatitis Cholestatic

		Jaundice Pruritus					
Dose	Duration		Report Source	Product	Role	Manufacturer	Route
			Foreign Health	Lioresal Tablet (Baclofen)	PS		ORAL
30 MG, DAILY,							
ORAL	12 MON		Professional				
			Other	Imurel Tablet (Azathioprine)	SS		ORAL
100 MG,							
DAILY, ORAL	9 YR						
				Di-Antalvic Capsule (Aporex)	SS		ORAL
6 DF, DAILY,							
ORAL							
				Rivotril Solution (Clonazepam)	SS		ORAL
ORAL							
				Minidril Tablet (Neovlar 21)	SS		ORAL
1 DF, DAILY,							
ORAL							
				Azantac Unknown (Ranitidine Hydrochloride)	SS		ORAL
1 DF, DAILY,							
ORAL	7 MON						

Date:02/17/99ISR Number: 3200636-XReport Type:Expedited (15-DaCompany Report #98D--10901
Age:30 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Life-Threatening	Condition Aggravated	Foreign	Lioresal Solution	PS		
INTRATHECAL	DAILY,					
	Dysphagia	Health				
INTRATHEKAL						
	Paralysis Flaccid	Professional	Bactrim	C		
	Quadriplegia		Mylepsinum	C		

			Akatinol Memantine	C		

Date:02/17/99ISR Number: 3200643-7Report Type:Expedited (15-DaCompany Report #990645
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Dysphagia	Health	Lioresal	PS		INTRATHECAL	DAILY,	
	Paralysis Flaccid	Professional				INTRATHECAL		
	Paresis							
	Quadriplegia							

Date:02/18/99ISR Number: 3203378-XReport Type:Expedited (15-DaCompany Report #99USA10036
Age:46 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Accidental Overdose	Health	Baclofen Tablet 10					
	Aggression	Professional	Mg (Baclofen)	PS		ORAL	900 MG,	
	Confusional State						DAILY, ORAL	
	Convulsion							
	Drug Ineffective							

Date:02/19/99ISR Number: 3203023-3Report Type:Expedited (15-DaCompany Report #990633
Age: Gender:Not SpecifiI/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Spastic Paralysis	Other	Lioresal Intrathecal (Baclofen Injection)	PS		INTRATHECAL	140 MCG,	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

DAILY,

INTRATHECAL

Date:02/25/99ISR Number: 3208015-6Report Type:Expedited (15-DaCompany Report #200701
Age:13 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Confusional State Illusion Overdose Psychotic Disorder	Foreign Other	Naproxen (Naproxen) Baclofen (Baclofen)	PS SS		ORAL ORAL	10 DOSE FORM	

Date:02/25/99ISR Number: 3211358-3Report Type:Periodic Company Report #9805405
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Dependence Hypertonia Influenza Like Illness Insomnia	Consumer	Zoloft Tablets Baclofen Ambien Provera Climara	PS SS SS C C		ORAL	50.00 MG	TOTAL;DAILY;ORAL

Date:03/05/99ISR Number: 3212283-4Report Type:Direct Company Report #
Age:11 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Medication Error		Baclofen	PS		INTRATHECAL	385 MCG/DAY	

Initial or Prolonged
INTRATHECAL

Date:03/15/99ISR Number: 3220879-9Report Type:Expedited (15-DaCompany Report #99USA10037
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Gastrointestinal Obstruction	Health Professional	Lioresal Tablet 10 Mg (Baclofen)	PS		ORAL	10 MG, Q8H, ORAL	
	Peritonitis							
	Sepsis		Dilantin Tablet	C				
			Synthroid Tablet	C				

Date:03/16/99ISR Number: 3222091-6Report Type:Expedited (15-DaCompany Report #001-0945-990140
Age:55 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Drug Interaction	Health Professional	Neurontin Capsules 300 Mg (Gabapentin)	PS			900 MG (300 MG, TID)	
Hospitalization - Initial or Prolonged	Hepatic Necrosis							
	Hepatotoxicity							
	Multi-Organ Failure		(Ciclosporin)	SS				
			(Azathioprine)	SS				
			(Prednisone)	SS				
			(Ranitidine)	SS				
			(Baclofen)	SS				
			(Atorvastatin)	SS				
			(Ketoconazole)	SS				
			Acetaminophen (Paracetamol)	SS				

			Niacin (Nicotinic Acid)	SS		
			Dilaudid (Hydromorphone Hydrochloride)	SS		
			(Alprazolam)	SS		
			(Losartan)	SS		
			(Atenolol)	SS		
			(Diltiazem)	C		

Date:03/19/99ISR Number: 3223446-6Report Type:Periodic Company Report #98F--11092
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Ileus Paralytic	Foreign Health Professional Other	Lioresal Solution For Injection (Baclofen)	PS		INTRATHECAL	140 MCG, DAILY, INTRATHECAL	
			Lioresal Tablet (Baclofen)	SS		ORAL		

Date:03/19/99ISR Number: 3223690-8Report Type:Expedited (15-DaCompany Report #98J--10368
Age:63 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Asthenia Depressed Level Of Consciousness Disorientation Dry Mouth Insomnia Sedation	Foreign Health Professional	Lioresal Tablet (Baclofen)	PS		ORAL	10 MG ONCE ORAL	
			Calcium Carbonate	C				
			Tegretol	C				
			Zantac	C				
			Landesen	C				
			Lendormin	C				
			Norvasc	C				

			Imidapril	C			

Date:04/06/99ISR Number: 3234694-3Report Type:Expedited (15-DaCompany Report #99GB-10214
Age:13 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Confusional State	Foreign	Baclofen	PS		ORAL	DAILY, ORAL
Initial or Prolonged	Hallucination	Health	Naproxen	SS		ORAL	ORAL
	Illusion	Professional					
	Intentional Misuse	Other					
	Psychotic Disorder						

Date:04/09/99ISR Number: 3236615-6Report Type:Expedited (15-DaCompany Report #99USA10387
Age:47 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Ileus Paralytic	Health	Lioresal Tablet				
Initial or Prolonged		Professional	(Baclofen)	PS		ORAL	DAILY, ORAL
			Ditropan	C			
			Reglan	C			
			Megace	C			

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/12/99ISR Number: 3238057-6Report Type:Expedited (15-DaCompany Report #98D-11022
Age:14 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Anorexia	Health	Lioresal (Baclofen)	PS		ORAL	5 MG DAILY,	
Hospitalization -	Apathy	Professional						
ORAL							3	DAY
Initial or Prolonged	Electrolyte Imbalance	Other	Travad	SS				
RECTAL							1 DF, DAILY,	
Other	Fatigue							
RECTAL							8	DAY
	Gastrooesophageal Reflux		Rivotril	C				
	Disease		Antra	C				
	Hypernatraemia							
	Hypokalaemia							
	Metabolic Alkalosis							
	Oral Intake Reduced							
	Pyrexia							
	Screaming							

Date:04/14/99ISR Number: 4515941-4Report Type:Direct Company Report #USP 52243
Age:70 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Gastrointestinal		Baclofen	PS	Goldline			
TABLET								
	Haemorrhage		Lotensin	SS	Novartis			
TABLET								
	Haemorrhage							
	Medication Error							
	Myocardial Infarction							

Date:04/22/99ISR Number: 3244511-3Report Type:Direct Company Report #
Age:70 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Encephalopathy	Health	Baclofen					

	PS		ORAL	10 MG PO TID	2	DAY		
Hospitalization -	Multiple Sclerosis		Professional		Neurontin		SS	
300MG MWF	10	DAY						
Initial or Prolonged	Respiratory Acidosis				Synthroid		C	
	Sepsis				Colace		C	
					Phos-Lo		C	
					Nephron Caps		C	
					Cortisone		C	
					Senokot		C	
					Prevacid		C	
					Restoril		C	
					Ventolin		C	
					Atrovent		C	
					Calcitonin		C	
					Vicodin		C	

Date:04/22/99ISR Number: 3244513-7Report Type:Direct Company Report #
Age:53 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Aphasia	Health	Baclofen	PS		ORAL	10 MG BID PRN	
Hospitalization -	Confusional State	Professional						
BUT PATIENT								
Initial or Prolonged	Encephalopathy							
ONLY TOOK 3								
	Grand Mal Convulsion							
PILLS TOTAL	3	DAY						
	Mental Impairment							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/23/99ISR Number: 3245793-4Report Type:Expedited (15-DaCompany Report #B0064757
Age:7 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Blood Creatinine	Foreign	Zinacef	PS			30 MG/KG /	
Hospitalization -	Increased	Health						THREE TIMES
Initial or Prolonged	Blood Urea Increased	Professional						PER /
Other	Dehydration						INTRAGASTRIC	
	Drug Toxicity		Vigabatrin	SS			750 MG/KG /	
	Hepatocellular Damage							TWICE PER
	Hypernatraemia							DAY/
	Renal Failure Acute						INTRAGASTRIC	
			Baclofen	SS			5 G / THREE	
								TIMES PER DAY
								/
							INTRAGASTRIC	
			Cephalexin	SS			250 MG /	
								TWICE PER DAY
								/
							INTRAGASTRIC	
			Carbamazepine	SS			300 MG /	
								TWICE PER DAY
								/
							INTRAGASTRIC	

Date:04/27/99ISR Number: 3246969-2Report Type:Direct Company Report #
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Gastrointestinal Haemorrhage		Baclofen	PS	Goldline			
	Haemorrhage		Lotensin (Benazepril)	SS	Novartis			
	Medication Error							
	Myocardial Infarction							

Date:04/27/99ISR Number: 3247009-1Report Type:Expedited (15-DaCompany Report #R99-014
Age:53 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Convulsion	Health Professional	Baclofen Tablets (Strength Unk)					
Other Required Intervention to Prevent Permanent Impairment/Damage	Depressed Level Of Consciousness		Watson Labs.,Miami	PS	Watson Labs.,Miami			
			Megace	C				
			Tums	C				
			Norvasc (Prn Hypertension)	C				
			Synthroid	C				
			Epogen	C				
			Ativan Qhs	C				
			Prozac (Qhs)	C				

Date:04/29/99ISR Number: 3249987-3Report Type:Expedited (15-DaCompany Report #001-0945-990140
Age:55 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Drug Interaction	Health Professional	Neurontin Capsules 300 Mg (Gabapentin)	PS			900 MG (300 MG, TID)	
Hospitalization - Initial or Prolonged	Hepatic Necrosis							
	Hepatotoxicity							
	Multi-Organ Failure		Ciclosporin	SS				

Azathioprine	SS
Prednisone	SS
Losartan	SS
Atenolol	SS
Diltiazem	SS
Ranitidine	SS
Alprazolam	SS
Baclofen	SS
Dilaudid (Hydromorphone Hydrochloride)	SS
Atorvastatin	SS
Niacin (Nicotinic Acid)	SS
Ketoconazole	SS
Acetaminophen (Paracetamol)	SS
Ambien	C
Aspirin	C
Dicyclomine	C
Lasix	C
Lonox	C
Nizoral	C
Vitamin E	C
Niaspan	C
Erythromycin	C
Tylenol	C

Date:04/30/99ISR Number: 3251124-6Report Type:Expedited (15-DaCompany Report #99HQ-10171
Age:42 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agitation Bradycardia Coma Confusional State Cough Delirium Disorientation Drug Withdrawal Syndrome Dysarthria Haemodialysis	Foreign Literature Health Professional	Baclofen Unknown (Baclofen)	PS		ORAL	200 MG DAILY	ORAL

Hallucination
Hyporeflexia
Hypotension
Hypotonia
Insomnia
Loss Of Consciousness
Lung Infiltration
Pyrexia
Respiratory Depression
Simple Partial Seizures

Date:05/03/99ISR Number: 3252140-0Report Type:Expedited (15-DaCompany Report #990665
Age: Gender:Male I/FU:I

Outcome PT
Hospitalization - Csf White Blood Cell
Initial or Prolonged Count Positive

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Meningitis							
	Pyrexia							
		Health Professional	Lioresal (R) Intrathecal (Baclofen Injection)	PS				
						INTRATHECAL	UNK, DAILY,	
						INTRATHECAL		

Date:05/03/99ISR Number: 3252141-2Report Type:Expedited (15-DaCompany Report #990665
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Csf Culture Positive	Health Professional	Lioresal (R) Intrathecal (Baclofen Injection)	PS				
	Mechanical Complication Of Implant					INTRATHECAL	UNK, DAILY,	
	Meningitis					INTRATHECAL		
	Pyrexia							

Date:05/03/99ISR Number: 3252629-4Report Type:Expedited (15-DaCompany Report #98--D10338
Age:61 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Asthma	Foreign Health Professional	Lioresal Tablet (Baclofen)	PS		ORAL	75 MG, DAILY,	
	Condition Aggravated					ORAL		
	Drug Interaction		Theophyllin Unknown (Theophyllin)	SS			200 MG, DAILY	
			Catapressan (Clonidine Hydrochloride)	SS				

Date:05/04/99ISR Number: 3256747-6Report Type:Expedited (15-DaCompany Report #99F--10373
Age:62 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Encephalopathy	Foreign	Lioresal Tablet (Baclofen)	PS		ORAL	5 MG,	DAILY,ORAL 6 DAY
	Personality Change Due To A General Medical Condition	Health Professional						
		Other	Rifadine Capsule (Rifampicin)	SS		ORAL	ORAL	
			Inh Tablet (Isoniazid)	SS		ORAL	ORAL	
			Rimifon Tablet (Isoniazid)	SS		ORAL	ORAL	
			Amlor Capsule	C				
			Triatec Tablet	C				

Date:05/07/99ISR Number: 3256703-8Report Type:Expedited (15-DaCompany Report #99USA10488
Age:30 MON Gender:Male I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Condition Aggravated
	Muscle Rigidity
	Neutrophil Count Increased
	Pyrexia
	Staphylococcal Sepsis

	White Blood Cell Count Increased						
		Report Source	Product	Role	Manufacturer	Route	Dose Duration
		Health Professional	Baclofen Tablet 5 Mg (Baclofen)	PS			INTRATHECAL 5 MG, TID, GASTRIC DRIP
			Amphotericin B Solution For Infusio	C			
			Ceftazidime	C			
			Clindamycin	C			
			Tylenol	C			
			Benadryl	C			
			Lactinex	C			
			Nystatin	C			

Date:05/17/99ISR Number: 3264030-8Report Type:Expedited (15-DaCompany Report #8-99130-093A
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Other	Respiratory Arrest	Foreign Health Professional	Efexor Tablets (Venlafaxine Hydrochloride)	PS		ORAL	ORAL
			Baclofen Tablets	SS		ORAL	ORAL
			Temazepam	SS			
			Unspecified Medications	C			

Date:05/19/99ISR Number: 3265938-XReport Type:Expedited (15-DaCompany Report #G99-245 (99F-10373)
Age:62 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Coma Confusional State Electroencephalogram	Foreign Health Professional	Lioresal Tablet (Baclofen)	PS		ORAL	5 MG DAILY ORAL 6 DAY

	Abnormal Encephalopathy	Other	Rifadine Capsules (Rifampicin)	SS		ORAL
ORAL						
	Overdose Personality Change Due To A General Medical Condition		Inh Tablet (Isoniazid)	SS		ORAL
ORAL						
			Rimifan Tablet (Isoniazide)	SS		ORAL
ORAL						
			Amlor Capsule	C		
			Triatec Tablet	C		

Date:05/19/99ISR Number: 3330432-4Report Type:Periodic Company Report #5833/20771
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
	Pain	Consumer	Detrol Tablets	PS		ORAL
		Company Representative	Baclofen	SS		

Date:05/20/99ISR Number: 3265117-6Report Type:Expedited (15-DaCompany Report #99-05-0121
Age:70 YR Gender:Male I/FU:I

Outcome
Death
Hospitalization -

Initial or Prolonged

	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Encephalopathy	Health	Baclofen Tablets	PS		ORAL	10MG TID ORAL	
	Multiple Sclerosis	Professional	Neurontin Tablets	SS		ORAL	300MG MWF	
	Respiratory Acidosis						ORAL	
	Sepsis		Synthroid	C				
			Colace	C				
			Nephrocaps	C				
			Cortisone	C				
			Senokot	C				
			Prevacid	C				
			Restoril	C				
			Ventolin	C				
			Vicodin	C				
			Atrovent	C				
			Calcitonin	C				

Date:05/20/99ISR Number: 3265118-8Report Type:Expedited (15-DaCompany Report #99-05-0122
Age:53 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Grand Mal Convulsion	Health	Baclofen - Zenith					
Hospitalization -	Mental Impairment	Professional	Goldline Pharm.					
Initial or Prolonged	Speech Disorder		Tablets	PS	Zenith Goldline Pharm.	ORAL	10MG BID ORAL	

Date:05/21/99ISR Number: 3268966-3Report Type:Direct Company Report #
Age:39 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Hypersensitivity	Health	Propulsid 10mg &					
Hospitalization -	Malaise	Professional	Premarin 0.625mg	PS			DAILY	
Initial or Prolonged	Mechanical Complication		Premarin	SS				
Disability	Of Implant		Baclofen 10mg &					

Required Intervention to Prevent Permanent Impairment/Damage			Tynelos Extract Str	SS		
			Tynelo Extract Str	SS		
			Steffe Stainless Stell Plates + Screws	C		

Date:05/24/99ISR Number: 3269151-1Report Type:Expedited (15-DaCompany Report #99USA10565
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Hospitalization - Initial or Prolonged	Coma Haemodialysis Hypothermia Overdose Respiratory Failure	Health Professional	Lioresal Tablet (Baclofen)	PS		ORAL	DAILY, ORAL	

Date:05/26/99ISR Number: 3269925-7Report Type:Expedited (15-DaCompany Report #
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Overdose	Health Professional	Baclofen (Unknown Strenght) Watson					

Laboratories. Miami PS Watson Laboratories

Date:05/27/99ISR Number: 3271184-6Report Type:Expedited (15-DaCompany Report #001-0945-990421
Age:70 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Back Pain	Health	Neurontin					
	Encephalopathy	Professional	(Gabapentin)	PS			300 MG ON	
	Liver Function Test						MON, WED &	
	Abnormal						FRI, UNKNOWN	
	Mental Impairment		(Baclofen)	SS		ORAL	30 MG (10 MG,	
	Respiratory Acidosis						TID) PER ORAL	
	Sepsis		Colace (Docusate Sodium)	C				
			Phoslo (Calcium Acetate)	C				
			(Cortisone)	C				
			Nephrocaps (Folic Acid, Vitamins Nos)	C				
			Prevacid (Lansoprazole)	C				
			Restoril (Temazepam)	C				
			(Calcitonin)	C				
			Vicodin (Paracetamol, Hydrocodone Bitartrate)	C				
			Senokot (Senna Fruit)	C				
			Ventolin (Salbutamol)	C				
			Atrovent (Ipratropium Bromide)	C				
			Synthroid (Levothyroxine Sodium)	C				
			Cordarone (Amiodarone Hydrochloride)	C				

Date:06/01/99ISR Number: 3274301-7Report Type:Expedited (15-DaCompany Report #99GB-10342
Age: Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Complications Of Maternal Exposure To Therapeutic Drugs Convulsion Neonatal Drug Withdrawal Convulsions	Foreign Health Professional Other	Lioresal Unknown (Baclofen)	PS			DAILY	

Date:06/01/99ISR Number: 3274347-9Report Type:Expedited (15-DaCompany Report #99F-10446
Age:75 YR Gender:Male I/FU:I

Outcome	PT	Report Source
Hospitalization - Initial or Prolonged	Agitation Confusional State Medication Error	Foreign Health Professional

Other

Product	Role	Manufacturer	Route	Dose	Duration
Lioresal Tablet (Baclofen)	PS		ORAL	15 MG, DAILY,	ORAL 12 DAY
Topalgic Capsule (Tramadol Hydrochloride)	SS		ORAL	300 MG,	DAILY, ORAL 10 WK
Lipur Tablet	C				
Stilnox Tablet	C				
Spasfon Unknown	C				

Date:06/02/99ISR Number: 3274552-1Report Type:Expedited (15-DaCompany Report #99-05-0121
Age:70 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Encephalopathy	Health	Baclofen Tablets	PS		ORAL	10MG TID ORAL	
Hospitalization - Initial or Prolonged	Mental Impairment	Professional	Neurontin Tablets	SS		ORAL	300MG MWF ORAL	
	Respiratory Acidosis							
	Sepsis							
			Synthroid	C				
			Colace	C				
			Nephrocaps	C				
			Cortisone	C				
			Senokot	C				
			Prevacid	C				
			Restoril	C				
			Ventolin	C				
			Vicodin	C				
			Atrovent	C				
			Calcitonin	C				

Date:06/07/99ISR Number: 3277800-7Report Type:Expedited (15-DaCompany Report #99F--10373
Age:65 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Coma	Foreign Health Professional	Lioresal Tablet (Baclofen)	PS		ORAL	5 MG, DAILY,	
	Confusional State							
	Dialysis							
ORAL							6	DAY
	Electroencephalogram		Rifadine Capsule	C				
	Abnormal		Mopral Capsule	C				
	Encephalopathy		Amlor Capsule	C				
	Personality Change Due To		Inh Tablet	C				
	A General Medical		Pirilene Tablet	C				
	Condition		Triatec Tablet	C				
			Fozitec Tablet	C				

Date:06/09/99ISR Number: 3279012-XReport 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	Accident At Home		Baclofen	PS		ORAL	25MG PO Q 6H	
	Fall		Gabapentin	SS			300MG PO TID	
	Sedation							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/09/99ISR Number: 3279224-5Report Type:Expedited (15-DaCompany Report #207195
Age:51 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Depression Dyspnoea Intentional Misuse Lethargy Suicide Attempt	Health Professional	Valium Tablets (Diazepam)	PS		ORAL	PER ONE DOSE ORAL	
			Baclofen (Baclofen)	SS		ORAL	PER ONE DOSE ORAL	
			Ativan (Lorazepam)	SS		ORAL	1 PER ONE DOSE ORAL	
			Glyburide (Glyburide)	SS		ORAL	1 PER ONE DOSE ORAL	
			Glatiramer Acetate (Glatiramer Acetate)	SS		SUBCUTANEOUS	20 MG DAILY	
			Trazodone (Trazodone Hydrochloride)	SS		ORAL	1 PER ONE DOSE ORAL	
			Doxazosin Mesilate	C				
			Fosinopril Sodium	C				
			Naproxen	C				

Date:06/10/99ISR Number: 3280430-4Report Type:Expedited (15-DaCompany Report #99GB-10355
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Complications Of Maternal Exposure To Therapeutic	Foreign Health	Baclofen Unknown (Balcofen)	PS			DAILY	

	Drugs	Professional	Hydrocortisone			
	Premature Baby	Other	Unknown (Hydrocortisone)	SS		
			Tylex Unknown (Paracetamol + Codeine)	SS		

Date:06/11/99ISR Number: 3281482-8Report Type:Expedited (15-DaCompany Report #685/9866
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Intraventricular Haemorrhage	Foreign Consumer Company Representative	Solu-Cortef Sterile Powder	PS				
			Codeine Phosphate	SS				
			Baclofen	SS				

Date:06/11/99ISR Number: 3281491-9Report Type:Expedited (15-DaCompany Report #1895/17498
Age:51 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	Dyspnoea	Consumer	Micronase Tablets	PS		ORAL		
	Intentional Misuse		Baclofen	SS				
	Lethargy		Ativan	SS				
	Suicide Attempt		Valium	SS				
			Trazadone	SS				
			Copaxone	C				

Date:06/14/99ISR Number: 3282275-8Report Type:Expedited (15-DaCompany Report #WAES 99065034
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Intraventricular Haemorrhage	Foreign	Tab Hydrocortone (Hydrocortisone)	PS		ORAL		
			Codeine	SS				
			Baclofen	SS				

Date:06/14/99ISR Number: 3282517-9Report Type:Expedited (15-DaCompany Report #99GB-10361
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Complications Of Maternal Exposure To Therapeutic Drugs	Foreign Health Professional	Baclofen Unknown (Baclofen)	PS		TRANSPLACENTAL	UNK,	DAILY,
	Intraventricular Haemorrhage Neonatal Premature Baby	Other	Hydrocortisone Unknown (Hydrocortisone)	SS		TRANSPLACENTAL	UNK,	UNK,
			Codeine Phosphate Unknown (Codeine Phosphate)	SS		TRANSPLACENTAL	UNK,	UNK,

Date:06/14/99ISR Number: 3282551-9Report Type:Expedited (15-DaCompany Report #WAES 99065034
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Intraventricular	Foreign	Tab Hydrocortone					
Other	Haemorrhage	Company	(Hydrocortisone)	PS		ORAL	PO	
		Representative	Codeine	SS				
			Baclofen	SS				

Date:06/21/99ISR Number: 3288113-1Report Type:Expedited (15-DaCompany Report #99F--10510
Age:34 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Mouth Ulceration	Foreign Health Professional	Lioresal Tablet (Baclofen)	PS		ORAL	10 MG, BID, ORAL	
			Brexin Tablet (Piroxicam Beta Cyclodextrin)	SS		ORAL	40 MG, DAILY, ORAL	14 MON

Date:06/22/99ISR Number: 3290028-XReport Type:Expedited (15-DaCompany Report #199912638HMRI
Age:51 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Depression		Glyburide	PS		ORAL	PO	1 DAY
	Dyspnoea		Copaxone	SS				
	Intentional Misuse		Baclofen	SS			1	DAY
	Lethargy		Lorazepam	SS			1	DAY
	Suicide Attempt		Diazepam (Valium)	SS			1	DAY

			Trazodone	SS		
1 DAY						
			Doxazosin Mesilate	C		
			Naproxen	C		
			Fosinopril	C		

Date:06/23/99ISR Number: 3292386-9Report Type:Periodic Company Report #108820USA
Age:40 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Dysphagia Headache	Consumer	Copaxone (Glatiramer Acetate)	PS		
SUBCUTANEOUS 20 MILLIGRAMS QD	Hypertonia					
SUBCUTANEOUS	Neck Pain					
			Baclofen	SS		
			Neurontin	C		
			Baclofen	C		
			Zanaflex	C		
			Prevacid	C		
			Prozac	C		
			Voltaren	C		
			Macrodantin	C		
			Detrol	C		
			Demerol	C		

Date:06/25/99ISR Number: 3291427-2Report Type:Expedited (15-DaCompany Report #R99-036
Age:67 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Delusion Hallucination	Health Professional	Baclofen Tablets, 10 Mg. Watson Labs.	PS	Watson Labs	
10 MG BID						
			Sodium Bicarbonate	C		
			Lasix	C		
			Zithromax	C		
			Ativan	C		
			Lactulose	C		

Date:06/28/99ISR Number: 3292922-2Report Type:Expedited (15-DaCompany Report #99CDN10339
Age: Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Overdose	Foreign Health Professional Other	Lioresal Tablet (Baclofen)	PS		ORAL	UNK, DAILY, ORAL	

Date:06/29/99ISR Number: 3294411-8Report Type:Expedited (15-DaCompany Report #500790
Age:63 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Eosinophilia	Foreign Health Professional	Dantrium Capsules, Dose Unspecified (Dantrolene Sodium)	PS		ORAL	ORAL	
			Lioresal (Baclofen)	SS		ORAL	ORAL	
			Tegretol (Carbamazepine)	SS		ORAL	1200 MG	DAILY; ORAL
			...	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/30/99ISR Number: 3295119-5Report Type:Expedited (15-DaCompany Report #99F--10561
Age:50 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Arrhythmia	Foreign	Lioresal Tablet					
Life-Threatening	Malaise	Health	(Baclofen)	PS		ORAL	60 MG, DAILY,	
	Pulmonary Embolism	Professional					ORAL	
		Other	Tanakan Tablet (Ginkgo Tree Leaves Extract)	SS		ORAL	120 MG, DAILY,	ORAL
			Avonex Solution For Injection (Interferon Beta)	SS			INTRAMUSCULAR	INTRAMUSCULAR

Date:06/30/99ISR Number: 3295501-6Report Type:Expedited (15-DaCompany Report #WAES 99065034
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Haemorrhage Intracranial	Foreign	Tab Hydrocortone					
	Haemorrhagic Stroke	Other	(Hydrocortisone)	PS		ORAL	PO	
	Intraventricular Haemorrhage		Codeine	SS				
			Baclofen	SS				

Date:07/06/99ISR Number: 3297918-2Report Type:Expedited (15-DaCompany Report #208768
Age:51 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Depression	Other	Valium (Diazepam)	PS				
	Dyspnoea		Glyburide (Glyburide)	SS				
	Lethargy		Baclofen (Baclofen)	SS				
	Suicide Attempt		Ativan (Lorazepam)	SS				
			Trazodone (Trazodone					

			Hydrochloride)	SS		
			Copaxone (Glatiramer Acetate)	SS		
			Doxazosin Mesilate	C		
			Naproxen	C		
			Fosinopril	C		

Date:07/06/99ISR Number: 3298006-1Report Type:Expedited (15-DaCompany Report #99F--10570
Age:60 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Convulsion Electroencephalogram Abnormal Epilepsy Pain Pneumonia Pneumonia Aspiration	Foreign Health Professional	Lioresal Tablet (Baclofen)	PS		ORAL	60 MG DAILY ORAL	
			Bi-Profenid Tablet (Ketoprofen)	SS		ORAL	300 MG DAILY ORAL	4 DAY
			Anafranil Tablet (Clomipramine Hydrochloride)	SS		ORAL	50 MG DAILY ORAL	
			Topalgic Capsule (Tramadol Hydrochloride)	SS		ORAL	300 MG DAILY ORAL	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/06/99ISR Number: 3298147-9Report Type:Expedited (15-DaCompany Report #WAES 99065036
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Complications Of Maternal Exposure To Therapeutic Drugs	Foreign Other	Tab Hydrocortisone (Hydrocortisone)	PS		ORAL	PO	
	Haemorrhage Intracranial		Acetaminophen/Codeine Phosphate	SS				
	Premature Baby		Baclofen	SS				

Date:07/07/99ISR Number: 3298833-0Report Type:Expedited (15-DaCompany Report #8-99176-137A
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	Foreign Health	Orudis (Ketoprofen)	PS		ORAL	150 MG TWICE DAILY ORAL	
	Blood Potassium Increased	Professional	Baclofen	SS				
	Convulsion		Clomipramine Hydrochloride	SS		ORAL	50 MG DAILY ORAL	
	Electroencephalogram Abnormal							
	Pneumonia Aspiration		Tramadol Hydrochloride Injection	SS			300 MG DOSE	

Date:07/09/99ISR Number: 3300471-8Report Type:Expedited (15-DaCompany Report #001-0945-990421
Age:70 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Alanine Aminotransferase Increased Aspartate	Health Professional	Neurontin (Gabapentin)	PS			300 MG ON MON, WED, &	

	Aminotransferase					
FRI						
	Increased		(Baclofen)	SS		ORAL
30 MG (10 MG,						
	Encephalopathy					
TID), PER						
	Mental Impairment					
ORAL						
	Respiratory Acidosis		Colace	C		
	Sepsis		Phoslo	C		
			Cortisone	C		
			Nephrocaps	C		
			Prevacid	C		
			Restoril	C		
			(Calcitonin)	C		
			Vicodin	C		
			Senokot	C		
			Ventolin	C		
			Atrovent	C		
			Synthroid	C		
			Cordarone	C		

Date:07/12/99ISR Number: 3301916-XReport Type:Expedited (15-DaCompany Report #PRIUSA1999003300
Age:60 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Convulsion	Foreign	Ultram (50 Mg			
	Pneumonia Aspiration	Health	Tablet) (Tramadol			
		Professional	Hydrochloride)	PS		ORAL
300 MG,						
DAILY, ORAL						
			Clomipramine			
			(Clomipramine)	SS		ORAL
50 MG, ORAL						

			Ketoprofen (Ketoprofen)	SS		ORAL 300 MG , ORAL
			Baclofen (Baclofen)	SS		ORAL 60 MG, 1 IN 1 DAILY, ORAL
			Ultram (50 Mg Tablet) (Tramadol Hydrochloride)	SS		
INTRAVENOUS	300 MG, IV					

Date:07/19/99ISR Number: 3306499-6Report Type:Expedited (15-DaCompany Report #99USA10808
Age:63 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Apallic Syndrome Coma	Health Professional	Baclofen Tablet 10 Mg (Baclofen)	PS		ORAL	10 MG, BID,	
ORAL							5	YR

Date:07/19/99ISR Number: 3306720-4Report Type:Expedited (15-DaCompany Report #99GB-10342
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Complications Of Maternal Exposure To Therapeutic Drugs	Foreign Health Professional	Lioresal Unknown (Baclofen)	PS		UNKNOWN	UNK, DAILY,	
	Convulsion Neonatal Drug Withdrawal Syndrome Neonatal	Other						

Date:08/03/99ISR Number: 3323197-3Report Type:Periodic Company Report #99-01-0009
Age:41 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Drug Withdrawal Syndrome	Consumer	Baclofen Tablets	PS		ORAL	10MG BID	ORAL

Date:08/06/99ISR Number: 3320399-7Report Type:Expedited (15-DaCompany Report #19990700899
Age:13 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Acquired Cardiac Septal Defect	Foreign	Naropin	PS			EPIDURAL	20 MG 1 EP
		Literature	Baclofen	SS				
	Atrioventricular Block	Other	Imipramine	SS				
	Drug Level Above Therapeutic							
	Grand Mal Convulsion							
	Medication Error							
	Tachycardia							

Date:08/12/99ISR Number: 3324846-6Report Type:Expedited (15-DaCompany Report #99GB-10503
Age:60 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Muscular Weakness	Foreign	Baclofen Unknown					
	Respiratory Depression	Health Professional	(Baclofen)	PS		ORAL	2.5 MG, Other	DAILY, ORAL
		Other	Rifampicin	C				
			Folic Acid	C				

			Sytron	C		
			Ciprofloxacin	C		
			Prozac	C		
			Teicoplanin	C		
			Clexane	C		

Date:08/24/99ISR Number: 3333416-5Report Type:Expedited (15-DaCompany Report #99F--10775
Age:50 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Suicide Attempt Toxicologic Test Abnormal	Foreign Health Professional	Lioresal Tablet (Baclofen)	PS		ORAL	DAILY, ORAL

Date:08/24/99ISR Number: 3333419-0Report Type:Expedited (15-DaCompany Report #99D-10338
Age:61 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Asthma Condition Aggravated Drug Interaction Sedation	Foreign Health Professional Other	Lioresal Tablet (Baclofen)	PS		ORAL	10 MG, DAILY, ORAL
			Theophyllin (Theophylline)	SS		ORAL	200 MG, DAILY, ORAL
			Catapressan (Clonidine Hydrochloride)	SS			
			Aponal	C			
			Zyrtec	C			
			Bronchoretard Mite	C			
			Mono-Embolex	C			
			Euphylong	C			
			Bronchorcort	C			

Date:09/03/99ISR Number: 3341955-6Report Type:Expedited (15-DaCompany Report #500806
Age:38 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Convulsion Drug Level Below Therapeutic Medication Error	Foreign Health Professional	Dantrium Capsules, 100mg (Dantrolene Sodium)	PS		ORAL	300 MG DAILY;	ORAL
			Floxyfral (Fluvoxamine Maleate)	SS		ORAL	100 MG DAILY;	ORAL
			Lioresal (Baclofen)	SS		ORAL	40 MG DAILY;	ORAL
			Tegretol (Carbamazepine)	SS		ORAL	400 MG DAILY;	ORAL
			Tiapridal (Tiapride)	SS		ORAL	200 MG DAILY;	ORAL
			Floxyfral	C				
			Lioresal	C				
			Stablon	C				
			Tegretol	C				
			Tiapridal	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/08/99ISR Number: 3343153-9Report Type:Expedited (15-DaCompany Report #214164
Age:48 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Petechiae Vascular Purpura	Foreign Other	Valium (Diazepam) 1%	PS		ORAL	4 DROP DAILY	
			Lutheran (Chlormadinone Acetate) 5 Mg	SS		ORAL	5 MG DAILY	
			Depakine (Valproate Sodium)	SS		ORAL	ORAL	
			Lioresal (Baclofen) 10 Mg	SS		ORAL	30 MG 3 PER DAY	ORAL
			Forlax (Polyethylene Glycol) 10gram	SS		ORAL	30 GRAM DAILY	ORAL

Date:09/20/99ISR Number: 3352151-0Report 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	Hallucination Mental Impairment		Baclofen	PS		ORAL	20MG QID PO	

Date:09/21/99ISR Number: 3352953-0Report 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	Confusional State Dyspnoea Hallucination		Baclofen Dantrolene	PS SS		ORAL ORAL	30MG QID PO 100MG QID PO	

Date:09/23/99ISR Number: 3356209-1Report Type:Expedited (15-DaCompany Report #97F--10835
Age:80 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agitation Confusional State	Foreign Health Professional Other	Lioresal Tablet (Baclofen)	PS		ORAL	ORAL	2 DAY

Date:09/27/99ISR Number: 3359188-6Report Type:Expedited (15-DaCompany Report #99D--10869
Age:40 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Bacterial Infection Pyrexia	Foreign Health Professional	Lioresal Unknown (Baclofen) Keltican	PS C			100 MG DAILY	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/30/99ISR Number: 3361707-0Report Type:Expedited (15-DaCompany Report #99USA11111
Age:40 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Ventricular Tachycardia	Health Professional	Lioresal Tablet (Baclofen)	PS		ORAL	40 MG, ONCE, ORAL	

Date:09/30/99ISR Number: 3362069-5Report Type:Expedited (15-DaCompany Report #99HQ-10414
Age:70 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Convulsion	Foreign	Baclofen Unknown					
	Delirium	Literature	(Baclofen)	PS		ORAL	100 MG DAILY	
	Drug Ineffective	Health					ORAL	
	Loss Of Consciousness	Professional	Diazepam Unknown					
	Sedation	Other	(Diazepam)	SS		ORAL	20 MG DAILY	
							ORAL	
			Dantrolene Unknown					
			(Dantrolene)	SS		ORAL	400 MG DAILY	
							ORAL	

Date:10/01/99ISR Number: 3362835-6Report Type:Expedited (15-DaCompany Report #99F--10832
Age:48 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Vascular Purpura	Foreign	Lioresal Tablet					
		Health	(Baclofen)	PS		ORAL	30 MG DAILY	
		Professional					ORAL	
		Other	Luteran Tablet					

			(Chlormadinone Acetate)	SS			ORAL
5 MG DAILY							
ORAL							
			Depakine Solution (Valproate Sodium)	SS			ORAL
1 DF, DAILY							
ORAL							

Date:10/14/99ISR Number: 3371020-3Report Type:Direct Company Report #
Age:50 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Sudden Death	Health	Naltrexone	PS		SUBCUTANEOUS	SUBCUTANEOUS	
		Professional	Baclofen	SS				
			Dexamethasone	SS				
			Fentanyl	SS				
			Citric Acid/Sodium Citrate	SS				
			Glycopyrrolate	SS				
			Midazolam	SS				
			Octreotide Acetate	SS				
			Trazodone	SS				
			Vercuronium	SS				
			Propofol	SS				
			Nalmefene	SS				
			Ketamine Hcl	SS				
			Clonidine	C				
			Diazepam	C				
			Naltrexone	C				
			Enalapril Maleate	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/14/99ISR Number: 3371022-7Report Type:Direct Company Report #
Age:43 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Sudden Death	Health	Naltrexone	PS		SUBCUTANEOUS		SUBCUTANEOUS
		Professional	Baclofen	SS				
			Citric Acid/Sodium Citrate	SS				
			Glycopyrrolate	SS				
			Ketamine Hcl	SS				
			Fentanyl	SS				
			Dexamethasone	SS				
			Midazolam	SS				
			Octreotide Acetate	SS				
			Vercuronium	SS				
			Trazodone	SS				
			Propofol	SS				
			Nalmefene	SS				
			Cefazolin Sodium	C				
			Clonidine	C				
			Droperidol	C				
			Metoclopramide Hcl	C				
			Naloxone Hcl	C				
			Ondanstetron Hcl	C				

Date:10/15/99ISR Number: 3373864-0Report Type:Expedited (15-DaCompany Report #99CDN10608
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Thrombocytopenia	Foreign	Lioresal Tablet					
	White Blood Cell Count Increased	Health	(Baclofen)	PS		ORAL	ORAL	
		Professional						
		Other						

Date:10/19/99ISR Number: 3374904-5Report Type:Direct Company Report #
Age:44 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Death		Death	Naltrexone	PS
SUBCUTANEOUS	1000MG			
SUBCUTANEOUS				
			Baclofen	SS
			Dexamethasone	SS
			Fentanyl	SS
			Citric Acid/Sodium Citrate	SS
			Glycopyrrolate	SS
			Midazolam	SS
			Octreotide Acetate	SS
			Trazodone	SS
			Vercuronium	SS
			Propofol	SS
			Nalmefene	SS
			Ketamine Hcl	SS
			Cefadroxil	C
			Cefazolin Sodium	C
			Clonidine	C
			Naltrexone	C

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/25/99ISR Number: 3382435-1Report Type:Expedited (15-DaCompany Report #99USA11187
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Muscle Twitching Paraesthesia Peripheral Nerve Injury	Consumer	Lioresal Tablet 20 Mg (Baclofen)	PS		ORAL	80 MG, DAILY, ORAL	

Date:11/01/99ISR Number: 3386792-1Report Type:Expedited (15-DaCompany Report #99F--10775
Age:53 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Bradycardia Coma Hypothermia Lung Disorder Suicide Attempt	Foreign Health Professional Other	Lioresal Tablet (Baclofen)	PS		ORAL	UNK, DAILY, ORAL	
			Theralene Drpos (Alimemazine Tartrate)	SS			UNK, DAILY, ORAL	
			Lysanxia Tablet (Prazepam)	SS		ORAL	UNK, UNK, ORAL	
			Tegretol Tablet (Carbamazepine)	SS		ORAL	UNK, UNK, ORAL	
			Athymil Tablet (Mianserin Hydrochloride)	SS		ORAL	UNK, UNK, ORAL	

Date:11/01/99ISR Number: 3387173-7Report Type:Expedited (15-DaCompany Report #94280-
Age:50 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain Upper	Foreign	Lioresal Suspension (Baclofen)	PS		ORAL	5 MG, TID,	
Other	Anorexia	Health Professional					ORAL	10 DAY
	Depression							
	Eye Excision	Other	Haloperidol Capsule	C				
	Intraocular Melanoma		Daktarin Oral Gel Gel	C				
	Lethargy		Lactulose Syrup	C				
	Malignant Melanoma Stage Iv		Bisacodyl Tablet	C				
	Pain		Prednisolone Tablet	C				
			Mst 60 Tablet 60	C				
			Normax	C				
			Cyclizine	C				

Date:11/01/99ISR Number: 3387232-9Report Type:Expedited (15-DaCompany Report #S9432751
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Lung Disorder	Foreign	Lioresal (Baclofen)	PS		ORAL	DAILY, ORAL	25 DAY
	Vertigo	Health Professional Other						

Date:11/04/99ISR Number: 3388750-XReport Type:Expedited (15-DaCompany Report #R99-079
Age:47 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Aphasia Aspiration Crying Dyskinesia Euphoric Mood Intentional Misuse Memory Impairment Mental Impairment Mood Altered Suicide Attempt Tongue Disorder Vomiting	Health Professional	Baclofen Tablets 10mg, Watson Laboratories, Inc., Miami Klonopin Prescription Antihistamines	PS C C	Watson Laboratories, Inc.,	ORAL	APPROX. 40 TABS ORAL	

Date:11/15/99ISR Number: 3397773-6Report Type:Expedited (15-DaCompany Report #208768
Age:51 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Depression Dyspnoea Lethargy Suicide Attempt	Other	Valium (Diazepam) Glyburide (Glyburide) Baclofen (Baclofen) Ativan (Lorazepam) Trazodone (Trazodone Hydrochloride) Copaxone (Glatiramer Acetate) Doxazosin Mesilate (Doxazosin Mesylate) Naproxen (Naproxen) Fosinopril (Fosinopril Sodium)	PS SS SS SS SS C C C		ORAL ORAL		

Date:11/22/99ISR Number: 3404821-3Report Type:Expedited (15-DaCompany Report #99D--11039
Age:59 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Pemphigoid	Foreign Health Professional Other	Lioresal (Baclofen)	PS		ORAL	25 MG	QID ORAL
			Antibiotics	C				
			Sirdalud	C				

Date:11/23/99ISR Number: 3405354-0Report Type:Direct Company Report #
Age:73 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Grand Mal Convulsion		Zanaflex 4mg	PS		ORAL	2TABS BID	
Hospitalization - Initial or Prolonged			Lioresal 20mg	SS		ORAL	1 TAB TID	ORAL
			Diltantin	C				
			Prozac	C				
			Kcl	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/01/99ISR Number: 3411828-9Report Type:Expedited (15-DaCompany Report #R99-073
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Feeling Cold Hypoaesthesia Muscle Disorder Muscle Twitching Neck Pain	Consumer	Baclofen 10 Mg Tablets, Watson Laboratories, Inc. (Miami)	PS	Watson Laboratories, Inc (Miami)		UNKNOWN	1 TABLET QID
	Pain						UNKNOWN	
	Paraesthesia Peripheral Nerve Injury Radiculopathy		Ibuprofen & Nnaproxen Prazosin Aspirin Nabumetone Gabapentin Atenolol Methocarbamol Hydroxyzine Lansoprazole Tylenol #3 Hydrochlorothiazide Trazodone	 C C C C C C C C C C C C				

Date:12/01/99ISR Number: 3414799-4Report Type:Periodic Company Report #AR-1295
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Abdominal Pain Headache	Consumer	Baclofen Tablets, 10 Mg (Danbury/Schein)	PS	Danbury/Schein	ORAL	10 MG TID	
	Rash Papular						(ORAL),	
							INCREASED TO	
							10 MG BID	
							(ORAL)	
			Wellbutrin Premarin	C C				

Motrin	C
Ultram	C

Date:12/06/99ISR Number: 3414086-4Report Type:Expedited (15-DaCompany Report #99F--11057
Age:48 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dermatitis Bullous Eosinophilia Linear Iga Disease Rash Macular Rash Pruritic	Foreign Health Professional Other	Lioresal Tablet (Baclofen)	PS		ORAL	80 MG, DAILY, ORAL	
			Aspegic Powder (Lysine Acetylsalicylate)	SS		ORAL	ORAL	
			Xanax Tablet (Alprazolam)	SS		ORAL	ORAL	
			Tilcotil Tablet (Tenoxicam)	SS		ORAL	ORAL	
			Prozac Capsule (Fluoxetine)	SS		ORAL	20 MG, DAILY, ORAL	
			Ciflox Tablet (Ciprofloxacin Hydrochloride)	SS		ORAL	750 MG, BID, ORAL	10 DAY

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/13/99ISR Number: 3420462-6Report Type:Expedited (15-DaCompany Report #99F--11107
Age:70 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Confusional State Delirium	Foreign Health Professional Other	Lioresal Tablet (Baclofen)	PS		ORAL	DAILY, ORAL

Date:12/17/99ISR Number: 3425536-1Report Type:Expedited (15-DaCompany Report #99B-10098
Age:53 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Other	Haemoglobin Decreased Pancytopenia White Blood Cell Count Decreased	Foreign Health Professional	Lioresal Unknown (Baclofen) Prothiaden Prepulsid	PS C C		ORAL	55 MG, DAILY, ORAL

Date:12/27/99ISR Number: 3431260-1Report Type:Expedited (15-DaCompany Report #99J--10474
Age:51 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Life-Threatening	Abdominal Pain Lower Amnesia Anxiety Blood Creatinine Increased Blood Urea Increased Chest Discomfort Condition Aggravated Delusion Difficulty In Walking Fall Hallucination Hypoaesthesia	Foreign Health Professional Other	Lioresal Tablet (Baclofen)	PS		ORAL	45 MG, DAILY

	Insomnia						
	Persecutory Delusion						
	Suicide Attempt						

Date:12/28/99ISR Number: 3432094-4Report Type:Expedited (15-DaCompany Report #R99-079
Age:47 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Affect Lability Aspiration Bradyphrenia Crying Dyskinesia	Health Professional	Baclofen Tablets 10 Mg, Watson Laboratories, Inc., Miami	PS	Watson Laboratories, Inc., Miami	ORAL	APPROX. 15 TO 20 TABS, ORAL
	Euphoric Mood						
	Intentional Misuse		Thyroid	C			
	Memory Impairment		Celexa	C			
	Sedation		Zyprexa	C			
	Suicidal Ideation		Ibuprofen	C			
	Suicide Attempt		Klonopin	C			
	Tongue Disorder						
	Vomiting						

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/28/99ISR Number: 3432734-XReport Type:Expedited (15-DaCompany Report #222988
Age:70 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Confusional State	Foreign	Valium Tablets					
	Convulsion	Other	(Diazepam)	PS		ORAL	20 MG DAILY	
	Delirium					ORAL		
	Loss Of Consciousness		Baclofen (Baclofen)	SS		ORAL	100 MG DAILY	
	Sedation					ORAL		
			Dantrolene (Dantrolene)	SS		ORAL	400 MG DAILY	

Date:12/29/99ISR Number: 3433661-4Report Type:Direct Company Report #
Age:64 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Confusional State		Baclofen	PS		ORAL	40MG PO TID	
Initial or Prolonged	Delirium						/2 MONTHS	
	Difficulty In Walking						PRIOR TO	
	Dysarthria						EVENT	2 MON
	Paranoia		Zantac	C				
			Cardura	C				
			Atenolol	C				
			Naproxen	C				

Date:01/03/00ISR Number: 3435538-7Report Type:Expedited (15-DaCompany Report #99IND10060
Age:17 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Hospitalization - Initial or Prolonged	Dermatitis Hypersensitivity	Foreign Health	Lioresal Unknown (Baclofen)	PS		ORAL 10 MG TID
	Oedema	Professional				ORAL
	Pruritus	Other	Promethazine Pacitane	C C		

Date:01/05/00ISR Number: 3437781-XReport Type:Expedited (15-DaCompany Report #99D--11189
Age:70 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Other	Coma Condition Aggravated	Foreign Health	Lioresal Tablet (Baclofen)	PS		ORAL 5 MG, BID,
	Extrapyramidal Disorder	Professional				ORAL
	Haemodialysis Overdose Renal Impairment Sedation	Other	Altra	C		

Date:01/06/00ISR Number: 3439790-3Report Type:Expedited (15-DaCompany Report #HQ0042430DEC1999
Age:58 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Hospitalization - Initial or Prolonged Other	Burns Second Degree Dermatitis Exfoliative Erythema Multiforme Pain Rash Erythematous	Health Professional	Temesta Tablet (Lorazepam) Deroxat (Paroxetine Hydrochloride) Klean-Prep (Macrogol, Potassium	PS SS		

			Chloride, Sodium Bicarbonate, Sodium Chloride, Sodium Lioresal (Baclofen) Normacol (Frangula Extract, Sterculia)	 SS SS SS			

LAVEMENT-PHOS

PHATE

(29-SEP-99),

STERCULIA

GOMME

Date:01/18/00ISR Number: 3446137-5Report Type:Expedited (15-DaCompany Report #HQ0042430DEC1999
Age:58 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Burns Second Degree Erythema Multiforme Pain Skin Exfoliation	Health Professional	Temesta Tablet (Lorazepam) Deroxat (Paroxetine Hydrochloride) Klean-Prep (Macrogol, Potassium Chloride, Sodium Bicarbonate, Sodium Chloride, Sodium Lioresal (Baclofen) Normacol (Frangula Extract, Sterulia)	PS SS SS SS				

SEE IMAGE

Date:01/18/00ISR Number: 3453033-6Report Type:Periodic Company Report #98USA11801
Age:49 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Confusional State Convulsion	Health Professional	Baclofen Tablet 20 Mg (Baclofen)	PS		ORAL	40 MG, QID,	

	Coordination Abnormal					
ORAL						
	Hallucination		Amantadine Tablet	C		

Date:01/19/00ISR Number: 3445217-8Report Type:Direct Company Report #
Age:43 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Coma	Health	Baclofen	PS		ORAL	TITRATED AS	
Initial or Prolonged	Medication Error	Professional					ABOVE PO	
	Renal Failure Chronic		Norvasc	C				
			Nephrocaps	C				
			Insulin	C				
			Capoten	C				
			Calcium Acetate	C				
			Tenex	C				
			Aspirin	C				

Date:01/28/00ISR Number: 3447828-2Report Type:Expedited (15-DaCompany Report #222988
Age:70 YR Gender:Male I/FU:F

Outcome	PT
Other	Confusional State
	Convulsion
	Delirium

	Localised Infection Loss Of Consciousness Respiratory Depression	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Sedation	Foreign Other	Valium Tablets (Diazepam)	PS		ORAL	20 MG DAILY ORAL
			Baclofen (Baclofen)	SS		ORAL	100 MG DAILY ORAL
			Dantrolene (Dantrolene)	SS		ORAL	400 MG DAILY ORAL
			Hypnovel (Inj) (Midazolam Hydrochloride)	SS			

Date:01/31/00ISR Number: 3449090-3Report Type:Expedited (15-DaCompany Report #99D--11039
Age:59 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Autoimmune Disorder Blister	Foreign Health	Lioresal Tablet (Baclofen)	PS		ORAL	25 MG QID ORAL
	Dermatitis Bullous	Professional					
	Erythema Inflammation Pemphigoid Rash Erythematous Rash Macular Skin Disorder Skin Lesion Urticaria	Other	Penicillin Unknown (Penicillin Nos) Mono-Embolex Ampoule Calcium Dispersible Tablet 500 Trusopt Drops Ampho-Moronal Suspension Tavanic Tablet Bifiteral Vigantoletten Antibiotics Musaril	SS C C C C C C C C			

			Sirdalud	C		
			Fungizid-Ratiopharm	C		

Date:02/10/00ISR Number: 3456364-9Report Type:Expedited (15-DaCompany Report #00GB-10093
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Bone Marrow Depression	Foreign	Baclofen Unknown					
	Hepatic Function Abnormal	Health	(Baclofen)	PS		ORAL	40 MG, QD,	
	Liver Function Test	Professional					ORAL	
	Abnormal	Other	Amitriptyline					
	Neutropenia		Unknown					
	Thrombocytopenia		(Amitriptyline)	SS		ORAL	50 MG, DAILY,	
							ORAL	
			Amoxycillin	C				
			Erythromycine	C				
			Paracetamol	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/11/00ISR Number: 3456482-5Report Type:Direct Company Report #
Age:67 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Sedation		Baclofen	PS		ORAL	5MG PO BID	

Date:02/14/00ISR Number: 3457939-3Report Type:Expedited (15-DaCompany Report #00D--10137
Age:82 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain	Foreign	Lioresal Unknown				25 MG, TID,	
	Accidental Overdose	Health	(Baclofen)	PS			UNKNOWN	
	Confusional State	Professional						
	Extensor Plantar Response							
	Medication Error							
	Muscle Contractions Involuntary							
	Respiratory Disorder							
	Restlessness							
	Urinary Retention							

Date:02/22/00ISR Number: 3460039-XReport 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	Bradycardia		Baclofen	PS		IT	175 MCG/24HR	
	Ventricular Extrasystoles							
			Tavist	C				
			Motrin	C				
			Phenergan	C				
			Symmetral	C				
			Feldene	C				

			Tylenol Extra Strength	C		

Date:02/23/00ISR Number: 3462203-2Report Type:Periodic Company Report #9938788
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Amnesia	Consumer Health Professional	Zoloft Tablets	PS		ORAL	50.00 MG	TOTAL:DAILY:ORAL
			Baclofen	SS		ORAL	80.00 MG	TOTAL:DAILY:ORAL
			Zanaflex	C				
			Urex	C				
			Vitamin C	C				

Date:02/24/00ISR Number: 3462241-XReport Type:Expedited (15-DaCompany Report #222988
Age:70 YR Gender:Male I/FU:F

Outcome	PT
Other	Confusional State
	Delirium

Drug Ineffective Epilepsy Infection	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Loss Of Consciousness Respiratory Depression	Foreign Other	Valium Tablets (Diazepam)	PS		ORAL	20 MG DAILY ORAL
Sedation		Baclofen (Baclofen)	SS		ORAL	100 MG DAILY ORAL
		Dantrolene (Dantrolene)	SS		ORAL	400 MG DAILY ORAL
		Hypnovel (Inj) (Midazolam Hydrochloride)	SS			

Date:02/25/00ISR Number: 3463979-0Report Type:Expedited (15-DaCompany Report #00F-10154
Age:34 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Blood Bilirubin Increased Hepatitis Cholestatic	Foreign Health	Lioresal (Baclofen)	PS		ORAL	90 MG, DAILY, ORAL
	Jaundice Liver Function Test Abnormal	Professional Other	Dantrium (Dantrolene Sodium)	SS		ORAL	150 MG, DAILY, ORAL 12 WK
			Prozac Solution (Fluoxetine)	SS		ORAL	40 MG, DAILY, ORAL
			Fragmine Solution For Injec	C			
			Valium Tablet	C			
			Haldol Tablet	C			

			Debridat Tablet	C		

Date:02/29/00ISR Number: 3464591-XReport Type:Expedited (15-DaCompany Report #00-0180
Age:27 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Depressed Level Of Consciousness	Health Professional	Baclofen Tablets (Strength Unknown)				
	Drug Level Above		Watson Labs. Miami	PS	Watson Labs. Miami		120 MG QD
	Therapeutic Loss Of Consciousness Nephritis Interstitial Renal Failure		Unasyn (Strength Unknown), Pfizer	SS	Pfizer		
			Percocet	C			
			Ditropan	C			

Date:03/03/00ISR Number: 3469265-7Report Type:Expedited (15-DaCompany Report #A005891
Age:27 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Dialysis	Health Professional	Unasyn For Injection	PS			
	Drug Level Above		Baclofen	SS		ORAL	120.00 MG
Required	Therapeutic						TOTAL:DAILY:O
Intervention to	Loss Of Consciousness						RAL
Prevent Permanent	Nephritis Interstitial		Percocet	SS		ORAL	ORAL
Impairment/Damage			Ditropan	C			

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/23/00ISR Number: 3478991-5Report Type:Expedited (15-DaCompany Report #00-0263
Age:71 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hallucination Urinary Incontinence Vomiting	Health Professional	Baclofen Tablets 10 Mg, Watson Laboratories, Inc. Miami	PS	Watson Laboratories, Inc. Miami	ORAL	10 MG, BID, PO	
			Lopressor	C				
			Zantac	C				
			Nephro Caps	C				
			Prinivil	C				
			Aspirin	C				
			Nitroglycerin Sublingual	C				
			Isosorbide Dintirate	C				

Date:03/24/00ISR Number: 3538615-5Report Type:Periodic Company Report #USA012831
Age:66 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Weight Increased	Consumer Other	Meridia	PS	Knoll Pharmaceutical Co Sub Basf Corp	ORAL	15 MG OD PO	
			Morphine	SS				
			Baclofen	SS				
			Hydrochlorothiazide	C				
			Tylox	C				
			Soma	C				

Date:03/30/00ISR Number: 3482753-2Report Type:Expedited (15-DaCompany Report #A005891
Age:27 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Depressed Level Of	Health	Unasyn For Injection	PS				

Initial or Prolonged	Consciousness	Professional	Baclofen	SS		ORAL
120.00 MG						
Required	Dialysis					
TOTAL:DAILY:O						
Intervention to	Drug Level Above					
RAL						
Prevent Permanent	Therapeutic		Percocet	SS		ORAL
ORAL						
Impairment/Damage	Loss Of Consciousness		Ditropan	C		
	Nephritis Interstitial					
	Renal Failure					

Date:04/03/00ISR Number: 3483863-6Report Type:Expedited (15-DaCompany Report #00GB-10239
Age:19 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Life-Threatening	Agitation	Foreign	Baclofen Unknown			
	Cyanosis	Health	(Baclofen)	PS		ORAL
80 MG QD,						
	Hypoxia	Professional				
ORAL						
	Respiratory Failure	Other	Dantrolene Unknown			
			(Dantrolene)	SS		ORAL
200 MG,						
DAILY, ORAL						
			Zanaflex Unknown			
			(Tizanidine			
			Hydrochloride)	SS		ORAL
10 MG DAILY,						
ORAL						
			Voltarol	C		

Bisacodyl	C
Lactulose	C
Cefuroxime	C
Temazepam	C
Motilium	C
Ephedrine	C
Frusemide	C
Glycerol	C
Maxolon	C
Morphine	C
Paracetamol	C
Potassium Chloride	C
Senna	C
Cyclizine	C

Date:04/06/00ISR Number: 3484628-1Report Type:Direct Company Report #USP 52914
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Cardiac Arrest		Lioresal (Baclofen)	PS	Novartis			
	Depressed Level Of Consciousness							
	Grand Mal Convulsion							
	Hypothermia							
	Medication Error							
	Overdose							
	Respiratory Arrest							

Date:04/06/00ISR Number: 3484728-6Report Type:Direct Company Report #
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Condition Aggravated	Health	Lioresal - Baclofen	PS			10MG QD	
	Muscle Spasms	Professional						

Date:04/19/00ISR Number: 3490511-8Report Type:Expedited (15-DaCompany Report #00-0365
Age:42 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Anxiety Chest Discomfort Decreased Appetite Disturbance In Attention	Consumer	Baclofen Tablets 10 Mg, Watson Laboratories, Inc.	PS	Watson Laboratories, Inc.	
10 MG, TID						
	Fatigue		Celebrex	C		
	Insomnia		Advil	C		
	Palpitations		Prilosec	C		
	Panic Attack		Trazadone	C		
	Restlessness		Ornade	C		
	Tinnitus					

Date:04/24/00ISR Number: 3491470-4Report Type:Direct Company Report #
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
	Condition Aggravated		Lioresal	PS		
	Muscle Spasms		...	C		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/08/00ISR Number: 3497219-3Report Type:Expedited (15-DaCompany Report #00-0416
Age:55 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Distension Abdominal Pain Upper Asthenia Blood Pressure Increased Diarrhoea Dyspnoea Extrasystoles Muscle Disorder Nervousness	Consumer	Baclofen Tablets, 10 Mg, Watson Laboratories, Inc. Miami Ultram 100mg, Klonopin Diazepam Vioxx Albuterol Inhaler Methadone	PS SS C C C C C	Watson Laboratories, Inc., Miami Ortho Pharmaceuticals		6 TABS A DAY	

Date:05/09/00ISR Number: 3497748-2Report Type:Expedited (15-DaCompany Report #00-0469
Age:42 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Depression Hallucination Paranoia Psychotic Disorder Sedation Speech Disorder	Health Professional Other	Baclofen Tablets 10 Mg, Watson Laboratories, Inc. Miami Minoxidil Lopressor Zoloft Renagel	PS C C C C	Watson Laboratories, Inc., Miami		5 MG INCREASED TO 10 MG (UNKNOWN FREQUENCY)	

Date:05/09/00ISR Number: 3497770-6Report Type:Expedited (15-DaCompany Report #00-0180
Age:27 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain Agitation Coma Convulsion Depressed Level Of Consciousness Drug Toxicity Loss Of Consciousness Nephritis Interstitial Renal Failure Renal Impairment	Health Professional	Baclofen Tablets (Strength Unknown) Watson Laboratories Inc	PS	Watson Laboratories Inc		120 MG QD	
			Unasyn (Strength Unknown), Pfizer	SS	Pfizer			

Date:05/09/00ISR Number: 3497773-1Report Type:Expedited (15-DaCompany Report #00-0365
Age:42 YR Gender:Male I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Anxiety Chest Discomfort Decreased Appetite Disturbance In Attention

	Fatigue Insomnia Palpitations	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
	Panic Attack Restlessness Tinnitus	Consumer	Baclofen Tablets 10 Mg, Watson Laboratories, Inc. Miami Div.	PS	Watson Laboratories, Inc. Miami Div.	
10 MG, TID						
			Celebrex	C		
			Advil	C		
			Prilosec	C		
			Trazadone	C		
			Ornade	C		

Date:05/16/00ISR Number: 3500940-1Report Type:Direct Company Report #
Age:73 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization -	Dizziness		Baclofen	PS		
10MG TID						
Initial or Prolonged	Dyspnoea		Lipitor	C		
			Reglain	C		
			Lanoxin	C		
			Pepecid	C		
			Cardizem	C		
			Flovet	C		
			Coumadin	C		
			Prednisone	C		
			Combivant	C		

Date:05/22/00ISR Number: 3503501-3Report Type:Direct Company Report #
Age:46 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Life-Threatening	Angina Pectoris	Health	Baclofen/Lioreseal	PS		
110 MG QID >						
Hospitalization -	Myocardial Infarction	Professional				
TO 120 MG QID						
Initial or Prolonged			...	C		

Required
Intervention to
Prevent Permanent
Impairment/Damage

Date:05/31/00ISR Number: 3506698-4Report 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	Hepatitis		Baclofen 20mg Tab	PS				
			Azathioprine 50 Mg Tab	SS				
			Interferon Beta 1b Vi Inj	C				
			Syringe 2.5-3ml/Ndl	C				
			Tuberculin Syringe	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/02/00ISR Number: 3507665-7Report Type:Expedited (15-DaCompany Report #99F--10645
Age:65 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Aggression	Foreign	Lioresal	PS	Novartis Pharmaceuticals Corp	ORAL	5 MG, DAILY,	
	Agitation	Literature					ORAL	
	Blood Bicarbonate Increased	Health Professional	Rifampicin	C				
	Blood Creatinine Increased	Other	Rimifon	C				
	Blood Urea Increased		Pirilene	C				
	Confusional State		Mopral	C				
	Diabetes Mellitus		Fozitec	C				
	Electroencephalogram Abnormal		Hemodialysis	C				
	Encephalopathy							
	Haemoglobin Decreased							
	Hyperglycaemia							
	Infarction							
	Muscle Rigidity							
	Nervous System Disorder							

Date:06/06/00ISR Number: 3508574-XReport Type:Expedited (15-DaCompany Report #00-0469
Age:42 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Cognitive Disorder	Health Professional	Baclofen	PS	Watson Laboratories Inc		5 MG TID; 10	
	Delusional Disorder, Persecutory Type	Other					MG TID	
	Depression		Minoxidil	C				
	Hallucination		Lopressor	C				
	Post-Traumatic Stress Disorder		Zoloft	C				
	Psychotic Disorder		Renagel	C				
	Sedation							
	Speech Disorder							

Date:06/06/00ISR Number: 3508575-1Report Type:Expedited (15-DaCompany Report #00-0416
Age:55 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Distension	Consumer	Baclofen	PS	Watson Laboratories Inc		6 TABS A DAY	
	Abdominal Pain Upper							
	Asthenia		Ultram	SS				
	Blood Pressure Increased		Klonopin	C				
	Diarrhoea		Diazepam	C				
	Drug Dependence		Vioxx	C				
	Drug Withdrawal Syndrome		Albuterol	C				
	Dyspnoea		Methadone	C				
	Extrasystoles							
	Fatigue							
	Muscle Disorder							
	Nervousness							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/23/00ISR Number: 3518929-5Report Type:Expedited (15-DaCompany Report #00-749
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Coma Disorientation	Other	Baclofen	PS	Watson Laboratories Inc	ORAL	20 MG QID PO	
	Hyperhidrosis Speech Disorder		Ultram 50 Mg Tablets, Ortho-Mcneil	SS	Ortho-Mcneil	ORAL	QD PO	
			Urecholine 25 Mg Merck	SS	Merck		25 MG TID	
			Dilantin	C				
			Gabatril	C				
			Ogen	C				
			Pepcid	C				
			Symmetrel	C				

Date:06/26/00ISR Number: 3519908-4Report Type:Expedited (15-DaCompany Report #00D-10813
Age:82 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blister Haemorrhage	Foreign Health Professional Other	Lioresal	PS	Novartis Pharmaceuticals Corp		45 MG, TID,	
			Furosemid	C				

Date:06/26/00ISR Number: 3520800-XReport Type:Expedited (15-DaCompany Report #WAES 00061841
Age:66 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dyspnoea Pneumonitis	Foreign Health Professional Other	Zocor	PS	Merck Research Laboratories Div Merck Co Inc	ORAL		
			Tegretol (Carbamazepine)	SS		ORAL	1 GM DAILY	62 MON

			Lioresal (Baclofen)	SS		ORAL
5MG						

Date:06/27/00ISR Number: 3520695-4Report Type:Expedited (15-DaCompany Report #1382058A
Age:52 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Completed Suicide	Literature	Tylenol	PS	Mcneil Consumer	
		Health			Products Co Div	
		Professional			Mcneilab Inc	ORAL
PO						
			Baclofen	SS		ORAL
PO						
			Methocarbamol	C		

Date:07/10/00ISR Number: 3580989-3Report Type:Periodic Company Report #USA013334
Age:40 YR Gender:Female I/FU:I

Outcome	PT
	Chest Pain
	Decreased Appetite
	Dry Mouth
	Haemorrhoids
	Headache
	Increased Appetite
	Insomnia

Nausea
Pain In Extremity

Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Consumer	Meridia	PS	Knoll Pharmaceutical Co Sub Basf Corp			
Other	Generic Robitussin D	SS				
	Pro-Image	SS				
	Allegra	SS				
	Sudafed	SS				
	Benadryl	SS				
	Cardizem	SS				
	Aspirin	SS		ORAL	TAB UNK PO	
	Motrin	SS				
	Aleve	SS				
	Vioxx	SS				
	Naproxen	SS		ORAL	TAB UNK PO	
	Darvocet-N	SS				
	Vicodin	SS				
	Baclofen	SS		ORAL	TAB UNK PO	
	Phernilin-Forte (50/650 Mg)	SS		ORAL	TAB UNK PO	

Date:07/12/00ISR Number: 3528336-7Report Type:Expedited (15-DaCompany Report #00F--10582
Age:66 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dyspnoea Pneumonia	Foreign Health Professional	Lioresal	PS	Novartis Pharmaceuticals Corp	ORAL	5MG, DAILY, ORAL	
		Other	Tegretol Tablet (Carbamazepine)	SS		ORAL	UNK, DAILY, ORAL	2 MON
			Lodales Tablet (Simvastatin)	SS		ORAL	ORAL	

Date:07/20/00ISR Number: 3532343-8Report 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	Neutropenia		Prevacid	PS			30MG GT QD	
	Pyrexia		Baclofen	SS			10MG TID	
			Insulin	C				
			Aspirin	C				
			Vitamin C	C				
			Ativan	C				
			Oscal With Vit D	C				
			Pericolace	C				
			Cipro Eye Drops	C				
			Erythromycin	C				
			Lopressor	C				
			Nitro Patch	C				
			Robittusin Dm	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/26/00ISR Number: 3535742-3Report Type:Expedited (15-DaCompany Report #00D-10813
Age:82 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blister Dermatitis Bullous	Foreign Health	Lioresal	PS	Novartis Pharmaceuticals Corp		1 DF, DAILY,	
	Drug Eruption	Professional					PERCUTANEOUS	
	Haemorrhage	Other	Furosemid	C				
			...	C				
			...	C				
			...	C				

Date:08/03/00ISR Number: 3543697-0Report Type:Periodic Company Report #99-08-0254
Age:48 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Nausea Respiratory Depression	Consumer	Baclofen	PS	Zenith Goldline Pharmaceuticals		INTRATHECAL	525MEG/DAY
							INTRATHECAL	
			Prozac	C				
			Prempro	C				

Date:08/03/00ISR Number: 3543699-4Report Type:Periodic Company Report #00-04-0188
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Oedema Peripheral	Consumer	Baclofen	PS	Zenith Goldline Pharmaceuticals	ORAL	20 MG ORAL	
			Diuretics	C				

Date:08/03/00ISR Number: 3543703-3Report Type:Periodic Company Report #00-05-0222
Age:75 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Vision Blurred	Consumer	Baclofen	PS	Zenith Goldline Pharmaceuticals	ORAL	5MG TID ORAL	
			Hytrin	C				
			Verapamil	C				

Date:08/04/00ISR Number: 3541259-2Report Type:Direct Company Report #
Age:17 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Creatinine Increased		Baclofen	PS		INTRATHECAL PUMP	VARIES VIA	
	Blood Urea Increased					INTRATHECAL		
	Dehydration		Bisacodyl	C				
	Oedema		Lasix	C				
			Aldactone	C				

Date:08/08/00ISR Number: 3588659-2Report Type:Periodic Company Report #USA013973
Age:46 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Constipation	Consumer	Vicoprofen	PS	Knoll Pharmaceutical Co Sub Basf Corp	ORAL	1 TAB TID PO	
		Other	Baclofen	SS		ORAL	TAB PO	

			Neurontin	C		
			Zocor	C		
			Avapro	C		
			Multivitamins	C		

Date:08/09/00ISR Number: 3546777-9Report Type:Expedited (15-DaCompany Report #033-0945-M0000066
Age:67 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Coma	Foreign	Neurontin	PS	Parke Davis			
	Dyspnoea	Health			Pharmaceuticals Ltd	ORAL	200 MG DAILY	
	Laryngeal Disorder	Professional					PER ORAL	
	Lung Disorder		Laroxyl					
	Respiratory Depression		(Amitriptyline Hydrochloride)	SS		ORAL	25 MG DAILY	
							PER ORAL	
			Lioresal (Baclofen)	SS		ORAL	15 MG DAILY	
							PER ORAL	
			Lexomil (Bromazepam)	SS		ORAL	9 MG DAILY	
							PER ORAL	
			Levothyrox (Levothyroxine Sodium)	C				
			Diffu-K (Potassium Chloride)	C				

Date:08/10/00ISR Number: 3548292-5Report Type:Expedited (15-DaCompany Report #00GB-10309
Age:44 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Delusional Disorder, Persecutory Type	Foreign Health	Lioresal	PS	Novartis Pharmaceuticals Corp	ORAL	7.5 MG DAILY	

		Professional					
ORAL							
		Other	Diazepam	C			
			Diclofenac	C			
			Zopiclone	C			
			Fluoxetine	C			

Date:08/10/00ISR Number: 3548299-8Report Type:Expedited (15-DaCompany Report #00F--10677
Age:67 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Life-Threatening	Coma	Foreign	Lioresal	PS	Novartis		
Hospitalization -	Depressed Level Of	Health			Pharmaceuticals Corp	ORAL	15 MG DAILY
Initial or Prolonged	Consciousness	Professional					
ORAL							
	Drug Interaction	Other	Lexomil Tablet				
	Dyspnoea		(Bromazepam)	SS		ORAL	9 MG DAILY
	Laryngeal Disorder						
ORAL							
	Lung Disorder		Laroxyl Tablet				
	Overdose		(Amitriptyline				
	Respiratory Depression		Hydrochloride)	SS		ORAL	25 MG
	Respiratory Disorder						
DAILYORAL							
			Neurontin Capsule				
			(Gabapentin)	SS		ORAL	200 MG DAILY
ORAL							
			Diffu-K Capsule	C			
			Levothyrox Tablet	C			

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/13/00ISR Number: 3570383-3Report Type:Direct Company Report #
Age:55 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Agitation		Metabolite	PS		ORAL	1 PO QD	
	Circulatory Collapse		Baclofen	SS		ORAL	1 PO QD	
	Coma		St John'S Wort	SS				
	Convulsion		Melatonin	SS				
	Drug Abuser							

Date:09/15/00ISR Number: 3572537-9Report Type:Expedited (15-DaCompany Report #HQ0900212SEP2000
Age:52 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Activated Partial	Health	Robaxin	PS	Ah Robins Co	ORAL	ORAL	
Life-Threatening	Thromboplastin Time	Professional	Acetaminophen	SS		ORAL	ORAL	
Hospitalization -	Prolonged		Baclofen	SS		ORAL	ORAL	
Initial or Prolonged	Blood Bicarbonate Decreased							
	Blood Pressure Fluctuation							
	Coma							
	Hypothermia							
	Loss Of Consciousness							
	Pco2 Decreased							
	Po2 Increased							
	Pupillary Reflex Impaired							
	Suicide Attempt							

Date:09/22/00ISR Number: 3578905-3Report Type:Expedited (15-DaCompany Report #PHBS2000CA08880
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Cerebrovascular Accident	Foreign	Lioresal	PS	Novartis			

Initial or Prolonged	Confusional State	Health			Pharmaceuticals Corp	ORAL
5 MG, TID,						
	Disorientation	Professional				
ORAL						
		Other				

Date:09/25/00ISR Number: 3579462-8Report Type:Expedited (15-DaCompany Report #PHEH2000US08592
Age:37 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Abdominal Pain	Consumer	Lioresal	PS	Novartis	
	Alanine Aminotransferase				Pharmaceuticals Corp	ORAL
30 MG, QID,						
	Increased					
ORAL						
	Aspartate		Valproic Acid	C		
	Aminotransferase		Phenobarbital	C		
	Increased					
	Blood Alkaline					
	Phosphatase Increased					
	Liver Function Test					
	Abnormal					

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/28/00ISR Number: 3582584-9Report 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	Mental Impairment		Baclofen	PS				

Date:10/04/00ISR Number: 3587645-6Report Type:Expedited (15-DaCompany Report #A032407
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Aphasia	Consumer	Procardia	PS	Pfizer Inc		30.00 MG	TOTAL: TID
Disability Required Intervention to Prevent Permanent Impairment/Damage	Brain Contusion		Guaifenesin/Phenylpropanolamine	SS			QID	
	Drug Interaction		Dantrium	SS			75.00 MG	TOTAL: TID
	Dysphagia		Baclofen	SS			80.00 MG	TOTAL: QID
	Parenteral Nutrition		Zanaflex	C				
	Pneumonia		Claritin	C				
	Road Traffic Accident		Cranberry Juice	C				
	Skin Ulcer							
	T-Cell Lymphoma							

Date:10/06/00ISR Number: 3590703-3Report Type:Expedited (15-DaCompany Report #PHEH2000US08924
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Coma	Health Professional	Lioresal	PS	Novartis Pharmaceuticals Corp	ORAL	100 MG, ORAL	1 DAY
	Overdose							
	Psychotic Disorder							

Date:10/13/00ISR Number: 3594850-1Report Type:Expedited (15-DaCompany Report #PHEH2000US09173
Age:84 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hallucination Psychotic Disorder	Health Professional	Lioresal	PS	Novartis Pharmaceuticals Corp	ORAL	20 MG QID ORAL	

Date:10/18/00ISR Number: 3597570-2Report Type:Expedited (15-DaCompany Report #A032407
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Accident	Consumer	Procardia	PS	Pfizer Inc		30.00 MG	
Initial or Prolonged	Aspiration	Health					TOTAL: TID	
Disability	Brain Contusion	Professional	Guaifenesin/Phenylpr					
Required	Dysphagia		opanolamine	SS			QID	
Intervention to	Mutism		Dantrium	SS			75.00 MG	
Prevent Permanent	Pneumonia						TOTAL: TID	
Impairment/Damage	Refusal Of Treatment By		Baclofen	SS			80.00 MG	
	Relative						TOTAL: QID	
	T-Cell Lymphoma		Zanaflex	C				
	Ulcer		Claritin	C				
	Vomiting		Cranberry Juice	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/20/00ISR Number: 3598920-3Report Type:Direct Company Report #
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Confusional State Euphoric Mood Hypotension Lethargy Memory Impairment Psychomotor Hyperactivity		Baclofen Apap 650 Mg Asaec 81 Mg Levothyroxine 0.1 Mg Hct/Triamterene Tc#3 1-2 Tab Baclofen	PS C C C C C C		ORAL	1PO BID	

Date:10/23/00ISR Number: 3600637-3Report Type:Expedited (15-DaCompany Report #PHFR2000GB01595
Age:2 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Aphasia Coma Convulsion Diarrhoea Face Oedema Sedation	Foreign Health Professional Other	Lioresal	PS	Novartis Pharmaceuticals Corp	ORAL	2.5 ML, BID, ORAL (SEE IMAGE)	17 DAY

Date:10/24/00ISR Number: 3600288-0Report Type:Expedited (15-DaCompany Report #00-1458
Age:60 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Arrhythmia Depressed Level Of Consciousness Drug Interaction Hypotension Loss Of Consciousness Sinus Bradycardia Syncope	Health Professional Other	Baclofen	PS	Watson Laboratories Inc			

Date:10/24/00ISR Number: 3600465-9Report Type:Direct Company Report #
Age:33 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Required	Confusional State Convulsion Headache		Lioresal Intrathecal-Medtronic	PS	Medtronic		INTRATHECAL	100MG
Intervention to Prevent Permanent Impairment/Damage	Mental Impairment						INTRATHECAL; 50MG	
			Oxycodone	C				

Date:10/25/00ISR Number: 3601207-3Report Type:Direct Company Report #
Age:84 YR Gender:Female I/FU:I

Outcome	PT
Life-Threatening	Acute Psychosis
Hospitalization - Initial or Prolonged	Bradycardia Cardiac Arrest
Disability	Condition Aggravated Confusional State Delirium

	Depressed Level Of Consciousness Dissociation Hallucination Mania Medication Error Speech Disorder	Report Source	Product	Role	Manufacturer	Route	Dose Duration
			Baclofen	PS			20 MG QD RECEIVED X3 DOSES

Date:10/31/00ISR Number: 3605245-6Report Type:Expedited (15-DaCompany Report #PHRM2000FR01545
Age:40 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Life-Threatening	Atrial Fibrillation	Foreign Health Professional	Lioresal	PS	Novartis Pharmaceuticals Corp	ORAL	ORAL

Date:11/02/00ISR Number: 3605925-2Report Type:Expedited (15-DaCompany Report #PHEH2000US09173
Age:84 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged Disability	Acute Psychosis Arthralgia Cardiac Arrest Confusional State Delirium Depressed Level Of Consciousness Dissociation Hallucination Ischaemic Stroke Mania Medication Error Pain In Extremity Pressure Of Speech	Health Professional	Lioresal	PS	Novartis Pharmaceuticals Corp	ORAL	20 MG, QID, ORAL

	Psychotic Disorder					
	Single Photon Emission					
	Computerised Tomogram					
	Abnormal					
	Speech Disorder					

Date:11/21/00ISR Number: 3614710-7Report Type:Expedited (15-DaCompany Report #00-1458 FOL #1
Age:60 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Arrhythmia	Health Professional	Baclofen	PS	Watson Laboratories Inc			
	Blood Pressure Increased							
	Depressed Level Of Consciousness	Other	Neurontin	C				
			Celebrex	C				
	Disorientation		Plavis	C				
	Dizziness		Zoloft	C				
	Drug Interaction		Sinequan	C				
	Heart Rate Decreased		Methadone	C				
	Hypotension		Aspirin	C				
	Loss Of Consciousness							
	Petit Mal Epilepsy							
	Sinus Bradycardia							
	Speech Disorder							
	Syncope							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/21/00ISR Number: 3615604-3Report Type:Expedited (15-DaCompany Report #001-0945-M0001206
Age:53 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain Upper Blood Electrolytes Decreased Disorientation Drug Interaction Drug Level Above Therapeutic Hypertension Memory Impairment Migraine Muscle Contractions Involuntary Tachycardia Tremor	Consumer	Neurontin (Methadone) Morphine Baclofen Zoloft (Sertraline Hydrochloride) Clonidine Cardizem (Diltiazem Hydrochloride) (Potassium) Theophylline Hydrochlorothiazide Flovent (Fluticasone Propionate) (Fluocinonide) Combivent (Ipratropium Bromide, Salbutamol Sulfate) Teargen (Benzalkonium Chloride) Vitamin B12 (Cyancobalamin) Vasocon (Phenylmercuric Acetate, Sodium Carbonate Anhydrous, Naphazoline) Docusate Compazine (Prochlorperazine Edisylate)	PS SS SS SS C C C C C C C C C C C C C	Parke Davis Pharmaceuticals Ltd	ORAL ORAL ORAL ORAL	1800 MG (600 MG TID) PER ORAL PER ORAL PER ORAL	

(Capsaicin)	C
Herbal Natural Estrogen	C
Vitamin E (Tocopherol)	C
Coenzyme Q10 (Ubidecarenone)	C
Stresstab(Vitamins Nos)	C
(Garlic)	C
Very Green Supplement	C
Echinacea Extract	C
Vicodin (Paracetamol, Hydrocodone Bitartrate)	C
Bacitracin /Polymixin Ointment)	C
Benadryl (Diphenhydramine Hydrochloride)	C

			Ibuprofen	C		
			Nystatin Cream	C		

Date:11/21/00ISR Number: 3615652-3Report Type:Expedited (15-DaCompany Report #PHEH2000US08924
Age:84 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Acute Psychosis Agitation	Health Professional	Lioresal	PS	Novartis Pharmaceuticals Corp	ORAL	20 MG, QID,
Disability	Cardiac Arrest					ORAL	
Other	Cerebral Ischaemia Coma Computerised Tomogram Abnormal Confusional State Delirium Disorientation Hallucination Overdose Psychotic Disorder Single Photon Emission Computerised Tomogram Abnormal Speech Disorder Thinking Abnormal		Hydroxyurea (Hydroxycarbamide) Synthroid Nifedipine Flovent (Fluticasone Propionate)	C C C C			

Date:11/21/00ISR Number: 3616938-9Report Type:Expedited (15-DaCompany Report #001-0945-M001206
Age:53 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Abdominal Pain Upper Blood Electrolytes Decreased Disorientation	Consumer	Neurontin	PS	Parke Davis Pharmaceuticals Ltd	ORAL	1800 MG (600 MG, TID) PER ORAL
	Drug Level Above		Methadone	SS		ORAL	PER ORAL

	Therapeutic	Morphine	SS	ORAL PER ORAL
	Dysgraphia	Baclofen	SS	ORAL PER ORAL
	Hypertension	Zoloft	C	
	Migraine	Clonidine	C	
	Movement Disorder	Cardizem	C	
	Pain	Potassium	C	
	Tachycardia	Theophylline	C	
	Tremor	Hydrochlorothiazide	C	
		Flovent	C	
		Fluocinonide	C	
		Combivent	C	
		Teargen	C	
		Vitamin B12	C	
		Vasocon	C	
		Docusate	C	
		Compazine	C	
		Capsaicin	C	
		Herbal Natural		
		Estrogen	C	
		Vitamin E	C	
		Coenzyme Q10	C	
		Stresstab	C	
		Garlic	C	
		Very Green		

Supplement	C
Echinacea Extract	C
Vicodin	C
Bacitracin/Polymixin Ointment	C
Benadryl	C
Ibuprofen	C
Nystatin Cream	C

Date:11/22/00ISR Number: 3617857-4Report Type:Expedited (15-DaCompany Report #PHEH2000US09173
Age:84 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Bradycardia	Health Professional	Lioresal	PS	Novartis Pharmaceuticals Corp	ORAL	20 MG, QID, ORAL	
Disability	Brain Stem Ischaemia							
	Cardiac Arrest							
	Cerebrovascular Disorder		Hydroxyurea	C				
	Confusional State		Synthroid	C				
	Delirium		Flovent	C				
	Depressed Level Of Consciousness		Nifedipine-Slow Release	C				
	Dissociation							
	Hallucination							
	Logorrhoea							
	Mania							
	Medication Error							
	Pain In Extremity							
	Psychotic Disorder							
	Sick Sinus Syndrome							
	Single Photon Emission Computerised Tomogram Abnormal							
	Speech Disorder							
	Thinking Abnormal							

Date:11/28/00ISR Number: 3618194-4Report Type:Expedited (15-DaCompany Report #HQ0900212SEP2000
Age:52 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Death	Activated Partial Thromboplastin Time Prolonged Blood Bicarbonate Decreased Blood Pressure Fluctuation Completed Suicide Electroencephalogram Abnormal Haemorrhage Hypothermia Loss Of Consciousness Pco2 Decreased Po2 Decreased	Literature	Robaxin Acetaminophen (Paracetamol) Baclofen (Baclofen,)	PS SS SS	Ah Robins Co	ORAL ORAL ORAL
Life-Threatening						
Hospitalization - Initial or Prolonged						

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/29/00ISR Number: 3618933-2Report Type:Expedited (15-DaCompany Report #PHFR2000GB01907
Age:5 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Renal Failure	Foreign Health Professional Other	Lioresal	PS	Novartis Pharmaceuticals Corp		700 UG/DAILY	

Date:12/06/00ISR Number: 3622690-3Report Type:Expedited (15-DaCompany Report #00-1678
Age:77 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Anorexia	Other	Baclofen	PS	Watson Laboratories Inc	ORAL	5 MG, BID,	
	Condition Aggravated						PO; 2.5 MG,	
	Dysphagia						BID, PO	
	Failure To Thrive							
	Sedation		Lopressor	C				
	Speech Disorder		Zantac	C				

Date:12/11/00ISR Number: 3626940-9Report Type:Expedited (15-DaCompany Report #PHRM2000FR01800
Age:80 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Confusional State	Foreign Health Professional Other	Lioresal	PS	Novartis Pharmaceuticals Corp	ORAL	30 MG/DAY, ORAL	
	Memory Impairment		Comtan Tablet	C				
			Modopar (Levodopa, Benserazide Hydrochloride) Capsule	C				
			Requip (Ropinirole Hydrochloride)					

			Tablet	C		

Date:12/12/00ISR Number: 3627611-5Report Type:Expedited (15-DaCompany Report #2000-12-0048
Age:24 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Convulsion	Foreign Health Professional	Polaramine	PS	Schering Corp Sub Schering Plough Corp	INTRAVENOUS	5 MG QD	
		Other	Cortancyl Injectable	SS		INTRAVENOUS	50 MG QD	
			Lioresal Tablets	SS		ORAL	2 QD	
			Skenan Capsules	SS		ORAL	30 MG QD	

Date:12/18/00ISR Number: 3633508-7Report Type:Expedited (15-DaCompany Report #PHRM2000FR01837
Age:80 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Interaction International Normalised Ratio Increased	Foreign Health Professional	Lioresal	PS	Novartis Pharmaceuticals Corp	ORAL	5 MG, BID,	
		Other	Coumadine (Warfarin Sodium) Tablet	SS		ORAL	UNK, UNK,	
ORAL	4	DAY						

			Gardenal "Specia" (Phenobarbital) Tablet	SS		ORAL	UNK, UNK,
ORAL	4 DAY						

Date:01/03/01ISR Number: 3641648-1Report Type:Expedited (15-DaCompany Report #001-0945-M0000196
Age:40 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Arthralgia Asthenia	Consumer	Neurontin	PS	Parke Davis Pharmaceuticals Ltd	ORAL	900 MG(300 MG
Other	Blood Potassium Decreased						TID):2400MG(8
	Carpal Tunnel Syndrome						00MG
	Cholelithiasis						TID):2100MG(7
	Cholestasis						00MG
	Decreased Activity		Baclofen	SS		ORAL	80 MG PER
	Dental Caries						ORAL
	Depression		Ms Contin	SS			1600 MG
	Difficulty In Walking		Propulsid	SS			
	Dry Mouth		Methadone	SS			2500 MG
	Fall		Percocet	SS			1 OR 2 (Q 4 H
	Fatigue						PRN)
	Gallbladder Disorder		Valium	SS			80 MG
	Gallbladder Pain		Zanaflex	SS		ORAL	8 MG PER ORAL
	Headache		Zoloft	SS		ORAL	200 MG PER
	Hypoaesthesia						ORAL

		Hypothyroidism		Hydrochlorothiazide	SS		ORAL
100 MG PER							
		Joint Dislocation					
ORAL							
		Lethargy		Veetids	SS		ORAL
2000 MG PER							
		Liver Function Test					
ORAL	1 WK						
		Abnormal		Synthroid	SS		
		Lymphadenopathy		Oxy Ir (Oxycodone			
		Malnutrition		Hydrochloride)	SS		
8-10 DAILY							
		Movement Disorder		Lasix	SS		
80 MG							
		Nervous System Disorder		Ritalin	SS		
80 MG							
		Oedema Peripheral		K-Dur	SS		
20 MCG							
		Osteoporosis		Seroquel	SS		
		Ovarian Cyst		Ketamine	SS		
		Pain In Extremity		Klonopin	SS		
		Pruritus		Corgard	SS		
		Skin Discolouration		Relafen	SS		
		Skin Ulcer		Celebrex	SS		
800 MG							
		Tendon Disorder		Carafate	SS		
4 MG							
		Vomiting		Dextromethorphan	SS		
200 MG							
		Weight Decreased		Nadolol	SS		
		Weight Increased		Tegaderm	SS		

Date:01/08/01ISR Number: 3648961-2Report Type:Expedited (15-DaCompany Report #00-1678 FOL# 1
Age:77 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Anorexia	Other	Baclofen Tablets 10					
Other	Condition Aggravated		Mg,	PS	Watson Laboratories			
	Decreased Appetite				Inc	ORAL	2.5 MG BID PO	
	Dysphagia		Baclofen Tablets 10					
	Eating Disorder		Mg	SS		ORAL	5 MG BID PO	
	Failure To Thrive		Lopressor	C				
	Sedation		Zantac	C				
	Speech Disorder							

Date:01/22/01ISR Number: 3652975-6Report Type:Expedited (15-DaCompany Report #PHBS2001US00534
Age:27 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Coma	Literature	Lioresal	PS	Novartis Pharmaceuticals Corp		120 MGDAY	
	Convulsion	Health						
	Drug Interaction	Professional	Unasyn(Sultamicillin)	SS				
	Drug Toxicity							
	Electroencephalogram Abnormal							
	Haemodialysis							
	Lethargy							

Date:01/23/01ISR Number: 3652741-1Report Type:Expedited (15-DaCompany Report #00-1458 FOL #2
Age:60 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Pressure Increased	Health Professional	Baclofen	PS	Watson Laboratories Inc			
	Depressed Level Of Consciousness	Other	See B5	SS				
	Dizziness		See B5	C				
	Drug Interaction							
	Hypotension							
	Loss Of Consciousness							
	Sinus Bradycardia							
	Speech Disorder							
	Syncope							

Date:02/02/01ISR Number: 3658416-7Report Type:Expedited (15-DaCompany Report #01-0081
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Overdose	Health Professional	Baclofen	PS	Watson Laboratories Inc			
		Company Representative	Klonopin Tablets	SS	Hoffmann-Laroche			

Date:02/05/01ISR Number: 3660536-8Report Type:Periodic Company Report #A009870
Age:72 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Headache	Consumer	Zyrtec	PS	Pfizer Inc	ORAL	10 MG TOTAL	
	Pruritus						DAILY ORAL	
			Baclofen	SS		ORAL	20 MG TOTAL	
							BID ORAL	
			Flonase	SS		NASAL	BID NASAL	

Date:02/08/01ISR Number: 3662369-5Report Type:Direct Company Report #
Age:76 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Mental Impairment		Baclofen	PS				
	Vomiting							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/08/01ISR Number: 3662373-7Report 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	Confusional State Hallucination		Baclofen	PS				

Date:02/15/01ISR Number: 3666007-7Report Type:Direct Company Report #
Age:80 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Confusional State		Baclofen	PS			10MG TID	
	Disorientation		Naproxen	C				
			Fluoxetine	C				
			Levothyroxine	C				
			Lisinopril	C				
			Terazosin	C				

Date:02/28/01ISR Number: 3671474-9Report Type:Expedited (15-DaCompany Report #001-0945-M0000462
Age:72 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Aphonia	Health Professional	Neurontin	PS	Parke Davis Pharmaceuticals Ltd	ORAL	900 MG (300 MG, TID), PER ORAL	
	Blood Glucose Increased							
	Cellulitis							
	Disturbance In Attention							
	Dizziness		Baclofen (Baclofen)	SS		ORAL	75 MG (25 MG, TID), PER ORAL	
	Headache							
	Nausea							
	Tremor		(Insulin)	C				
	Vision Blurred		Aleve (Naproxen Sodium)	C				

Date:02/28/01ISR Number: 3672718-XReport Type:Periodic Company Report #A037642
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Intentional Misuse Suicide Attempt	Other	Zoloft	PS	Pfizer Pharmaceuticals Inc			
			Glyburide	SS				
			Penicillin	SS				
			Baclofen	SS				
			Ibuprofen	C				
			Fluoxetine	C				

Date:03/01/01ISR Number: 3672327-2Report Type:Expedited (15-DaCompany Report #PHBS2001BE02018
Age:68 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Body Temperature Increased	Foreign Health Professional	Lioresal	PS	Novartis Pharmaceuticals Corp	ORAL	5 MG, TID, ORAL	
		Other	Loramet (Lormetazepam)	C				
			D-Cure	C				
			Dafalgan Codeine (Paracetamol)	C				
			Folc Acid	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/01/01ISR Number: 3683080-0Report Type:Periodic Company Report #2000AU04364
Age:72 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dry Mouth	Other	Plendil	PS	Astrazeneca Pharmaceuticals Lp			
	Dry Skin							
	Dry Throat		Cozaar	SS				
	Glossodynia		Oxybutynin "Generics Uk"	SS		ORAL	5 MG TID PO	
	Nasal Dryness							
	Pruritus		Baclofen	C				
			Insulin	C				
			Nitro Patch	C				

Date:03/06/01ISR Number: 3674694-2Report Type:Direct Company Report #
Age:46 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Nausea		Baclofen Intrathecal Pump	PS		INTRAVENOUS	2000MCG/ML-20 ML IV	
	Vomiting							
	Weight Decreased							
			Verapamil	C				
			Premarin	C				
			Omeprazole	C				
			Cisapride	C				
			Diazepam	C				
			Trazadone	C				

Date:03/06/01ISR Number: 3674755-8Report Type:Expedited (15-DaCompany Report #PHEH2001US01929
Age:2 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Accidental Overdose	Health Professional	Lioresal	PS	Novartis Pharmaceuticals Corp	ORAL	ORAL	
Required Intervention to Prevent Permanent	Coma							
	Convulsion							
	Respiratory Depression							

Impairment/Damage

Date:03/13/01ISR Number: 3681032-8Report Type:Expedited (15-DaCompany Report #PHBS2001BE02018
Age:68 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Body Temperature Increased	Foreign Health Professional Other	Lioresal	PS	Novartis Pharmaceuticals Corp	ORAL	5 MG TID ORAL	
			Loramet (Lorametazepam)	C				
			D-Cure	C				
			Folic Acid	C				
			Dafalgan Codeine (Paracetamol)	C				

Date:03/16/01ISR Number: 3683086-1Report Type:Expedited (15-DaCompany Report #HQ5452112N0V1999
Age:51 YR Gender:Male I/FU:F

Outcome	PT
Death	Bronchitis Acute
	Cardiac Failure Congestive

	Collapse Of Lung Drug Interaction Drug Level Above Therapeutic	Report Source Consumer	Product Reglan	Role PS	Manufacturer Ah Robins Co	Route ORAL	Dose Duration
	Dyspnoea Respiratory Depression Respiratory Failure Sedation		Baclofen Dantrium (Dantrolene Sodium) Darvocet-N (Dextropropoxyphene/ Paracetamol) Imipramine	SS SS SS SS		ORAL ORAL ORAL	FOUR TIMES DAILY, ORAL ORAL

Date:03/19/01ISR Number: 3684033-9Report Type:Direct Company Report #
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Medication Error		Baclofen Tegretol Estradiol	PS SS SS	Novartis		

Date:03/19/01ISR Number: 3684297-1Report Type:Expedited (15-DaCompany Report #PHEH2001US02375
Age:50 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Other	Electrocardiogram Q Waves	Health Professional	Lioresal	PS	Novartis Pharmaceuticals Corp	ORAL	10 MG, QD ORAL

Date:03/19/01ISR Number: 3684313-7Report Type:Expedited (15-DaCompany Report #2000COU1502
Age:34 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Literature	Coumadin	PS	Dupont Merck			
		Health			Pharmaceutical Co	ORAL	PO	
		Professional	Ni (Amitriptyline)	SS		ORAL	PO	
			Ni (Baclofen)	SS		ORAL	PO	

Date:03/26/01ISR Number: 3690183-3Report Type:Expedited (15-DaCompany Report #PHBS2001BE02884
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Ageusia	Foreign	Lioresal	PS	Novartis			
	Anosmia	Health			Pharmaceuticals Corp	ORAL	5 MG, TID,	
		Professional						
		Other					ORAL	2 DAY

Date:03/30/01ISR Number: 3699553-0Report Type:Periodic Company Report #A013553
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hypertonia	Consumer	Cardura	PS	Pfizer Laboratories			
					Div Pfizer Inc	ORAL	2.00 MG	
							TOTAL: DAILY:	
							ORAL	
			Baclofen	SS		ORAL	60.00 MG	

TOTAL: QID:

ORAL

			Ativan	C		
			Macrodantin	C		
			Plendil	C		

Date:03/30/01ISR Number: 3706283-5Report Type:Expedited (15-DaCompany Report #PHHO2000DE01410
Age:58 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Aphasia Epilepsy	Foreign Study Health Professional	Sandoglobulin Or Placebo (Placebo Placebo)	PS		INTRAVENOUS	QMO,	
		Other	Baclofen (Baclofen)	SS		INTRAVENOUS		
			Ds-103-282 (Tizanidine Hydrochloride)	SS				
			Orfiril (Valproate Sodium)	C				
			Neuromet (Oxiracetam)	C				

Date:04/02/01ISR Number: 3694560-6Report Type:Expedited (15-DaCompany Report #PHBS2000CA08880
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Cerebrovascular Accident Confusional State Disorientation	Foreign Health Professional Other	Lioresal	PS	Novartis Pharmaceuticals Corp	ORAL	5 MG, TID,	ORAL

Date:04/03/01ISR Number: 3695879-5Report Type:Expedited (15-DaCompany Report #PHBS2001CA03213
Age: Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Gastric Haemorrhage	Foreign Health Professional Other	Lioresal	PS	Novartis Pharmaceuticals Corp	ORAL	60 MG/DAY, ORAL	

Date:04/03/01ISR Number: 3696156-9Report Type:Expedited (15-DaCompany Report #PHEH2001US01929
Age:2 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	Accidental Overdose Body Temperature Decreased Bradycardia Coma Convulsion Drug Level Above Therapeutic Hypothermia Lethargy Respiratory Depression	Health Professional	Lioresal	PS	Novartis Pharmaceuticals Corp	ORAL	ORAL	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/04/01ISR Number: 3700039-5Report Type:Expedited (15-DaCompany Report #01-0396
Age:54 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anorexia Condition Aggravated	Consumer	Baclofen	PS	Watson Laboratories Inc		20 MG PO QID	
	Dry Mouth		Baclofen	SS	Qualitest	ORAL	20 MG PO QID	
	Headache Multiple Sclerosis		Baclofen	SS	Schein Pharmaceuticals	ORAL	20 MG QID PO	
	Nausea Paraesthesia		Topamax Ms Tegretol & Klonopin Fioriceet Demerol Phenergan Ditropan	C C C C C C				

Date:04/05/01ISR Number: 3699720-6Report Type:Expedited (15-DaCompany Report #PHBS2001GB03223
Age:36 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Aspartate Aminotransferase	Foreign Literature	Lioresal	PS	Novartis Pharmaceuticals Corp		10 MG/ADY	
	Increased Blood Creatine Phosphokinase Increased Blood Lactate Dehydrogenase Increased Depressed Level Of Consciousness Drug Withdrawal Syndrome Hyperhidrosis Leukocytosis Muscle Rigidity Neuroleptic Malignant Syndrome Pyrexia Tachycardia	Health Professional	Amitriptyline (Amitriptyline)	SS			50 MG/DAY	

Date:04/05/01ISR Number: 3700147-9Report 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	Hypoglycaemia Lethargy		Phenytoin Baclofen	PS SS			10 MG TID	
			Warfarin Insulin Gemfibrozil Carvedilol	C C C C				

Date:04/23/01ISR Number: 3708764-7Report Type:Expedited (15-DaCompany Report #01-0580
Age:60 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Ammonia Increased Asthenia Coma Difficulty In Walking	Health Professional	Baclofen	PS	Watson Laboratories Inc		10 MG - 20 MG TID (SEE TEXT)	
	Disorientation Lethargy		Zoloft Prevacid	C C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/25/01ISR Number: 3710988-XReport Type:Expedited (15-DaCompany Report #PHBS2001AU03911
Age:51 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Aggression	Foreign	Lioresal	PS	Novartis Pharmaceuticals Corp	ORAL		
	Choking	Consumer						
	Dysphagia	Other	Diazepam	C				
	Hallucination		Clonazepam	C				
	Tongue Oedema		Clonidine (Clonidine)	C				
			Temazepam	C				
			Sulfamethoxazole (Sulfamethoxazole)	C				
			Duphalac	C				
			Coloxyl With Senna (Sennoside A+B)	C				
			Memantine (Memantine)	C				
			Ergocalciferol	C				
			Alendronate	C				
			Serenase	C				

Date:04/30/01ISR Number: 3715017-XReport Type:Expedited (15-DaCompany Report #PHFR2001GB01322
Age:59 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Condition Aggravated	Foreign	Lioresal	PS	Novartis Pharmaceuticals Corp	ORAL	30 MG, TID,	
	Drug Withdrawal Syndrome	Health						
	Ileus Paralytic	Professional						
	Paranoia	Other	Diazepam	C				
			Tramadol (Tramadol)	C				
			Ranitidine (Ranitidine)	C				
			Warfarin (Warfarin)	C				
			Carbamazepine	C				
			Dantrolene (Dantrolene)	C				

Date:05/01/01ISR Number: 3714490-0Report Type:Direct Company Report #
Age:44 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Face Oedema Swelling		Baclofen (10mg Tab)	PS				

Date:05/10/01ISR Number: 3720659-1Report Type:Direct Company Report #
Age:38 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	Accidental Overdose Bradycardia Hyporeflexia Hypotension Respiratory Disorder		Lioresal Intrathecal / 10mg/ 20cc / Novartis For Medtronic	PS	Novartis For Medtronic	INTRATHECAL	4.17MCG.	HOUR
			Medtronic Synchromed Pump	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/11/01ISR Number: 3722392-9Report Type:Expedited (15-DaCompany Report #PHBS2001AU03911
Age:51 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Aggression Choking Dysarthria Dysphagia Hallucination Tongue Oedema	Foreign Health Professional Other	Lioresal Diazepam Clonazepam Clonidine (Clonidine) Temazepam Sulfamethoxazole (Sulfamethoxazole) Duphalac Coloxy With Senna (Sennoside A+B) Memantine (Memantine) Erogcalciferol Alendronate Serenase	PS C C C C C C C C C C	Novartis Pharmaceuticals Corp	ORAL ORAL	100 MG/DAY,	

Date:05/14/01ISR Number: 3724028-XReport Type:Expedited (15-DaCompany Report #20010820
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Coma Hepatocellular Damage Renal Failure Acute	Foreign Health Professional	Lioresal Modopar (Levodopa, Benserazide Hydrochloride) Myolastan (Tetrazapam) Deroxat Urbanyl (Clobazam) Rivotril	PS C C C C C	Medtronic Inc	INTRATHECAL INTRATHECAL	0.025 MCG, DAILY, 1 DAY	

			Durogesic (Fentanyl) Transtherapeutic System	C		
			Forlax (Macrogol)	C		

Date:05/17/01ISR Number: 3724859-6Report Type:Expedited (15-DaCompany Report #01-0396 FOL.#1
Age:54 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Anorexia Asthenia	Consumer	Baclofen	PS	Watson Laboratories Inc	ORAL	20 MG PO QID
	Condition Aggravated Dry Mouth		Baclofen 10 Mg, Qualitest	SS	Qualitest	ORAL	2 MG PO QID
	Face Oedema Headache		Baclofen	SS	Schein Pharmaceuticals	ORAL	20 MG QID PO
	Multiple Sclerosis		Topamax	C			
	Nausea		...	C			
	Pain		Tegretol	C			
	Paraesthesia		Klonopin	C			
	Weight Increased		Fioricet	C			
			Demerol	C			
			Phenergan	C			

Ditropan	C
Oxybutynin	C
Promethazine	C
Meperidine	C
Potassium	C
Furosemide	C
Alprazolam	C
..	C
Pevacid	C
...	C
Imitrex Injection	C
Neurontin	C

Date:05/21/01ISR Number: 3726917-9Report Type:Expedited (15-DaCompany Report #PHBS2001DE04906
Age:25 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Overdose Sleep Apnoea Syndrome	Foreign Literature Health Professional Other	Lioresal	PS	Novartis Pharmaceuticals Corp		40 MG/D	

Date:05/23/01ISR Number: 3727480-9Report Type:Direct Company Report #
Age:44 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Medication Error		Lioresal 2000 Mcg/Ml	PS		INTRATHECAL	180MCG	1 DAY
Initial or Prolonged						INTRATHECAL		

Date:05/23/01ISR Number: 3727772-3Report Type:Direct Company Report #
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Required	Alanine Aminotransferase	Baclofen (10mg)	PS
20MG BID GT			
Intervention to	Increased		
PRIOR TO			
Prevent Permanent	Aspartate		
ADMISSION			
Impairment/Damage	Aminotransferase	Acetaminophen	C
	Increased		
	Blood Alkaline		
	Phosphatase Increased		
	Blood Creatine		
	Phosphokinase Increased		

Date:05/23/01ISR Number: 3727773-5Report Type:Direct Company Report #
Age:18 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required	Alanine Aminotransferase		Baclofen 10mg	PS				
10MG QID								
Intervention to	Increased		Solu-Medrol	C				
Prevent Permanent	Aspartate		Propranolol	C				
Impairment/Damage	Aminotransferase		Hazepam	C				
	Increased		Clonidine	C				
	Blood Lactate							
	Dehydrogenase Increased							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/29/01ISR Number: 3729550-8Report Type:Direct Company Report #
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Coma Drooling Dyskinesia Medication Error Speech Disorder Urinary Incontinence Vomiting		Baclofen Gabapentin Clonazepam Buspirone Alprazolam Diazepam	PS C C C C C		ORAL	DOSE UNKNOWN PO X 1	

Date:06/04/01ISR Number: 3733094-7Report Type:Expedited (15-DaCompany Report #PHEH2001US02961
Age:15 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Extravasation Medication Error	Health Professional	Lioresal	PS	Novartis Pharmaceuticals Corp	ORAL	30 MG, TID, ORAL; 30 MG,	ONCE/SINGLE

Date:06/07/01ISR Number: 3734646-0Report Type:Direct Company Report #
Age:44 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Coma Medication Error		Baclofen (Lioresal 2000mg / Ml)	PS	Novartis	INTRATHECAL	2000 MG/ML	Other 4X5 ML AMPULES
			Lioresal 500mg/Ml (Baclofen)	SS	Novartis	INTRATHECAL	500 MG/ML	

20ML AMPULE

Date:06/11/01ISR Number: 3737262-XReport Type:Periodic Company Report #2000-09-1047
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Interaction Skin Disorder	Consumer	Claritin	PS	Schering Corp Sub Schering Plough Corp	ORAL	10 MG/QD	ORAL
			Zanaflex (Tizanidine Hcl) Tablets	SS		ORAL	4-8 MG/PRN	ORAL
			Dantrium	SS			25 MG/TID	
			Procardia	SS			10 MG/TID	
			Docusate Sodium	SS		ORAL	1/2-2 TSP/BID	ORAL
			Senokot	SS				
			Baclofen	SS			20 MG/QID	
			Milk Of Magnesia	SS			2 TBS/Q3D	
			Simethicone	SS			80-160 MG/QID	
			Entex La Tablets	SS			1/2 TAB/QID	

Date:06/11/01ISR Number: 3740489-4Report Type:Periodic Company Report #20010823
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hypoventilation Sedation	Health Professional	Lioresal	PS	Medtronic Inc	INTRATHECAL	UNK MCG, DAILY,	

INTRATHECAL

Date:06/15/01ISR Number: 3740755-2Report Type:Expedited (15-DaCompany Report #PHBS2001DE04906
Age:25 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Nightmare	Foreign	Lioresal	PS	Novartis Pharmaceuticals Corp		40 MG/D	
	Overdose	Literature						
	Sleep Apnoea Syndrome	Health						
	Sleep Attacks	Professional						
	Sleep Disorder	Other						

Date:06/15/01ISR Number: 3740882-XReport Type:Expedited (15-DaCompany Report #PHEH2001US04787
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Anxiety	Consumer	Lioresal	PS	Novartis Pharmaceuticals Corp		INTRATHECAL	INTRATHECAL
Other	Emotional Disorder							
	Injury							
	Medication Error							

Date:06/20/01ISR Number: 3743119-0Report Type:Expedited (15-DaCompany Report #01-0396 FOL.#2
Age:54 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anorexia	Consumer	Baclofen	PS	Watson Laboratories Inc	ORAL	20 MG PO QID	
	Anxiety							
	Asthenia		Baclofen Tablets 10 Mg, Qualitest	SS		ORAL	20 MG PO QID	
	Condition Aggravated							
	Drug Effect Decreased		Baclofen Tablets 20 Mg, Schein Pharmaceuticals	SS	Schein Pharmaceuticals	ORAL	20 MG QID PO	
	Dry Mouth							
	Face Oedema							
	Headache							

Multiple Sclerosis	Topamax	C
Nausea	Tegregol	C
Paraesthesia	Klonopin	C
Weight Increased	Fioricet	C
	Demerol	C
	Phenergan	C
	Ditropan	C
	Oxybutynin	C
	Promethazine	C
	Meperidine	C
	Potassium	C
	Furosemide	C
	Alprazolam	C
	Baclofen	C
	Prevacid	C
	Clonazepam	C
	Imitrex Injection	C
	Neurontin	C

Date:06/26/01ISR Number: 3748127-1Report Type:Expedited (15-DaCompany Report #031-0945-M0100017
Age: Gender:Female I/FU:I

Outcome	PT	Report Source
Other	Drug Interaction	Foreign
	Loss Of Consciousness	Health

Professional

			Product	Role	Manufacturer	Route
Dose	Duration					
			Neurontin	PS	Pfizer Inc	ORAL
PER ORAL						
			Baclofen (Baclofen)	SS		ORAL
PER ORAL						

Date:06/28/01ISR Number: 3749867-0Report Type:Expedited (15-DaCompany Report #20010826
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization -	Hypotonia	Health	Lioresal	PS	Medtronic Inc	
INTRATHECAL	UNK MCG DAILY					
Initial or Prolonged	Medication Error	Professional				
INTRATHECAL						
Required	Overdose					
Intervention to	Pocket Erosion					
Prevent Permanent						
Impairment/Damage						

Date:06/28/01ISR Number: 3750110-7Report Type:Expedited (15-DaCompany Report #PHRM2000FR01837
Age:80 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Life-Threatening	Drug Interaction	Foreign	Lioresal	PS	Novartis	
Hospitalization -	International Normalised	Health			Pharmaceuticals Corp	ORAL
15 MG/DAY,						
Initial or Prolonged	Ratio Increased	Professional				
ORAL						
Other		Other	Coumadine (Warfarin Sodium) Tablet	SS		ORAL
5 MG/DAY,						
ORAL	3 DAY					
			Gardenal "Specia" (Phenobarbital)Table t	SS		ORAL
50 MG/DAY,						

ORAL 3 DAY

Date:06/29/01ISR Number: 3750713-XReport Type:Expedited (15-DaCompany Report #2012485
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Coma	Health	Oxycontin	PS	Purdue Pharma Lp	ORAL	40 MG PO	
Required Intervention to Prevent Permanent Impairment/Damage		Professional Company Representative	Baclofen (Lioresal)	SS				

Date:07/02/01ISR Number: 3751328-XReport Type:Expedited (15-DaCompany Report #PHFR2001GB01825
Age:82 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agitation	Foreign	Lioresal	PS	Novartis Pharmaceuticals Corp	ORAL	10 MG, TID, ORAL	
	Confusional State	Health						
	Drug Withdrawal Syndrome	Professional						
	Hallucination, Visual	Other	Lisinopril (Lisinopril)	C				
			Fursemid	C				
			Allopurinol	C				

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Date:07/13/01ISR Number: 3758525-8Report Type:Expedited (15-DaCompany Report #PHFR2001GB01980
Age:53 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Apnoea	Foreign	Lioresal	PS	Novartis			
	Cheyne-Stokes Respiration	Health			Pharmaceuticals Corp	ORAL	5 MG, BID,	
	Drug Interaction	Professional					ORAL (SEE	
		Other					IMAGE)	
			Enalapril (Enalapril)	C				
			Atenolol	C				
			Nortriptyline (Nortriptyline)	C				
			Co-Dydramol (Dihydrocodeine Bitartrate, Paracetamol)	C				

Date:07/16/01ISR Number: 3759890-8Report Type:Expedited (15-DaCompany Report #PHBS2001ES06967
Age:35 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Optic Atrophy	Foreign	Lioresal	PS	Novartis			
	Papilloedema	Health			Pharmaceuticals Corp	ORAL	ORAL	
		Professional	Neurontin					
		Other	(Gabapentin)	C				
			Paroxetine	C				
			Omeprazole	C				
			Levothroid	C				

Date:07/23/01ISR Number: 3763107-8Report Type:Periodic Company Report #01-04-0187
Age:59 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Face Oedema	Consumer	Baclofen	PS	Zenith Goldline			

	Hypoaesthesia Oral				Pharmaceuticals	ORAL
20 MG BID						
	Polyuria					
ORAL						
	Sleep Disorder		Neurontin	C		
			Prozac	C		
			Prempro	C		
			Calcium Qd	C		
			Magnesium Qd	C		
			Zinc Qd	C		
			Multivitamins	C		

Date:07/23/01ISR Number: 3763620-3Report Type:Expedited (15-DaCompany Report #034-0945-M0100007
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Optic Atrophy	Foreign	Neurontin	PS	Pfizer Inc	ORAL
100 MG TID,						
Initial or Prolonged	Papilloedema	Health				
PER ORAL						
Other		Professional	Baclofen (Baclofen)	SS		ORAL
10 MG TID,						
PER ORAL						
			Paroxetine (Paroxetine)	SS		ORAL
20 MG (20 MG,						
DAILY), PER						
ORAL						
			Omeprazol (Omeprazole)	SS		ORAL
20 MG (20 MG,						

DAILY), PER

ORAL

			Levothyroxine (Levothyroxine)	SS		ORAL

100 MG (100

MG, DAILY),

PER ORAL

Date:07/24/01ISR Number: 3764144-XReport Type:Expedited (15-DaCompany Report #PHNU2001DE01547
Age:40 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Coagulopathy	Health	Lioresal (Baclofen)					
Hospitalization -	Convulsion	Professional	Solution	PS				
635								
Initial or Prolonged	Drug Level Below	Other						
MICROGRAM;								
	Therapeutic							
DAY								
	Drug Withdrawal Syndrome		Insulin Basal					
	Medication Error		(Insulin Isophane					
	Multi-Organ Failure		Human Semisynthetic)	C				
	Muscle Spasms		Magnesium	C				
			Rivotril					
			(Clonazepam)	C				
			Benzodiazephines	C				

Date:07/24/01ISR Number: 3764147-5Report Type:Expedited (15-DaCompany Report #PHBS2001NL07024
Age:54 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Coma	Health	Lioresal Intrathecal					
Hospitalization -	Drug Interaction	Professional	(Baclofen) Solution					
Initial or Prolonged		Other	For Injection	PS				
INTRATRACHEAL	0.05 MG, DAY;							

INJECTION NOS

			Gabapentin			

			(Gabapentin) Tablet	SS			ORAL
3 TABLETS,							
DAY; ORAL							
			Carbasalate Calcium	C			
			Galenic/Amoxicillin/ Clavulanic Acid (Amoxicillin, Clavulanic Acid)	C			
			Fentanyl	C			
			Flucloxacillin	C			
			Nadroparin	C			
			Insulin	C			
			Morphine Sulfate	C			
			Paracetamol	C			
			Metoprolol	C			
			Morphine	C			

Date:07/24/01ISR Number: 3764171-2Report Type:Expedited (15-DaCompany Report #20010833
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Decubitus Ulcer	Health Professional	Lioresal (Baclofen Injection)	PS	Medtronic Inc	INTRA-ARTICULAR	MCG,	DAILY,
Required Intervention to Prevent Permanent Impairment/Damage	Drug Withdrawal Syndrome					INTRATHECAL		
	Implant Site Reaction							
	Mental Disorder							

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Date:07/24/01ISR Number: 3764173-6Report Type:Expedited (15-DaCompany Report #20010832
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Drug Withdrawal Syndrome	Health	Lioresal	PS	Medtronic Inc	INTRATHECAL	635 MCG,	
Hospitalization -	Multi-Organ Failure	Professional						DAILY,
Initial or Prolonged						INTRATHECAL		
			Exclude Treatment Of Event	C				

Date:07/24/01ISR Number: 3764174-8Report Type:Expedited (15-DaCompany Report #20010831
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Coma	Health	Lioresal	PS	Medtronic Inc	INTRATHECAL	50 MCG,	
Initial or Prolonged	Drug Interaction	Professional						DAILY,
						INTRATHECAL		

Date:07/24/01ISR Number: 3764270-5Report Type:Expedited (15-DaCompany Report #20010834
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Complications Of Maternal	Foreign	Lioresal	PS	Medtronic Inc	INTRATHECAL	MCG, DAILY,	
	Exposure To Therapeutic	Health						
	Drugs	Professional				INTRATHECAL		
	Convulsion Neonatal							
	Drug Withdrawal Syndrome Neonatal							

Date:07/25/01ISR Number: 3765648-6Report Type:Expedited (15-DaCompany Report #PHRM2001FR1687
Age:88 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agitation Hepatitis Vomiting	Foreign Health Professional	Lioresal	PS	Novartis Pharmaceuticals Corp	ORAL	10 MG, BID, ORAL	
		Other	Prepulsid (Cisapride)	SS		ORAL	10 MG, TID, ORAL	
			Noctamid (Lormetazepam)	SS		ORAL	1 MG, QD, ORAL	
			Ogast (Lansoprazole)	SS		ORAL	30 MG, QD, ORAL	

Date:07/26/01ISR Number: 3765465-7Report Type:Expedited (15-DaCompany Report #01-07-0392
Age:43 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blood Creatine Phosphokinase Increased Oedema Peripheral Pain In Extremity	Literature	Baclofen	PS	Zenith Goldline Pharmaceuticals	ORAL	ORAL	
			Doxepin Tablets	SS		ORAL	100MG HS ORAL	
			Methadone Hydromorphone	C C				

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Date:07/26/01ISR Number: 3766327-1Report Type:Expedited (15-DaCompany Report #031-0945-M0100017
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Other	Drug Interaction	Foreign	Neurontin	PS	Pfizer Inc	ORAL	PER ORAL
	Loss Of Consciousness	Health	Baclofen	SS		ORAL	PER ORAL
		Professional	Insuline (Insulin Human)	C			
			Dantroleen	C			
			Morfine Sulfate	C			
			Paracetamol	C			
			Metoprolol	C			
			Cabasalate Calcium	C			
			Flucloxacilline	C			
			Augmentin (Clavulanate Potassium, Amoxicillin Trihydrate)	C			
			Nadroparine	C			

Date:07/27/01ISR Number: 3766908-5Report Type:Expedited (15-DaCompany Report #2012485
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Life-Threatening	Apnoea	Health	Oxycontin	PS	Purdue Pharma Lp	ORAL	40 MG Q8H PO
Other	Coma	Professional	Baclofen (Lioresal)	SS		ORAL	20 MG TID PO
Required Intervention to Prevent Permanent Impairment/Damage	Delirium	Company Representative	Paxil (Paroxetine)	C			
	Drug Withdrawal Syndrome		Lansoprazole	C			
	Hypotension		Detrol La (Tolterodine Tartrate)	C			
			Actos (Pioglitazone)	C			

Date:07/30/01ISR Number: 3768763-6Report Type:Expedited (15-DaCompany Report #PHBS2001CA03353
Age:58 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Coma	Foreign	Lioresal	PS	Novartis			
Life-Threatening	Completed Suicide	Health			Pharmaceuticals Corp	ORAL	SEE IMAGE	
Hospitalization - Initial or Prolonged	Depressed Level Of Consciousness Hypoxic Encephalopathy Intentional Misuse Pupillary Reflex Impaired Respiratory Arrest	Professional Other	Pentoxifylline (Pentoxifylline)	C				

Date:07/31/01ISR Number: 3768548-0Report Type:Expedited (15-DaCompany Report #20010842
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Convulsion	Health	Lioresal	PS	Medtronic Inc		50 MCG TEST	
		Professional					DOSE,	
							INTRATHECAL	
			Oral Baclofen	C				

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Freedom Of Information (FOI) Report

Date:08/06/01ISR Number: 3771463-XReport Type:Direct Company Report #
Age:15 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Cardio-Respiratory Arrest		Baclofen	PS		INTRATHECAL	1000MICRO DAY	
Hospitalization - Initial or Prolonged	Medication Error					INTRATHECAL		
Required Intervention to Prevent Permanent Impairment/Damage	Respiratory Depression							

Date:08/08/01ISR Number: 3773296-7Report Type:Expedited (15-DaCompany Report #01-1110
Age:18 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Coma	Health Professional	Baclofen Tablets, Unknown Manufacturer/Strength	PS		APPROXIMATELY 9 TABLETS		

Date:08/08/01ISR Number: 3783894-2Report Type:Direct Company Report #
Age:48 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Condition Aggravated		Lioresal 2000 Mcg./Cc	PS	Medtronic	INTRATHECAL	350 MCG./	
	Failure Of Implant		Medtronic					
	Hypertonia					INTRATHECAL		
	Pruritus		Baclofen	C				
			Diazepam	C				
			Benadryl	C				
			Vistaril	C				
			Atarax	C				

Date:08/09/01ISR Number: 3773028-2Report Type:Direct Company Report #
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Cough		Baclofen	PS		ORAL	20 TID PO	2 MON
			Mexitil	C				

Date:08/09/01ISR Number: 3775068-6Report Type:Expedited (15-DaCompany Report #PHBS2001JP06832
Age:65 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Constipation	Foreign	Diovan	PS	Novartis Pharmaceuticals Corp	ORAL	80 MG/DAY, ORAL	
	Eosinophilia	Health						
	Face Oedema	Professional						
	Haemorrhage Subcutaneous	Other	Luvox(Fluvoxamine Maleate)	SS		ORAL	50 MG/DAY, ORAL	
	Headache							
	Hyponatraemia		Evamyl(Lormetazepam)	SS		ORAL	1G/DAY, ORAL	
	Malaise		Lioresal (Baclofen, Baclofen) Unknown	SS		ORAL	10 MG/DAY, ORAL	
	Nasal Congestion							
	Petechiae		Bufferin (Aluminum Glycinate, Magnesium					
	Pyrexia							

Carbonate)	C
Ruefrien (Levoglutamide, Azulene)	C
Danoil	C
Sennosides A+B (Sennoside A+B)	C

Date:08/14/01ISR Number: 3777357-8Report Type:Expedited (15-DaCompany Report #20010844
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Health Professional	Lioresal INTRATHECAL	PS	Medtronic Inc	INTRATHECAL	MCG, DAILY,	

Date:08/20/01ISR Number: 3781176-6Report Type:Expedited (15-DaCompany Report #20010846
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardiac Arrest	Health Professional	Lioresal INTRATHECAL	PS	Medtronic Inc	INTRATHECAL	975 MCG, DAILY,	
	Vomiting		Oral Baclofen	C				

Date:08/28/01ISR Number: 3783895-4Report Type:Direct Company Report #
Age:31 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Withdrawal Syndrome		Lioresal 2000 Mcg INTRATHECAL	PS			200MCG/DAY	
Required Intervention to	Infected Skin Ulcer		Baclofen	C				
			Diazepam	C				

Prevent Permanent Impairment/Damage			Benadryl	C		

Date:08/29/01ISR Number: 3784137-6Report Type:Expedited (15-DaCompany Report #20010852
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Chills Decubitus Ulcer Heart Rate Increased	Foreign Health Professional	Lioresal (R) Intrathecal (Baclofen Injection)	PS		INTRATHECAL	MCG, DAILY,	
	Injection Site Infection					INTRATHECAL		
	Pruritus Pyrexia							

Date:09/06/01ISR Number: 3788553-8Report Type:Direct Company Report #
Age:11 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Body Temperature Increased		Lioresal (Intrathecal)	PS		INTRATHECAL	INTRATHECAL Required 50MCG	
Intervention to Prevent Permanent Impairment/Damage	Headache Sedation Vomiting							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/11/01ISR Number: 3791461-XReport Type:Expedited (15-DaCompany Report #PHBS2001JP06832
Age:65 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Constipation	Foreign	Diovan (Valsartan)					
	Diabetes Mellitus	Health	Tablet	PS		ORAL	80 MG/DAY,	
	Dysuria	Professional					ORAL	
	Eosinophilia	Other	Luvox(Fluvoxamine					
	Face Oedema		Maleate)	SS		ORAL	50MG/DAY,	
	Gastritis						ORAL	
	Haemorrhage Subcutaneous		Evamyl(Lormetazepam)	SS		ORAL	1 G/DAY, ORAL	
	Hypertension		Lioresal(Baclofen,					
	Hypertonia		Baclofen) Unknown	SS		ORAL	10 MG/DAY,	
	Hyponatraemia						ORAL	
	Insomnia		Bufferin (Aluminium					
	Malaise		Glycinate, Magnesium					
	Nasal Congestion		Carbonate)	C				
	Petechiae		Ruefrien					
	Pyrexia		(Levoglutamide,					
	White Blood Cell Count		Azulene)	C				
	Decreased		Daonil	C				
			Sennosides A+B					
			(Sennoside A+B)	C				

Date:09/13/01ISR Number: 3792940-1Report Type:Direct Company Report #
Age:75 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Confusional State		Baclofen	PS		ORAL	PO	
	Delirium							
	Dialysis							
	Renal Failure Chronic							

Date:09/24/01ISR Number: 3798599-1Report Type:Expedited (15-DaCompany Report #PHBS2001JP06832
Age:65 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Cerebral Infarction	Foreign	Diovan (Valsartan)					
	Constipation	Health	Tablet	PS		ORAL	80 MG/DAY,	
	Dermatitis	Professional					ORAL	
	Diabetes Mellitus	Other	Luvox (Fluvoxamine					
	Dysuria		Maleate)	SS		ORAL	50 MG/DAY,	
	Eosinophilia						ORAL	
	Gastritis		Evamyl					
	Haemorrhage Subcutaneous		(Lormetazepam)	SS		ORAL	1 G/DAY, ORAL	
	Headache		Lioresal (Baclofen,					
	Hemiplegia		Baclofen) Unknown	SS		ORAL	10 MG/DAY,	
	Hypertension						ORAL	
	Hypertonia		Bufferin (Aluminium					
	Hyponatraemia		Glycinate, Magnesium					
	Insomnia		Carbonate)	C				
	Malaise		Ruefrien					
	Nasal Congestion		(Levoglutamide,					
	Pyrexia		Azulene)	C				
			Daonil	C				
			Sennosides A+B					
			(Sennosides A+B)	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/26/01ISR Number: 3798777-1Report 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	Mental Disorder		Baclofen	PS			5 MG QID	
			Simavastatin	C				
			Prevacid	C				
			Metoprolol	C				
			Levofloxacin	C				
			Lorazepam(?)	C				
			Sertraline	C				
			Olanzapine(?)	C				
			Oxycontin	C				
			Oxycodone	C				

Date:10/11/01ISR Number: 3808140-2Report Type:Expedited (15-DaCompany Report #20010857
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cerebral Ischaemia	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		INTRATHECAL	MCG, DAILY,	
	Convulsion							
	Depressed Level Of Consciousness		Tetracaine	C			INTRATHECAL	
	Drug Withdrawal Syndrome		Morphine	C				
	Myocardial Infarction							
	Shock							
	Tachycardia							

Date:10/12/01ISR Number: 3809873-4Report Type:Expedited (15-DaCompany Report #2000COU1548
Age:59 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Gastrooesophageal Reflux Disease	Consumer	Coumadin (Crystalline Warfarin Sodium)	PS		ORAL	PO	
	International Normalised Ratio Decreased		Neurontin					

	Prothrombin Time	(Gabapentin)	SS
	Shortened	Tegretol	
	Transient Ischaemic	(Carbamazepine)	SS
	Attack	Dilantin (Phenytoin	
	Trigeminal Neuralgia	Sodium)	SS
		Ni (Baclofen)	SS
		Vioxx (Rofecoxib)	SS
		Lanoxin (Digoxin)	SS
		Ni Verapamil	SS
		Lipitor	
		(Atorvastatin	
		Calcium)	SS
		Ni Other (S) -	
		Unspecified	SS

Date:10/18/01ISR Number: 3812154-6Report Type:Expedited (15-DaCompany Report #PHBS2001JP06832
Age:65 YR Gender:Female I/FU:F

Outcome	PT
Other	Constipation
	Dermatitis
	Diabetes Mellitus
	Dysuria

	Eosinophil Count Increased Eosinophilia	Report Source	Product	Role	Manufacturer	Route Dose Duration
	Face Oedema	Foreign	Diovan(Valsartan)	PS		ORAL 80 MG/DAY,
	Gastritis	Health				ORAL
	Haemorrhage Subcutaneous Hypertension	Professional Other	Luvox (Fluvoxamine Maleate)	SS		ORAL 50 MG/DAY,
	Hypertonia					ORAL
	Hyponatraemia		Evamyl(Lormetazepam)	SS		ORAL 1 G/DAY, ORAL
	Insomnia Malaise		Lioresal(Baclofen, Baclofen)	SS		ORAL 10 MG/DAY,
	Nasal Congestion					ORAL
	Pyrexia White Blood Cell Count Decreased		Ruefrien (Levoglutamide, Azulene) Daonil Sennosides A+B (Sennoside A+B) Bufferin (Aluminium Glycinate, Magnesium Carbonate)	C C C C		

Date:10/19/01ISR Number: 3811476-2Report 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	Delirium		Baclofen	PS		ORAL 10MG PO Q8
			Lansoprazole Oscal Codeine	C C C		

Date:10/23/01ISR Number: 3813827-1Report Type:Expedited (15-DaCompany Report #PHHO2001FR08069
Age:80 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Sedation Urinary Incontinence	Foreign Study Health Professional Other	Trileptal (Trileptal T22413+) Unknown	PS		ORAL	300 MG, BID, ORAL	
			Zoloft (Sertraline Hydrochloride)	SS				
			Lioresal (Baclofen) Unknown	SS				
			Mopral (Omeprazole)	C				

Date:10/24/01ISR Number: 3814930-2Report Type:Expedited (15-DaCompany Report #PHRM2001FR02290
Age:72 YR Gender:Female I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	C-Reactive Protein Increased Depressed Level Of Consciousness Diarrhoea Hypertension Klebsiella Infection Proteus Infection Pulmonary Embolism Pyrexia

	Sedation White Blood Cell Count Increased	Report Source	Product	Role	Manufacturer	Route	Dose Duration
		Foreign Health	Lioresal (Baclofen) Tablet, 10 Mg	PS		ORAL	10 MG, TID, ORAL
		Professional					
		Other	Tanakan (Ginkgo Biloba Extract)	SS		ORAL	1 DF, TID, ORAL
			L-Thyroxin (Levothyroxine Sodium)	SS		ORAL	ORAL
			Cacit (Citric Acid, Calcium Carbonate) Effervescent Tablet	SS		ORAL	1 DF, QD, ORAL
			Isoptin (Verapamil Hydrochloirde) Capsule	SS		ORAL	120 MG, TID, ORAL
			Diovenor (Diosmin) Tablet	SS		ORAL	600 MG, QD, ORAL
			Peflacine (Pefloxacin Mesilate)	C			

Date:10/24/01ISR Number: 3815299-XReport Type:Expedited (15-DaCompany Report #FRA002754
Age:72 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration

Hospitalization - Initial or Prolonged	Depressed Level Of Consciousness Diarrhoea Drug Tolerance Decreased Gait Disturbance Inflammation Klebsiella Infection Proteus Infection Pulmonary Embolism Pyrexia Sedation Urinary Tract Infection	Foreign Health Professional Other	Isoptine Diovenor Lioresal Tanakan L Thyroxine Cacit D3 Pefloxacine	PS SS SS SS SS SS C		ORAL ORAL ORAL ORAL ORAL

120 MG TID PO
600 MG QD PO
1 UNK TID PO
1 UNK TID PO
1 UNK PO

Date:10/31/01ISR Number: 3818971-0Report Type:Expedited (15-DaCompany Report #2000COU1548
Age:59 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - Initial or Prolonged	Gastrooesophageal Reflux Disease International Normalised Ratio Decreased Medication Error Prothrombin Time Shortened Transient Ischaemic Attack Trigeminal Neuralgia	Consumer	Coumadin (Crystalline Warfarin Sodium) Neurontin (Gabapentin) Tegretol (Carbamazepine) Ni (Baclofen) Vioxx (Rofecoxib) Lanoxin (Digoxin) Ni (Verapamil)	PS SS SS SS SS SS SS		ORAL

Dose Duration
PO

			Lipitor(Atorvastatin Sodium)	SS		
			Ni (Other (S) - Unspecified)	SS		
			Ni(Baclofen)	SS		
			Dilantin(Phenytoin Sodium)	SS		

Date:10/31/01ISR Number: 3819293-4Report Type:Expedited (15-DaCompany Report #PHFR2001GB01825
Age:82 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agitation	Foreign	Baclofen	PS		ORAL	20 MG, TID, ORAL	
	Cerebral Atrophy	Literature						
	Confusional State	Health Professional	Lisinopril (Lisinopril)	C				
	Drug Withdrawal Syndrome							
	Hallucination, Visual	Other	Fursemid	C				
	Renal Impairment		Naproxen	C				
			Allopurinol	C				

Date:11/05/01ISR Number: 3820744-XReport Type:Expedited (15-DaCompany Report #02657
Age:48 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Literature	Clonazepam	PS				
	Intentional Misuse		Baclofen	SS				

Date:11/06/01ISR Number: 3820948-6Report Type:Expedited (15-DaCompany Report #20010866
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardiac Arrest	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		INTRATHECAL	380 MCG, DAILY,	
	Condition Aggravated							
	Hypertonia							

	Meningitis		
INTRATHECAL			
	Mental Impairment	Baclofen	C
	Sepsis		

Date:11/12/01ISR Number: 3823676-6Report Type:Expedited (15-DaCompany Report #20010872
Age: Gender:Male I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Aspiration
	Body Temperature Increased
	Drug Withdrawal Syndrome
	Enterococcal Bacteraemia
	Hypertonia
	Infection
	Laboratory Test Abnormal
	Obstructive Airways Disorder
	Oral Intake Reduced
	Oxygen Saturation Decreased
	Post Procedural Complication

Staphylococcal Infection
Wound Infection

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
		Health Professional	Lioresal (R) Intrathecal (Baclofen Injection)	PS		INTRATHECAL	MCG, DAILY,	

INTRATHECAL

Date:11/15/01ISR Number: 3825528-4Report Type:Direct Company Report #
Age:6 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Medication Error		Morphine	PS		INTRATHECAL	INTRATHECAL	
Hospitalization - Initial or Prolonged	Mental Impairment Overdose Respiratory Depression Toxicologic Test Abnormal		Baclofen	SS				

Date:11/16/01ISR Number: 3827865-6Report Type:Expedited (15-DaCompany Report #PHRM2001FR02458
Age:50 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Sinus Bradycardia	Foreign Health Professional Other	Lioresal(Baclofen) Tablet	PS		ORAL	ORAL	

Date:11/21/01ISR Number: 3828566-0Report Type:Expedited (15-DaCompany Report #20010885
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	No Adverse Drug Effect	Health	Lioresal Intrathecal					

Initial or Prolonged Professional (Baclofen Injection) PS
MCG, DAILY,

INTRATHECAL

Date:11/26/01ISR Number: 3828466-6Report Type:Expedited (15-DaCompany Report #B0126849A
Age:42 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Multiple Sclerosis		Zyban	PS	Glaxo Wellcome	ORAL	150MG Per day	
			Interferon Beta	SS			UNKNOWN	
			Lioresal	SS			UNKNOWN	

Date:11/26/01ISR Number: 3828480-0Report Type:Expedited (15-DaCompany Report #B0126849A
Age:42 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Multiple Sclerosis		Zyban	PS	Glaxo Wellcome	ORAL	150MG Per day	
			Interferon Beta	SS			UNKNOWN	
			Lioresal	SS			UNKNOWN	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/26/01ISR Number: 3828494-0Report Type:Expedited (15-DaCompany Report #B0126849A
Age:42 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Multiple Sclerosis		Zyban	PS	Glaxo Wellcome	ORAL	150MG Per day	UNKNOWN
			Interferon Beta	SS				
			Lioresal	SS				UNKNOWN

Date:11/26/01ISR Number: 3828508-8Report Type:Expedited (15-DaCompany Report #B0126849A
Age:42 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Multiple Sclerosis		Zyban	PS	Glaxo Wellcome	ORAL	150MG Per day	UNKNOWN
			Interferon Beta	SS				
			Lioresal	SS				UNKNOWN

Date:11/26/01ISR Number: 3828522-2Report Type:Expedited (15-DaCompany Report #B0126849A
Age:42 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Multiple Sclerosis		Zyban	PS	Glaxo Wellcome	ORAL	150MG Per day	UNKNOWN
			Interferon Beta	SS				
			Lioresal	SS				UNKNOWN

Date:11/26/01ISR Number: 3829691-0Report Type:Expedited (15-DaCompany Report #20010894
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Death		Blood Creatine Phosphokinase Increased Blood Glucose Decreased Body Temperature Increased Hypoaesthesia Protein Total Increased	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		
INTRATRACHEAL	967 MCG, DAILY, INTRATHECAL			See B5	C		

Date:11/26/01ISR Number: 3829700-9Report Type:Expedited (15-DaCompany Report #990710
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agitation Condition Aggravated Csf White Blood Cell Count Positive Hypertonia Procedural Site Reaction	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS			INTRATRACHEAL DAILY, INTRATHECAL	

Date:11/26/01ISR Number: 3830022-0Report Type:Expedited (15-DaCompany Report #2001895
Age: Gender:Female I/FU:I

Outcome	PT
Life-Threatening Hospitalization - Initial or Prolonged	Agitation Anxiety Confusional State Drug Withdrawal Syndrome Hyperhidrosis Muscle Contractions

		Involuntary				
		Pyrexia				
		Rhabdomyolysis				
			Report Source	Product	Role	Manufacturer	Route	Dose	Duration
			Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		INTRATHECAL	DAILY,

INTRATHECAL

Date:11/26/01ISR Number: 3830035-9Report Type:Expedited (15-DaCompany Report #20010890
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Blood Creatine Phosphokinase Increased	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		INTRATHECAL	DAILY,	
Hospitalization - Initial or Prolonged	Culture Urine Positive					INTRATHECAL		
	Drug Withdrawal Syndrome							
	Pyrexia							
	Renal Impairment							
	Rhabdomyolysis							
	White Blood Cell Count Increased							

Date:11/26/01ISR Number: 3830067-0Report Type:Expedited (15-DaCompany Report #20010892
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agitation	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		INTRATHECAL	840 MCG,	
	Blood Pressure Diastolic Increased					DAILY,		
	Condition Aggravated					INTRATHECAL		
	Convulsion							
	Disorientation							
	Headache							
	Heart Rate Increased							

	Hyperhidrosis
	Hypertonia
	Infection
	Insomnia
	Loss Of Consciousness
	Paraesthesia
	Pyrexia
	Respiratory Rate
	Increased

Date:11/26/01ISR Number: 3830278-4Report Type:Expedited (15-DaCompany Report #20010891
Age: Gender:Male I/FU:I

Outcome	PT
Life-Threatening	Agitation
Hospitalization -	Blood Pressure Decreased
Initial or Prolonged	Condition Aggravated
	Crying
	Disseminated
	Intravascular Coagulation
	Ecchymosis
	Electrolyte Imbalance
	Erythema
	Grand Mal Convulsion
	Heart Rate Increased

		Hypertonia Liver Function Test Abnormal Neuroleptic Malignant Syndrome Pyrexia Rhabdomyolysis Streptococcal Infection Swelling Tremor White Blood Cell Count Increased	Report Source Health Professional	Product Lioresal Intrathecal(Baclofen Injection)	Role PS	Manufacturer	Route INTRATHECAL
Dose 350 MG, DAILY, INTRATHECAL	Duration						

Date:11/30/01ISR Number: 3832998-4Report Type:Expedited (15-DaCompany Report #PHBS2001NL11719
Age:70 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Death	Cheyne-Stokes Respiration	Foreign	Lioresal (Baclofen)	PS		ORAL
	Hypotension	Health Professional	Tramadol (Tramadol)	C		
	Respiratory Tract Infection		Lorazepam	C		
	Somnolence	Other	Naproxen	C		

Dose	Duration
ORAL	

Date:12/03/01ISR Number: 3833761-0Report Type:Expedited (15-DaCompany Report #11807
Age:44 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Death	Cardiac Arrest	Literature	Oxybutynin Generic (Oxybutynin Chloride)	PS		
	Depressed Level Of Consciousness	Health Professional	Cyclobenzaprine Generic (Cyclobenzaprine)	SS		
	Grand Mal Convulsion		Clorazepate	SS		
	Overdose		Propoxyphene	SS		
			Amitriptyline	SS		

Dose	Duration

Baclofen	SS
Cisapride	SS
Omeprazole	SS
Diosmin	SS
Glycopyrrolate	SS
Flumazenil	SS
Diazepam	SS
Phenytoin	SS

Date:12/05/01ISR Number: 3834978-1Report Type:Expedited (15-DaCompany Report #20010903
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Coma	Health	Lioresal Intrathecal					
	Drug Withdrawal Syndrome	Professional	(Baclofen Injection)	PS		INTRATHECAL	220 MCG,	
	Somnolence						DAILY,	
						INTRATHECAL		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/10/01ISR Number: 3837502-2Report Type:Direct Company Report #
Age:48 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Abnormal Behaviour		Baclofen	PS		ORAL	ONE PILL QHS	
	Hallucination						ORAL	
	Psychotic Disorder		Ambien 10 Mg	SS		ORAL	5-10 MG QHS	
	Sleep Walking						ORAL	
			Hydrocodone	C				
			Synthroid	C				
			Ultram	C				
			Celexa	C				
			Ibuprofen	C				
			Premarin	C				

Date:12/12/01ISR Number: 3839452-4Report Type:Expedited (15-DaCompany Report #PHBS2001GR12167
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Difficulty In Walking	Foreign	Baclofen (Baclofen)					
Other	Hypotonia	Literature	(Continued)	PS			5 MG, BID,	
	Myocardial Infarction	Health					UNKNOWN	
	Overdose	Professional						
		Other						

Date:12/14/01ISR Number: 3840494-3Report Type:Expedited (15-DaCompany Report #EMADSS2001007235
Age:49 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Depressed Level Of Consciousness	Foreign Health	Risperdal (Tablet) (Risperidone)	PS		ORAL	1 MG, 1 IN 1	
	Drug Interaction	Professional					DAY (S), ORAL	

	Salivary Hypersecretion	Other	Lioseral (Baclofen)	SS		ORAL 5 MG, 3 IN 1 DAY (S), ORAL

Date:12/17/01ISR Number: 3839290-2Report Type:Expedited (15-DaCompany Report #B0126849A
Age:42 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Hospitalization -	Difficulty In Walking		Zyban	PS	Glaxo Wellcome	ORAL 150MG Per day
Initial or Prolonged	Faecal Incontinence		Interferon Beta	SS		SUBCUTANEOUS
	Multiple Sclerosis		Lioresal	SS		ORAL 3UNIT per day
	Urinary Incontinence		Paracetamol	C	Glaxo Wellcome	ORAL 1000MG Twice per day

Date:12/17/01ISR Number: 3840847-3Report Type:Expedited (15-DaCompany Report #2001AP05251
Age:44 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Death	Cardiac Arrest	Literature	Amitriptyline	PS		
Life-Threatening	Completed Suicide	Health	Omeprazole	SS		
	Depressed Level Of	Professional	Propoxyphene	SS		
	Consciousness		Clonazepam	SS		
	Grand Mal Convulsion		Oxybutynin	SS		
	Overdose		Cyclobenzaprine	SS		
	Toxicologic Test Abnormal		Baclofen	SS		
			Cisapride	SS		
			Diosmin	SS		

			Glycopyrralate	SS		

Date:12/18/01ISR Number: 3840807-2Report Type:Direct Company Report #
Age:11 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Body Temperature Increased		Lioresal Intrathecal	PS		INTRATHECAL	50 MCG	INTRATHECAL
Required Intervention to Prevent Permanent Impairment/Damage	Headache Somnolence Vomiting							

Date:12/24/01ISR Number: 3844508-6Report Type:Expedited (15-DaCompany Report #PHFR2001GB03410
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Arrhythmia	Foreign	Lioresal(Baclofen)	PS		ORAL	20 MG, TID,	
	Drug Withdrawal Syndrome	Health					ORAL	
	Gastric Haemorrhage Sepsis	Professional Other						

Date:12/28/01ISR Number: 3847123-3Report Type:Expedited (15-DaCompany Report #0311-01(0)
Age:14 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Deafness Tinnitus Vertigo	Health Professional	Baclofen 10 Mg Tablets, Usp (Unknown)	PS		ORAL	3 TABS DAILY PO	

Date:12/31/01ISR Number: 3846935-XReport Type:Expedited (15-DaCompany Report #002-0981-M0100666
Age:68 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Asthenia	Foreign	Atorvastatin					
	Blood Pressure Increased	Consumer	(Atorvastatin)	PS		ORAL	PER ORAL	
	Cerebrovascular Accident		(Acetylsalicylic					
	Drug Hypersensitivity		Acid)	SS		ORAL	PER ORAL	
	Fall		(Ranitidine)	SS		ORAL	PER ORAL	
	Muscle Spasms		(Conjugated					
	Paraesthesia		Estrogens)	SS		ORAL	PER ORAL	
	Pruritus		(Losartan)	SS		ORAL	PER ORAL	
			(Atenolol)	SS		ORAL	PER ORAL	
			(Amiodarone)	SS		ORAL	PER ORAL	
			(Baclofen)	SS		ORAL	PER ORAL	
			(Citalopram)	SS		ORAL	PER ORAL	
			(Trazodone)	SS		ORAL	PER ORAL	
			(Heparin)	SS				

Date:01/14/02ISR Number: 3852300-1Report Type:Expedited (15-DaCompany Report #20020937
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Respiratory Arrest	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS			INTRATHECAL	DAILY,

INTRATHECAL

Date:01/17/02ISR Number: 3854196-0Report Type:Expedited (15-DaCompany Report #200210022BFR
Age:24 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Bradycardia Drug Interaction	Health Professional	Ciflox (Ciprofloxacin)	PS		ORAL	1000 MG DAILY	
	Hypotension	Other						
ORAL								
	Hypotonia Malaise		Sirdalud (Tizanidine Hydrochloride)	SS		ORAL	SEE IMAGE	
			Lioresal (Baclofen)	SS		ORAL	SEE IMAGE	
			Myolastan (Tetrazepam)	SS		ORAL	75 MG DAILY	
ORAL								
			Voltarene	C				
			Zyloric	C				
			Verospiron	C				
			Pantozol	C				
			L!Snesium	C				
			Melperon	C				
			Zocor	C				

Date:01/18/02ISR Number: 3855599-0Report Type:Periodic Company Report #PHBS2001US03558
Age:46 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain Jejunostomy Nausea Vomiting	Consumer	Lioresal (Baclofen) Ampoule	PS				
			Betaseron (Albumin Human, Interferon Beta)	SS				
SUBCUTANEOUS	SUBCUTANEOUS							
			Verapamil (Verapamil)	C				

Trazadone	C
Imodium (Loperamide Hydrochloride)	C
Prilosec (Omeprazole)	C
Percocet (Oxycodone Hydrochloride, Paracetamol)	C
Robaxin (Methocarbamol)	C
Celexa (Citalopram Hydrobromide)	C
Valium	C
Neurontin (Gabapentin)	C
Urecholine (Bethanechol Chloride)	C
Oxycontin (Oxycodone Hydrochloride)	C

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/18/02ISR Number: 3855600-4Report Type:Periodic Company Report #PHBS2001US05962
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Accidental Overdose Hypoventilation Somnolence	Health Professional	Lioresal Intrathecal	PS		INTRATHECAL	2000 MCG, INTRATHECAL	

Date:01/18/02ISR Number: 3855871-4Report Type:Expedited (15-DaCompany Report #PHBS2002AU00570
Age:14 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Apnoea Bradycardia Brain Oedema Coma Convulsion Depressed Level Of Consciousness Drug Screen Positive Encephalitis Headache Hyperhidrosis Hyperreflexia Hypertension Hyporeflexia Lethargy Nausea Overdose Pupil Fixed Vomiting	Foreign Literature Health Professional Other	Baclofen (Baclofen) Tablet Tramadol Hydrochloride (Tramadol Hydrochloride) Aspirine (Acetylsalicylic Acid)	PS SS SS		ORAL ORAL	500 MG, ONCE/SINGLE, ORAL	

Date:01/23/02ISR Number: 3859372-9Report Type:Expedited (15-DaCompany Report #20010903
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Coma	Health	Lioresal Intrathecal					
	Drug Withdrawal Syndrome	Professional	(Baclofen Injection)	PS		INTRATHECAL	220 MCG,	
	Pneumonitis						DAILY,	
	Somnolence						INTRATHECAL	

Date:01/23/02ISR Number: 3859515-7Report Type:Expedited (15-DaCompany Report #20010846
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardiac Arrest	Health	Lioresal					
	Clonic Convulsion	Professional	(Intrathecal					
	Medical Device		(Baclofen Injection)	PS		INTRATHECAL	975 MCG,	
	Complication						DAILY,	
	Pneumonia						INTRATHECAL	
	Vomiting		Baclofen	C				

Date:01/23/02ISR Number: 3860015-9Report Type:Direct Company Report #CTU 159872
Age:45 YR Gender:Male I/FU:I

Outcome
Life-Threatening
Hospitalization -

Initial or Prolonged
Disability

PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Cardio-Respiratory Arrest Coma Convulsion Drug Withdrawal Syndrome Muscle Spasticity Pyrexia		Lioresal 2000 Mcg./Cc Medtronic	PS	Medtronic	INTRATRACHEAL INTRATRACHEAL	650 MCG	DAY
		Valium	C				

Date:01/25/02ISR Number: 3860390-5Report Type:Expedited (15-DaCompany Report #PHRM2002FR00519
Age:24 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Bradypnoea Drug Interaction Hypotension Hypotonia Malaise Skin Infection	Foreign Health Professional Other	Lioresal(Baclofen)Tablet	PS		ORAL	30 MG DAILY,	ORAL
			Sirdalud(Tizanidine Hydrochloride)	SS		ORAL	12 MG DAILY,	ORAL
			Myolastan(Tetrazepam)	SS		ORAL	75 MG PER	DAY, ORAL
			Ciflox(Ciprofloxacin)Tablet	SS			1 G DAILY	
			Voltarene Lp (Diclofenac Sodium)	C				

Date:01/29/02ISR Number: 3861185-9Report Type:Expedited (15-DaCompany Report #PHBS2002AR01041
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Depressed Level Of Consciousness Muscle Contractions Involuntary Somnolence	Foreign Health Professional Other	Lioresal(Baclofen)Tablet	PS		ORAL	10 MG, ONCE/SINGLE, ORAL	

Date:01/29/02ISR Number: 3862026-6Report Type:Expedited (15-DaCompany Report #PHBS2002AR01041
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Depressed Level Of Consciousness Muscle Contractions Involuntary Somnolence	Foreign Health Professional Other	Lioresal (Baclofen)	PS		ORAL	10 MG, ONCE/SINGLE; ORAL	

Date:01/30/02ISR Number: 3862391-XReport Type:Expedited (15-DaCompany Report #PHEH2002US00956
Age:16 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Pancreatitis	Health Professional	Lioresal (Baclofen)	PS				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/04/02ISR Number: 3865357-9Report Type:Expedited (15-DaCompany Report #PHRM2001FR01766
Age:31 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Phlebitis	Foreign Health Professional Other	Lioresal (Baclofen) Tablet	PS		ORAL		
			Lioresal Inthratecal (Baclofen) Solution For Injection	SS		INTRATHECAL	80 MCG/DAY,	INTRATHECAL
			Previscan (Fluindione) Tablet	C				
			Lysanxia (Prazepam) Tablet	C				
			Zyrtec (Cetirizine Hydrochloride)	C				

Date:02/08/02ISR Number: 3867290-5Report Type:Expedited (15-DaCompany Report #PHBS2002IT01370
Age:56 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Asphyxia	Foreign	Baclofen (Baclofen)	PS			2 G ONCE	SINGLE
	Completed Suicide	Literature						
	Cyanosis	Health Professional	Dipyrone (Metamizole Sodium)	SS			20 G ONCE	SINGLE
	Drug Toxicity							
	Intentional Misuse							
	Petechiae		Oxybutynin (Oxybutynin)	SS			0.15 G ONCE	SINGLE
			Terazosin (Terazosin)	SS			0.09 G ONCE	SINGLE

			Laxatives (No Ingredients/Substances)	SS		ORAL	40 PILLS ONCE SINGLE
			Acetylsalicylic Acid (Acetylsalicylic Acid)	SS			3.3 G ONCE SINGLE
			Defibrotide (Defibrotide)	C			8.4 G ONCE SINGLE

Date:02/08/02ISR Number: 3867329-7Report Type:Expedited (15-DaCompany Report #PHRM2002FR00519
Age:24 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Bradycardia Drug Interaction Hypotension Hypotonia Malaise	Foreign Health Professional Other	Lioresal (Baclofen) Tablet	PS		ORAL	30 MG DAILY, ORAL
			Sirdalud (Tizanidine Hydrochloride) Unknown	SS		ORAL	12 MG DAILY, ORAL
			Myolastan (Tetrazepam)	SS		ORAL	75 MG PER DAY, ORAL
			Ciflox (Ciprofloxacin)				

				Tablet	SS		
1 G DAILY							
				Voltarene Lp (Diclofenac Sodium)	C		

Date:02/13/02ISR Number: 3875557-XReport Type:Periodic Company Report #2012150
Age:52 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Overdose	Health Professional Other	Oxycodone Hydrochloride (Similar To Nda 20-553)	PS		ORAL	PO	
			Paroxetine	SS		ORAL	PO	
			Baclofen (Lioresal)	SS				

Date:02/13/02ISR Number: 3877776-5Report Type:Periodic Company Report #2011912
Age:46 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Health Professional Company Representative	Oxycontin Cr Tablets, 20 Mg (Oxycodone Hydrochloride)	PS		ORAL	20 MG BID PO	
			Oxycontin Cr Tablets, 40 Mg (Oxycodone Hydrochloride)	SS		ORAL	40 MG BID PO	
			Baclofen	SS				
			Cocaine	SS				

Date:02/19/02ISR Number: 3871971-7Report Type:Expedited (15-DaCompany Report #PHFR2002GB00742
Age:65 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Other	Depressed Level Of Consciousness	Foreign Health	Baclofen (Baclofen) Unknown	PS			ORAL 10 MG/DAY,
	Hyperreflexia	Professional					ORAL
	Muscle Spasticity	Other	Gabapentin (Gabapentin)	C			
			Tramadol (Tramadol)	C			
			Lisinopril (Lisinopril)	C			
			Ciprofloxacin (Ciprofloxacin)	C			

Date:02/19/02ISR Number: 3872784-2Report Type:Expedited (15-DaCompany Report #20020950
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Muscle Spasticity	Health Professional	Lioresal Intrathecal	PS		INTRATHECAL	DAILY,
	Myalgia						
	Nausea					INTRATHECAL	
	Syncope						

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/21/02ISR Number: 3873324-4Report Type:Expedited (15-DaCompany Report #PHBS2001NL11719
Age:70 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Aortic Valve Stenosis	Foreign	Lioresal (Baclofen)	PS		ORAL		
	Bronchitis	Health	Tramadol	C				
	Cerebral Ischaemia	Professional	Lorazepam	C				
	Cheyne-Stokes Respiration	Other	Naproxen	C				
	Hypotension							
	Pyrexia							
	Respiratory Tract Infection							
	Somnolence							

Date:02/26/02ISR Number: 3875806-8Report Type:Expedited (15-DaCompany Report #PHFR2002GB00809
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Body Temperature Decreased	Foreign Health	Baclofen (Baclofen)	PS		ORAL	2.5 MG/DAY, ORAL	
	Bradycardia	Professional						
	Depressed Level Of Consciousness	Other						
	Hypotonia							
	Somnolence							

Date:02/28/02ISR Number: 3890069-5Report Type:Periodic Company Report #001-0945-M0100980
Age:56 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dry Mouth	Consumer	Neurontin (Gabapentin)	PS				
	Libido Decreased		Baclofen	SS				
	Oedema Peripheral		Acetylsalicylic Acid, Caffeine					
	Overdose		Anhdyrous, Butalbital	C				
	Pain		Unknown					
	Weight Increased							
	White Blood Cell Count							

			Chemotherapeutic Agent	C		

Date:03/06/02ISR Number: 3880297-7Report Type:Expedited (15-DaCompany Report #PHBS2002AU02650
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Foreign	Lioresal(Baclofen)	PS		ORAL	ORAL	
	Depression	Health Professional Other						

Date:03/12/02ISR Number: 3882125-2Report Type:Direct Company Report #CTU 163293
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hallucination		Baclofen	PS		ORAL	10MG PO BID	
	Mental Status Changes		Duragesic Patch	SS			75MCG Q 72H	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/12/02ISR Number: 3882919-3Report Type:Expedited (15-DaCompany Report #PHBS2002JP03106
Age:60 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Eosinophilia	Foreign	Lioresal (Baclofen)					
	Lung Infiltration	Health	Tablet	PS		ORAL	1 TABLET/D,	
	Pneumonia	Professional					ORAL	
		Other	Selegiline Hydrochloride	C				
			Herbal Extracts	C				

Date:03/12/02ISR Number: 3882921-1Report Type:Expedited (15-DaCompany Report #PHRM2002FR00857
Age:52 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Amaurosis Fugax	Foreign	Lioresal Intrathecal					
	Retinal Vein Thrombosis	Health	(Baclofen) Solution					
		Professional	For Injection	PS		INTRATHECAL	50 UG,	
		Other					ONCE/SINGLE,	
							INTRATHECAL	

Date:03/14/02ISR Number: 3886768-1Report Type:Periodic Company Report #2002087109US
Age:42 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Delusion	Health	Solu-Medrol(Methylprednisolone)Powder,					
	Disorientation	Professional						
	Hallucination		Sterile	PS		INTRAVENOUS	IV	
	Psychotic Disorder		Baclofen	SS				
			Klonopin (Clonazepam)	SS				

Date:03/15/02ISR Number: 3884609-XReport Type:Expedited (15-DaCompany Report #20020981
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Hospitalization - Initial or Prolonged	Coma Medication Error	Health Professional	Lioresal Intrathecal(Baclofen Injection)	PS		INTRATHECAL	100 MCG, DAILY, Intervention to Prevent Permanent Impairment/Damage	Required

Date:03/20/02ISR Number: 3886160-XReport Type:Expedited (15-DaCompany Report #PHFR2002GB00491
Age:73 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Haematemesis	Foreign Health	Lioresal (Baclofen) Tablet	PS			5 MG/DAY,	
		Professional Other	Ranitidine (Ranitidine)	C				
			Laxatives (No Ingredients / Substances)	C				
			Bendrofluazide (Bendroflumethiazide)	C				

				Prochlorperazine (Prochlorperazine)	C		

Date:03/20/02ISR Number: 3886166-0Report Type:Expedited (15-DaCompany Report #PHFR2002GB01045
Age: Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Jaundice	Foreign Health	Lioresal (Baclofen) Unknown	PS			10 MG, TID,	
		Professional Other	Antiepileptics (No Ingredients / Substances)	C				

Date:03/20/02ISR Number: 3886170-2Report Type:Expedited (15-DaCompany Report #PHBS2002AU02650
Age:47 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide Major Depression	Foreign Health	Lioresal (Baclofen) Tablet	PS		ORAL	20 MG/DAY, ORAL	
		Professional Other	Cipramil	C				

Date:03/28/02ISR Number: 3890215-3Report Type:Expedited (15-DaCompany Report #309913
Age:69 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Coma		Rivotril	PS	Roche			
	Confusional State		Temesta	SS				
	Dyskinesia		Lioresal	SS				
	Hallucination							
	Medication Error							
	Memory Impairment							

Date:03/28/02ISR Number: 3891135-0Report Type:Periodic Company Report #CIP00001154
Age:49 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Clonic Convulsion Cognitive Deterioration Condition Aggravated Confusional State Drug Interaction Dysarthria Medication Error Memory Impairment Muscle Spasms Somnolence Speech Disorder	Health Professional	Dantrium (Dantrolene Sodium) Capsule, Unknownmg	PS		ORAL	50 MG 3 TIMES DAILY; 25 MG 3 TIMES DAILY; 30 MG 3 TIMES 30 MG 3 TIMES DAILY, ORAL; 20 MG 3 TIMES DAILY	
			Baclofen (Baclofen) Tablet	SS		ORAL		
			Norvasc (Amlodipine Besilate)	C				
			Norpramin (Desipramine Hydrochloride)	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/01/02ISR Number: 3893540-5Report Type:Expedited (15-DaCompany Report #309913
Age:69 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Coma	Foreign	Rivotril					
	Confusional State	Other	(Clonazepam)	PS		ORAL	5 UNIT DAILY	
	Dyskinesia					ORAL		
	Hallucination		Temesta (Lorazepam)	SS		ORAL	ORAL	
	Medication Error		Lioresal (Baclofen)	SS		INTRAVENOUS	INTRAVENOUS	
	Memory Impairment							

Date:04/02/02ISR Number: 3894029-XReport Type:Expedited (15-DaCompany Report #A206119
Age:50 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Anorgasmia	Consumer	Viagra Tablets	PS		ORAL	50.00 MG	TOTAL:PRN:ORAL
	Ejaculation Failure							
	Erectile Dysfunction							
	Hypoaesthesia		Doxepin	SS			300.00 MG	
	Medication Error							TOTAL
	Overdose		Hydroxyzine	SS				
	Penis Disorder		Baclofen	SS				
	Priapism		Seroquel	C				
			Chloral Hydrate	C				
			Remeron	C				

Date:04/03/02ISR Number: 3895302-1Report Type:Expedited (15-DaCompany Report #PHBS2002PL03764
Age:29 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Asthenia	Foreign	Baclofen (Baclofen)					

Initial or Prolonged	Fear	Literature	Unknown	PS		
10 MG, BID						
Other	Loss Of Consciousness	Health				
	Nausea	Professional				
	Poisoning	Other				
	Vomiting					

Date:04/08/02ISR Number: 3895870-XReport Type:Expedited (15-DaCompany Report #309913
Age:69 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Coma		Rivotril	PS	Roche			
	Confusional State		Temesta	SS				
	Dyskinesia		Lioresal	SS				
	Hallucination							
	Memory Impairment							

Date:04/08/02ISR Number: 3897791-5Report Type:Expedited (15-DaCompany Report #FR8947603APR2002
Age:69 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Coma	Health	Temesta (Lorazepam,					
	Confusional State	Professional	Unspec, 0)	PS		ORAL		
ORAL								
	Hallucination	Other	Lioresal (Baclofen)	SS				
INTRAVENOUS							1 DOSE	50
	Memory Impairment							
TIMES PER								
	Muscle Contractions							
DAY,								
	Involuntary							
INTRAVENOUS								
			Rivotril					

			(Clonazepam)	SS		ORAL
5 DOSES						
DAILY, ORAL						

Date:04/10/02ISR Number: 3898289-0Report Type:Expedited (15-DaCompany Report #FR8947603APR2002
Age:69 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Coma	Health	Temesta (Lorazepam,					
Disability	Confusional State	Professional	Unspec, 0)	PS		ORAL		
ORAL								
	Hallucination	Other	Lioresal (Baclofen)	SS				
INTRAVENOUS							1 DOSE	50
	Medication Error							
TIMES PER DAY								
	Memory Impairment		Rivotril					
	Muscle Contractions		(Clonazepam)	SS		ORAL		
5 DOSES DAILY								
	Involuntary		Astrocytoma	C				

Date:04/10/02ISR Number: 3898469-4Report Type:Expedited (15-DaCompany Report #309913
Age:69 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Coma	Foreign	Rivotril					
	Confusional State	Other	(Clonazepam)	PS		ORAL		
5 UNIT DAILY								
	Dyskinesia							
ORAL								
	Hallucination		Temesta (Lorazepam)	SS		ORAL		
ORAL								
	Medication Error		Lioresal (Baclofen)	SS				
INTRAVENOUS	INTRAVENOUS							
	Memory Impairment							

Date:04/11/02ISR Number: 3899096-5Report Type:Expedited (15-DaCompany Report #20020997
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Unevaluable Event	Foreign Health Professional	Lioresal(R) Intrathecal (Baclofen Injection)	PS		INTRATHECAL	100 MCG	ONCE

INTRATHECAL

Date:04/15/02ISR Number: 3901520-6Report Type:Expedited (15-DaCompany Report #A206119
Age:50 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Drug Effect Decreased Ejaculation Disorder Erectile Dysfunction Priapism	Consumer	Viagra Tablets Doxepin	PS SS		ORAL	50.00 MG 300.00 MG	TOTAL:PRN:ORA L TOTAL
			Hydroxyzine	SS				
			Baclofen	SS				
			Seroquel	C				
			Chloral Hydrate	C				
			Remeron (Subject Drug)	C				

Date:04/16/02ISR Number: 3902278-7Report Type:Expedited (15-DaCompany Report #PHBS2002CL04226
Age:57 YR Gender:Male I/FU:I

Outcome	PT	Report Source
Other	Pulmonary Fibrosis	Foreign Consumer

			Other				
				Product	Role	Manufacturer	Route
Dose	Duration						
				Lioresal(Baclofen) Tablet	PS		ORAL
SEE IMAGE	1095 DAY						
				Enalapril (Enalapril)	C		
				Diazepam	C		

Date:04/22/02ISR Number: 3903758-0Report Type:Expedited (15-DaCompany Report #309913
Age:69 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Life-Threatening	Coma		Rivotril	PS	Roche	
	Confusional State		Temesta	SS		
	Dyskinesia		Lioresal	SS		
	Hallucination					
	Memory Impairment					

Date:04/23/02ISR Number: 3906120-XReport Type:Expedited (15-DaCompany Report #309913
Age:69 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Life-Threatening	Coma	Foreign	Rivotril			
	Confusional State	Other	(Clonazepam)	PS		ORAL
5 UNIT DAILY						
	Dyskinesia					
ORAL						
	Hallucination		Temesta (Lorazepam)	SS		ORAL
ORAL						
	Memory Impairment		Lioresal (Baclofen)	SS		
INTRADISCAL						
(INTRASPINAL)	1 DOSE FORM 1					
PER 50 DAY						
INTRADISCAL						

(INTRASPINAL)

Date:04/26/02ISR Number: 3908528-5Report Type:Expedited (15-DaCompany Report #PHBS2002PL03764
Age:29 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Accommodation Disorder	Foreign	Baclofen(Baclofen)	PS			10 MG, BID	
	Anxiety	Literature						
	Asthenia	Health						
	Coma	Professional						
	Dyspnoea	Other						
	Fear							
	Hypoaesthesia							
	Hypotonia							
	Loss Of Consciousness							
	Nausea							
	Salivary Hypersecretion							
	Somnolence							
	Therapeutic Agent							
	Toxicity							
	Vomiting							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/06/02ISR Number: 3912132-2Report Type:Expedited (15-DaCompany Report #02-04-0381
Age:55 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Chromaturia Diabetes Mellitus Fatigue Hepatitis Hepatocellular Damage Liver Function Test Abnormal Pancreatic Disorder Pyrexia Swelling Weight Decreased	Consumer	Baclofen Tablets Bumex Ditropan Xl	PS C C	Ipi	ORAL ORAL		

Date:05/06/02ISR Number: 3912537-XReport Type:Expedited (15-DaCompany Report #20021028
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Drug Withdrawal Syndrome	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		INTRATHECAL	MCG, DAILY , INTRATHECAL	

Date:05/13/02ISR Number: 3916451-5Report Type:Direct Company Report #CTU 167997
Age:48 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hypersensitivity		Zanaflex Baclofen	PS SS				

Date:05/20/02ISR Number: 3919685-9Report Type:Expedited (15-DaCompany Report #PHRM2002FR01351
Age:66 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Coma Hypothalamo-Pituitary Disorders Hypotonia Multiple Sclerosis Relapse Nervous System Disorder	Foreign Health Professional Other	Lioresal(Baclofen) Tablet Neurontin (Gabapentin) Aldalix Capsule	PS C C		ORAL	10 MG, QD, ORAL	

Date:05/22/02ISR Number: 3922404-3Report Type:Expedited (15-DaCompany Report #PHRM2002FR00857
Age:52 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability Other	Amaurosis Fugax Hypotension Retinal Vein Thrombosis	Foreign Health Professional Other	Lioresal Intrathecal(Baclofen) Solution For Injection Lioresal "Novartis" (Baclofen) Tablet Seropram(Citalopram	PS SS		ORAL	INTRATHECAL 50 MG, ONCE/SINGLE, INTRATHECAL 75 MG/DAY, ORAL	

			Hydrovromide) Tablet	SS		ORAL	20 MG/DAY, ORAL
			Tardyferon(Ferrous Sulfate) Tablet	SS		ORAL	2 TABS/DAY, ORAL
			Dulcolax(Bisacodyl)	SS			

Date:05/23/02ISR Number: 3922620-0Report Type:Expedited (15-DaCompany Report #2002-DE-01032GD (0)
Age:38 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Angiogram Abnormal Angiogram Retina Abnormal Blindness Conjunctival Hyperaemia Drug Toxicity Eye Disorder Fundoscopy Abnormal Maculopathy Retinogram Abnormal Retinopathy	Literature	Mexiletine (Mexiletine Hydrochloride)	PS		ORAL	DAILY, PO
			Clonidine (Clonidine)	SS		ORAL	PO
			Morphine (Morphine)	SS		ORAL	PO
			Trazodine (Trazodine Hydrochloride)	SS			
			Pentosan Polysulfate (Pentosan Polysulfate)	SS			
			Gabapentin (Gabapentin)	SS			
			Lidocaine Hydrochloride (Lidocaine Hydrochloride)	SS		INTRAVENOUS	385.7 MG (SINGLE DOSE INFUSION), IV
			Baclofen (Baclofen)	SS		ORAL	PO
			Methadone Hydrochloride (Methadone				

Hydrochloride)	SS		ORAL

PO

Lorazepam (Lorazepam)	SS		
Hydroxyzine Hydrochloride Hydroxyzine Hydrochloride)	SS		
Glimepiride (Oral Antidiabetics)	SS		
Promethazine Hydrochloride (Promethazine Hydrochloride)	SS		
Fluoxetine Hydrochloride (Fluoxetine Hydrochloride)	SS		
Sucralfate (Sucralfate)	SS		

Date:05/24/02ISR Number: 3923365-3Report Type:Expedited (15-DaCompany Report #PHNU2001DE02477
Age:30 YR Gender:Male I/FU:I

Outcome
Life-Threatening
Hospitalization -

Initial or Prolonged

	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Aspiration Bronchial	Foreign	Lioresal(Baclofen)					
	Blood Creatine Phosphokinase Increased	Health Professional	Tablet, 25mg	PS		ORAL	1000 MG,	ONCE/SINGLE,
	Blood Creatine Phosphokinase Mb	Other						ORAL
	Coma							
	Convulsion							
	Intentional Misuse							

Date:05/28/02ISR Number: 3924413-7Report Type:Expedited (15-DaCompany Report #2002-DE-01032GD (0)
Age:38 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blindness Retinal Degeneration Retinopathy Scotoma	Literature	Mexiletine (Mexiletine Hydrochloride) (Nr) (Mexiletine-Hcl)	PS		ORAL	PO	
	Toxicologic Test Abnormal		Clonidine (Clonidine) (Nr) (Clonidine-Hcl)	SS		ORAL	PO	
			Morphine (Morphine) (Nr) (Morphine-Hcl)	SS		ORAL	PO	
			Trazodone (Trazodone Hydrochloride) (Nr) (Trazodone-Hcl)	SS				
			Pentosan Polysulfate (Pentosan Polysulfate)	SS				
			Gabapentin (Gabapentin) (Nr)	SS				
			Lidocaine Hydrochloride (Lidocaine					

		Hydrochloride)	SS	
INTRAVENOUS (SINGLE DOSE INFUSION) IV	385.27 MG			
		Baclofen (Baclofen) (Nr)	SS	ORAL
PO				
		Methadone Hydrochloride (Methadone Hydrochloride)	SS	ORAL
PO				
		Lorazepam (Lorazepam) (Nr)	SS	
		Hydroxyzine Hydrochloride (Hydroxyzine Hydrochloride) (Nr)	SS	
		Glimepiride (Oral Antidiabetics) (Nr)	SS	
		Promethazine Hydrochloride (Promethazine Hydrochloride)	SS	
		Sucralfate (Sucralfate) (Nr)	SS	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/04/02ISR Number: 3928123-1Report Type:Expedited (15-DaCompany Report #02-04-0381
Age:55 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Chromaturia	Consumer	Baclofen - Ipi Tablets	PS		ORAL	10 MG	
Other	Diabetes Mellitus		Bumex	C				
	Fatigue		Fluid Retention	C				
	Gastrointestinal Disorder		Ditropan	C				
	Hepatitis		Cenestin	C				
	Hypertension							
	Nasopharyngitis							
	Pancreatic Disorder							
	Pyrexia							
	Swelling							
	Urinary Tract Infection							
	Weight Decreased							

Date:06/06/02ISR Number: 3928907-XReport Type:Direct Company Report #CTU 169646
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agitation		Baclofen	PS		INTRATHECAL	100MCG/DAY	CONTINOUS
	Confusional State							
	Muscle Spasticity							
	Pyrexia							
			Pediasure	C				
			Mellaril	C				
			Albuterol	C				
			Decadron	C				
			Mylicon	C				
			Zyrtec	C				
			Vancomycin	C				
			Aminophylline	C				
			Tegretol	C				
			Robanul	C				
			Diamox	C				
			Reglan	C				
			Zantac	C				

Date:06/12/02ISR Number: 3932877-8Report Type:Expedited (15-DaCompany Report #PHBS2002JP03106
Age:60 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Eosinophilia	Foreign	Lioresal(Baclofen)					
	Lung Infiltration	Health	Tablet	PS		ORAL	5 MG/DAY,	
	Pneumonia	Professional					ORAL	
		Other	Herbal Extracts Nos (No Ingredients/Substances)	SS		ORAL	ORAL	
			Selegilene Hydrochloride	C				

Date:06/12/02ISR Number: 3933087-0Report Type:Expedited (15-DaCompany Report #PHBS2002AU05729
Age:41 YR Gender: I/FU:I

Outcome	PT
Other	Alanine Aminotransferase Increased
	Aspartate

	Aminotransferase Increased Gamma-Glutamyltransferase Increased	Report Source	Product	Role	Manufacturer	Route	Dose Duration
		Foreign	Lioresal (Baclofen)	PS		ORAL	10 MG, TID,
		Health					ORAL
		Professional					
		Other					

Date:06/12/02ISR Number: 3933340-0Report Type:Expedited (15-DaCompany Report #PHBS2002JP03106
Age:60 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Eosinophilic Pneumonia Lung Infiltration	Foreign	Lioresal(Baclofen)				
		Health	Tablet	PS		ORAL	1 TABLET/D,
	Pneumonia	Professional					ORAL
		Other	Selegiline Hydrochloride (Selegiline Hydrochloride)				
			Tablet	SS		ORAL	ORAL
			Herbal Extracts Nos (No Ingredients/Substanc es)	SS		ORAL	ORAL

Date:06/12/02ISR Number: 3933653-2Report Type:Expedited (15-DaCompany Report #PHBS2002JP06406
Age:20 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Hypercapnia	Foreign	Lioresal(Baclofen)				
		Health	Tablet	PS		ORAL	120 MG/D,
		Professional					ORAL

		Other	Phenobarbital(Phenobarbital)	SS		ORAL 200 MG/D, ORAL
			Depakene	C		
			Benzalin	C		

Date:06/18/02ISR Number: 3935686-9Report Type:Expedited (15-DaCompany Report #20021066
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Medical Device Complication	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		INTRATHECAL	UNK MCG, DAILY, INTRATHECAL	

Date:06/18/02ISR Number: 3935689-4Report Type:Expedited (15-DaCompany Report #20021064
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Csf Test Abnormal Musculoskeletal Stiffness Pain Pyrexia	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		INTRATRACHEAL INTRATHECAL	50 MCG, ONCE,	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/24/02ISR Number: 3939049-1Report Type:Expedited (15-DaCompany Report #02-04-0381
Age:55 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Chromaturia	Health Professional	Baclofen - Ipi Tablets	PS	Ipi	ORAL	10MG ORAL	
	Dehydration		Bumex	C				
	Diabetes Mellitus		Ditropan	C				
	Fatigue		Cenestin	C				
	Gastroenteritis		Glucotrol Xl	C				
	Hepatitis		Quinine Sulfate	C				
	Hepatocellular Damage							
	Hypertension							
	Inflammation							
	Muscle Spasms							
	Nasopharyngitis							
	Oedema							
	Pancreatic Disorder							
	Proteus Infection							
	Urinary Tract Infection							
	Weight Decreased							

Date:06/26/02ISR Number: 3940300-2Report Type:Expedited (15-DaCompany Report #PHNU2002DE01956
Age:3 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hypokalaemia	Foreign	Lioresal(Baclofen)					
		Health	Tablet	PS		ORAL	25 MG, QID,	
		Professional					ORAL	
		Other	Topamax(Topiramate)	C				

Date:07/01/02ISR Number: 3943008-2Report Type:Expedited (15-DaCompany Report #20021082
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Gastric Atony	Foreign	Lioresal Intrathecal					
	Pancreatitis	Health	(Baclofen Injection)	PS		INTRATHECAL	100 MCG,	

Required		Professional				
ONCE,						
Intervention to						
INTRATHECAL						
Prevent Permanent			Sirdalud (Tizanidine			
Impairment/Damage			Hydrochloride)	C		
			Lioresal Intrathecal			
			25 Mcg	C		

Date:07/03/02ISR Number: 3944385-9Report Type:Expedited (15-DaCompany Report #PHBS2002AU02650
Age:47 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Adrenoleukodystrophy	Foreign	Lioresal(Baclofen)					
	Completed Suicide	Health	Tablet	PS		ORAL	10 MG, BID,	
	Depression	Professional					ORAL	
	Drug Toxicity	Other	Cipramil	C				
	Pulmonary Oedema							
	Thyroid Disorder							
	Toxicologic Test Abnormal							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/05/02ISR Number: 3946585-0Report Type:Expedited (15-DaCompany Report #CIP02001062
Age:52 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dehydration Grand Mal Convulsion	Foreign Health Professional Other	Dantrium (Dantrolene Sodium) Capsule, Unknown	PS		ORAL	150 MG DAILY,	ORAL
			Baclofen (Baclofen) Unknown, Unknown	SS		ORAL	60 MG DAILY,	ORAL
			Tetrahydrocannabinol (Tetrahydrocannabinol) Capsule, Unknown	SS		ORAL	8 DF DAILY,	ORAL

Date:07/08/02ISR Number: 3945815-9Report Type:Direct Company Report #CTU 171775
Age:51 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Drug Effect Decreased Drug Withdrawal Syndrome Pharmaceutical Product Complaint		Baclofen 10 Mg Watson	PS	Watson	ORAL	50 MG DAILY	ORAL
			Crixivan	C				
			Combivir	C				
			Albuterol	C				
			Fosamax	C				
			Nephrocaps	C				

Date:07/18/02ISR Number: 3955373-0Report Type:Expedited (15-DaCompany Report #20021105
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Ineffective Muscle Spasms	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		INTRATHECAL	DAILY, Required INTRATHECAL	

Intervention to Prevent Permanent Impairment/Damage

Date:07/24/02ISR Number: 3953478-1Report Type:Expedited (15-DaCompany Report #2002111158GB
Age:14 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Anxiety	Foreign Health Professional	Cyklokapron (Tranexamic Acid) Solution, Sterile	PS		ORAL	ORAL	
			Baclofen	SS				
			Mefenamic Acid	C				

Date:07/25/02ISR Number: 3954880-4Report Type:Expedited (15-DaCompany Report #PHBS2002IT08366
Age:72 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Hypersensitivity Generalised Erythema	Foreign Health Professional Other	Lioresal(Baclofen)	PS		ORAL	37.5 MG/DAY, ORAL	
			Ditropan(Oxybutynin)	SS		ORAL	7.5 MG/DAY, ORAL	

			Rivotril(Clonazepam)	SS		ORAL
ORAL						
			Omnic (Tamsulosin Hydrochloride)	SS		ORAL
ORAL						

Date:08/01/02ISR Number: 3957636-1Report Type:Expedited (15-DaCompany Report #PHBS2002JP06406
Age:20 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Convulsion	Foreign	Lioresal (Baclofen)			
	Disease Recurrence	Health	Tablet	PS		ORAL
SEE IMAGE						
	Drug Level Changed	Professional	Phenobarbital			
	Hypercapnia	Other	(Phenobarbital)	SS		ORAL
SEE IMAGE						
	Pyrexia		Depakene	C		
	Respiratory Failure		Benzalin	C		
			Piracetam	C		
			Lactic Acid (Lactic Acid)	C		
			Ambroxol Hydrochloride (Ambroxol Hydrochloride)	C		

Date:08/01/02ISR Number: 3958288-7Report Type:Expedited (15-DaCompany Report #PHNU2002DE02465
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Oedema Peripheral	Foreign	Lioresal(Baclofen)			
		Health	Unknown	PS		
		Professional	Ribif (Interferon			
		Other	Beta)	SS		

Date:08/01/02ISR Number: 3958294-2Report Type:Expedited (15-DaCompany Report #PHFR2002GB02296
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Psychotic Disorder	Foreign Health Professional Other	Baclofen(Baclofen) Unknown	PS		ORAL	180 MG, QD, ORAL	

Date:08/06/02ISR Number: 3959397-9Report Type:Expedited (15-DaCompany Report #PHNU2002DE01956
Age:3 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hypokalaemia	Foreign Health Professional Other	Lioresal (Baclofen)	PS	Novartis	ORAL	2.5 MG, QID, ORAL;REGIMEN 2-8, SEE IMAGE	
			Topamax (Topiramate)	C				
			...	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/14/02ISR Number: 3962179-5Report Type:Direct Company Report #CTU 174064
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	Coma Hypotonia Medication Error Muscle Spasticity		Baclofen For Intrathecal Use 6000 Micrograms/Ml Compound By Priorty One	PS	Compound By Priorty One	INTRATHECAL	1260 MCG/D	
			Valium	C		INTRATHEAL		
			Flagyl	C				

Date:08/20/02ISR Number: 3965671-2Report Type:Expedited (15-DaCompany Report #20021138
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Withdrawal Syndrome Medical Device	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		INTRATHECAL	MCG, DAILY,	
	Complication					INTRATHECAL		
	Pharmaceutical Product Complaint							

Date:08/21/02ISR Number: 3966609-4Report Type:Expedited (15-DaCompany Report #PHNU2002DE02752
Age:65 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Accidental Overdose Fatigue	Foreign Health	Lioresal (Baclofen) Tablet	PS		SEE IMAGE		
	Hypertension	Professional Other						

Date:08/21/02ISR Number: 3966610-0Report Type:Expedited (15-DaCompany Report #PHBS2002BR09516
Age:59 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Anorexia	Foreign	Lioresal (Baclofen)					
	Paralysis	Consumer	Tablet	PS		ORAL	SEE IMAGE	
	Vomiting	Other						

Date:09/03/02ISR Number: 3969243-5Report Type:Expedited (15-DaCompany Report #WAES 0208CHE00033
Age:72 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hypertension	Health Professional	Vioxx	PS	Merck & Co., Inc	ORAL	3	DAY
	Stupor		Baclofen	SS		ORAL		
			Deflazacort	SS		ORAL		
			Acetaminophen	C		ORAL		
			Amlodipine Besylate	C		ORAL		
			Aspirin	C		ORAL		
			Indapamide	C		ORAL		
			Calcium (Unspecified) And Vitamin D (Unspecified)	C		ORAL		
			Cozaar	C		ORAL		
			Hydrochlorothiazide					

			And Losartan Potassium	C		ORAL

Date:09/03/02ISR Number: 3971521-0Report Type:Expedited (15-DaCompany Report #20021163
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Burning Sensation Feeling Cold Hypoaesthesia Muscle Spasticity	Health Professional	Lioresal 2000 Mcg/Ml Intratheca (Baclofen Injectino)	PS		INTRATHECAL	580 MCG, DAILY, INTRATHECAL	

Date:09/04/02ISR Number: 3969979-6Report Type:Expedited (15-DaCompany Report #320345
Age:41 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Leukopenia Overdose Renal Failure Acute Thrombocytopenia		Rivotril Deroxat Methotrexate Lioresal Neurontin Topalgic Xanax	PS SS SS SS SS SS C	Roche		DAILY.	8 DAY 8 DAY 8 DAY 8 DAY 8 DAY 8 DAY

Date:09/05/02ISR Number: 3972264-XReport Type:Expedited (15-DaCompany Report #PHBS2002IT10106
Age:52 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Hospitalization - Initial or Prolonged	Erythema	Foreign Health Professional Other	Lioresal (Baclofen)	PS		ORAL 75 MG/DAY ORAL
			Ditropan (Oxybutynin)	SS		ORAL 7.5 MG/DAY, ORAL
			Rivotril (Clonazepam) Drops	SS		ORAL 15 DROPS/DAY ORAL
			Omnic (Tamsulosin Hydrochloride)	C		

Date:09/05/02ISR Number: 3972269-9Report Type:Expedited (15-DaCompany Report #PHBS2002CH10098
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Hospitalization - Initial or Prolonged	Hypertensive Crisis Stupor	Foreign Health Professional Other	Lioresal (Baclofen)	PS		ORAL 75 MG/DAY, ORAL
			Vioxx (Rofecoxib)	SS		ORAL 25 MG/DAY,ORAL
			Calcort (Deflazacort)	SS		ORAL 15 MG/DAY, ORAL
			Dafalgan (Paracetamol)	C		
			Norvasc	C		
			Aspirine	C		
			Fludex (Indapamide)	C		
			Calcimagon-D3	C		
			Cosaar (Losartan			

			Potassium)	C		
			Losartan Potassium W/Hydrochlorothiazide (Losartan Potassium)	C		

Date:09/05/02ISR Number: 3972270-5Report Type:Expedited (15-DaCompany Report #PHNU2002DE02854
Age:31 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Cholelithiasis	Foreign	Lioresal (Baclofen)	PS		ORAL	25 MG, TID,	
	Hepatic Steatosis	Health				ORAL		
	Hepatitis	Professional Other	Propranolol	C				

Date:09/05/02ISR Number: 3972271-7Report Type:Expedited (15-DaCompany Report #PHNU2002DE02857
Age:4 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Accidental Overdose	Foreign	Lioresal (Baclofen)					
	Apathy	Health	Tablet	PS		ORAL	25 MG, BID,	
	Bradycardia	Professional				ORAL		
	Clonic Convulsion	Other	Lioresal "Novartis"					
	Fatigue		Tablet	C				
	Medication Error		Botox (Botulinum Toxin Type A)	C				

Date:09/05/02ISR Number: 3972283-3Report Type:Expedited (15-DaCompany Report #PHBS2002JP06406
Age:20 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Pyrexia	Foreign	Lioresal (Baclofen)					
	Respiratory Failure	Health	Tablet	PS		ORAL	SEE IMAGE	
		Professional	Phenobarbital					

		Other	(Phenobarbital)	SS			ORAL
SEE IMAGE							
			Depakene	C			
			Benzalin	C			
			Lactic Acid (Lactic Acid)	C			
			Ambroxol Hydrochloride (Ambroxol Hydrochloride)	C			

Date:09/05/02ISR Number: 3972659-4Report Type:Expedited (15-DaCompany Report #PHBS2002JP08298
Age:73 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Drug Level Increased	Foreign	Lioresal (Baclofen)					
	Loss Of Consciousness	Health	Tablet	PS		ORAL	10 TO 20	
		Professional					MG/DAY	ORAL
		Other	Primperan (Metoclopramide)	C				
			Calcium Carbonate Tablet	C				
			Pantosin (Panthethine)	C				
			Nitorol Tablet	C				

				Lasix	C		
				Methycobal (Mecobalamin) Tablet	C		
				Erispan (Fludiazepam) Tablet	C		
				Halcion (Triazolam)	C		

Date:09/06/02ISR Number: 3971404-6Report Type:Expedited (15-DaCompany Report #320345
Age:41 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Leukopenia	Consumer	Rivotril	PS	Roche			8 DAY
Initial or Prolonged	Overdose		Deroxat	SS				8 DAY
	Renal Failure Acute		Methotrexate	SS			DAILY.	8 DAY
	Thrombocytopenia		Lioresal	SS				8 DAY
			Neurontin	SS				8 DAY
			Topalgic (Tramadol)	SS				8 DAY
			Xanax	C				

Date:09/09/02ISR Number: 3973743-1Report Type:Expedited (15-DaCompany Report #20021156
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Other	Lioresal? Intrathecal (Baclofen Injection)	PS			INTRATHECAL	MCG, DAILY,
							INTRATHECAL	

Date:09/09/02ISR Number: 3973758-3Report Type:Expedited (15-DaCompany Report #20021167
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Condition Aggravated Drug Withdrawal Syndrome Incoherent Medical Device Complication Muscle Spasticity Pyrexia	Health Professional	Lioresal? Intrathecal (Baclofen Injection)	PS		INTRATHECAL	MCG, DAILY, INTRATHECAL	

Date:09/09/02ISR Number: 3973862-XReport Type:Expedited (15-DaCompany Report #2002054640
Age:77 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Arrhythmia Atrial Fibrillation Cardiac Disorder Dizziness Drug Interaction Drug Level Above Therapeutic Drug Toxicity Vomiting	Foreign Health Professional Other	Norvasc (Amlodipine) Carbamazepine (Carbamazepine) Lioresal (Baclofen) Digitoxin Ferroglycine Sulfate Complex Furosemide Karvea Hct Glibenclamide	PS SS SS C C C C C		ORAL ORAL ORAL	10 MG (BID), ORAL 600 MG (BID), ORAL 25 MG (DAILY), ORAL	

			Pantoprazole Sodium	C			
			Budesonide	C			
			Oxitropium Bromide	C			

Date:09/11/02ISR Number: 3974286-1Report Type:Expedited (15-DaCompany Report #PHNU2002DE02963
Age:77 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Atrial Flutter Blood Pressure Systolic Increased Dizziness Drug Interaction Drug Toxicity Nausea Vertigo	Foreign Study Health Professional Other	Lioresal (Baclofen) Carbamazepine Azu(Carbamazepine) 200 Mg Norvasc(Amlodipine Besilate)	PS SS SS		ORAL ORAL ORAL	25 MG, QD, 300 MG, BID, 5MG, BID,ORAL
			Digitoxin	C			
			Ferro "Sanol" (Ferroglycine Sulfate Complex)	C			
			Furorese	C			
			Karvezide(Irbesartan)	C			
			Maninil "Berlin-Chemie"	C			
			Pantozol (Pantoprazole Sodium)	C			
			Pulmicort	C			
			Ventilat (Oxitropium Bromide)	C			
			Oxcarbazepine	C			

Date:09/12/02ISR Number: 3975466-1Report Type:Expedited (15-DaCompany Report #PHBS2002JP08298
Age:73 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Depressed Level Of Consciousness	Foreign Health Professional	Lioresal (Baclofen) Tablet	PS		ORAL	10 TO 20 MG/DAY, ORAL	
	Drug Level Increased		Primperan (Metoclopramide)	C				
			Calcium Carbonate	C				
			Pantosin (Panthethine)	C				
			Nitorol	C				
			Lasix	C				
			Methycobal (Mecobalamin)	C				
			Erispan (Fludiazepam)	C				
			Halcion (Triazolam)	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/17/02ISR Number: 3977268-9Report Type:Expedited (15-DaCompany Report #B0278371A
Age:41 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Leukopenia Overdose Renal Failure Acute Thrombocytopenia	Foreign	Paxil Tablet (Paroxetine Hydrochloride)	PS		ORAL	20 MG ORAL	
			Tramadol Hydrochloride (Formulation Unknown) (Tramadol Hydrochloride)	SS		ORAL	ORAL	
			Gabapentin (Formulation Unknown) (Gabapentin)	SS		ORAL	ORAL	
			Clonazepam Injection (Clonazepam)	SS			INTRAVENOUS	INTRAVENOUS
			Baclofen Tablet (Baclofen)	SS		ORAL	ORAL	
			Methotrexate Tablet (Methotrexate)	SS		ORAL	ORAL	
			Alprazolam	C				

Date:09/17/02ISR Number: 3977332-4Report Type:Expedited (15-DaCompany Report #PHNU2002DE03089
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Interaction Muscle Spasticity	Foreign Health Professional Other	Lioresal(Baclofen) Tablet	PS		ORAL	ORAL	
			Dronabinol (Dronabinol)	SS				

Date:09/18/02ISR Number: 3978402-7Report Type:Expedited (15-DaCompany Report #20021182
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dyskinesia Feeling Hot Hypoaesthesia Injection Site Inflammation Injection Site Oedema Joint Stiffness Muscular Weakness Neck Pain Paraesthesia Pyrexia	Consumer Health Professional	Lioresal? Intrathecal (Baclofen Injection)	PS		INTRATHECAL	MCG, DAILY, INTRATHECAL	

Date:09/18/02ISR Number: 3978403-9Report Type:Expedited (15-DaCompany Report #20021185
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Meningitis Staphylococcal	Health Professional	Lioresal? Intrathecal (Baclofen Injection)	PS		INTRATHECAL	MCG, DAILY, INTRATHECAL	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/18/02ISR Number: 3979986-5Report Type:Expedited (15-DaCompany Report #PHBS2002BE10260
Age:1 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hepatotoxicity	Foreign	Baclofen (Baclofen)	PS		ORAL		
		Literature						
		Health Professional						
		Other						

Date:09/19/02ISR Number: 3977960-6Report Type:Expedited (15-DaCompany Report #PHBS2002IT10106
Age:52 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Erythema	Foreign	Lioresal (Baclofen)	PS		ORAL	75 MG/DAY,	ORAL
		Health Professional	Ditropan (Oxybutynin)	SS		ORAL	7.5 MG/DAY,	ORAL
		Other	Rivotril (Clonazepam) Drops	SS		ORAL	15 DROPS/DAY,	ORAL
			Omnic (Tamsulosin Hydrochloride)	C				

Date:09/19/02ISR Number: 3977967-9Report Type:Expedited (15-DaCompany Report #PHBS2002IT08366
Age:72 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Generalised Erythema	Foreign	Lioresal (Baclofen)	PS		ORAL	37.5 MG/DAY,	ORAL
		Health						

		Professional	Ditropan			
		Other	(Oxybutynin)	SS		
7.5 MG/DAY						
			Rivotril			
			(Clonazepam)	SS		ORAL
ORAL						
			Omnic (Tamsulosin			
			Hydrochloride)	SS		ORAL
0.4						
MG/DAY,ORAL						

Date:09/19/02ISR Number: 3978164-3Report Type:Expedited (15-DaCompany Report #PHBS2002JP08298
Age:73 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Life-Threatening	Drug Level Increased	Foreign	Lioresal(Baclofen)			
	Loss Of Consciousness	Health	Tablet	PS		ORAL
10 TO 20						
		Professional				
MG/DAY, ORAL						
		Other	Primperan			
			(Metoclopramide)	C		
			Calcium Carbonate	C		
			Pantosin			
			(Pantethine)	C		
			Nitrol	C		
			Lasix	C		
			Methycobal			
			(Mecobalamin)	C		
			Eripsan			
			(Fludiazepam)	C		
			Halcion (Triazolam)	C		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/19/02ISR Number: 3978322-8Report Type:Expedited (15-DaCompany Report #20021187
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Hospitalization - Initial or Prolonged	Unevaluable Event	Health Professional	Lioresal? Intrathecal (Baclofen Injection)	PS			INTRATHECAL	MCG, DAILY,

INTRATHECAL

Date:09/25/02ISR Number: 3981657-6Report Type:Expedited (15-DaCompany Report #PHNU2002DE02857
Age:4 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Accidental Overdose Apathy Bradycardia Clonic Convulsion Coma Dyskinesia Fatigue Grand Mal Convulsion Hypotonia Medication Error Miosis Pupillary Light Reflex Tests Abnormal Somnolence Tremor	Foreign Health Professional Other	Lioresal (Baclofen) Tablet Lioresal "Novartis" Tablet Botox (Botulinum Toxin Type A)	PS C C		ORAL	25 MG, BID,	ORAL

Date:09/25/02ISR Number: 3981956-8Report Type:Expedited (15-DaCompany Report #PHHO2001FR08069
Age:80 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Incontinence Somnolence	Foreign Study	Trileptal (Trileptal T22413+)	PS		ORAL	300 MG, BID,	

		Health					
ORAL							
		Professional	Zoloft (Sertraline				
		Other	Hydrochloride)	SS			
			Lioresal (Baclofen)	SS			
30 MG, TID,							
			Mopral (Omeprazole)	C			

Date:10/02/02ISR Number: 3984603-4Report Type:Expedited (15-DaCompany Report #PHHO2001FR08069
Age:80 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Incontinence	Foreign	Trileptal (Trileptal					
Initial or Prolonged	Somnolence	Study	T22413+)					
		Health	Trileptal(Trileptal)	PS		ORAL	300 MG, BID,	
		Professional						
ORAL								
		Other	Zoloft (Sertraline					
			Hydrochloride)	SS				
			Lioresal (Baclofen)					
			Unknown	SS			30 MG, TID	
			Mopral (Omeprazole)	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/02/02ISR Number: 3986831-0Report Type:Expedited (15-DaCompany Report #PHBS2002JP06406
Age:40 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Drug Level Increased Epilepsy Hypercapnia Pyrexia Respiratory Depression Respiratory Failure	Foreign Health Professional Other	Lioresal(Baclofen)Tablet Phenobarbital (Phenobarbital)	PS SS		ORAL ORAL	120 MG/DAY, ORAL; SEE IMAGE 200 MG/D, ORAL; SEE IMAGE
			Depakene	C			
			Benzalin	C			
			Lactic Acid(Lacticf Acid)	C			
			Ambroxol Hydrochloride(Ambrox ol Hydrochloride)	C			
			Piracetam	C			

Date:10/07/02ISR Number: 3989632-2Report Type:Expedited (15-DaCompany Report #PHBS2002AR11469
Age:52 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Activated Partial Thromboplastin Time Abnormal Agitation Alanine Aminotransferase Increased Aspartate Aminotransferase Increased Blood Alkaline	Foreign Health Professional Other	Lioresal (Baclofen) Heparin (Heparin) Acetylsalicylic Acid Omeprazole (Omeprazole) Alplax (Alprazolam) Trapax Tablet Folic Acid Calcium Carbonate	PS C C C C C C C		ORAL	10 MG, TID, ORAL

	Phosphatase Increased Blood Bilirubin Increased Confusional State Prothrombin Time Shortened		Erythropoietin (Erythropoietni)	C		

Date:10/08/02ISR Number: 3989955-7Report Type:Expedited (15-DaCompany Report #02P-163-0201357-00
Age:44 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Death Life-Threatening Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Cardiac Arrest Depressed Level Of Consciousness Grand Mal Convulsion Intentional Misuse	Literature Health Professional	Dipotassium Clorazepate (Tranxene) (Clorazepate Dipotassium) Amitriptyline Dextropropoxyphene Oxybutynin Cyclobenzaprine Baclofen Cisapride Omeprazole Diosmin Glycopyrronium Bromide	PS SS SS SS SS SS SS SS SS SS		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/08/02ISR Number: 3990003-3Report Type:Expedited (15-DaCompany Report #D0039382A
Age:30 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Accidental Exposure Blood Pressure Systolic Decreased Therapeutic Agent Toxicity	Foreign Health Professional	Lamictal Tablet (Lamotrigine)	PS		ORAL	500 MG SINGLE DOSE ORAL	
			Oxcarbazepine Tablet (Oxcarbazepine)	SS		ORAL	2400 MG SINGLE DOSE ORAL	
			Baclofen Tablet (Baclofen)	SS		ORAL	10 MG SINGLE DOSE ORAL	
			Levetiracetam Tablet (Levetiracetam)	SS		ORAL	2000 MG SINGLE DOSE ORAL	

Date:10/09/02ISR Number: 3991016-8Report Type:Expedited (15-DaCompany Report #PHFR2002GB03125
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Photosensitivity Reaction	Foreign Health Professional	Diclofenac (Diclofenac)	PS			UNK, UNK, UNKNOWN	
		Other	Lioresal(Baclofen) Unknown	SS				
			Librium "Hoffman" (Chlordiazeoxide Hydrochloride)	C				

			Dothiepin (Dosulepin)	C		

Date:10/15/02ISR Number: 3993753-8Report Type:Expedited (15-DaCompany Report #NSADSS2002032587
Age:57 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Blood Glucose Increased	Literature	Tylenol With Codeine					
	Blood Ph Decreased	Health	(Unspecified)					
	Completed Suicide	Professional	(Acetaminophen/Codei					
	Intentional Misuse		ne)	PS		ORAL	ORAL	
	Renal Impairment		Baclofen (Baclofen)	SS		ORAL	ORAL	
	Respiratory Arrest							

Date:10/16/02ISR Number: 3993679-XReport Type:Expedited (15-DaCompany Report #20021187
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Drug Level Below	Health	Lioresal Intrathecal					
Hospitalization -	Therapeutic	Professional	(Baclofen Injection)	PS				
INTRATHECAL							DAILY,	
Initial or Prolonged	Medical Device							
INTRATHECAL								
	Complication							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/17/02ISR Number: 3995652-4Report Type:Expedited (15-DaCompany Report #PHBS2002BR11953
Age:34 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Coma Intentional Misuse	Foreign Health Professional	Lioresal (Baclofen) Tablet	PS		ORAL	40 TABLETS/D, ORAL	
	Miosis							
	Respiratory Depression Suicide Attempt	Other	Phenobarbital (Phenobarbital)	SS				

Date:10/17/02ISR Number: 3997059-2Report Type:Expedited (15-DaCompany Report #GRP02000157
Age:35 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Hospitalization - Initial or Prolonged	Anaemia Arthritis Beta Haemolytic	Foreign Health Professional	Dantamacrin(Dantrolene Sodium) Capsule, Unknownmg	PS		ORAL	ORAL	
	Streptococcal Infection Blister	Other	Timonil(Carbamazepine)	SS		ORAL	ORAL	
	Candida Pneumonia Epidermolysis		Lioresal "Novartis" (Baclofen)	SS		ORAL	ORAL	
	Erythema Pancytopenia		Oxybutynin(Oxybutynin)	SS		ORAL	ORAL	
	Peritonsillar Abscess Photosensitivity Reaction		Tranxilium(Clorazepate Dipotassium)	SS		ORAL	ORAL	
			Acimethin(Methionine)	SS		ORAL	ORAL	
			Fragmin(Heparin-Fraction, Sodium Salt)	SS		ORAL	ORAL	
			Nystatin(Nystatin)	SS		ORAL	ORAL	

Date:10/24/02ISR Number: 3995588-9Report Type:Expedited (15-DaCompany Report #D0039382A
Age:30 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Pressure Systolic Decreased	Health Professional	Lamictal	PS	Glaxo Wellcome	ORAL	500MG Single	dose 1 DAY
	Drug Toxicity		Trileptal	SS		ORAL	2400MG Single	dose 1 DAY
			Lioresal	SS		ORAL	10MG Single	dose 1 DAY
			Keppra	SS		ORAL	2000MG Single	dose 1 DAY

Date:10/25/02ISR Number: 4000730-XReport Type:Expedited (15-DaCompany Report #20021200
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Catheter Related Complication	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		INTRATHECAL	MCG,	DAILY,
	Discomfort					INTRATHECAL		

Date:10/25/02ISR Number: 4000769-4Report Type:Expedited (15-DaCompany Report #EMADSS2002006188
Age:38 YR Gender:Male I/FU:I

Outcome	PT	Report Source
Other	Convulsion	Foreign
	Drug Interaction	Health

Professional

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
			Topalgic					
			Tramadol Hydrochloride)	PS				
			Deroxat (Paroxetine Hydrochloride)	SS				
			Lioresal (Baclofen)	SS				
			Neurontin (Gabapentin)	C				

Date:10/28/02ISR Number: 4001488-0Report Type:Expedited (15-DaCompany Report #20021202
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Discomfort	Health	Lioresal Intrathecal					
Hospitalization -	Gastric Dilatation	Professional	(Baclofen Injection)	PS				
INTRATHECAL							MCG,	DAILY,
Initial or Prolonged	Gastric Volvulus							
INTRATHECAL								
	Intestinal Dilatation							
	Post Procedural Complication							
	Upper Gastrointestinal Haemorrhage							
	Urinary Retention							

Date:10/29/02ISR Number: 3998819-4Report Type:Expedited (15-DaCompany Report #US-BRISTOL-MYERS SQUIBB COMPANY-12081485
Age:63 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Haematemesis		Warfarin Sodium	PS	Bristol-Myers Squibb			
Initial or Prolonged	Ulcer				Company	ORAL		
Daily dose:								
as per INR								
			Acetylsalicylic Acid	SS		ORAL		
			Diclofenac	SS		ORAL		
			Baclofen	SS		ORAL		

			Folic Acid	C		ORAL
			Co-Amilofruse	C		ORAL

Daily dosage:

5/40

			Simvastatin	C		ORAL
			Epilim	C		ORAL
			Uniphyllin	C		ORAL
			Co-Codamol	C		ORAL

Date:10/30/02ISR Number: 4003291-4Report Type:Expedited (15-DaCompany Report #PHBS2002AU05729
Age:41 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Alanine Aminotransferase Increased	Foreign Health Professional	Lioresal (Baclofen) Unknown	PS		ORAL	10 MG, TID, ORAL	
	Aspartate Aminotransferase Increased	Other	Mormison	C				
			Stilnox (Zolpidem)	C				
	Gamma-Glutamyltransferase Increased		Valium	C				
			Endone (Oxycodone Hydrochloride)	C				
			Pethidine (Pethidine)	C				

				Zomig (Zolmitriptan)	C		
				Maxolon	C		
				Prochlorperazine Maleate (Prochlorperazine Maleate)	C		
				Brevinor (Noresthisterone)	C		
				Diclocil (Dicloxacillin Sodium Monohydrate)	C		

Date:10/31/02ISR Number: 4004234-XReport Type:Expedited (15-DaCompany Report #PHFR2002GB03125
Age:49 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Disability Other	Photosensitivity Reaction	Foreign Health Professional	Diclofenac(Diclofenac) Unknown	PS		ORAL	75 MG, TID; ORAL
		Other	Lioresal(Baclofen) Unknown	SS		ORAL	10 MG/DAY, ORAL
			Librium "Hoffman" (Chlordiazepoxide Hydrochloride)	C			
			Dothiepin (Dosulepin)	C			

Date:11/04/02ISR Number: 4006150-6Report Type:Expedited (15-DaCompany Report #PHFR2002GB03463
Age:63 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Gastrointestinal Ulcer Haematemesis Haemoglobin Decreased	Foreign Health Professional	Diclofenac (Diclofenac)	PS		ORAL	75 MG/DAY, ORAL

	International Normalised Ratio Increased	Other	Baclofen (Baclofen)	SS			ORAL 10 MG/DAY, ORAL
			Warfarin (Warfarin)	SS			ORAL ORAL
			Aspirine (Acetylsalicylic Acid)	SS			ORAL 75 MG/DAY, ORAL
			Folic Acid	C			
			Co-Amilofruse	C			
			Simvastatin	C			
			Epilim	C			
			Uniphyllin "Napp"	C			
			Co-Codamol (Paracetamol)	C			

Date:11/05/02ISR Number: 4006957-5Report Type:Expedited (15-DaCompany Report #PHNU2002DE02752
Age:65 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Hospitalization - Initial or Prolonged	Accidental Overdose	Foreign	Lioresal (Baclofen)			
	Fatigue	Health	Tablet	PS		ORAL SEE IMAGE
	Hypertension	Professional				
		Other				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/06/02ISR Number: 4008525-8Report Type:Expedited (15-DaCompany Report #PHBS2002JP12793
Age:4 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Fanconi Syndrome Acquired	Foreign	Lioresal (Baclofen)	PS		ORAL	10 MG/DAY,	
	Renal Tubular Disorder	Health					ORAL	
		Professional						
		Other						

Date:11/06/02ISR Number: 4008526-XReport Type:Expedited (15-DaCompany Report #PHRM2002FR02640
Age:19 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Neutropenia	Foreign	Lioresal (Baclofen)					
		Health	Tablet	PS		ORAL	SEE IMAGE	
		Professional	Fraxiparine					
		Other	(Heparin-Fraction, Calcium Salt)					
			Solution	SS		SUBCUTANEOUS	1 DF, QD,	
						SUBCUTANEOUS		

Date:11/08/02ISR Number: 4012252-0Report Type:Expedited (15-DaCompany Report #PHNU2002DE02854
Age:31 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Cholangitis	Foreign	Lioresal (Baclofen)					
	Cholelithiasis	Health	Tablet	PS		ORAL	25 MG, TID,	
	Hepatic Steatosis	Professional					ORAL; 25 MG,	
		Other					TID, ORAL	
			Propra-Ratiopharm	C				

Date:11/11/02ISR Number: 4007050-8Report Type:Expedited (15-DaCompany Report #US-BRISTOL-MYERS SQUIBB COMPANY-12081485
Age:63 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Haematemesis	Health Professional	Warfarin Sodium	PS	Bristol-Myers Squibb Company	ORAL	Daily dose: as per INR	
	Haemoglobin Decreased							
	International Normalised Ratio Increased		Acetylsalicylic Acid	SS		ORAL		
	Ulcer		Diclofenac	SS		ORAL		
			Baclofen	SS		ORAL	Daily dosage: 5/40	
			Folic Acid	C		ORAL		
			Co-Amilofruse	C		ORAL		
			Simvastatin	C		ORAL		
			Epilim	C		ORAL		
			Uniphyllin	C		ORAL		
			Co-Codamol	C		ORAL		

Date:11/13/02ISR Number: 4012308-2Report Type:Expedited (15-DaCompany Report #200214441FR
Age:36 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Neutropenia	Foreign Other	Heparin-Fraction, Sodium Salt (Lovenox)	PS		SUBCUTANEOUS	40 MG QD SC	5 WK
			Baclofen (Lioresal)	SS		ORAL	10 MG TID PO	13 DAY

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/15/02ISR Number: 4013153-4Report Type:Expedited (15-DaCompany Report #PHNU2002DE03679
Age:45 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Condition Aggravated	Foreign	Lioresal (Baclofen)					
	Pyrexia	Health	Tablet	PS		ORAL	30MG/DAY,	
		Professional					ORAL	
		Other	Metoclopramide	C				
			Tavor	C				
			Heparin	C				

Date:11/18/02ISR Number: 4013548-9Report Type:Expedited (15-DaCompany Report #2002003941
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Drug Withdrawal Syndrome	Health	Zoloft (Sertraline					
Initial or Prolonged	Grand Mal Convulsion	Professional	Hydrochloride)	PS		ORAL		
ORAL								
Other	White Blood Cell Count		Baclofen (Baclofen)	SS				
	Increased		Klonopin					
			(Clonazepam)	SS			3 MG (TID)	
			Atenolol	C				
			Fentanyl	C				
			Morphine	C				
			Simvastatin	C				

Date:11/18/02ISR Number: 4013896-2Report Type:Expedited (15-DaCompany Report #PHBS2002TW13256
Age:61 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Asthenia	Foreign	Baclofen(Baclofen)	PS			5 MG, TID	
Initial or Prolonged	Drug Toxicity	Literature						
	Haemodialysis	Health						
	Hyporeflexia	Professional						
	Hypotonia	Other						
	Nausea							

Speech Disorder
Toxic Induced
Encephalopathy
Vision Blurred
Vomiting

Date:11/20/02ISR Number: 4016764-5Report Type:Expedited (15-DaCompany Report #PHBS2002JP12793
Age:4 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Fanconi Syndrome Acquired	Foreign	Lioresal (Baclofen)	PS		ORAL	10 MG/DAY,	ORAL
	Renal Tubular Disorder	Health Professional Other	Valproic Acid (Valproic Acid)	SS		ORAL	450 MG/DAY,	ORAL
			Excergan (Zonisamide)	C				
			Rivotril	C				
			Phenobal	C				
			Dantrium (Dantrolene Sodium)	C				
			Mucodyne	C				
			Meptin (Procaterol Hydrochloride)	C				

			Clarith (Clarithromycin)	C			

Date:11/20/02ISR Number: 4016785-2Report Type:Expedited (15-DaCompany Report #PHBS2002BR13602
Age:22 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agitation Hypotension Intentional Misuse Mydriasis Suicide Attempt	Foreign Health Professional Other	Lioresal (Baclofen) Tablet	PS		ORAL	20 TABLETS, ONCE/SINGLE, ORAL	
			Amitripyline (Amitriptyline) Tablet	SS		ORAL	20 DF, ONCE/SINGLE, ORAL	
			Oxybutynin (Oxybutynin) Tablet	SS		ORAL	10 TABLETS, ONCE/SINGLE, ORAL	
			Diazepam (Diazepam) Tablet	SS		ORAL	10 TABLETS, ONCE/SINGLE, ORAL	

Date:11/22/02ISR Number: 4016036-9Report Type:Expedited (15-DaCompany Report #EMADSS2002006188
Age:38 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Hospitalization - Initial or Prolonged	Convulsion	Foreign Health Professional	Topalgic (Unspecified) (Tramadol Hydrochloride)	PS
Other	Drug Interaction			
300 MG, DAILY				
			Deroxat (Paroxetine Hyrochloride)	SS
20 MG, DAILY				
			Lioresal (Baclofen)	SS
30 MG, DAILY				
			Neurontin (Gabapentin)	C

Date:11/26/02ISR Number: 4017585-XReport Type:Expedited (15-DaCompany Report #PHBS2002CL04226
Age:57 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Pulmonary Fibrosis	Foreign	Lioresal(Baclofen)Tablet	PS		ORAL
	Sarcoidosis	Consumer				
SEE IMAGE 1095 DAY						
			Enalapril (Enalapril)	C		
			Diazepam	C		

Date:12/02/02ISR Number: 4020521-3Report Type:Expedited (15-DaCompany Report #20021236
Age: Gender:Male I/FU:I

Outcome	PT
Death	Brain Death
	Coma
	Hypotonia
	Pupil Fixed

		Ventricular Fibrillation					
			Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
			Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		
INTRATHECAL	UNK MCG,						
DAILY,							
INTRATHECAL							

Date:12/02/02ISR Number: 4020792-3Report Type:Expedited (15-DaCompany Report #20021235
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Clonic Convulsion Muscle Spasticity	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		
INTRATHECAL 536 MCG, DAILY, INTRATHECAL	Pneumonia					
			Tizanidine	C		
			Lorazepam	C		
			Clonazepam	C		

Date:12/02/02ISR Number: 4020794-7Report Type:Expedited (15-DaCompany Report #20021232
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Csf Bacteria Identified Diphtheria	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		
INTRATHECAL MCG, DAILY, INTRATHECAL	Drug Withdrawal Syndrome Meningitis					

Date:12/03/02ISR Number: 4022059-6Report Type:Expedited (15-DaCompany Report #PHBS2002BR13602
Age:22 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agitation Heart Rate Increased Hypotension Intentional Misuse Mydriasis Suicide Attempt	Foreign Health Professional Other	Lioresal (Baclofen) Tablet	PS		ORAL	20 TABLETS, ONCE/SINGLE, ORAL	
			Amitriptyline (Amitriptyline) Tablet	SS		ORAL	20 DF, ONCE/SINGLE, ORAL	
			Oxybutynin (Oxybutynin) Tablet	SS		ORAL	10 TABLETS, ONCE/SINGLE, ORAL	
			Diazepam (Diazepam) Tablet	SS		ORAL	10 TABLETS, ONCE/SINGLE, ORAL	

Date:12/09/02ISR Number: 4020800-XReport Type:Direct Company Report #CTU 182317
Age:56 YR Gender:Male I/FU:I

Outcome
Life-Threatening
Hospitalization -

Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
			Asthenia		Baclofen 2000.0 Ug/Ml	PS		INTRADISCAL (INTRASPINAL)
	19.8	UG/HR	Difficulty In Walking					
			Dyspnoea					
			Medication Error					
			Pharmaceutical Product Complaint					

Date:12/09/02ISR Number: 4023061-0Report Type:Expedited (15-DaCompany Report #02P-163-0205269-00
Age:37 YR Gender:Unknown I/FU:I

Outcome	Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Death			Completed Suicide	Literature	Hydrocodone/Acetaminophen (Vicodin) (Hydrocodone/Acetaminophen)	PS		
				Health	Venlafaxine	SS		
				Professional	Baclofen	SS		

Date:12/09/02ISR Number: 4023117-2Report Type:Expedited (15-DaCompany Report #PHNU2002DE03679
Age:45 YR Gender:Male I/FU:F

Outcome	Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other			Condition Aggravated	Foreign	Lioresal (Baclofen)			
			Pyrexia	Health	Tablet	PS		ORAL
SEE IMAGE								
				Professional	Metoclopramide (Metoclopramide)	C		
				Other	Tavor	C		
					Heparin (Heparin)	C		

Date:12/10/02ISR Number: 4024891-1Report Type:Expedited (15-DaCompany Report #PHNU2002DE03089
Age: Gender:Unknown I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Interaction	Foreign	Lioresal (Baclofen)					
	Muscle Spasticity	Health	Tablet	PS		ORAL		
ORAL								
		Professional	Dronabinol					
		Other	(Dronabinol)	SS				
CHANGING								
DOSAGE								
			Mydocalm					
			"Strathmann"					
			(Tolperisone					
			Hydrochloride)	C				
			Sirdalud	C				
			Benzodiazepines	C				

Date:12/11/02ISR Number: 4025240-5Report Type:Expedited (15-DaCompany Report #PHRM2002FR02963
Age:36 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Agranulocytosis	Foreign	Lioresal (Baclofen)					
Initial or Prolonged	Pyrexia	Health	Tablet	PS				
10 MG, TID,								
	White Blood Cell Count	Professional						
INTRAGASTRIC								
	Decreased	Other	Lovenox					
			(Heparin-Fraction,					

			Sodium Salt) Solution For Injection	SS			
SUBCUTANEOUS	40 MG, QD; SUBCUTANEOUS						

Date:12/16/02ISR Number: 4027524-3Report Type:Expedited (15-DaCompany Report #PHFR2002GB04053
Age:46 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Haematemesis	Foreign	Baclofen(Baclofen)					
	Haemoglobin Decreased	Health	Unknown	PS		ORAL	20 MG/DAY, ORAL	
	Oesophagitis	Professional						
		Other	Diazepam	C				
			Lactulose	C				

Date:12/16/02ISR Number: 4027526-7Report Type:Expedited (15-DaCompany Report #PHFR2002GB04054
Age:82 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Haematemesis	Foreign	Baclofen (Baclofen)					
	Haemoglobin Decreased	Health	Unknown	PS		ORAL	5MG/DAY , ORAL	
		Professional						
		Other	Lanzoprazole(Lanzoprazole)	C				
			Amoxicillin	C				

Date:12/16/02ISR Number: 4032190-7Report Type:Expedited (15-DaCompany Report #USA-2002-008204
Age:42 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Optic Neuritis	Study	Betaseron					
Hospitalization -	Pneumonia	Health	(Interferon Beta -					

Initial or Prolonged	Quadriplegia	Professional	1b) Injection	PS			
SUBCUTANEOUS	SEE IMAGE						
Disability			Baclofen (Baclofen)	SS			
INTRATHECAL	INTRATHECAL						
			Albuterol	C			
			Tequin (Gatifloxacin)	C			
			Neurontin (Gabapentin)	C			
			Multivitamins (Ergocalciferol, Retinol, Panthenol)	C			
			Mandelamine "Park-Davis" (Methenamine Mandelate)	C			
			Diovan "Novartis" (Valsartan)	C			
			Elavil	C			

Date:12/18/02ISR Number: 4027955-1Report Type:Expedited (15-DaCompany Report #02-12-1104
Age:82 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Haematemesis	Foreign Other	Baclofen - Ipi Tablets	PS		ORAL	5MG QD ORAL	
			Lansoprazole	C				
			Amoxicillin	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/20/02ISR Number: 4029155-8Report Type:Direct Company Report #CTU 183156
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Coma		Baclofen 10mg					
Required	Heart Rate Decreased		Upsher-Smith	PS	Upsher-Smith	ORAL	5MG ONCE	ORAL
Intervention to Prevent Permanent Impairment/Damage	Hypotension		Compazine	C				
			Vicodin	C				
			Glipizide Xl	C				
			Isosorbide Er	C				
			Lovastatin	C				
			Methylphenidiate	C				

Date:12/30/02ISR Number: 4036646-2Report Type:Expedited (15-DaCompany Report #PHNU2002DE04194
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Asthenia	Foreign	Lioresal (Baclofen)					
	Depressed Level Of Consciousness	Health Professional	Tablet	PS		ORAL	12.5 MG, BID, ORAL; 10 MG, BID, ORAL; 5 MG, BID, ORAL	
	Drug Level Above Therapeutic	Other						
	Dysarthria		L-Thyroxin Henning					
	Fatigue		Berlin	C				
	Muscular Weakness		Dreisavit	C				
	Narcolepsy		Nexium Mups (Esomeprazole)	C				
	Overdose		Lactulose	C				
	Reflux Oesophagitis		Mcp Hexal	C				
	Vomiting		Baldrian-Dispert (Valeriana Officinalis Root)	C				

Date:12/31/02ISR Number: 4040235-3Report Type:Expedited (15-DaCompany Report #SAG/INT-10/0/13/10/1
Age:58 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Aphasia Disease Recurrence Epilepsy Grand Mal Convulsion Multiple Sclerosis Relapse Postictal State Pyrexia	Foreign Health Professional Other	Sandoglobulin Or Placebo (Placebo Placebo) (Sandoglobulin Or Placebo) Baclofen (Baclofen) Capsule Ds 103-282 (Tizanidine Hydrochloride) Capsule Neuromet (Oxiracetam) Orfiril (Valproate Sodium)	PS SS SS C C		INTRAVENOUS INTRAVENOUS	QMO,	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/06/03ISR Number: 4036977-6Report Type:Direct Company Report #CTU 183902
Age:51 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Ineffective		Baclofen 10 Mg					
	Pharmaceutical Product		Rosemont/Geneva	PS	Rosemont/Geneva		10 MG 3 X A	
	Complaint							DAY

Date:01/08/03ISR Number: 4038506-XReport Type:Direct Company Report #CTU 184078
Age:50 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Drug Withdrawal Syndrome		Baclofen 20 Mg					
Hospitalization -	Hip Fracture		Watson	PS	Watson	ORAL	20 MG TID	
Initial or Prolonged	Road Traffic Accident						ORAL	
Disability	Spinal Compression		Oxycontin	C				
	Fracture		Oxycodone	C				
	Syncope		Fibercon	C				
	Tibia Fracture		Sennacot	C				
			Colace	C				
			Benadryl	C				

Date:01/10/03ISR Number: 4040943-4Report Type:Expedited (15-DaCompany Report #20010894
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Blood Creatine	Health	Lioresa					
	Phosphokinase Increased	Professional	(Baclofen Injection)	PS			INTRATHECAL	967 MCG DAILY
	Body Temperature						INTRATHECAL	
	Increased		See B5	C			INTRATHECAL	
	Csf Glucose Abnormal							
	Csf Protein Abnormal							
	Hypoaesthesia							

	Lung Disorder Post Procedural Complication					

Date:01/13/03ISR Number: 4041205-1Report Type:Direct Company Report #CTU 184305
Age:51 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Difficulty In Walking Muscle Spasticity		Baclofen 10mg Rosemont	PS	Rosemont		10MG 3X DAY
	Pharmaceutical Product Complaint		Baclofen 10mg Geneva	SS	Geneva		

Date:01/16/03ISR Number: 4042953-XReport Type:Direct Company Report #CTU 184755
Age:49 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Dyspnoea Pharmaceutical Product		Baclofen - Watson - 10mg Tabs	PS	Watson	ORAL	1T PO TID
	Complaint Pharyngeal Oedema						

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/21/03ISR Number: 4045117-9Report Type:Expedited (15-DaCompany Report #B0286936A
Age:40 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Death	Literature	Aspirin (Formulation					
		Health	Unknown) (Aspirin)	PS		ORAL		
ORAL								
		Professional	Paracetamol (Formulation Unknown)					
			(Acetaminophen)	SS		ORAL		
ORAL								
			Baclofen (Formulation Unknown	SS		ORAL		
ORAL								

Date:01/23/03ISR Number: 4046877-3Report Type:Expedited (15-DaCompany Report #PHNU2003DE00472
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Delusional Disorder,	Foreign	Lioresal (Baclofen)	PS				
	Persecutory Type	Health	Norvasc	C				
	Hallucination	Professional	Sandocal "Novartis" (Sodium)	C				
			Stilnox (Zolpidem)	C				
			Marcumar (Phenprocoumon)	C				

Date:02/03/03ISR Number: 4050591-8Report Type:Direct Company Report #CTU 185805
Age:47 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Anal Sphincter Atony		Enoxaparin-Lovenox-					
Hospitalization -	Back Pain		100 Mg Aventis	PS	Aventis			
SUBCUTANEOUS	100 MG EVERY							
Initial or Prolonged	Cellulitis							
12								
Disability	Deep Vein Thrombosis							
SUBCUTANEOUS								
Required	Hyporeflexia		Baclofen-Intrathecal					

Intervention to	Implant Site Infection		Drug In Pump Geigy	SS	Geigy	
INTRATHECAL	CONTINUOUS					
Prevent Permanent	Implant Site Reaction					
INTRATHECAL						
Impairment/Damage	Operative Haemorrhage		Warfarin	C		
	Paraplegia					
	Subdural Haematoma					

Date:02/05/03ISR Number: 4051268-5Report Type:Expedited (15-DaCompany Report #WAES 0208CHE00033
Age:72 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Hypertension		Vioxx	PS	Merck & Co., Inc	ORAL		
Initial or Prolonged	Stupor		Baclofen	SS		ORAL		
3 DAY								
			Deflazacort	SS		ORAL		
			Acetaminophen	C		ORAL		
			Amlodipine Besylate	C		ORAL		
			Aspirin	C		ORAL		
			Indapamide	C		ORAL		
			Calcium (Unspecified) And Vitamin D (Unspecified)	C		ORAL		
			Cozaar	C		ORAL		
			Hydrochlorothiazide And Losartan Potassium	C		ORAL		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/05/03ISR Number: 4053353-0Report Type:Expedited (15-DaCompany Report #DCC03003 BAC
Age:51 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Difficulty In Walking	Consumer	Baclofen	PS	Usp	ORAL	10 MG ORAL
	Muscle Spasticity	Other	Estrace	C			
			Lasix	C			
			Xanax	C			
			Effexor	C			
			Detrol	C			
			Loricet	C			

Date:02/14/03ISR Number: 4056899-4Report Type:Direct Company Report #CTU 186719
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Required Intervention to Prevent Permanent Impairment/Damage	Areflexia		Lioresal Intrathecal(Baclofen Injection)	PS		INTRATHECAL	400-420 MCG DAILY
	Coma						
	Hypotonia						
	Hypoventilation						
	Irritability						

Date:02/24/03ISR Number: 4065260-8Report Type:Expedited (15-DaCompany Report #HQWYE522020FEB03
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Death	Adverse Drug Reaction	Consumer	Infumorph (Morphine Sulfate, Injection)	PS		INTRASPINAL	
			Baclofen (Baclofen)	SS			

Date:02/27/03ISR Number: 4067358-7Report Type:Expedited (15-DaCompany Report #PHNU2003DE00538
Age:31 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Abortion	Foreign	Lioresal(Baclofen)					
	Complications Of Maternal	Health	Tablet, 10mg	PS		ORAL	SEE IMAGE	
	Exposure To Therapeutic	Professional						
	Drugs	Other						
	Maternal Drugs Affecting							
	Foetus							

Date:03/04/03ISR Number: 4070019-1Report Type:Expedited (15-DaCompany Report #20031317
Age:58 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Coma	Consumer	Lioresal					
Initial or Prolonged	Drug Effect Decreased	Health	Intrathecal(Baclofen					
	Hyperpyrexia	Professional	Injection)	PS		INTRATHECAL	DAILY,	
	Medical Device						INTRATHECAL	
	Complication							
	Overdose							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/07/03ISR Number: 4071715-2Report Type:Expedited (15-DaCompany Report #03-02-0220
Age:17 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Areflexia	Literature	Baclofen	PS		INTRATHECAL	75-350UG/D	
Initial or Prolonged	Asthenia	Health				INTRATHECAL	11	MON
Other	Catheter Related Complication	Professional						
	Clonic Convulsion							
	Deep Vein Thrombosis							
	Hypotonia							
	Migration Of Implant							
	Muscle Spasticity							
	Post Procedural Complication							

Date:03/07/03ISR Number: 4072935-3Report Type:Expedited (15-DaCompany Report #PHNU2002DE04194
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Asthenia	Foreign	Lioresal(Baclofen)					
Hospitalization -	Coma	Health	Tablet	PS		ORAL	10 MG, BID,	
Initial or Prolonged	Convulsion	Professional				ORAL	5 MG, BID,	ORAL
	Depressed Level Of Consciousness	Other	L-Thyroxin "Henning Berlin"	C				
	Drug Level Above Therapeutic		Dreisavit	C				
	Dysarthria		Nexium Mups (Esomeprazole)	C				
	Fall		Lactulose	C				
	Fatigue		Mcp "Hexal"	C				
	Haemodialysis		Baldrian-Dispert (Valeriana Officinalis Root)	C				
	Liver Disorder							
	Muscular Weakness							
	Narcolepsy							
	Overdose							
	Reflux Oesophagitis							
	Renal Failure							

Date:03/13/03ISR Number: 4076154-6Report Type:Expedited (15-DaCompany Report #PHNU2003DE00472
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Delusional Disorder, Persecutory Type	Foreign Health	Lioresal(Baclofen) Unknown	PS		ORAL	ORAL	
	Hallucination	Professional Other	Norvasc	C				
			Sandocal "Novartis" Sodium	C				
			Stilnox (Zolpidem)	C				
			Marcumar(Phenprocoumon)	C				

Date:03/17/03ISR Number: 4077770-8Report Type:Expedited (15-DaCompany Report #2003009487
Age: Gender:Female I/FU:I

Outcome	PT
Other	Alopecia
	Arrhythmia
	Blood Pressure Increased
	Cardiac Failure

	Dizziness						
	Drug Hypersensitivity						
	Heart Rate Increased	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Hypotension	Foreign	Neurontin				
	Memory Impairment	Consumer	(Gabapentin)	PS		ORAL	50 MG, ORAL
	Myocardial Infarction		Nitrostat (Glyceryl				
	Pain		Trinitrate)	SS			
	Pulmonary Hypertension		Lidocaine	SS			
	Restlessness		Baclofen	SS			
	Somnolence		K-Lyte	C			
	Thinking Abnormal		Irbesartan	C			
	Tricuspid Valve Disease		Spironolactone	C			
	Weight Decreased		Oxygen	C			
	Weight Increased		Taurine	C			
			All Other				
			Therapeutic Products	C			
			Atenolol	C			

Date:03/18/03ISR Number: 4077977-XReport Type:Expedited (15-DaCompany Report #DCC03003 BAC
Age:51 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Difficulty In Walking	Consumer	Baclofen Tablets,				
Initial or Prolonged	Muscle Spasticity	Other	Usp	PS		ORAL	10 MG ORAL
	Pharmaceutical Product		Estrace	C			
	Complaint		Lasix	C			
			Xanax	C			
			Effexor	C			
			Detrol	C			
			Loricet	C			

Date:03/20/03ISR Number: 4080533-0Report Type:Expedited (15-DaCompany Report #20031307
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Required	Drug Withdrawal Syndrome	Foreign	Lioresal Intrathecal				
Intervention to	Medical Device	Health	(Baclofen Injection)	PS			
INTRATHECAL							DAILY,

Prevent Permanent Impairment/Damage	Complication Pharmaceutical Product Complaint	Professional					

Date:03/20/03ISR Number: 4080569-XReport Type:Expedited (15-DaCompany Report #20031298
Age:22 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Withdrawal Syndrome Heart Rate Increased Post Procedural Complication Pyrexia	Health Professional Company Representative	Lioresal Intrathecal (Baclofen Injection)	PS			INTRATHECAL	INTRATHECAL

Date:03/20/03ISR Number: 4080761-4Report Type:Expedited (15-DaCompany Report #PHBS2003CH02731
Age:32 YR Gender:Female I/FU:I

Outcome	PT
Other	Abortion Spontaneous Complications Of Maternal

	Exposure To Therapeutic Drugs Maternal Drugs Affecting Foetus	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
	Unintended Pregnancy	Foreign	Lioresal(Baclofen)	PS		
30 MG/DAY						
		Health Professional Other				

Date:03/26/03ISR Number: 4083983-1Report Type:Expedited (15-DaCompany Report #2003CG00392
Age:80 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Abdominal Distension	Foreign	Zestril	PS		ORAL
10 MG QD PO						
Initial or Prolonged	Abnormal Faeces	Health	Mopral	SS		ORAL
20 MG QD PO						
	Anorexia	Professional	Bricanyl	SS		
RESPIRATORY						
	C-Reactive Protein	Other				
(INHALATION) 2 PUFF DAILY						
	Increased					
IH						
	Cardioactive Drug Level		Lasilix	SS		ORAL
10 MG QD PO						
	Increased		Digoxine	SS		ORAL
0.25 MG QD PO						
	Drug Interaction		Rilutek	SS		ORAL
50 MG TID PO						
	Electrocardiogram St		Isoptine	SS		ORAL
40 MG BID PO						
	Segment Depression		Hexaquine	SS		ORAL
2 DF TID PO						
	Nausea		Levothyrox	SS		ORAL
75 UG QD PO						
	Oxygen Saturation		Lioresal Ciba-Geigy	SS		ORAL
2 DF DAILY PO						
	Decreased		Kardegic	SS		ORAL
160 MG QD PO						
	Renal Impairment		Atrovent	SS		
RESPIRATORY						
	Speech Disorder					
(INHALATION) 1PUFF DAILY						

	Tongue Dry						
IH							
	Vomiting		Solupred	SS			
			Deroxat	SS			ORAL
20 MG QD PO							
			Forlax	SS			

Date:03/27/03ISR Number: 4086939-8Report Type:Expedited (15-DaCompany Report #PHFR2003GB01258
Age:84 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Obsessive-Compulsive	Foreign	Baclofen (Baclofen)	PS		ORAL	10 MG, TID,	
	Personality Disorder	Health					ORAL	
	Paranoia	Professional	Co-Codamol	C				
		Other	Folic Acid	C				
			Risedronate Sodium (Risedronate Sodium)	C				
			Perindopril (Perindopril)	C				
			Aspirne	C				
			Bumetanide (Bumetanide)	C				

Date:04/04/03ISR Number: 4090087-0Report Type:Expedited (15-DaCompany Report #PHNU2003DE01380
Age:70 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Interaction	Foreign	Lioresal (Baclofen)					
	Fatigue	Health	Tablet, 10mg	PS		ORAL	50 MG/DAY,	
	Pain In Extremity	Professional					ORAL	
	Weight Increased	Other	Neurontin (Gabapentin)	SS				
1800MG/DAY								
			Saroten "Bayer					

Vital" (Amitriptyline Hydrochloride)	SS	Bayer Vital
L-Thyroxin "Henning Berlin"	C	
Candesartan (Candesartan)	C	
Oxybutynin (Oxybutynin)	C	

Date:04/04/03ISR Number: 4091000-2Report Type:Expedited (15-DaCompany Report #PHNU2003DE01333
Age:5 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Coma Hypothermia	Foreign Health Professional Other	Lioresal (Baclofen) Tablet	PS		ORAL	15 MG/DAY, ORAL	

Date:04/07/03ISR Number: 4089788-XReport Type:Expedited (15-DaCompany Report #03-03-0381
Age:14 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Clonic Convulsion Discomfort Dyspnoea Hyperpyrexia Medical Device Complication Muscle Spasticity Post Procedural Complication Respiratory Rate Increased	Literature Health Professional	Baclofen	PS		INTRATHECAL	536-107UG INTRATHECAL	5 YR

Date:04/08/03ISR Number: 4091612-6Report Type:Expedited (15-DaCompany Report #20021163
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Burning Sensation Feeling Cold	Health Professional	Lioresal? Intrathecal(Baclofen Injection)	PS		INTRATHECAL	275 MCG, DAILY, INTRATHECAL	

Date:04/08/03ISR Number: 4092307-5Report Type:Expedited (15-DaCompany Report #20031346
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Medication Error Respiratory Disorder	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		INTRATHECAL	MCG, DAILY, INTRATHECAL	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/09/03ISR Number: 4092451-2Report Type:Expedited (15-DaCompany Report #DEU-2002-0000223
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Insomnia Tooth Disorder	Foreign Other	Oxygesic 40 Mg(Oxycodone Hydrochloride) Cr Tablet	PS		ORAL	40 MG, TID,	ORAL
			Neurontin(Gabapentin)	SS		ORAL	600 MG, Q6H,	ORAL
			Baclofen(Baclofen)	SS			30 MG, DAILY,	ORAL
			Tramal	C				

Date:04/09/03ISR Number: 4092532-3Report Type:Expedited (15-DaCompany Report #PHNU2003DE00538
Age:31 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Abortion Complications Of Maternal Exposure To Therapeutic Drugs Maternal Drugs Affecting Foetus Pregnancy	Foreign Health Professional Other	Lioresal(Baclofen) Tablet, 10mg	PS		ORAL	SEE IMAGE	

Date:04/09/03ISR Number: 4092915-1Report Type:Expedited (15-DaCompany Report #20031343
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Death	Foreign	Lioresal Intrathecal					

			Health	(Baclofen Injection)	PS	
INTRATHECAL	UNK MCG,					
			Professional			
DAILY,						
INTRATHECAL						

Date:04/15/03ISR Number: 4095246-9Report Type:Expedited (15-DaCompany Report #03-04-0444
Age:9 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Accidental Overdose	Literature	Baclofen	PS				
INTRATHECAL	99.8-777UG							
Initial or Prolonged	Blood Pressure Decreased	Health						
INTRATHECAL	3 YR							
Other	Coma	Professional	Ranidine	C				
	Delayed Recovery From Anaesthesia		Scopolamine	C				
	Haemodynamic Instability							
	Heart Rate Decreased							
	Heart Rate Increased							
	Implant Site Reaction							
	Medical Device Complication							
	Respiratory Depression							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/15/03ISR Number: 4095976-9Report Type:Expedited (15-DaCompany Report #PHBS2003IT03668
Age:79 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Cardiac Failure	Foreign	Lioresal (Baclofen)					
	Dyspnoea	Health Professional Other	Unknown	PS		ORAL	ORAL	

Date:04/17/03ISR Number: 4098157-8Report Type:Expedited (15-DaCompany Report #HQWYE640614APR03
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Withdrawal Syndrome	Health Professional	Infumorph (Morphine Sulfate, Injection)	PS		INTRADISCAL (INTRASPINAL)	INTRASPINAL	
	Myocardial Infarction							
	Pharmaceutical Product Complaint		Baclofen (Baclofen,)	SS		INTRADISCAL (INTRASPINAL)	INTRASPINAL	

Date:04/17/03ISR Number: 4098265-1Report Type:Expedited (15-DaCompany Report #HQWYE640714APR03
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Decubitus Ulcer	Health Professional	Infumorph (Morphine Sulfate, Injection)	PS		INTRADISCAL (INTRASPINAL)	INTRASPINAL	
	Loss Of Consciousness							
	Rhabdomyolysis		Baclofen (Baclofen)	SS		INTRADISCAL (INTRASPINAL)	INTRASPINAL	

Date:04/17/03ISR Number: 4098292-4Report Type:Expedited (15-DaCompany Report #DEU-2002-0000223
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Insomnia Sleep Disorder Tooth Disorder	Foreign Other	Oxygesic 40 Mg (Oxycodone Hydrochloride) Cr Tablet	PS		ORAL	40 MG, TID,	ORAL
			Neurontin (Gabapentin)	SS		ORAL	600 MG, Q6H,	ORAL
			Baclofen	SS		ORAL	30 MG. DAILY	ORAL
			Tramal	C				

Date:04/21/03ISR Number: 4099464-5Report Type:Expedited (15-DaCompany Report #20031357
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Coma Overdose	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		INTRATHECAL	DAILY,	INTRATHECAL

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/21/03ISR Number: 4099466-9Report Type:Expedited (15-DaCompany Report #20031364
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Decubitus Ulcer Loss Of Consciousness Overdose	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		INTRATHECAL	DAILY, INTRATHECAL	
	Rhabdomyolysis		Morphine	C				

Date:04/24/03ISR Number: 4102658-3Report Type:Expedited (15-DaCompany Report #ZANA001068
Age:14 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Clonic Convulsion Condition Aggravated	Literature Health	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	ORAL	
	Dyspnoea Hyperpyrexia Mechanical Complication Of Implant Medical Device Complication Muscle Spasms Respiratory Rate Increased	Professional	Baclofen (Baclofen) Lorazepam Clonazepam	SS C C		INTRATRACHEAL	INTHC	

Date:04/25/03ISR Number: 4101033-5Report Type:Direct Company Report #USP 55815
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Medication Error		Metoprolol	PS		QUARTER TABS		
			Baclofen	SS		QUARTER TABS		

Date:04/28/03ISR Number: 4103900-5Report Type:Expedited (15-DaCompany Report #PHBS2003IT03668
Age:79 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Cardiac Failure	Foreign	Lioresal					
	Dyspnoea	Health	(Baclofen)Unknown	PS		ORAL	30 MG/DAY,	
		Professional						
		Other	Lanoxin Drops	C			ORAL	
			Sintrom	C				
			Tenoretic	C				

Date:05/02/03ISR Number: 4106535-3Report Type:Expedited (15-DaCompany Report #20031374
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Meningitis	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		INTRATHECAL	MCG, DAILY,	
			Intrethecal Morphine	C		INTRATHECAL		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/02/03ISR Number: 4107134-XReport Type:Expedited (15-DaCompany Report #20031364
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Decubitus Ulcer Loss Of Consciousness Overdose	Health Professional	Lioresal Intrathecal(Baclofen Injection)	PS		INTRATHECAL	DAILY,	
	Pharmaceutical Product					INTRATHECAL		
	Complaint Rhabdomyolysis		Morphine	C				

Date:05/02/03ISR Number: 4107135-1Report Type:Expedited (15-DaCompany Report #20031375
Age:34 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Agitation Atrial Fibrillation Confusional State Hallucination, Visual Hyperpyrexia Hypertension Somnolence Tachycardia Tremor	Health Professional	Lioresal Intrathecal(Baclofen Injection)	PS		INTRATHECAL	700 MCG, DAILY, INTRATHECAL	

Date:05/02/03ISR Number: 4107136-3Report Type:Expedited (15-DaCompany Report #20031357
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Depressed Level Of Consciousness Nausea Overdose	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		INTRATHECAL	DAILY, INTRATHECAL	

Vomiting

Date:05/07/03ISR Number: 4109166-4Report Type:Expedited (15-DaCompany Report #PHBS2003IE4292
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Depression Mania	Foreign Health Professional Other	Lioresal(Baclofen) Solution	PS				

Date:05/07/03ISR Number: 4109598-4Report Type:Expedited (15-DaCompany Report #HQWYE931328APR03
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Meningitis	Health Professional	Infumorph (Morphine Sulfate, Injection)	PS		INTRASPINAL		
			Baclofen (Balofen,)	SS		INTRASPINAL		

Date:05/07/03ISR Number: 4109850-2Report Type:Expedited (15-DaCompany Report #20031379
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Treatment Noncompliance	Health Professional	Lioresal Intrathecal (Baclofen Inje)	PS		INTRATHECAL	DAILY,	
			Oral Baclofen	C		INTRATHECAL		

Date:05/12/03ISR Number: 4111021-0Report Type:Expedited (15-DaCompany Report #HQWYE64061APR03
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Withdrawal Syndrome Myocardial Infarction	Health Professional	Infumorph (Morphine Sulfate, Injection)	PS		INTRASPINAL		
			Baclofen (Baclofen,)	SS		INTRA-UTERINE	INTRASPINAL	

Date:05/14/03ISR Number: 4114069-5Report Type:Direct Company Report #CTU 193045
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Abnormal Behaviour Confusional State Restlessness Speech Disorder Urinary Tract Infection		Baclofen 5mg Bid X 7 Days Then 10mg Bid	PS		5MG BID X 7 DAYS THEN 10MG BID		

Date:05/15/03ISR Number: 4112986-3Report Type:Expedited (15-DaCompany Report #20031384
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agitation Coma Headache Overdose Swelling	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		INTRATHECAL	DAILY, Required Intervention to Prevent Permanent Impairment/Damage	

Date:05/15/03ISR Number: 4113334-5Report Type:Expedited (15-DaCompany Report #20031397
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Affect Lability Depression	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		INTRATHECAL	DAILY,	

INTRATHECAL

Date:05/19/03ISR Number: 4115291-4Report Type:Expedited (15-DaCompany Report #PHFR2003GB01925
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Aphonia	Foreign Health Professional Other	Lioresal(Baclofen) Tablet	PS		ORAL	5 MG, BID,	

ORAL

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/02/03ISR Number: 4122338-8Report Type:Expedited (15-DaCompany Report #20031387
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Drug Withdrawal Syndrome	Health	Lioresal Intrathecal					
	Migration Of Implant	Professional	(Baclofen Injection)	PS		INTRATHECAL	DAILY,	
	Muscle Spasticity					INTRATHECAL		
	Myoclonus							
	Rebound Effect							

Date:06/04/03ISR Number: 4123307-4Report Type:Direct Company Report #CTU 194851
Age:60 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Dizziness		Haloperidol	PS			2MG BID	
Initial or Prolonged	Syncope		Baclofen	SS			10MG TID	
			Guaifenesin	C				
			Atenolol	C				
			Lorazepam	C				
			Meclizine	C				
			Venlafaxine	C				
			Fosinopril	C				
			Hctz	C				
			Fosinopril	C				

Date:06/04/03ISR Number: 4124610-4Report Type:Expedited (15-DaCompany Report #20031416
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Medication Error	Health	Lioresal					
Initial or Prolonged	Muscle Spasms	Professional	(Baclofen Injection)	PS		INTRATHECAL	MCG, DAILY,	
	Tachycardia					INTRATHECAL		

Date:06/12/03ISR Number: 4128745-1Report Type:Expedited (15-DaCompany Report #PHBS2003BR05490
Age:53 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Facial Palsy	Foreign Consumer	Lioresal (Baclofen) Tablet	PS		ORAL	10 MG/DAY, ORAL	
		Other	Fluoxetine Hydrochloride (Fluoxetine Hydrochloride)	C				
			Pyridoxine Hydrochloride	C				
			Naprosyn	C				
			Omeprazole (Omeprazole)	C				
			Alprazolam (Alprazolam)	C				

Date:06/13/03ISR Number: 4129705-7Report Type:Expedited (15-DaCompany Report #20031406
Age: Gender:Male I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Blood Pressure Increased
	Device Failure

	Drug Withdrawal Syndrome					
	Heart Rate Increased					
	Hyperhidrosis	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
	Muscle Spasms	Health	Lioresal Intrathecal			
	Muscle Spasticity	Professional	(Baclofen Injection)	PS		
INTRATHECAL	UNK MCG,					
	DAILY,					
	INTRATHECAL					

Date:06/16/03ISR Number: 4130141-8Report Type:Expedited (15-DaCompany Report #03-06-0687
Age:46 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization -	Blood Pressure Increased	Health	Baclofen - Ipi			
Initial or Prolonged	Feeling Abnormal	Professional	Tablets	PS		ORAL
SEE IMAGE						
	High Density Lipoprotein					
	Decreased					
	Hypokalaemia					
	Sinus Tachycardia					

Date:06/16/03ISR Number: 4130826-3Report Type:Expedited (15-DaCompany Report #20031422
Age:9 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization -	Device Failure	Health	Lioresal			
Initial or Prolonged	Lethargy	Professional	Intrathecal(Baclofen			
	Overdose		Injection)	PS		
INTRATHECAL	MCG, DAILY,					
	Somnolence					
INTRATHECAL						
	Vomiting					

Date:06/20/03ISR Number: 4133795-5Report Type:Expedited (15-DaCompany Report #20031423
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Apnoeic Attack Blood Pressure Decreased Catheter Related Complication Drug Ineffective Pain Paralysis Somnolence	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		INTRATHECAL	DAILY, INTRATHECAL	
			Dilaudid	C				
			Clonidine	C				

Date:06/27/03ISR Number: 4138389-3Report Type:Expedited (15-DaCompany Report #PHFR2003GB01925
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Aphonia	Foreign Health Professional Other	Lioresal(Baclofen) Tablet	PS		ORAL	5 MG, BID, ORAL	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/30/03ISR Number: 4138358-3Report Type:Direct Company Report #CTU 112871
Age:35 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Dizziness		Blacofen 10mg	PS			1 TWICE A DAY	
	Medication Error							
	Nausea							

Date:07/08/03ISR Number: 4145177-0Report Type:Expedited (15-DaCompany Report #PHNU2003DE02314
Age:68 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dizziness	Foreign	Esidrix (Hydrochlorothiazide) Tablet	PS		ORAL	25 MG, QD, ORAL	
	Drug Interaction	Study						
	Eye Rolling	Health						
	Fall	Professional						
	Hypertension	Other	Baclofen (Baclofen, Baclofen)	SS		ORAL	25 MG, ORAL	
	Orthostatic Hypotension							
	Tremor		Benalapril (Enalapril) Tablet, 5mg	SS		ORAL	5 MG, QD ORAL	
			Doxepin (Doxepin) Capsule	SS		ORAL	75 MG, QD, ORAL	
			Celebrex Capsule	C				
			Metoclopramide (Metoclopramide) Solution	C				

Date:07/08/03ISR Number: 4145181-2Report Type:Expedited (15-DaCompany Report #PHBS2003JP06722
Age:37 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Other	Depressed Level Of Consciousness Muscular Weakness Sleep Apnoea Syndrome	Foreign Health Professional Other	Lioresal (Baclofen)	PS		

Date:07/14/03ISR Number: 4148239-7Report Type:Expedited (15-DaCompany Report #20031447
Age:22 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Death	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		INTRATHECAL	MCG, DAILY,	

INTRATHECAL

Date:07/15/03ISR Number: 4149280-0Report Type:Expedited (15-DaCompany Report #PHNU2003DE02530
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Faecaloma Intestinal Obstruction	Foreign Health	Lioresal (Baclofen) Unknown	PS			30 MG, QID,	
		Professional Other	Duragesic (Fentanyl)	SS				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/16/03ISR Number: 4150063-6Report Type:Expedited (15-DaCompany Report #PHBS2003JP06722
Age:37 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Depressed Level Of Consciousness	Foreign Health	Lioresal Intrathecal $Me(Baclofen)Ampoulr	PS		INTRATHECAL	INTRATHECAL	
	Muscular Weakness	Professional						
	Sleep Apnoea Syndrome	Other						

Date:07/16/03ISR Number: 4150797-3Report Type:Expedited (15-DaCompany Report #PHNU2003DE02627
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Diarrhoea	Foreign	Lioresal					
	Incontinence	Health	(Baclofen)	PS			10 MG, TID	
	Muscle Spasticity	Professional						
		Other						

Date:07/17/03ISR Number: 4150464-6Report Type:Expedited (15-DaCompany Report #PHNU2003DE01380
Age:70 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Interaction	Foreign	Lioresal(Baclofen)					
	Fatigue	Health	Tablet, 10 Mg	PS		ORAL	50 MG/DAY,	
	Pain In Extremity	Professional					ORAL	
	Weight Increased	Other	Neurontin (Gabapentin)	SS			1800 MG/DAY,	
			Saroten "Bayer Vital" (Amitriptyline Hydrochloride)	SS	Bayer Vital			
			L-Thyroxin "Henning Berlin"	C				
			Candesartan (Candesartan)	C				

			Oxybutynin (Oxybutynin)	C		

Date:07/18/03ISR Number: 4152559-XReport Type:Expedited (15-DaCompany Report #20031457
Age:32 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Clonus Drug Withdrawal Syndrome Hyperreflexia	Health Professional	Lioresal Intrathecal(Baclofen Injection)	PS		INTRATHECAL	420 MCG, DAILY, INTRATHECAL; 200 UG/DAY	
	Hypertonia Pruritus Pyrexia Tachycardia		Baclofen (Baclofen) Diazepam (Diazepam)	C C				

Date:07/22/03ISR Number: 4154090-4Report Type:Expedited (15-DaCompany Report #PHNU2003DE02530
Age: Gender:Female I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Abdominal Distension Constipation Gastrointestinal Motility

	Disorder						
	Intestinal Obstruction						
	Vomiting						
		Report Source	Product	Role	Manufacturer	Route	Dose
Duration							
		Foreign	Lioresal (Baclofen)	PS			
SEE IMAGE							
		Health	Duragesic (Fentanyl)	SS			
		Professional	Sirdalud	C			
		Other					

Date:07/28/03ISR Number: 4157797-8Report Type:Expedited (15-DaCompany Report #20031464
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose
Duration							
Hospitalization -	Catheter Related	Health	Lioresal Intrathecal				
Initial or Prolonged	Complication	Professional	(Baclofen Injection)	PS			
INTRATHECAL DAILY,							
	Convulsion						
INTRATHECAL							
	Meningitis						
	Muscle Spasticity						

Date:07/30/03ISR Number: 4160273-XReport Type:Expedited (15-DaCompany Report #PHBS2003DE07067
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose
Duration							
Life-Threatening	Autonomic Nervous System	Foreign	Lioresal Intrathecal				
Hospitalization -	Imbalance	Literature	$Me (Baclofen)				
Initial or Prolonged	Cardiac Failure	Health	Ampoule	PS			
INTRATHECAL SEE IMAGE							
	Catheter Related	Professional					
	Complication						
	Device Failure						
	Dialysis						
	Disseminated						
	Intravascular Coagulation						
	Drug Withdrawal Syndrome						
	Hyperpyrexia						
	Hypertension						
	Hypotension						
	Metabolic Acidosis						

Multi-Organ Failure
Myocardial Infarction
Myoclonus
Pain
Pneumonia
Psychomotor Hyperactivity
Renal Failure
Respiratory Failure
Rhabdomyolysis
Tachycardia

Date:07/30/03ISR Number: 4160277-7Report Type:Expedited (15-DaCompany Report #20031467
Age: Gender: I/FU:I

Outcome	PT
Hospitalization -	Apnoea
Initial or Prolonged	Autonomic Nervous System
Required	Imbalance
Intervention to	Cardiac Failure
Prevent Permanent	Coagulopathy
Impairment/Damage	Drug Withdrawal Syndrome
	Hyperhidrosis

	Hypertension						
	Hypertonia						
	Hypotension	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Myocardial Infarction	Foreign	Lioresal Intrathecal					
	Myopathy	Health	(Baclofen Injection)	PS		INTRATHECAL	1220 MCG,	
	Pain	Professional					DAILY,	
	Pneumonia					INTRATHECAL		
	Pyrexia							
	Renal Failure							
	Tachycardia							

Date:07/30/03ISR Number: 4160283-2Report Type:Expedited (15-DaCompany Report #20031343
Age: Gender: I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardiac Failure	Foreign	Lioresal Intrathecal					
	Pneumonia	Health	(Baclofen Injection)	PS		INTRATHECAL	, DAILY,	
		Professional				INTRATHECAL		

Date:07/30/03ISR Number: 4160943-3Report Type:Expedited (15-DaCompany Report #20031470
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Coagulopathy	Literature	Lioresal					
Hospitalization -	Coma	Health	Intrathecal(Baclofen					
Initial or Prolonged	Drug Withdrawal Syndrome	Professional	Injection)	PS		INTRATHECAL	MCG, DAILY,	
Required	Hypertonia					INTRATHECAL		
Intervention to	Hypotension							
Prevent Permanent	Myopathy							
Impairment/Damage	Pyrexia							
	Respiratory Disorder							
	Sepsis							
	Tachycardia							

Date:07/30/03ISR Number: 4167827-5Report Type:Expedited (15-DaCompany Report #PHBS2003US07039
Age:45 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardio-Respiratory Arrest	Literature	Lioresal Intrathecal					
Hospitalization - Initial or Prolonged	Coma	Health Professional	(Baclofen) Ampoule	PS				
	Device Failure							
	Disseminated Intravascular Coagulation							
	Drug Withdrawal Syndrome							
	Hypotension							
	Lung Disorder							
	Muscle Rigidity							
	Muscle Spasticity							
	Rhabdomyolysis							
	Tachycardia							
	Urosepsis							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/01/03ISR Number: 4163066-2Report Type:Expedited (15-DaCompany Report #2003-02108
Age:2 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain Upper	Consumer	Baclofen (Watson Laboratories)(Baclofen) Tablet, 20mg	PS		ORAL	12.5MG/2.5ML	
Other	Accidental Overdose						QAM, 5MG/ML	
	Aggression						QHS, ORAL	
	Dyskinesia							
	Electroencephalogram Abnormal							
	Hallucination							
	Headache							
	Insomnia							
	Lethargy							
	Medication Error							
	Pruritus							
	Respiratory Rate Decreased							
	Scratch							
	Screaming							

Date:08/04/03ISR Number: 4163552-5Report Type:Periodic Company Report #0254-02(0)
Age:52 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Dehydration	Foreign	Baclofen Tablets (Unknown Strength)					
Hospitalization - Initial or Prolonged	Grand Mal Convulsion	Health Professional	Usp (Danbury/Watson)	PS		ORAL	60 MG DAILY	
							PO	
			Cannador	SS		ORAL	8 DF DAILY PO	
			Dantrolene	SS		ORAL	150 MG DAILY	
							PO	

Date:08/04/03ISR Number: 4163554-9Report Type:Periodic Company Report #0255-02(0)
Age:55 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Atrial Fibrillation	Foreign	Baclofen Tablets Usp					
Hospitalization -	Dehydration	Health	(Unknown Strength)					
Initial or Prolonged	Grand Mal Convulsion	Professional	(Danbyry/Watson)	PS		ORAL	60 MG DAILY	
	Infection						PO	
			Placebo Therapy	SS		ORAL	10 MG DAILY	
							PO	
			Lansoprazole	C				
			Viagra	C				

Date:08/06/03ISR Number: 4166353-7Report Type:Expedited (15-DaCompany Report #20031379
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accident	Health	Lioresal Intrathecal					
	Atrophy	Professional	(Baclofen Injection)	PS			INTRATHECAL	DAILY,
	Chronic Obstructive						INTRATHECAL	
	Pulmonary Disease		Baclofen	C				
	Emphysema							
	Injury							
	Pulmonary Congestion							
	Pulmonary Oedema							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/11/03ISR Number: 4166762-6Report Type:Direct Company Report #CTU 199720
Age:22 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Depressed Level Of Consciousness		Baclofen Inj	PS		INTRATHECAL	5000MCG IT	

Date:08/11/03ISR Number: 4167972-4Report Type:Periodic Company Report #03-03-0386
Age:32 MON Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anorexia	Consumer	Baclofen - Ipi Tablets	PS	Ipi	ORAL	75MG QD ORAL	
	Coma							
	Diarrhoea		Tegretol	C				
	Hypoventilation		Dilantin	C				
	Malaise		Aspirin	C				
	Muscle Twitching		Zyrtec	C				
	Overdose		Benadryl	C				
	Vomiting		Vancomycin	C				
			Zantac	C				
			Gentamicin	C				
			Zofran	C				
			Lovenox	C				
			Pulmicort	C				

Date:08/12/03ISR Number: 4166043-0Report Type:Expedited (15-DaCompany Report #PHBS2003NL08166
Age:8 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hypernatraemia		Lioresal	PS	Novartis Sector: Pharma	ORAL	2.5 mg, BID	
	Liver Function Test Abnormal							
	Pyrexia							
	Restlessness							
	Rhabdomyolysis							

Date:08/13/03ISR Number: 4169349-4Report Type:Expedited (15-DaCompany Report #20031485
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Pressure Increased Muscle Spasticity Nausea Post Procedural Complication Pyrexia Reflexes Abnormal Urinary Tract Infection	Health Professional	Lioresal Intrathecal (Baclofen Injection) - 2000mcg/Ml	PS		INTRATHECAL	1200 MCG, DAILY, INTRATHECAL	

Date:08/14/03ISR Number: 4168190-6Report Type:Expedited (15-DaCompany Report #PHNU2003DE02970
Age:15 YR Gender:Male I/FU:I

Outcome	PT
Other	Alanine Aminotransferase Increased Aspartate Aminotransferase Increased

Gamma-Glutamyltransferase Increased Liver Function Test Abnormal	Report Source	Product Lioresal Lioresal	Role PS SS	Manufacturer Novartis Sector: Pharma Novartis Sector: Pharma	Route ORAL ORAL	Dose Duration UNK 50mg/day

Date:08/22/03ISR Number: 4173452-2Report Type:Direct Company Report #CTU 200544
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Activities Of Daily Living Impaired Body Temperature Increased Cognitive Disorder Confusional State Diplopia Drug Withdrawal Syndrome Malaise Medication Error Memory Impairment Speech Disorder Tachycardia Thinking Abnormal Vomiting		Baclofen Pump	PS			

Date:08/25/03ISR Number: 4172857-3Report Type:Expedited (15-DaCompany Report #PHBS2003TW08684
Age:73 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Abnormal Behaviour Apathy		Baclofen	PS	Novartis Sector: Pharma		UNKNOWN 15 mg/day
	Atrial Fibrillation		Acetaminophen	C			UNKNOWN 1500 mg/day

		Creatinine Renal		Carbamazepine	C		
UNKNOWN	300 mg/day						
		Clearance Increased		Glipizide	C		
UNKNOWN	5 mg/day						
		Depressed Level Of		Meloxicam	C		
UNKNOWN	7.5 mg, BID						
		Consciousness		Diazepam	C		
UNKNOWN	5 mg/day						
		Locked-In Syndrome		Zolpidime			
		Mental Impairment		Hemitartare	C		
UNKNOWN	10 mg/day						
		Proteinuria					
		Speech Disorder					
		Urinary Incontinence					

Date:08/25/03ISR Number: 4178410-XReport Type:Expedited (15-DaCompany Report #20031498
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Cardiac Arrest	Health	Lioresal Intrathecal					
	Emotional Distress	Professional	(Baclofen Injection)	PS				
INTRATHECAL	MCG, DAILY,							
	Loss Of Consciousness							
INTRATHECAL								
	Medication Error							
	Overdose							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/26/03ISR Number: 4179648-8Report Type:Expedited (15-DaCompany Report #PHBS2003TW08684
Age:73 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Apathy	Foreign	Baclofen (Baclofen)	PS			15 MG/DAY	
	Atrial Fibrillation	Literature	Acetaminophen	C				
	Back Pain	Health Professional Other	Carbamazepine	C				
	Depressed Level Of Consciousness		Glipizide (Glipizide)	C				
	Electroencephalogram Abnormal		Meloxicam (Meloxicam)	C				
	Insomnia		Diazepam	C				
	Locked-In Syndrome		Zolpidine Hemitartare (Zolpidem)	C				
	Mental Impairment							
	Pain							
	Proteinuria							
	Speech Disorder							
	Urinary Incontinence							

Date:08/28/03ISR Number: 4175020-5Report Type:Expedited (15-DaCompany Report #PHNU2003DE01333
Age:5 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Coma		Lioresal	PS	Novartis Sector: Pharma	ORAL	15mg/day	
Other	Hypothermia							
	Pneumonia Aspiration							

Date:08/28/03ISR Number: 4176562-9Report Type:Direct Company Report #CTU 200904
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Pharmaceutical Product		Baclofen (Generic)					
	Complaint		For Lioresal	PS		ORAL	20MG 1 PO	
							QHS, 10MG 1	
							PIO TID, 10MG	

1 BID PRN

Date:08/29/03ISR Number: 4179803-7Report Type:Expedited (15-DaCompany Report #20031501
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Withdrawal Syndrome Medication Error Postoperative Infection	Health Professional	Lioresal Intrathecal(Baclofen Injection)	PS		INTRATHECAL	DAILY,	

INTRATHECAL

Date:08/29/03ISR Number: 4182478-4Report Type:Expedited (15-DaCompany Report #2003UW10598
Age:13 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dysphagia Hallucination Respiratory Arrest	Health Professional	Iressa Iressa Baclofen	PS SS SS				

START DATE IS

PRIOR TO

02-AUG-2003

			Clonidine	SS				

START DATE IS

PRIOR TO

02-AUG-2003

			Methylphenidate	SS		
START DATE IS PRIOR TO 02-AUG-2003						
			Lorazepam	SS		
START DATE IS PRIOR TO 02-AUG-2003						
			Zoloft	SS		
START DATE IS PRIOR TO 02-AUG-2003						
			Benadryl	SS		
START DATE IS PRIOR TO 02-AUG-2003						

Date:09/03/03ISR Number: 4184486-6Report Type:Expedited (15-DaCompany Report #20031508
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Back Disorder Catheter Related Complication	Health Professional	Lioresal (Baclofen Injection)	PS		INTRATHECAL	DAILY,	INTRATHECAL
	Drug Withdrawal Syndrome		Oral Baclofen	C				
	Mental Status Changes							
	Muscle Rigidity							
	Muscle Spasticity							
	Oedema							
	Pyrexia							
	Rebound Effect							
	Stress							

Date:09/08/03ISR Number: 4180743-8Report Type:Expedited (15-DaCompany Report #PHBS2003NL09276
Age:62 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Interaction Hypotonia		Baclofen	PS	Novartis Sector: Pharma		UNKNOWN	12.5 mg, BID
	Muscle Twitching Muscular Weakness		Baclofen	SS	Novartis Sector: Pharma		UNKNOWN	12.5 mg/d
			Propofol	SS			UNKNOWN	2.5 mg/kg/d
			Propofol	SS			UNKNOWN	5 mg/kg/d
			Sufentanil	SS			UNKNOWN	0.25 ug/kg/d
			Sufentanil	SS			UNKNOWN	10 ug/d
			Atracurium	SS			UNKNOWN	0.6 mg/kg/d
			Atracurium	SS			UNKNOWN	35 mg/d
			Isoflurane	SS			UNKNOWN	0.6 - 1.0 vol%
			Morphine	SS			UNKNOWN	8 mg/d
			Diazepam	C			UNKNOWN	7.5 mg, BID
			Prednisone	C			UNKNOWN	20 mg, QD
			Levothyroxine	C			UNKNOWN	25 ug, QD
			Vitamin B12	C			UNKNOWN	
			Cefuroxime	C			INTRAVENOUS	1500 mg/d
			Clindamycin	C			INTRAVENOUS	600 mg/d
			Dexamethasone	C			INTRAVENOUS	10 mg/d

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/09/03ISR Number: 4186531-0Report Type:Direct Company Report #CTU 201499
Age: Gender: 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		Vancomycin Iv	PS		INTRAVENOUS	1 G IV Q12	SEE IMAGE
	Mental Status Changes		Baclofen 10 Mg Qid	SS				
	Renal Failure Acute							

Date:09/09/03ISR Number: 4188462-9Report Type:Expedited (15-DaCompany Report #20031516
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Death	Health Professional	Lioresal Intrathecal(Baclofen Injection)	PS		INTRATHECAL	MCG, DAILY, INTRATHECAL	

Date:09/09/03ISR Number: 4188463-0Report Type:Expedited (15-DaCompany Report #20031515
Age: 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	Lioresal Intrathecal (Baclofen Injection)	PS		INTRATHECAL	DAILY, INTRATHECAL	
	Drug Withdrawal Syndrome							
	Muscle Spasticity		Oral Baclofen	C				
	Pruritus							
	Pyrexia							
	Rebound Effect							

Date:09/09/03ISR Number: 4188465-4Report Type:Expedited (15-DaCompany Report #20031512
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Respiratory Disorder Rhabdomyolysis	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		INTRATHECAL	DAILY, INTRATHECAL	

Date:09/10/03ISR Number: 4188488-5Report Type:Expedited (15-DaCompany Report #20031517
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Death	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		INTRATHECAL	MCG, DAILY, INTRATHECAL	

Date:09/11/03ISR Number: 4200753-1Report Type:Periodic Company Report #2003163149US
Age:61 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Renal Failure Acute	Health Professional	Bextra (Valdecoxib) Tablet Glucophage	PS		ORAL	10 MG, BID; ORAL	365 DAY

		(Metformin Hydrochloride)	SS	ORAL
500 MG, BID;				
ORAL				
		Valium (Diazepam)	SS	ORAL
UNK, UNK;				
ORAL				
		Baclofen (Baclofen)	SS	
UNKNOWN	UNK, UNK, UNK			
		Diovan (Valsartan)	SS	
UNKNOWN	UNK, UNK, UNK			
		Zanaflex (Tizanidine Hydrochloride)	SS	ORAL
UNK, UNK;				
ORAL				
		Hydrocodone (Hydrocodone)	SS	
UNKNOWN	UNK, UNK, UNK			
		Niacin (Nicotinic Acid)	SS	ORAL
250 MG, QD;				
ORAL				
		Vasotec (Enalapril Maleate)	SS	ORAL
10 UNK, UNK;				
ORAL				
		Potassium Chloride (Potassium Chloride)	SS	ORAL
8 UNK, BID;				
ORAL				
		Tolterodine L-Tartrate	C	
		Ultram (Tramadol Hydrochloride)	C	
		Protonix (Pyritinol)	C	
		Lasix	C	
		Norvasc (Amlodipine Besilate)	C	
		Lortab	C	

Date:09/12/03ISR Number: 4190173-0Report Type:Expedited (15-DaCompany Report #2003CG01252
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Optic Neuropathy	Foreign Health Professional Other	Marcaine Lioresal "Ciba-Geigy" Catapressan	PS SS SS	 Ciba-Geigy			

Date:09/23/03ISR Number: 4195382-2Report Type:Direct Company Report #CTU 202278
Age:39 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Asthenia Decreased Appetite Feeling Abnormal Gastrointestinal Disorder Hyperaesthesia Pain Pharmaceutical Product Complaint Sleep Disorder Vision Blurred Vomiting		Baclofen	PS	Upsher Smiths Laboratoires			

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/23/03ISR Number: 4195536-5Report Type:Direct Company Report #CTU 202368
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	Blood Calcium Blood Chloride Blood Creatinine Blood Glucose Blood Potassium Blood Sodium Blood Urea Depressed Level Of Consciousness Haematocrit Mental Status Changes Pco2 Prescribed Overdose		Baclofen	PS			5 MG X 2 (ONLY)	

Date:09/24/03ISR Number: 4198354-7Report Type:Expedited (15-DaCompany Report #20031525
Age:38 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Death	Health Professional Company Representative	Lioresal Intrathecal(Baclofen Injection)	PS		INTRATHECAL	UNK MCG, DAILY, INTRATHECAL	

Date:09/24/03ISR Number: 4198922-2Report Type:Expedited (15-DaCompany Report #20031512
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to	Catheter Related Complication	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		INTRATHECAL	DAILY,	

Prevent Permanent Impairment/Damage	Respiration Abnormal						
	Rhabdomyolysis		Oral Baclofen	C			
	Therapeutic Response Decreased						

Date:09/29/03ISR Number: 4202431-1Report Type:Expedited (15-DaCompany Report #20031523
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Required Intervention to Prevent Permanent Impairment/Damage	Constipation	Health Professional	Lioresal Intrathecal(Baclofen Injection)	PS		INTRATHECAL	MCG, DAILY,
	Drug Ineffective						
	Dysarthria						
	Muscle Spasms						
	Pruritus						
	Pyrexia						

Date:09/29/03ISR Number: 4202432-3Report Type:Expedited (15-DaCompany Report #20031520
Age:50 YR Gender:Female I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Anxiety
	Catheter Related Complication
	Drug Withdrawal Syndrome

		Muscle Spasticity Nausea Pruritus	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
		Pyrexia Vomiting	Health Professional	Lioresal Intrathecal(Baclofen Injection)	PS		
INTRATHECAL	265 MCG, DAILY, INTRATHECAL						

Date:10/01/03ISR Number: 4203623-8Report Type:Expedited (15-DaCompany Report #2003039929
Age:64 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Death	Cardio-Respiratory Arrest	Literature	Doxepin (Caps)			
Other	Completed Suicide	Health Professional	(Doxepin)	PS		ORAL
ORAL						
			Baclofen (Baclofen)	SS		ORAL
ORAL						
			Quetiapine (Quetiapine)	SS		ORAL
ORAL						
			All Other Therapeutic Products	SS		ORAL
ORAL						

Date:10/07/03ISR Number: 4202376-7Report Type:Expedited (15-DaCompany Report #PHRM2003FR02525
Age:35 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization - Initial or Prolonged	Cytolytic Hepatitis Hepatic Necrosis		Lioresal	PS	Novartis Sector: Pharma	ORAL
20 mg/day						
			Di-Antalvic	SS		ORAL
6 DF/day	87840MIN					

Date:10/07/03ISR Number: 4210074-9Report Type:Periodic Company Report #DCC03003 BAC
Age:51 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Ineffective Muscle Spasticity	Consumer Other	Baclofen Tablets, Usp	PS		ORAL	10 MG ORAL	
			Estrace	C				
			Lasix	C				
			Xanax	C				
			Effexor	C				
			Detrol	C				
			Loricet	C				

Date:10/07/03ISR Number: 4210085-3Report Type:Periodic Company Report #DCC 03-010 BAC
Age:86 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Confusional State Somnolence	Consumer	Baclofen Tablets, Usp	PS		ORAL	10 MG QID	
							ORAL	1 DAY
			Diovan	C				
			Pravachol	C				
			Tums	C				
			Baby Aspirin	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/07/03ISR Number: 4210088-9Report Type:Periodic Company Report #DCC 03-008 BAC20
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hallucinations, Mixed	Health Professional	Baclofen Tablets, Usp 20 Mg	PS		ORAL	20 MG QD	ORAL
Other			Zonegren	C				
			Carbatrol	C				
			Risperdal	C				

Date:10/08/03ISR Number: 4203687-1Report Type:Expedited (15-DaCompany Report #PHNU2003DE03532
Age:57 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Thrombocytopenia		Lioresal	PS	Novartis Sector: Pharma		UNKNOWN	

Date:10/08/03ISR Number: 4203695-0Report Type:Expedited (15-DaCompany Report #PHRM2003FR02525
Age:35 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Cytolytic Hepatitis		Lioresal	PS	Novartis Sector:			
	Hepatic Necrosis				Pharma	ORAL	20 mg/day	
			Di-Antalvic	SS		ORAL	6 DF/day	87840MIN

Date:10/08/03ISR Number: 4207348-4Report Type:Direct Company Report #USP 080176
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Medication Error		Baclofen	PS				
			Baclofen	SS				

Date:10/08/03ISR Number: 4207422-2Report Type:Expedited (15-DaCompany Report #20031542
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Medication Error	Health	Lioresal Intrathecal(Baclofen Injection)	PS		INTRAVENOUS	75 MCG, BOLUS	EVERY 8 MINUTES
	Overdose	Professional				BOLUS		

Date:10/09/03ISR Number: 4205237-2Report Type:Expedited (15-DaCompany Report #PHFR2003GB03795
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Coma	Health	Baclofen	PS	Novartis Sector: Pharma		5 mg, TID	
	Musculoskeletal Stiffness	Professional						
	Renal Impairment		Aspirine	C				
			Trimethoprim	C				
			Salbutamol	C				
			Oxybutynin	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/14/03ISR Number: 4211478-0Report Type:Periodic Company Report #2003025236
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Convulsion	Health Professional	Neurontin (Gabapentin)	PS				
			Baclofen (Baclofen)	SS		OTHER	OTHER	
			Atenolol (Atenolol)	C				
			Bisacodyl (Bisacodyl)	C				
			Docusate Sodium (Docusate Sodium)	C				
			Vitamins	C				
			Magnesium Gluconate (Magnesium Gluconate)	C				

Date:10/17/03ISR Number: 4210416-4Report Type:Expedited (15-DaCompany Report #PHFR2003GB03937
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Confusional State Drug Withdrawal Syndrome Nightmare		Baclofen	PS	Novartis Sector: Pharma		20 mg, TID	

Date:10/20/03ISR Number: 4211969-2Report Type:Expedited (15-DaCompany Report #PHBS2003CA11214
Age: Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Hospitalization - Initial or Prolonged	Convulsion Pyrexia Sepsis		Lioresal	PS	Novartis Sector: Pharma	ORAL	40 mg, BID	

Date:10/20/03ISR Number: 4215525-1Report Type:Expedited (15-DaCompany Report #20031551
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	Coagulopathy	Foreign Health Professional	Lioresal Intrathecal(Baclofen Injection)	PS		INTRATHECAL	UNK MCG, DAILY, INTRATHECAL	

Date:10/21/03ISR Number: 4215104-6Report Type:Expedited (15-DaCompany Report #PHNU2003DE03532
Age:45 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Thrombocytopenia		Lioresal	PS	Novartis Sector: Pharma	ORAL	20mg/day	

Date:10/22/03ISR Number: 4213554-5Report Type:Expedited (15-DaCompany Report #PHFR2003GB03912
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death Other	Colitis Death Diarrhoea		Lioresal	PS	Novartis Sector: Pharma	ORAL		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/22/03ISR Number: 4213555-7Report Type:Expedited (15-DaCompany Report #PHFR2003GB03795
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Death	Cerebrovascular Accident		Baclofen	PS	Novartis Sector:		
Hospitalization -	Coma				Pharma		5 mg, TID
Initial or Prolonged	Musculoskeletal Stiffness		Aspirine	C			
	Renal Impairment		Trimethoprim	C			
			Salbutamol	C			
			Oxybutynin	C			

Date:10/24/03ISR Number: 4217495-9Report Type:Expedited (15-DaCompany Report #PHBS2003JP06722
Age:37 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Depressed Level Of		Lioresal Intrathecal				
Initial or Prolonged	Consciousness		$Me	PS	Novartis Sector:		
	Muscular Weakness				Pharma	ORAL	
	Sleep Apnoea Syndrome						

Date:10/24/03ISR Number: 4217514-XReport Type:Direct Company Report #CTU 204544
Age:84 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Abasia		Baclofen/Lioresal 20				
Initial or Prolonged	Aphasia		Mg Ivax-Zenith	PS	Ivax-Zenith	ORAL	20 MG BID -PO
	Asthenia						(4 DOSES)
	Convulsion						
	Drooling						
	Feeding Disorder						
	Gait Disturbance						

Date:10/27/03ISR Number: 4221164-9Report Type:Expedited (15-DaCompany Report #20031565
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Convulsion Dystonia Hypoglycaemia	Health Professional	Lioresal Intrathecal(Baclofen Injection)	PS		INTRATHECAL	UNK MCG	DAILY
			Glucose	C		INTRATHECAL		
			Oral Baclofen	C				
			Antibiotics	C				

Date:10/28/03ISR Number: 4220492-0Report Type:Direct Company Report #CTU 204679
Age:62 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Blood Glucose Increased Drug Toxicity		Arsenic Trioxide 0.25 Mg Kg	PS		INTRAVENOUS	20 MG QD	IV
			Ascorbic Acid 1000 Mg	SS		ASCORBIC ACID		IV
			Baclofen	SS				
			Ativan	C				
			Pepcid	C				
			Prochloperazine	C				
			Darvocet	C				

			Lexapro	C		
			Norvasc	C		
			Remeron	C		

Date:10/29/03ISR Number: 4221266-7Report Type:Expedited (15-DaCompany Report #PHBS2003US11591
Age:38 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Angiogram Abnormal Blindness Ocular Hyperaemia Retinogram Abnormal Scotoma		Baclofen	PS	Novartis Sector: Pharma	ORAL		
			Mexiletine Hydrochloride	SS		ORAL		
			Morphine Sulfate	C		ORAL		
			Morphine Sulfate	C		INTRATHECAL		
			Pentosan Polysulfate Sodium	C		UNKNOWN		
			Gabapentin	C		UNKNOWN		
			Lorazepam	C		UNKNOWN		
			Hydroxyzine Hydrochloride	C		UNKNOWN		
			Glimepiride	C		UNKNOWN		
			Promethazine Hydrochloride	C		UNKNOWN		
			Lidocaine Hydrochloride	C		INTRAVENOUS	385.27 mg	
			Clonidine Hydrochloride	C		UNKNOWN		
			Methadone Hydrochloride	C		UNKNOWN		
			Fluoxetine Hydrochloride	C		UNKNOWN		
			Trazodone	C		UNKNOWN		

			Sucralfate	C		

UNKNOWN

Date:10/29/03ISR Number: 4222057-3Report Type:Expedited (15-DaCompany Report #03-10-1333
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Coma	Foreign	Baclofen - Ipi					
	Musculoskeletal Stiffness	Other	Tablets	PS			5MG TID	
	Renal Impairment		Aspirin	C				
			Trimethoprim	C				
			Salbutamol	C				
			Oxybutynin	C				

Date:10/29/03ISR Number: 4223676-0Report Type:Expedited (15-DaCompany Report #KII-2003-0004111
Age:55 YR Gender:Female I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Anticonvulsant Drug Level Below Therapeutic
Other	Aphasia
	Blood Pressure Increased
	Confusional State
	Heart Rate Increased
	Hypoventilation
	Intentional Misuse
	Intentional Self-Injury

	Lethargy					
	Loss Of Consciousness					
	Miosis	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
	Moaning	Health	Oxycontin			
	Multiple Drug Overdose	Professional	Tablets(Oxycodone			
	Productive Cough		Hydrochloride) Cr			
	Pulmonary Oedema		Tablet	PS		ORAL
ORAL						
	Respiratory Rate		Demerol (Pethidine			
	Increased		Hydrochloride)	SS		
	Somnolence		Baclofen (Baclofen)	SS		
	Toxicologic Test Abnormal		Risperdal(Risperidon			
			e)	SS		
			Dilantin (Phenytoin			
			Sodium)	SS		
			Soma(Carisoprodol)	SS		
			Methadone(Methadone)	SS		

Date:11/05/03ISR Number: 4227756-5Report Type:Direct Company Report #CTU 205260
Age:88 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization -	Incoherent		Baclofen 10 Mg	PS		ORAL
10 MG QID PRN						
Initial or Prolonged	Medication Error					
ORAL						
	Somnolence		Asa	C		
			Oxycodone	C		

Date:11/05/03ISR Number: 4229148-1Report Type:Expedited (15-DaCompany Report #K200301699
Age:35 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Life-Threatening	Coma	Literature	Ketalar (Ketamine)			
Hospitalization -	Convulsion	Health	Injection, 900mg	PS		
TRANSDERMAL	900 MG,					
Initial or Prolonged	Drug Screen Positive	Professional				
TRANSDERMAL						
	Electroencephalogram		Baclofen(Baclofen)			

		Abnormal		900mg	SS		
TRANSDERMAL	900 MG,						
		Overdose					
TRANSDERMAL							
		Postictal State		Amitriptyline (Amitriptyline) 360mg	SS		
TRANSDERMAL	360						
MG,TRANSDERMA							
L							
				Lidocaine (Lidocaine) 900mg	SS		
TRANSDERMAL	900 MG,						
TRANSDERMAL							
				Ketoprofen(Ketoprofen) 1800mg	SS		
TRANSDERMAL	1800 MG,						
TRANSDERMAL							

Date:11/06/03ISR Number: 4230304-7Report Type:Expedited (15-DaCompany Report #K200301699
Age:35 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Coma	Literature	Ketalar					
Hospitalization -	Convulsion	Health	(Ketamine)Injection					
Initial or Prolonged	Drug Screen Positive	Professional	, 900 Mg	PS				
TRANSDERMAL	900							
	Medication Error							
MG,TRANSDERMA								
	Overdose							
L								
			Baclofen (Baclofen)					

				900 Mg	SS		
TRANSDERMAL	900 MG,						
TRANSDERMAL							
				Amitriptyline (Amitriptyline) 360 Mg	SS		
TRANSDERMAL	360 MG,						
TRANSD3RMAL							
				Lidocaine (Lidocaine) 900 Mg	SS		
TRANSDERMAL	900,						
TRANSDERMAL							
				Ketoprofen (Ketoprofen) 1800 Mg	SS		
TRANSDERMAL	1800, MG,						
TRANSDERMAL							

Date:11/07/03ISR Number: 4229011-6Report Type:Expedited (15-DaCompany Report #PHFR2003GB04243
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Peptic Ulcer		Lioresal	PS	Novartis Sector: Pharma			

Date:11/07/03ISR Number: 4231764-8Report Type:Expedited (15-DaCompany Report #2003UW14116
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Alopecia	Foreign	Xylocaine	PS				
	Angina Pectoris	Health Professional	Baclofen	SS				
	Arrhythmia		Neurontin	SS		ORAL	50 MG DAILY	
	Blood Pressure Increased	Other					PO	
	Cardiac Disorder		Nitrostat	SS			0.3	
	Cardiac Failure		Atenolol	C				
	Cardiac Valve Disease		Avapro	C				

Chest Pain	K-Lyte	C
Condition Aggravated	No Match	C
Disturbance In Attention	Oxygen	C
Dizziness	Taurine	C
Electrolyte Imbalance		
Heart Rate Increased		
Hypotension		
Memory Impairment		
Myocardial Infarction		
Pulmonary Hypertension		
Restlessness		
Somnolence		
Weight Decreased		
Weight Increased		

Date:11/10/03ISR Number: 4233596-3Report Type:Expedited (15-DaCompany Report #200313438GDS
Age:35 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Areflexia	Literature	Ketoprofen	PS		TRANSDERMAL	TRANSDERMAL	
Hospitalization - (TRANSCUTANEO	Coma	Health						
Initial or Prolonged US)	Convulsion	Professional						
	Overdose		Amitriptyline	SS		TRANSDERMAL	TRANSDERMAL	
						(TRANSCUTANEO		
						US)		
			Lidocaine	SS		TRANSDERMAL	TRANSDERMAL	
						(TRANSCUTANEO		
						US)		

				Ketamine	SS		
TRANSDERMAL (TRANSCUTANEOUS)	TRANSDERMAL						
				Baclofen	SS		
TRANSDERMAL (TRANSCUTANEOUS)	TRANSDERMAL						

Date:11/13/03ISR Number: 4234531-4Report Type:Expedited (15-DaCompany Report #PHRM2003FR02941
Age:56 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Gastric Ulcer Gastrointestinal Haemorrhage		Lioresal	PS	Novartis Sector: Pharma	ORAL	60 mg/day	

Date:11/13/03ISR Number: 4236035-1Report Type:Expedited (15-DaCompany Report #KII-2003-0005736
Age:28 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Drug Screen Positive Hyperhidrosis Hyperpyrexia Medication Error Multiple Drug Overdose Sinus Tachycardia Somnolence White Blood Cell Count	Study Health Professional Other	Morphine Sulfate(Similar To Nda 19-516)(Morphine Sulfate) Unknown	PS				
			Soma (Carisoprodol)	SS				
			Valium(Diazepam)	SS				
			Ace Inhibitor Nos()	SS				
			Antihistamine()	SS				
			Nortriptyline(Nortriptyline)	SS				
			Biguandes()	SS				
			Anticonvulsant()	SS				
			Ssri()	SS				
			Acetaminophen(Paracetamol)	SS				

			Acetylsalicylic Acid (Acetylsalicylic Acid0	SS		
			Baclofen(Baclofen)	SS		
			Zanaflex(Tizanidine Hydrochloride)	SS		

Date:11/13/03ISR Number: 4236056-9Report Type:Expedited (15-DaCompany Report #HQWYE674131OCT03
Age:63 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Dizziness	Health	Biso-Puren					
Hospitalization -	Drug Interaction	Professional	(Bisoprolol, Tablet)	PS		ORAL	5 MG 1X PER 1	
Initial or Prolonged	Hiatus Hernia	Other						
							DAY	3 YR
	Vomiting		Buprenorphine (Buprenorphine,)	SS				
							TRANSDERMAL	35 MCG, 1
							EVERY 3 DAYS	1 YR
			Lebic (Baclofen,)	SS		ORAL		
							10 (TABLETS),	
							ONE DAILY	1 YR
			Nitrangin Compositum (Glyceryl Trinitrate/Valerian Tincture,)	SS		ORAL		
							30 DROPS, TID	1 YR
			Nitrendipine					

(Nitrendipine,) SS ORAL
10 MG 2X PER

1 DAY 1 YR

Date:11/17/03ISR Number: 4236487-7Report Type:Expedited (15-DaCompany Report #20031567
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Withdrawal Syndrome Lethargy Muscle Spasticity	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		INTRATHECAL	MCG, DAILY, INTRATHECAL	

Date:11/18/03ISR Number: 4236827-9Report Type:Direct Company Report #CTU 206287
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Catheter Related Complication Muscle Spasticity Pharmaceutical Product Complaint		Lioresal Intrathecal (Baclofen Injection)	PS		INTRATHECAL	DAILY, INTRATHECAL	

Date:11/18/03ISR Number: 4236896-6Report Type:Direct Company Report #CTU 206278
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Oedema Peripheral		Lioresal Intrathecal (Baclofen Injection)	PS		INTRATHECAL	MCG, DAILY INTRATHECAL	

Date:11/18/03ISR Number: 4236897-8Report Type:Direct Company Report #CTU 206277
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Device Failure Drug Ineffective		Lioresal Intrathecal (Baclofen Injection)	PS		INTRATHECAL	MCG, DAILY	

INTRATHECAL

Date:11/18/03ISR Number: 4236898-XReport Type:Direct Company Report #CTU 206276
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 Device Failure Muscle Spasticity		Lioresal Intrathecal (Baclofen Injection)	PS		INTRATHECAL INTRATHECAL	MCG, DAILY	

Date:11/18/03ISR Number: 4236899-1Report Type:Direct Company Report #CTU 206275
Age: Gender:Male I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Clonus Device Failure Drug Withdrawal Syndrome Hypotension

Muscle Spasticity
Muscle Twitching

Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Lioresal Intrathecal (Baclofen Injection)	PS		INTRATHECAL	MCG, DAILY	

INTRATHECAL

Date:11/18/03ISR Number: 4236900-5Report Type:Direct Company Report #CTU 206286
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Alcohol Withdrawal Syndrome Device Failure		Lioresal Intrathecal (Baclofen Injection)	PS		INTRATHECAL	UNK MCG, DAILY	

INTRATHECAL

Date:11/18/03ISR Number: 4236901-7Report Type:Direct Company Report #CTU 206285
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Drug Effect Decreased Mechanical Complication Of Implant		Lioresal Intrathecal (Baclofen Injection)	PS		INTRATHECAL	UNK MCG. DAILY,	

INTRATHECAL

Date:11/18/03ISR Number: 4236902-9Report Type:Direct Company Report #CTU 206284
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Hospitalization - Agitation Lioresal Intrathecal
Initial or Prolonged Device Failure (Baclofen Injection) PS
INTRATHECAL UNK MCG,
Muscle Spasticity
DAILY,

INTRATHECAL

Date:11/18/03ISR Number: 4236903-0Report Type:Direct Company Report #CTU 206283
Age: Gender:Female I/FU:I

Outcome PT Report Source Product Role Manufacturer Route
Dose Duration
Required Muscle Spasticity Lioresal Intrathecal
Intervention to (Baclofen Injection) PS
INTRATHECAL UNK MCG DAILY
Prevent Permanent
, INTRATHECAL
Impairment/Damage

Date:11/18/03ISR Number: 4236904-2Report Type:Direct Company Report #CTU 206282
Age: Gender:Male I/FU:I

Outcome PT Report Source Product Role Manufacturer Route
Dose Duration
Required Medication Error Lioresal Intrathecal
Intervention to Muscle Spasticity (Baclofen Injection) PS
INTRATHECAL UNK MCG DAILY
Prevent Permanent
, INTRATHECAL
Impairment/Damage

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/18/03ISR Number: 4236906-6Report Type:Direct Company Report #CTU 206281
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Medical Device Complication Medication Error		Lioresal Intrathecal (Baclofen Injection)	PS		INTRATHECAL	UNK MCG, DAILY, INTRATHECAL	

Date:11/18/03ISR Number: 4236907-8Report Type:Direct Company Report #CTU 206280
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Medical Device Complication Overdose Pharmaceutical Product Complaint		Lioresal Intrathecal (Baclofen Injection)	PS		INTRATHECAL	UNK MCG, DAILY, INTRATHECAL	

Date:11/18/03ISR Number: 4236908-XReport Type:Direct Company Report #CTU 206279
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Medical Device Complication Muscle Spasticity		Lioresal Intrathecal (Baclofen Injection)	PS		INTRATHECAL	UNK MCG, DAILY, INTRATHECAL	

Date:11/19/03ISR Number: 4238788-5Report Type:Expedited (15-DaCompany Report #20031495
Age:36 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Abdominal Rigidity	Health	Lioresal					
Hospitalization -	Anoxia	Professional	Intrathecal(Baclofen					
Initial or Prolonged	Anoxic Encephalopathy		Injection)	PS				
INTRATRACHEAL							MCG,	DAILY,
	Autonomic Nervous System							
INTRATHECAL								
	Imbalance							
	Cardiac Disorder							
	Cervical Vertebra Injury							
	Device Failure							
	Feeling Abnormal							
	Lung Disorder							
	Overdose							
	Respiratory Arrest							

Date:11/19/03ISR Number: 4239065-9Report Type:Expedited (15-DaCompany Report #2003-03851
Age:64 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Death	Literature	Baclofen (Watson					
		Health	Laboratories)					
		Professional	(Baclofen) Tablet	PS				
			Clonazepam (Watson					
			Laboratories)					
			(Clonazepam) Tablet	SS				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/19/03ISR Number: 4246012-2Report Type:Expedited (15-DaCompany Report #20031600
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Hepatitis Acute	Foreign Health Professional	Lioresal Intrathecal(Baclofen Injection)	PS		INTRATHECAL		

Date:11/21/03ISR Number: 4240662-5Report Type:Expedited (15-DaCompany Report #20031590
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Erythema Meningitis Staphylococcal Swelling	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		INTRATHECAL	DAILY,	

Date:11/24/03ISR Number: 4239995-8Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0314709A
Age:53 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dysaesthesia		Clamoxyl	PS	Glaxosmithkline	ORAL	4	DAY
	Hypochloraemia		Laroxyl Drops	SS	Glaxosmithkline	ORAL	5DROP	Per day
	Hyponatraemia		Lioresal	SS		ORAL	9UNIT	Per day
	Pyrexia		Neurontin	SS		ORAL	2UNIT	Per day
			Rivotril Drops	SS			7DROP	per day
			Dantrium	SS	Glaxosmithkline	ORAL	3UNIT	Per day
			Heptamyl	C		ORAL	3TAB	Per day
			Diantalvic	C				
			Eductyl	C				

			Forlax	C		
			Oroken	C		
2 DAY						
			Rocephine	C		
INTRAVENOUS						
			Gentalline	C	Glaxosmithkline	
INTRAVENOUS						

Date:11/24/03ISR Number: 4241863-2Report Type:Expedited (15-DaCompany Report #2003-04000
Age:64 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Cardio-Respiratory Arrest	Literature	Baclofen (Watson Laboratories)(Baclofen) Tablet	PS	Watson Laboratories	
		Health Professional	Doxepin (Watson Laboratories) (Doxepin Hydrochloride) Capsule	SS		
			Quetiapine (Quetiapine)	SS		

Date:11/25/03ISR Number: 4242702-6Report Type:Expedited (15-DaCompany Report #2003117889
Age:53 YR Gender:Male I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Back Pain
	Blood Bicarbonate Abnormal
	Blood Uric Acid Decreased

		Dysaesthesia Heat Stroke Hypochloraemia	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
		Inappropriate Antidiuretic Hormone Secretion Pyrexia	Foreign Health Professional	Neurontin (Gabapentin)	PS		ORAL
800 MG, ORAL							
				Amoxicillin Trihydrate (Amoxicillin Trihydrate)	SS		ORAL
ORAL							
				Heptaminol Hydrochloride (Heptaminol Hydrochloride)	SS		ORAL
563.4 MG,							
ORAL							
				Amitriptyline Hydrochloride (Amitriptyline Hydrochloride)	SS		ORAL
ORAL							
				Baclofen (Baclofen)	SS		ORAL
90 MG, ORAL							
				Dantrolene Sodium (Dantrolene Sodium)	SS		ORAL
75 MG, ORAL							
				Clonazepam (Clonazepam)	C		
				Dextropropoxyphene (Dextropropoxyphene)	C		
				Paracetamol (Paracetamol)	C		
				Eductyl (Sodium Bicarbonate, Potassium Bitartrate)	C		
				Macrogol (Macrogol)	C		
				Cefixime (Cefixime)	C		
				Ceftriaxone (Ceftriaxone)	C		

Date:11/28/03ISR Number: 4244658-9Report Type:Expedited (15-DaCompany Report #FRP03000847
Age:53 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Back Pain Blood Osmolarity Decreased Blood Uric Acid Decreased Dysaesthesia Heat Stroke Hypochloraemia Hyponatraemia Inappropriate Antidiuretic Hormone Secretion Pyrexia Urine Sodium Abnormal	Foreign Health Professional Other	Dantrium (Dantrolene Sodium)Capsule, 25mg	PS		ORAL	25 MG, 3/DAY, ORAL	
			Clamoxyl(Amoxicillin Trihydrate)	SS		ORAL	ORAL	
			Hept-A-Myl(Heptamino l Hydrochloride)	SS		ORAL	563.4 MG, DAILY , ORAL	
			Laroxyl(Amitriptylin e Hydrochloride)	SS		ORAL	5 MG, DAILY , ORAL	
			Lioresal "Ciba-Geigy"(Baclofe n)	SS		ORAL	90 MG DAILY ORAL	
			Neurontin(Gabapentin)	SS		ORAL	800 MG, DAILY , ORAL	
			Rivotril(Clonazepam)	SS		ORAL	0.7 MG , DAILY ,ORAL	

				Di-Antalvic(Dextropropoxyphene Hydrochloride)	SS			
				Eductyl(Potassium Bitartrate, Sodium Bicarbonate)	SS			
				Forlax(Macrogol)	SS			
				Oroken(Cefixime)	SS			
2 DF, DAILY,								
				Rocephin(Ceftriaxone Sodium)	SS			
INJECTION NOS								
				Gentamycin-Mp(Gentamicin Sulfate)	SS			

Date:11/28/03ISR Number: 4245376-3Report Type:Expedited (15-DaCompany Report #20031610
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Meningitis	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		INTRATHECAL	MCG, DAILY,	
						INTRATHECAL		

Date:12/04/03ISR Number: 4247362-6Report Type:Expedited (15-DaCompany Report #2003AP04198
Age:35 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Coma	Literature	Lidocaine	PS		TRANSDERMAL	900 MG	DAILY
	Drug Level Above	Health				TD		
	Therapeutic	Professional	Amitriptyline	SS		TRANSDERMAL	360 MG	DAILY
	Drug Screen Positive					TD		
	Overdose		Ketamine	SS		TRANSDERMAL	900 MG	DAILY
						TD		

			Baclofen	SS		
TRANSDERMAL	900 MG DAILY					
TD						
			Ketoprofen	SS		
TRANSDERMAL	1800 MG DAILY					
TD						

Date:12/08/03ISR Number: 4247086-5Report Type:Expedited (15-DaCompany Report #PHNU2003DE03643
Age:67 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Death	Condition Aggravated		Lioresal Intrathecal	PS	Novartis Sector:	
Other	Drug Effect Decreased				Pharma	
	Drug Ineffective		Lioresal Intrathecal	SS	Novartis Sector:	
	Medication Error				Pharma	
297ng/day						
	Muscle Spasticity		Lioresal Intrathecal	SS	Novartis Sector:	
	Pneumonia				Pharma	
297ng/day						
	Respiratory Failure					

Date:12/08/03ISR Number: 4247334-1Report Type:Expedited (15-DaCompany Report #PHFR2003GB04243
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Other	Oesophageal Rupture		Lioresal	PS	Novartis Sector:	
	Peptic Ulcer				Pharma	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/08/03ISR Number: 4248474-3Report Type:Direct Company Report #CTU 207682
Age:54 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	Coma Drug Withdrawal Syndrome Dyskinesia Fatigue Flushing Heart Rate Increased Mydriasis Pupil Fixed Somnolence		Intrathecal Baclofen Pump	PS	Medtronic			

Date:12/08/03ISR Number: 4248588-8Report Type:Expedited (15-DaCompany Report #20031616
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Meningitis	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		INTRATHECAL	UNG MCG, DAILY, INTRATHECAL	

Date:12/08/03ISR Number: 4248589-XReport Type:Expedited (15-DaCompany Report #20031620
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Drug Withdrawal Syndrome Pruritus Pyrexia	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		INTRATHECAL	UNK MCG, DAILY, INTRATHECAL	

Date:12/08/03ISR Number: 4248590-6Report Type:Expedited (15-DaCompany Report #20031619
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Breath Holding	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		INTRATHECAL	MCG, DAILY,	

INTRATHECAL

Date:12/08/03ISR Number: 4248591-8Report Type:Expedited (15-DaCompany Report #20031615
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agitation Clonus Heart Rate Increased Muscle Spasticity Pruritus Pyrexia	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		INTRATHECAL	UNK MCG, DAILY, INTRATHECAL	

Date:12/08/03ISR Number: 4248790-5Report Type:Expedited (15-DaCompany Report #K200301829
Age:69 YR Gender:Female I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Blood Potassium Decreased Blood Sodium Decreased

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Chest Pain Dehydration Left Ventricular Failure Renal Failure Acute Vomiting	Foreign Health Professional Other	Altace Capsules (Ramipril)Capsule, 5mg	PS		ORAL	10 MG, QD,	ORAL
			Prozac (Fluoxetine Hydrochloride) Capsule, 20 Mg	SS		ORAL	20 MG, QD,	ORAL
			Lioresal "Ciba-Geigy"(Baclofen) Tablet, 10 Mg	SS		ORAL	40 MG, QD,	ORAL
			Lexomil (Bromazepam) Tablet, 12 Mg	SS		ORAL	9 MG, ORAL	
			Corvasal (Molsidomine) Tablet, 4 Mg	C				
			Cordarone (Amiodarone Hydrochloride) Tablet	C				
			Trinipatch (Glyceryl Trinitrate) Patch, 5mg	C				

Date:12/09/03ISR Number: 4249963-8Report Type:Expedited (15-DaCompany Report #20031628
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardio-Respiratory Arrest	Health Professional	Lioresal Intrathecal (Baclofen Injection) 500mcg/Ml	PS		INTRATHECAL	DAILY,	

INTRATHECAL

Date:12/10/03ISR Number: 4248881-9Report Type:Expedited (15-DaCompany Report #PHRM2003FR03170
Age:53 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Back Pain Blood Bicarbonate		Lioresal	PS	Novartis Sector: Pharma	ORAL	90 mg/day	
	Abnormal		Clamoxyl	SS		ORAL	5760 MIN	
	Blood Osmolarity		Hept-A-Myl	SS		ORAL	563.4 mg/day	
	Decreased		Laroxyl	SS		ORAL	5 drops/day	
	Blood Uric Acid Decreased		Dantrium	SS		ORAL	75 mg/day	
	Body Temperature		Neurontin	SS		ORAL	800 mg/day	
	Increased		Rivotril	SS		ORAL	7 drops/day	
	Dysaesthesia		Di-Antalvic	SS		ORAL		
	Heat Stroke		Eductyl	SS		RECTAL		
	Hypochloraemia Hyponatraemia Inappropriate Antidiuretic Hormone Secretion Pyrexia		Forlax	SS		ORAL		

Date:12/10/03ISR Number: 4248892-3Report Type:Expedited (15-DaCompany Report #PHRM2003FR03171
Age:69 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Potassium Decreased Chest Pain		Lioresal	PS	Novartis Sector: Pharma	ORAL	40 mg/day	
	Dehydration		Prozac	SS		ORAL	20 mg/day	
	Hyponatraemia Left Ventricular Failure Renal Failure Acute		Triatec /Fra/	SS		ORAL	5 mg, BID	
			Lexomil	SS		ORAL	.25 DF, TID	
			Corvasal	C		ORAL	4 mg, TID	
			Cordarone /Net/	C		ORAL	200 mg, QW5	
			Trinipatch	C		TRANSDERMAL		

Date:12/10/03ISR Number: 4248895-9Report Type:Expedited (15-DaCompany Report #PHRM2003FR03073
Age:11 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Chillblains Dermatitis Bullous		Lioresal	PS	Novartis Sector: Pharma	ORAL	20 mg/day	
	Peripheral Coldness		Zymafluor	C		ORAL		
	Peripheral Vascular Disorder Raynaud'S Phenomenon		Lubentyl	C		ORAL		

Date:12/12/03ISR Number: 4251841-5Report Type:Expedited (15-DaCompany Report #KII-2003-0004887
Age:44 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Other	Blood Pressure Decreased Decubitus Ulcer Depressed Level Of Consciousness Infection Medication Error Pyrexia	Study Health Professional Other	Morphine Sulfate (Similar To Nda 19-516)(Morphine Sulfate) Unknown	PS		ORAL	9 MG, TID, ORAL
			Baclofen (Baclofen)	SS			SEE TEXT
			Ambien (Zolpidem Tartrate)	SS			
			Benzodiazepine Derivatives ( )	SS			

Date:12/16/03ISR Number: 4252351-1Report Type:Expedited (15-DaCompany Report #FR-BRISTOL-MYERS SQUIBB COMPANY-12455887
Age:76 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Dermatitis Bullous Drug Interaction Pemphigoid Pruritus	Health Professional	Lopril	PS	Geneva Pharmaceuticals, Inc. (Novartis)	ORAL	Treated 2-3 years
			Loxen	SS		ORAL	Treated for 2-3 years
			Lioresal	I		ORAL	0.5 tab per day (0,5 DOSE X 3/D)
			Seropram	I		ORAL	Treated for 2-3 years
			Asasantine	I		ORAL	Treated for

2-3 years

Date:12/16/03ISR Number: 4252700-4Report Type:Expedited (15-DaCompany Report #03-12-1548
Age:62 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Muscle Twitching	Foreign	Baclofen	PS	Ipi	ORAL	12.5MG BID	
	Muscular Weakness	Literature					ORAL	
		Health	Propofol	SS			2.5MG/KG/HOUR	
		Professional					(S)	
		Other	Sufentanil	SS			0.25UG/KG	
							HOUR(S)	
			Isoflurane Inhalation Solution	SS			0.6-1.0 VOL%	
			Diazepam	C				
			Levothyroxine	C				
			Vitamin B 12 Injectable	C				
			Atracurium	C				
			Cefuroxime	C				
			Clindamycin	C				
			Dexamethasone	C				
			Morphine	C				
			Prednisone	C				

Date:12/17/03ISR Number: 4254524-0Report Type:Expedited (15-DaCompany Report #20031618
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Hyperaemia Hypotension Rash Erythematous Respiratory Rate	Health Professional	Lioresal Intrathecal (Baclofen Injection), 500mcg/Ml	PS		INTRATHECAL	100 MCG,	

	Decreased					
DAILY,						
	Somnolence					
INTRATHECAL						
	Tachycardia					

Date:12/17/03ISR Number: 4254528-8Report Type:Expedited (15-DaCompany Report #20031620
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Erythema	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		INTRATHECAL	DAILY, INTRATHECAL	
	Meningitis Staphylococcal							
	Pruritus							
	Swelling							

Date:12/17/03ISR Number: 4254987-0Report Type:Expedited (15-DaCompany Report #ZANA001112
Age:32 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Drug Interaction	Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	36 MG ORAL	
Other	Haemolysis		Baclofen (Baclofen)	SS				
			Neurontin (Gabapentin)	C				
			Ditropan (Oxybutynin)	C				
			Prednisone					

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

(Prednisone) C

Date:12/17/03ISR Number: 4271963-2Report Type:Periodic Company Report #USA-2003-0009873
Age:19 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Coma Loss Of Consciousness Overdose	Consumer Other	Oxycontin Tablets (Oxycodone Hydrochloride) Celebrex (Celecoxib) Baclofen (Baclofen) Ghb (Oxybate Sodium)	PS SS SS SS				

Date:12/17/03ISR Number: 4271964-4Report Type:Periodic Company Report #USA-2003-0009874
Age:18 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Loss Of Consciousness Overdose	Consumer Other	Oxycontin Tablets (Oxycodone Hydrochloride) Celebrex (Celecoxib) Baclofen (Baclofen) Ghb (Oxybate Sodium)	PS SS SS SS				

Date:12/18/03ISR Number: 4255375-3Report Type:Expedited (15-DaCompany Report #230032K03FRA
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Feeling Drunk Malaise Syncope	Foreign Consumer Health Professional	Rebif (Interferon Beta) Baclofen	PS SS		SUBCUTANEOUS ORAL	44 MCG, 3 IN 1 WEEKS, 2 DOSAGE FORMS, 3 IN 1	2 YR

DAYS, PER ORAL	Vasobral	SS	ORAL
1 DOSAGE FORMS, 3 IN 1 DAYS, PER ORAL	Modafinil	SS	ORAL
3 DOSAGE FORMS, 3 IN 1 DAYS, PER ORAL	Zopiclone	SS	
0.5 NOT REPORTED, 1 IN 1 DAYS, NOT REPORTED	Mianserin	SS	
NOT REPORTED, 1 IN 1 DAYS, NOT REPORTED	Fenofibrate	SS	
NOT REPORTED, 1 IN 1 DAYS, NOT REPORTED	Oxybutynin	SS	
NOT REPORTED, 2 IN 1 DAYS, NOT REPORTED	Dantrolene Sodium	SS	
NOT REPORTED, 3 IN 1 DAYS,			

NOT REPORTED

Date:12/18/03ISR Number: 4255551-XReport Type:Expedited (15-DaCompany Report #2003117889
Age:53 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Back Pain Blood Osmolarity	Foreign Health	Neurontin (Gabapentin)	PS		ORAL	800 MG, ORAL	
	Decreased Blood Uric Acid Decreased Dysaesthesia Heat Stroke	Professional	Amoxicillin Trihydrate (Amoxicillin Trihydrate)	SS		ORAL	ORAL	
	Hypochloraemia Hyponatraemia Inappropriate Antidiuretic Hormone Secretion Pyrexia		Amitriptyline Hydrochloride (Amitriptyline Hydrochloride)	SS		ORAL	ORAL	
			Dantrolene Sodium (Dantrolene Sodium)	SS		ORAL	75 MG, ORAL	
			Baclofen (Baclofen)	SS		ORAL	90 MG, ORAL	
			Heptaminol Hydrochloride (Heptaminol Hydrochloride)	C		ORAL	563.4 MG, ORAL	
			Clonazepam (Clonazepam)	C				
			Dextropropoxyphene (Dextropropoxyphene)	C				
			Paracetamol (Paracetamol)	C				
			Eductyl (Sodium Bicarbonate, Potassium Bitartrate)	C				
			Macrogol (Macrogol)	C				
			Cefixime (Cefixime)	C				
			Ceftriaxone					

			(Ceftriaxone)	C			
			Gentamicin (Gentamicin)	C			

Date:12/19/03ISR Number: 4255498-9Report Type:Expedited (15-DaCompany Report #99F--10645
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Aggression		Lioresal	PS		ORAL		
	Agitation		Pirilene	C		ORAL		
	Confusional State		Rimifon	C		ORAL		
	Electroencephalogram		Rifampicin	C		ORAL		
	Abnormal		Mopral	C		ORAL		
	Encephalopathy		Fozitec	C		ORAL		
	Muscle Rigidity		Hemodialysis	C				

UNKNOWN

Date:12/19/03ISR Number: 4255933-6Report Type:Direct Company Report #CTU 208449
Age:17 YR Gender:Male I/FU:I

Outcome
Life-Threatening
Hospitalization -

Initial or Prolonged

	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Accident		Baclofen-Intrathecal					
	Catheter Related		4000.0 Ug/Ml	PS				
INTRATHECAL							40.6 UG/HR	
	Complication							
975.0 UG/D IT								
	Device Failure							
	Drug Withdrawal Syndrome							
	Medication Error							
	Overdose							
	Respiratory Arrest							

Date:12/22/03ISR Number: 4257661-XReport Type:Expedited (15-DaCompany Report #20031642
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Diplegia	Health	Lioresal Intrathecal					
Initial or Prolonged	Overdose	Professional	(Baclofen Injection)	PS				
MCG, DAILY,								
	Therapeutic Response							
INTRATHECAL								
	Decreased							
	Urinary Incontinence							

Date:12/22/03ISR Number: 4257663-3Report Type:Expedited (15-DaCompany Report #20031525
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Bronchopneumonia	Health	Lioresal Intrathecal					
	Cerebral Palsy	Professional	(Baclofen Injection)	PS				
INTRATHECAL							MCG, DAILY,	
	Muscle Spasticity							
INTRATHECAL								
	Panic Reaction							

Date:12/23/03ISR Number: 4257952-2Report Type:Expedited (15-DaCompany Report #S03-FRA-05163-01
Age:76 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dermatitis Bullous Pemphigoid Pruritus	Foreign Health Professional Other	Seropram (Citalopram Hydrobromide)	PS				
			Lopril (Captoprol)	SS				
			Lioresal "Novartis" (Baclofen)	SS	"Novartis"	ORAL	0.5 UNK TID	PO
			Loxen (Nicardipine Hydrochloride)	SS				
			Dipyridamole	SS				

Date:12/24/03ISR Number: 4257446-4Report Type:Expedited (15-DaCompany Report #PHFR2003GB04829
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Psychotic Disorder		Baclofen	PS	Novartis Sector: Pharma		UNKNOWN	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/24/03ISR Number: 4257792-4Report Type:Expedited (15-DaCompany Report #PHRM2003FR03355
Age:76 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Pemphigoid Pruritus		Lioresal	PS	Novartis Sector: Pharma	ORAL	5 mg, TID	
			Loxen/Cardene	SS		ORAL		
			Lopril	SS		ORAL		
			Seropram	SS		ORAL		
			Asasantin	SS		ORAL		

Date:01/02/04ISR Number: 4263784-1Report Type:Expedited (15-DaCompany Report #ZANA001112
Age:32 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Other	Glucose-6-Phosphate Dehydrogenase Deficiency	Health Professional	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL	36 MG ORAL	
	Haemolysis		Baclofen (Baclofen)	SS				
	Refusal Of Treatment By Patient		Neurontin (Gabapentin)	C				
			Ditropan (Oxybutynin)	C				
			Predenisone (Prednisone)	C				

Date:01/06/04ISR Number: 4263864-0Report Type:Expedited (15-DaCompany Report #PHBS2003CH14515
Age:76 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Coma Fall		Lioresal	PS	Novartis Sector: Pharma	ORAL	20 mg/day	2880 MIN
Other	Somnolence		Temesta	SS			UNKNOWN	1440 MIN
	Stupor		Floxapen	C			INTRAVENOUS DRIP	
6 g								

			Insulin	C		
UNKNOWN						
			Actrapid	C		
UNKNOWN						
			Benerva	C		
UNKNOWN						

Date:01/06/04ISR Number: 4264762-9Report Type:Expedited (15-DaCompany Report #PHNU2003DE02970
Age:15 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Alanine Aminotransferase Increased	Health Professional	Lioresal	PS	Novartis Sector: Pharma	ORAL	UNK	
	Aspartate Aminotransferase Increased		Lioresal	SS	Novartis Sector: Pharma	ORAL	50mg/day	
	Gamma-Glutamyltransferase Increased							

Date:01/06/04ISR Number: 4266163-6Report Type:Expedited (15-DaCompany Report #KII-2003-0006601
Age:63 YR Gender:Female I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Disorientation
	Drug Interaction
Other	Mental Status Changes
	Pain

	Respiratory Rate Decreased Sinus Tachycardia	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Somnolence	Study Health Professional Other	Oxycodone Hydrochloride Fentanyl (Fentanyl) Amitriptyline (Amitriptyline) Ssri ( ) Baclofen (Baclofen) Gabapentin (Gabapentin) Tramadol (Tramadol) Cr Tablet Tolterodine (Tolterodine)	PS SS SS SS SS SS SS			

Date:01/07/04ISR Number: 4265026-XReport Type:Expedited (15-DaCompany Report #99F--10645
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Aggression Agitation Confusional State Electroencephalogram Abnormal Encephalopathy Muscle Rigidity		Lioresal Pirilene Rimifon Rifampicin Mopral Fozitec Hemodialysis	PS C C C C C C		ORAL ORAL ORAL ORAL ORAL ORAL	UNKNOWN

Date:01/07/04ISR Number: 4265753-4Report Type:Expedited (15-DaCompany Report #FR-ROCHE-354811
Age:76 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Pemphigoid	Consumer	Loxen Lp Lioresal Lopril Seropram Asasantin	PS SS SS SS SS	Roche	ORAL ORAL ORAL ORAL ORAL	

Date:01/07/04ISR Number: 4267133-4Report Type:Expedited (15-DaCompany Report #20031649
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Death	Coma	Foreign	Lioresal Intrathecal			
	Dyspnoea	Health	(Baclofen			
	Hypertonia	Professional	Injection)2000			
	Hypotonia		Mcg/Ml	PS		
INTRATHECAL	MCG, DAILY,					
	Medical Device					
INTRATHECAL						
	Complication		Antibiotics	C		
	Medical Device		Dexamethasone	C		
	Implantation					
	Proteus Infection					
	Urosepsis					

Date:01/07/04ISR Number: 4267152-8Report Type:Expedited (15-DaCompany Report #US-SHR-03-019043
Age:62 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Coma Injection Site Cellulitis Pyrexia	Consumer	Betaseron(Interferon Beta-1b) Betaseron(Interferon Beta -1b) Injection, 250ug	PS		SUBCUTANEOUS	8 MIU, EVERY 2 D, HS,	
			Baclofen (Baclofen)	SS		SUBCUTANEOUS		

Date:01/13/04ISR Number: 4270791-1Report Type:Expedited (15-DaCompany Report #20041663
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Distension Agitation Anorexia Constipation Drug Withdrawal Syndrome Pyrexia	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		INTRATHECAL	DAILY,	

Date:01/13/04ISR Number: 4271325-8Report Type:Expedited (15-DaCompany Report #20031610
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Csf Culture Positive Implant Site Infection Meningitis Staphylococcal Infection	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		INTRATHECAL	DAILY,	

Date:01/13/04ISR Number: 4271333-7Report Type:Expedited (15-DaCompany Report #20031616
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Csf Bacteria Identified Implant Site Infection Meningitis Staphylococcal Infection	Health Professional	Lioresal Intrathecal(Baclofen Injection)	PS		INTRATHECAL	DAILY, INTRATHECAL	
			Antibiotics	C				

Date:01/14/04ISR Number: 4269940-0Report Type:Expedited (15-DaCompany Report #PHNU2003DE02970
Age:15 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Alanine Aminotransferase Increased Aspartate Aminotransferase Increased Epstein-Barr Virus Antibody Positive Gamma-Glutamyltransferase Increased	Health Professional	Lioresal	PS	Novartis Sector: Pharma	ORAL	10 mg, 5QD	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/16/04ISR Number: 4275090-XReport Type:Expedited (15-DaCompany Report #2004001460
Age:37 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Condition Aggravated Neutropenia	Foreign Health	Triflucan (Fluconazole)	PS			1200 MG (TID)	
	Normochromic Normocytic Anaemia Septic Shock White Blood Cell Count Decreased	Professional	Baclofen (Baclofen)	SS		ORAL	ORAL	

Date:01/16/04ISR Number: 4275310-1Report Type:Expedited (15-DaCompany Report #KII-2003-0006846
Age:53 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Confusional State Drug Withdrawal Syndrome Flushing Hyperhidrosis Hypertension	Study Health Professional Other	Oxycodone Hydrochloride (Similar To Nda 20-553)(Oxycodone Hydrochloride)	PS		ORAL	ORAL	
	Mental Status Changes Overdose Somnolence Tachycardia		Morphine Sulfate (Similar No Nda19-516) (Morphine Sulfate) Unknown	SS		ORAL	ORAL	
			Baclofen (Baclofen)	SS		ORAL	ORAL	
			Neurontin (Gabapentin)	SS				
			Zinc (Zinc)	SS				
			Hydrochlorothiazide (Hydrochlorothiazide) Tablet	SS				
			Paxil ((Paroxetine Hydrochloride)	SS				
			Vitamin A (Retinol)	SS				
			Vitamin C (Ascorbic Acid)	C				

Date:01/20/04ISR Number: 4274648-1Report Type:Expedited (15-DaCompany Report #PHFR2004GB00566
Age:4 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Bradycardia Hypothermia		Baclofen	PS	Novartis Sector: Pharma	ORAL	6 mg, QID	
			Melatonin	C		ORAL	6m/day	

Date:01/20/04ISR Number: 4281437-0Report Type:Periodic Company Report #PHBS2003US10785
Age:17 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hypertonia	Health Professional	Lioresal Intrathecal $Me(Baclofen) Ampoule	PS		INTRATHECAL	INTRATHECAL	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/21/04ISR Number: 4277663-7Report Type:Expedited (15-DaCompany Report #20041668
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hypotension Hypothermia	Health Professional	Lioresal Intrathecal (Vaclofen Injection)	PS		INTRATHECAL	UNK MCG, DAILY,	
	Hypotonia							
	Medical Device Pain					INTRATHECAL		
	Mental Status Changes							
	Shock							

Date:01/22/04ISR Number: 4277500-0Report Type:Expedited (15-DaCompany Report #99F--10373
Age:65 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agitation Blood Bicarbonate Increased		Lioresal Hemodialysis	PS C	Novartis Sector: Pharma	ORAL	5 mg, QD 3 courses/week	8640 MIN
	Blood Creatinine Abnormal							
	Blood Glucose Increased		Rimifon	C		ORAL		
	Blood Urea Increased		Rifampicin	C		ORAL	900 mg/day	
	Coma		Inh	C		ORAL		
	Confusional State		Triatec	C		ORAL		
	Encephalopathy		Amlor	C		ORAL		
	Haemoglobin Decreased		Pirilene	C		ORAL	750 mg/day	
	Muscle Rigidity		Mopral	C		ORAL	40 mg/day	
	Personality Change Due To A General Medical Condition		Fozitec	C		ORAL	0.5 tab/day	
	Toxic Induced Encephalopathy							

Date:01/23/04ISR Number: 4279366-1Report Type:Expedited (15-DaCompany Report #230032K03FRA
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Feeling Drunk Malaise	Foreign Consumer	Rebif (Interferon Beta)	PS		SUBCUTANEOUS	44 MCG 3 IN 1 WEEKS	
	Syncope	Health Professional				SUBCUTANEOUS	2 DOSAGE FORMS, 3 IN 1 DAYS, PER ORAL	2 YR
			Baclofen	SS		ORAL	1 DOSAGE FORMS, 3 IN 1 DAYS, PER ORAL	
			Vasobral	SS		ORAL	3 DOSAGE FORMS, 3 IN 1 DAYS, PER ORAL	
			Modafinil	SS		ORAL	0.5 NOT REPORTED, 1 IN 1 DAYS, NOT REPORTED	
			Zopiclone	SS			NOT REPORTED, 1 IN 1 DAYS, NOT REPORTED	
			Mianserin	SS			NOT REPORTED	
			Fenofibrate	SS			NOT REPORTED	

1 IN 1 DAYS,

NOT REPORTED

	Oxybutynin	SS

NOT REPORTED,

2 IN 1 DAYS,

NOT REPORTED

	Dantrolene Sodium	SS

NOT REPORTED,

3 IN 1 DAYS,

NOT REPORTED

Date:01/23/04ISR Number: 4279515-5Report Type:Expedited (15-DaCompany Report #DSA_23795_2004
Age:76 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Coma	Foreign	Temesta	PS				
	Drug Interaction	Health	Lioresal	SS		ORAL	10 MG BID PO	
Other	Fall	Professional	Floxapen	C				
	Somnolence	Other	Insulatard	C				
			Actrapid Human	C				
			Benerva	C				

Date:01/30/04ISR Number: 4281985-3Report Type:Expedited (15-DaCompany Report #PHBS2004CA01117
Age:27 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Agitation		Lioresal	PS	Novartis Sector: Pharma	ORAL	1 tablet/day	4320 MIN
	Anger							
	Antisocial Behaviour		Lioresal	SS	Novartis Sector: Pharma	ORAL	1 tablet, BID	4320 MIN
	Constipation							
	Depression		Lioresal	SS	Novartis Sector: Pharma	ORAL	1 tablet, TID	4320 MIN
	Dry Mouth							

	Dysphagia		Lioresal	SS	Novartis Sector:	
	Eye Disorder				Pharma	ORAL
2 tablets,						
	Hallucination					
BID	4320 MIN					
	Hyperhidrosis		Lioresal	SS	Novartis Sector:	
	Insomnia				Pharma	ORAL
2 tablets,						
	Lethargy					
TID	2880 MIN					
	Mood Swings		Lioresal	SS	Novartis Sector:	
	Paranoia				Pharma	ORAL
1 tablet/day	5760 MIN					
	Thyroid Function Test		Domperidone	C		
UNKNOWN						
	Abnormal					
	Urine Output Decreased					

Date:02/03/04ISR Number: 4285825-8Report Type:Expedited (15-DaCompany Report #KII-2003-0007030
Age:51 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Coma	Study	Ms Contin Tablets			
Initial or Prolonged	Convulsion	Health	(Morphine Sulfate)			
Other	Medication Error	Professional	Cr Tablet	PS		ORAL
ORAL						
	Muscle Spasms	Other	Oxycodone			
	Overdose		Hydrochloride			
	Sleep Apnoea Syndrome		(Similar To Nda			
			20-553) (Oxycodone			
			Hydrocloride)	SS		
			Baclofen (Baclofen)	SS		ORAL
ORAL						

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/04/04ISR Number: 4284881-0Report Type:Expedited (15-DaCompany Report #PHRM2004FR00643
Age:37 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anaemia Coma		Lioresal	PS	Novartis Sector: Pharma	ORAL	87840MIN	
	Neutropenia		Triflucan	SS		ORAL	400 mg, TID	57600MIN
	Septic Shock							

Date:02/04/04ISR Number: 4284882-2Report Type:Expedited (15-DaCompany Report #PHFR2003GB04829
Age:41 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Delusion Hallucination, Auditory		Baclofen	PS	Novartis Sector: Pharma	ORAL	10 mg, QID	
	Hallucination, Visual		Risperidone	C		ORAL	4 mg, QD	
	Psychotic Disorder		Bendrofluazide	C		ORAL	2.5 mg, QD	
			Perindopril	C		ORAL	8 mg, QD	
			Metformin	C			1 g, BID	
			Rosiglitazone	C		ORAL	4 mg mane	
			Diazepam	C			5 mg, TID	

Date:02/05/04ISR Number: 4288479-XReport Type:Expedited (15-DaCompany Report #20041682
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Escherichia Infection Implant Site Infection Medical Device	Health Professional	Lioresal Intrathecal(Baclofen Injection)	PS		INTRATHECAL	MCG, DAILY,	

	Complication					
INTRATHECAL						
	Meningitis					
	Post Procedural					
	Complication					
	Pseudomonas Infection					

Date:02/09/04ISR Number: 4289929-5Report Type:Expedited (15-DaCompany Report #PHBS2004BR01170
Age:73 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hyperaemia		Lioresal	PS	Novartis Sector:			
	Hypersensitivity				Pharma	ORAL	10 mg, BID	
	Skin Exfoliation		Higroton	C			UNKNOWN	50 mg/day
			Foraseq	C			UNKNOWN	200 ug/day
			Puran T4	C			UNKNOWN	50 ug/day
			Marax	C			UNKNOWN	

Date:02/09/04ISR Number: 4290279-1Report Type:Expedited (15-DaCompany Report #20041678
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Bacterial Infection	Health	Lioresal Intrathecal					
Initial or Prolonged	Implant Site Infection	Professional	(Baclofen Injection)	PS				
INTRATHECAL							UNK MCG,	
							DAILY,	
							INTRATHECAL	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/09/04ISR Number: 4290283-3Report Type:Expedited (15-DaCompany Report #20031631
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Disease Recurrence Fall Muscle Spasticity Red Blood Cells Csf Positive Reflexes Abnormal	Health Professional	Lioresal Intrathecal (Baclofen Injection) 500mcg/Ml	PS		INTRATHECAL	UNK MCG, DAILY, INTRATHECAL	

Date:02/10/04ISR Number: 4293965-2Report Type:Expedited (15-DaCompany Report #20041689
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Cardio-Respiratory Arrest Catheter Related Complication Muscle Spasticity	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		INTRATHECAL	DAILY, INTRATHECAL	

Date:02/18/04ISR Number: 4297296-6Report Type:Expedited (15-DaCompany Report #200410574FR
Age:79 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Eczema		Lovenox	PS	Aventis Pharmaceuticals Inc.	SUBCUTANEOUS		
			Tegretol - Slow Release	SS		ORAL		
			Prozac 20 Mg	SS		ORAL		
			Mopral	SS		ORAL		
			Lioresal	SS		ORAL		
			Fludex 1.5 Mg Comprime Enrobe Lp	SS		ORAL		
			Praxilene	C				

			Motilium	C		
			Diffu K	C		ORAL
			Forlax	C		ORAL

Date:02/18/04ISR Number: 4300236-4Report Type:Expedited (15-DaCompany Report #20041704
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged Required	Device Failure Respiratory Failure Upper Respiratory Tract	Health Professional	Lioresal Inthrathecal (Baclofen Injection)	PS		
INTRATRACHEAL MCG, DAILY,						
Intervention to INTRATHECAL	Infection					
Prevent Permanent Impairment/Damage			Iv Valium And Ativan	C		

Date:02/19/04ISR Number: 4299078-8Report Type:Expedited (15-DaCompany Report #200412064GDDC
Age:79 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Eczema		Fludex	PS	Aventis Pharmaceuticals Inc.	ORAL
			Lovenox	SS	Aventis Pharmaceuticals Inc.	
SUBCUTANEOUS dose: UNK						
			Prozac	SS		ORAL

			Tegretol	SS		ORAL
dose: 2 DF						
			Mopral	SS		ORAL
dose: UNK						
			Lioresal	SS		
			Praxilene	C		
			Motilium	C		
			Diffu K	C		
			Forlax	C		
			Xyzal	C		

Date:02/20/04ISR Number: 4301283-9Report Type:Direct Company Report #CTU 212728
Age:83 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Aphasia		Baclofen	PS		ORAL	5 MG PO TID	
	Asthenia		Amlodipine	C				
	Depressed Level Of Consciousness		Buffered Aspirin	C				
			Calcium /Vit D	C				
	Lethargy		Clonazepam	C				
	Mutism		Clopidogrel	C				
			Cyanocobalamin	C				
			Enoxaparin	C				
			Escitalopram	C				
			Furosemide	C				
			..	C				
			Gabapentin	C				
			Hydrochlorothiazide	C				
			Levothyroxine	C				
			Multivitamin	C				
			Nystatin	C				
			Simvastatin	C				
			Vitamin E	C				
			Acetaminophen	C				
			Diphenhydramine	C				
			Insulin Lispro (Sliding Scale)	C				

Date:02/24/04ISR Number: 4303806-2Report Type:Expedited (15-DaCompany Report #04-02-0268
Age:55 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Bradycardia	Foreign	Baclofen - Ipi					
Other	Dizziness	Other	Tablets	PS		ORAL	80 MG	ORAL
			Gabapentin	C				
			Movicol	C				
			Salbutamol	C				
			Vitamin C	C				

Date:02/25/04ISR Number: 4304275-9Report Type:Expedited (15-DaCompany Report #20041668
Age: Gender:Male I/FU:F

Outcome	PT
Death	Epistaxis
Hospitalization - Initial or Prolonged	Hypotension
	Hypothermia
	Hypotonia
	Implant Site Reaction
	Mental Status Changes
	Mouth Haemorrhage

		Pain Shock					
			Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
			Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		
INTRATHECAL	DAILY, INTRATHECAL						

Date:02/25/04ISR Number: 4304452-7Report Type:Expedited (15-DaCompany Report #04-02-0271
Age:40 YR Gender:Male I/FU:I

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Other		Psychotic Disorder	Foreign Other	Baclofen Tablets - Ipi	PS	Ipi	ORAL
10MG QID ORAL							
				Risperidone	C		
				Bendrofluazide	C		
				Perindopril	C		
				Metformin	C		
				Rosiglitazone	C		
				Diazepam	C		

Date:02/25/04ISR Number: 4307179-0Report Type:Expedited (15-DaCompany Report #PHRM2004FR00853
Age:50 YR Gender:Male I/FU:I

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
		Headache Hyperhidrosis	Foreign Health	Lioresal (Baclofen)	PS		
INTRATHECAL	50 UG, ONCE/SINGLE	Hypotension Ileus Paralytic Urinary Retention	Professional Other				

Date:03/02/04ISR Number: 4309428-1Report Type:Expedited (15-DaCompany Report #PHFR2004GB01101
Age:55 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Bradycardia		Baclofen	PS	Novartis Sector:			
Other	Dizziness				Pharma	ORAL	80mg/day	
			Gabapentin	C		ORAL	300mg/day	
			Movicol	C		ORAL	1 sachet/day	
			Salbutamol	C			2.5ml/day	
			Vitamin C	C		ORAL	500mg/day	

Date:03/02/04ISR Number: 4311023-5Report Type:Expedited (15-DaCompany Report #KII-2003-0007440
Age:41 YR Gender:Female I/FU:I

Outcome	PT
Life-Threatening	Arrhythmia
Hospitalization - Initial or Prolonged	Blood Bicarbonate Decreased
Other	Blood Calcium Decreased
	Blood Glucose Increased
	Blood Potassium Decreased
	Body Temperature Increased
	Depressed Level Of Consciousness
	Drug Screen Positive
	Electrocardiogram Qt

Corrected Interval Prolonged Nausea Prothrombin Time Prolonged Red Blood Cell Sedimentation Rate Increased	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Study Health Professional Other	Morphine Sulfate (Similar To Nda 19-516) (Morphine Sulfate)	PS		ORAL	ORAL
Respiratory Arrest Syncope Torsade De Pointes Ventricular Extrasystoles Ventricular Tachycardia Vomiting White Blood Cell Count Increased		Vistaril(Hydroxyzine Embonate)	SS			
		Benadryl (Diphenhydramine Hydrochloride)	SS			
		Metformin (Metformin)	SS			
		Lipitor (Atorvastatin)	SS			
		Effexor (Venlafaxine Hydrochloride)	SS			
		Lasix (Furosemide)	SS			
		Potassium (Potassium)	SS			
		Reglan (Metoclopramide)	SS			
		Amfetamine (Amfetamine)	SS			
		Ambien (Zolpidem Tartrate)	SS			
		Acebutolol Hydrochloride (Acebutolol Hydrochloride)	SS			
		Baclofen (Baclofen)	SS			
		Nexium (Esomeprazole)	SS			
		Prilosec (Omeprazole)	SS			
		Quinine (Quinine)	SS			
		Promethazine (Promethazine)	SS			
		Klonopin (Clonazepam)	SS			
		Wellbutrin (Amfebutamone Hydrochloride)	SS			
		Celexa (Citalopram				

				Hydrobromide)	C		

Date:03/02/04ISR Number: 4311152-6Report Type:Expedited (15-DaCompany Report #20041727
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	Drug Withdrawal Syndrome Migration Of Implant Muscle Rigidity Muscle Spasticity Pruritus Pyrexia	Health Professional	Lioresal Intrathecal (Baclofen Injection) Baclofen	PS C		INTRATHECAL INTRATHECAL	MCG, DAILY,	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/03/04ISR Number: 4312143-1Report Type:Expedited (15-DaCompany Report #20041729
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Withdrawal Syndrome Muscle Spasticity	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS			INTRATHECAL	MCG, DAILY,
	Pyrexia						INTRATHECAL	

Date:03/04/04ISR Number: 4310967-8Report Type:Expedited (15-DaCompany Report #200410574FR
Age:79 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Eczema Psoriasis		Lovenox	PS	Aventis Pharmaceuticals Inc.		SUBCUTANEOUS	
			Tegretol - Slow Release	SS		ORAL		
			Prozac 20 Mg	SS		ORAL		
			Mopral	SS		ORAL		
			Lioresal	SS		ORAL		
			Fludex 1.5 Mg Comprime Enrobe Lp	SS		ORAL		
			Praxilene	C				
			Motilium	C				
			Diffu K	C		ORAL		
			Forlax	C		ORAL		

Date:03/04/04ISR Number: 4311492-0Report Type:Expedited (15-DaCompany Report #PHBS2004TW02803
Age:58 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Depressed Level Of Consciousness		Baclofen	PS	Novartis Sector: Pharma		UNKNOWN	5 mg, TID
	Toxic Induced Encephalopathy							

Date:03/04/04ISR Number: 4311515-9Report Type:Expedited (15-DaCompany Report #PHBS2004TW02804
Age:76 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Depressed Level Of Consciousness		Baclofen	PS	Novartis Sector: Pharma		UNKNOWN	10 mg, TID
	Neurotoxicity							

Date:03/04/04ISR Number: 4311516-0Report Type:Expedited (15-DaCompany Report #PHBS2004TW02802
Age:50 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agitation		Baclofen	PS	Novartis Sector: Pharma		UNKNOWN	5 mg, QID
	Blood Glucose Increased							
	Confusional State		Triazolam	C			UNKNOWN	0.25 mg/day
	Haemoglobin Decreased							
	Toxic Induced Encephalopathy							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/10/04ISR Number: 4314817-5Report Type:Expedited (15-DaCompany Report #PHRM2004FR01023
Age:79 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Eczema		Lioresal	PS	Novartis Sector: Pharma	ORAL		
			Tegretol Lp	SS		ORAL		
			Fludex	SS		ORAL	1.5 mg/day	
			Mopral	SS		ORAL	20 mg/day	
			Lovenox	SS		SUBCUTANEOUS		
			Prozac	SS		ORAL	20 mg/day	
			Praxilene	SS		ORAL		
			Motilium	SS		ORAL		
			Diffu K	SS		ORAL		
			Forlax	SS		ORAL		
			Xyzall	SS		ORAL		

Date:03/11/04ISR Number: 4316454-5Report Type:Expedited (15-DaCompany Report #PHNU2003DE04094
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Device Failure	Health Professional	Lioresal Intrathecal (Baclofen)	PS		INTRATHECAL	SEE IMAGE,	
	Drug Ineffective							
	Drug Level Fluctuating	Other				INTRATHECAL		
	Drug Withdrawal Syndrome							
	Electroencephalogram Abnormal							
	Muscle Spasticity							
	Sudden Death							

Date:03/12/04ISR Number: 4316048-1Report Type:Expedited (15-DaCompany Report #PHBS2004CA03144
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Life-Threatening Hospitalization - Initial or Prolonged	Cheyne-Stokes Respiration Respiratory Rate Decreased		Lioresal Inthratecal Lioresal Inthratecal	PS SS	Novartis Sector: Pharma Novartis Sector: Pharma	INTRATHECAL 530 INTRATHECAL 585
			Lioresal Clonazepam Depakene	SS C C		ORAL UNKNOWN UNKNOWN

Date:03/17/04ISR Number: 4320217-4Report Type:Expedited (15-DaCompany Report #ZANA001136
Age:24 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Hospitalization - Initial or Prolonged	Bradycardia Drug Interaction Hypotension Hypotonia Malaise Skin Infection	Foreign Health Professional Other	Sirdalud (Tizanidine Hydrochloride) Lioresal (Baclofen) Myolastan (Tetrazepam) Ciflox (Ciprofloxacin) Voltarene Lp (Diclofenac Sodium)	PS SS SS SS C		ORAL 12 MG DAILY ORAL 30 MG DAILY ORAL 75 MG DAILY ORAL 1 G DAILY

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/19/04ISR Number: 4319830-XReport Type:Expedited (15-DaCompany Report #PHRM2004FR01091
Age:19 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anorexia General Physical Health Deterioration Hypernatraemia Muscle Spasticity Somnolence		Lioresal	PS	Novartis Sector: Pharma	ORAL	15 mg, TID	15840MIN

Date:03/19/04ISR Number: 4321930-5Report Type:Expedited (15-DaCompany Report #20041729
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Withdrawal Syndrome Muscle Spasticity Pyrexia	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		INTRATHECAL	MCG, DAILY, INTRATHECAL	

Date:03/19/04ISR Number: 4322351-1Report Type:Expedited (15-DaCompany Report #ZANA001136
Age:24 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Bradycardia Drug Interaction Hypotension Hypotonia Malaise	Foreign Health Professional Other	Sirdalud (Tizanidine Hydrochloride) Lioresal (Baclofen) Myolastan (Tetrazepam)	PS SS SS		ORAL ORAL ORAL	12 MG DAILY 30 MG DAILY 75 MG DAILY	

			Ciflox (Ciprofloxacin)	SS			
1 G DAILY							
			Voltaren Lp Diclofenac Sodium)	C			

Date:03/22/04ISR Number: 4321082-1Report Type:Direct Company Report #CTU 214876
Age:55 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Confusional State		Baclofen 10mg Tablets	PS				
	Fatigue							
5 MG BID PRN								
	Mental Status Changes		Paracalitol	C				
	Somnolence		Epoetin	C				
			Ferrous Gluconate	C				
			Allopurinol	C				
			Warfarin	C				
			Nephrovite	C				
			Metoprolol	C				
			Oxycodone/Apap	C				

Date:03/23/04ISR Number: 4324819-0Report Type:Expedited (15-DaCompany Report #2004-01007
Age:62 YR Gender:Female I/FU:I

Outcome	PT
Other	Anaesthetic Complication
	Drug Interaction
	Hypotonia

Muscular Weakness

		Report Source	Product	Role	Manufacturer	Route	Dose	Duration
		Foreign Literature Health	Baclofen (Watson Laboratories) (Baclofen) Tablet	PS	Watson Laboratories	ORAL	12.5 MG, BID,	
		Professional					ORAL	
		Other	Isoflurane (Isoflurane)	SS		OTHER	0.6 TO 1.0	VOL%, OTHER
			Prednisone	C				
			Diazepam	C				
			Levothyroxine (Levothyroxine)	C				
			Vitamin B12 Injection	C				
			Propofol (Propofol)	C				
			Sufentanil (Sufentanil)	C				
			Cefuroxime (Cefuroxime)	C				
			Clindamycin (Clindamycin)	C				
			Dexamethasone	C				
			Atracurium (Atracurium)	C				
			Morphine (Morphine)	C				

Date:03/24/04ISR Number: 4325382-0Report Type:Expedited (15-DaCompany Report #20031619
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Breath Holding Cardiac Disorder	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		INTRATHECAL	MCG, DAILY,	
						INTRATHECAL		

Date:03/26/04ISR Number: 4323641-9Report Type:Expedited (15-DaCompany Report #PHNU2004DE01249
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain Acidosis Blood Ph Decreased Hypokalaemia Hyponatraemia Respiratory Failure Somnolence		Lioresal	PS	Novartis Sector: Pharma	UNKNOWN		

Date:03/29/04ISR Number: 4330481-3Report Type:Expedited (15-DaCompany Report #20031600
Age: Gender: I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Hepatitis	Foreign Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		INTRATHECAL	MCG,	DAILY, INTRATHECAL

Date:03/29/04ISR Number: 4330679-4Report Type:Expedited (15-DaCompany Report #PHFR2003GB04316
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Cholelithiasis	Health Professional	Baclofen Intrathecal (Baclofen) Unknown	PS		INTRATHECAL	INTRATHECAL	
	Hepatitis Acute	Other						

Date:03/29/04ISR Number: 4332202-7Report Type:Expedited (15-DaCompany Report #20041748
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Cerebrospinal Fluid Leakage	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		INTRATHECAL	DAILY, INTRATHECAL	
	Headache							
	Lymphoedema							
	Meningitis							

Date:03/30/04ISR Number: 4332873-5Report Type:Expedited (15-DaCompany Report #20041727
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Withdrawal Syndrome Pocket Erosion	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		INTRATHECAL	MCG, DAILY, Required INTRATHECAL	
Intervention to Prevent Permanent Impairment/Damage			Oral Baclofen	C				

Date:03/31/04ISR Number: 4328426-5Report Type:Expedited (15-DaCompany Report #PHBS2004SE04163
Age:89 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Difficulty In Walking		Lioresal	PS	Novartis Sector:			
Other	Drug Level Increased				Pharma			
	Fatigue		Triobe	C				
	Intentional Misuse							
	Pneumonia							

Date:04/02/04ISR Number: 4330283-8Report Type:Expedited (15-DaCompany Report #PHRM2004FR01370
Age:69 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Cardiac Failure		Lioresal	PS	Novartis Sector: Pharma	ORAL	10 mg/day	5760 MIN
	Confusional State							
	Dyspnoea							

Date:04/02/04ISR Number: 4330286-3Report Type:Expedited (15-DaCompany Report #PHBS2004SE04163
Age:89 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Difficulty In Walking		Lioresal	PS	Novartis Sector:			
Other	Drug Level Increased				Pharma	ORAL		
	Fatigue		Triobe	C				
	Intentional Misuse							
	Pneumonia							

Date:04/05/04ISR Number: 4334304-8Report Type:Expedited (15-DaCompany Report #20041774
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Meningitis Streptococcal Wound Secretion	Health Professional	Lioresal Intrathecal(Baclofen Injection)	PS		INTRATHECAL	MCG, DAILY, INTRATHECAL	

Date:04/05/04ISR Number: 4334359-0Report Type:Expedited (15-DaCompany Report #20041768
Age:4 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	Autonomic Nervous System Imbalance Blood Pressure Fluctuation Clonus Convulsion Drug Withdrawal Syndrome Hypoxia Muscle Spasticity Pneumonia Pyrexia Rales Respiratory Distress Respiratory Failure Tachycardia Tremor Wheezing	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		INTRATHECAL	DAILY, INTRATHECAL	

Date:04/08/04ISR Number: 4335915-6Report Type:Expedited (15-DaCompany Report #04-04-0494
Age:36 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Autonomic Nervous System	Foreign	Baclofen Tablets -					

Initial or Prolonged	Imbalance	Other	Ipi	PS	Ipi	ORAL
10MG HS ORAL						
	Blood Creatine		Amitriptyline	C		
	Phosphokinase Increased					
	Disorientation					
	Drug Withdrawal Syndrome					
	Muscle Rigidity					

Date:04/09/04ISR Number: 4335860-6Report Type:Expedited (15-DaCompany Report #PHFR2004GB01654
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Anaemia		Baclofen	PS	Novartis Sector:	
Initial or Prolonged	Duodenal Ulcer				Pharma	
10 mg, TID						
	Haemorrhage					

Date:04/09/04ISR Number: 4335861-8Report Type:Expedited (15-DaCompany Report #PHFR2004GB01655
Age:36 YR Gender:Male I/FU:I

Outcome	PT
Hospitalization -	Autonomic Nervous System
Initial or Prolonged	Imbalance
	Blood Creatine

	Phosphokinase Increased Disorientation Drug Withdrawal Syndrome Muscle Rigidity	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Neuroleptic Malignant Syndrome		Baclofen	PS	Novartis Sector: Pharma	ORAL	10mg/nocte
			Amitriptyline	C		ORAL	50mg/nocte

Date:04/09/04ISR Number: 4336483-5Report Type:Direct Company Report #CTU 216356
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Disability	Headache Screaming Tic		Baclofen 10mg Don'T Know - Is "Major Pharm A Mfr?	PS		ORAL	ONE TABLET, DAILY, ORAL
			Clonazepam	SS		ORAL	11/2 TABLET TWICE DAILY ORAL

Date:04/12/04ISR Number: 4339539-6Report Type:Expedited (15-DaCompany Report #20041771
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Enterococcal Infection Meningitis	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		INTRATHECAL	MCG, DAILY, INTRATHECAL

Date:04/13/04ISR Number: 4337273-XReport Type:Expedited (15-DaCompany Report #PHBS2004CA01117
Age:27 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Abnormal Behaviour		Lioresal	PS	Novartis Sector: Pharma	ORAL	1 tablet/day	4320 MIN
	Agitation							
	Anger		Lioresal	SS	Novartis Sector: Pharma	ORAL	1 tablet, BID	4320 MIN
	Antisocial Behaviour							
	Depression		Lioresal	SS	Novartis Sector: Pharma	ORAL	1 tablet, TID	4320 MIN
	Drug Hypersensitivity							
	Dry Mouth		Lioresal	SS	Novartis Sector: Pharma	ORAL	2 tablets, BID	4320 MIN
	Dysphagia							
	Eye Disorder							
	Hallucination		Lioresal	SS	Novartis Sector: Pharma	ORAL	2 tablets, TID	2880 MIN
	Hyperhidrosis							
	Infrequent Bowel Movements		Lioresal	SS	Novartis Sector: Pharma	ORAL	1 tablet/day	5760 MIN
	Insomnia							
	Lethargy		Domperidone	C			UNKNOWN	
	Mood Swings							
	Paranoia							
	Thyroid Function Test Abnormal							
	Urine Output Decreased							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/19/04ISR Number: 4343705-3Report Type:Expedited (15-DaCompany Report #KII-2004-0009468
Age:30 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Acidosis	Study	Oxycodone Hydrochloride	PS		ORAL	ORAL	
Other	Increased	Professional	Hydrocodone W/Acetaminophen	SS		ORAL	ORAL	
	Anion Gap Increased	Other	Baclofen (Baclofen)	SS		ORAL	ORAL	
	Aspartate							
	Aminotransferase Increased							
	Asthenia							
	Blood Bicarbonate Decreased							
	Blood Bilirubin Increased							
	Blood Potassium Decreased							
	Blood Pressure Systolic Decreased							
	Body Temperature Decreased							
	Chromaturia							
	Coma							
	Convulsion							
	Diarrhoea							
	Drug Screen Positive							
	Eye Rolling							
	Heart Rate Decreased							
	Heart Rate Increased							
	Liver Disorder							
	Multiple Drug Overdose							
	Mydriasis							
	Oliguria							
	Prothrombin Time Prolonged							
	Pupil Fixed							
	Rhonchi							
	Vomiting							

Date:04/19/04ISR Number: 4344071-XReport Type:Expedited (15-DaCompany Report #20031649
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Coma	Foreign	Lioresal Intrathecal					
	Device Failure	Health	(Baclofen Injection)					
	Hypertonia	Professional	2000mcg/Ml	PS				
INTRATHECAL							MCG,	DAILY,
	Hypotonia							
INTRATHECAL								
	Proteus Infection		Antibiotics	C				
	Respiratory Failure		Dexamethasone	C				
	Urosepsis							

Date:04/21/04ISR Number: 4343187-1Report Type:Expedited (15-DaCompany Report #PHRM2004FR01508
Age:64 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Dermatitis Exfoliative		Lioresal	PS	Novartis Sector:			
Initial or Prolonged	Erythema				Pharma	ORAL		
5 mg, TID							12960MIN	
	Pruritus		Augmentin Injection	SS				
INTRAVENOUS							1 g, TID	11520MIN
	Purpura		Pyostacine	SS		ORAL		
1000 mg, BID							2880 MIN	
	Rash Maculo-Papular		Gentalline	C				
INTRAVENOUS							1 DF, TID	10080MIN
			Oflocet	C		ORAL		
200 mg, BID							11520MIN	

			Loxen	C		ORAL
150 mg/day						
			Insulatard	C		
SUBCUTANEOUS						
			Humalog	C		
SUBCUTANEOUS						

Date:04/21/04ISR Number: 4345636-1Report Type:Expedited (15-DaCompany Report #20041811
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Blood Pressure Ambulatory Abnormal	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		
INTRATHECAL MCG, DAILY ,						
	Coma					
INTRATHECAL						
	Medication Error					
	Overdose					
	Somnolence					

Date:04/21/04ISR Number: 4345637-3Report Type:Expedited (15-DaCompany Report #20041748
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Cerebrospinal Fluid Leakage	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		
INTRATHECAL MCG, DAILY,						
	Lymphoedema					
INTRATHECAL						
	Meningitis					

Date:04/23/04ISR Number: 4344763-2Report Type:Expedited (15-DaCompany Report #PHBS2004IE05132
Age: Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Gastrointestinal Haemorrhage		Lioresal	PS	Novartis Sector: Pharma	ORAL

Date:04/28/04ISR Number: 4349760-9Report Type:Expedited (15-DaCompany Report #04-04-0599
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cerebrovascular Accident	Foreign	Baclofen-Ipi Tablets	PS	Ipi		5MG TID	
Other	Coma	Other	Aspirin	C				
	Musculoskeletal Stiffness		Trimethoprim	C				
	Renal Impairment		Salbutamol	C				
	Sudden Death		Oxybutynin	C				

Date:04/29/04ISR Number: 4350043-1Report Type:Expedited (15-DaCompany Report #PHFR2004GB01654
Age:74 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anaemia		Baclofen	PS	Novartis Sector: Pharma	ORAL	20 mg, TID	
	Duodenal Ulcer							
	Haemorrhage		Oxybutynin	C		ORAL	2.5 mg, BID	
	Haemorrhage		Rabeprazole	C		ORAL	10 mg/day	
	Nephrolithiasis		Ferrous Gluconate	C		ORAL	UNK, PRN	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/29/04ISR Number: 4352673-XReport Type:Expedited (15-DaCompany Report #20041819
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Weight Decreased	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		INTRATHECAL	MCG, DAILY, INTRATHECAL	

Date:04/29/04ISR Number: 4353011-9Report Type:Expedited (15-DaCompany Report #20041818
Age: Gender: I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Bradycardia	Foreign	Lioresal Intrathecal					
	Cardiac Arrest	Health	(Baclofen Injection)	PS		INTRATHECAL	DAILY, INTRATHECAL	
	Pain	Professional						
	Procedural Complication							
	Syncope Vasovagal							

Date:05/04/04ISR Number: 4353176-9Report Type:Direct Company Report #CTU 217952
Age:41 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Neutropenia		Baclofen 10 Mg And 15 Mg	PS			10-15 MG TID -QID BY MOUTH	

Date:05/06/04ISR Number: 4353892-9Report Type:Expedited (15-DaCompany Report #PHFR2004GB01886
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Other	Atrioventricular Block		Baclofen	PS	Novartis Sector: Pharma	
			Dantrolene	C		

Date:05/07/04ISR Number: 4356502-XReport Type:Expedited (15-DaCompany Report #PHBS2004NL05381
Age:40 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
	Dysgeusia	Health	Lioresal (Baclofen)			
	Parosmia	Professional	Solution For			
		Other	Injection	PS		
			Nifedipine (Nifedipine)	C		
			Amiloride W/Hydrochlorothiazide (Amiloride)	C		
			Tramadol (Tramadol)	C		
			Carbamazepine (Carbamazepine)	C		

Date:05/14/04ISR Number: 4358475-2Report Type:Expedited (15-DaCompany Report #PHBS2004IE05132
Age: Gender:Unknown I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Gastrointestinal Haemorrhage		Lioresal	PS	Novartis Sector: Pharma	ORAL

5 mg, BID

			Dantrolene	C		
UNKNOWN	UNK, UNK					

Date:05/17/04ISR Number: 4359226-8Report Type:Direct Company Report #CTU 218739
Age:61 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Mental Status Changes		Baclofen	PS		
10 MG QID						
Initial or Prolonged			Oxycodone	C		
			Fentanyl	C		
			Temazepam	C		

Date:05/17/04ISR Number: 4359684-9Report Type:Direct Company Report #CTU 218832
Age:48 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
	Weight Increased		Baclofen 20 Mg 6			
			Times A Day Zenith	PS	Zenith	
			Nadolol 80 Mg A Day			
			Mylan	SS	Mylan	
			Lipitor 10 Mg A D			
			Oral	SS		
			Amitriptylin 50 Mg			
			Ad Oral	SS		

Date:05/17/04ISR Number: 4360834-9Report Type:Expedited (15-DaCompany Report #PHRM2004FR00853
Age:48 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Headache	Health	Lioresal Intrathecal			
Initial or Prolonged	Hyperhidrosis	Professional	(Baclofen) Solution			
	Hypotension	Other	For Injection	PS		
INTRATRACHEAL 50 UG,						
	Ileus Paralytic					
ONCE/SINGLE,						
	Urinary Retention					
INTRATHECAL 1 DAY						

				Forlax (Macrogol) Powder	C		

Date:05/17/04ISR Number: 4360835-0Report Type:Expedited (15-DaCompany Report #PHRM2004FR01564
Age:78 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Hospitalization - Initial or Prolonged	Coma Depressed Level Of Consciousness	Health Professional Other	Lioresal Intratecal (Baclofen) Solution For Injection	PS		INTRATHECAL	INTRATHECAL	
	Drug Level Above Therapeutic Escherichia Infection Implant Site Infection Interstitial Lung Disease Kussmaul Respiration Meningitis Bacterial Miosis Musculoskeletal Stiffness Pneumonia Aspiration Shock		Lopril (Captopril) Nozinan (Levomepromazine Maleate) Captea (Captopril, Hydrochlorothiazide) Tablet	C C C				

Date:05/17/04ISR Number: 4361020-9Report Type:Expedited (15-DaCompany Report #20041833
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Catheter Related Complication	Foreign Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		INTRATHECAL	DAILY,	
	Device Failure					INTRATHECAL		
	Drug Ineffective							
	Meningitis							
	Overdose							

Date:05/17/04ISR Number: 4362222-8Report Type:Expedited (15-DaCompany Report #20041833
Age: Gender: I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Catheter Related Complication	Foreign Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		INTRATHECAL	MCG, DAILY,	
	Device Failure					INTRATHECAL		
	Device Ineffective							
	Overdose							

Date:05/18/04ISR Number: 4359916-7Report Type:Expedited (15-DaCompany Report #PHFR2004GB01886
Age:42 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Atrioventricular Block		Baclofen	PS	Novartis Sector: Pharma	ORAL		
	Cardiac Arrest							
	Convulsion		Dantrolene	SS		ORAL		
	Electrocardiogram Pr Prolongation							

Date:05/19/04ISR Number: 4360118-9Report Type:Expedited (15-DaCompany Report #PHBS2003CH14515
Age:67 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Creatinine Increased	Health Professional	Lioresal	PS	Novartis Sector: Pharma	ORAL	10 mg, TID	2880 MIN
Other	Bradycardia		Temesta	SS			UNKNOWN	1 mg/day 1440 MIN
	Coma		Floxapen	C		INTRAVENOUS		
	Drug Interaction					DRIP	6 g	
	Drug Level Decreased		Insulin	C			UNKNOWN	
	Fall		Actrapid	C			UNKNOWN	
	Somnolence		Benerva	C			UNKNOWN	
	Stupor		Prednisone	C			UNKNOWN	50 mg/day
			Diuretics	C			UNKNOWN	

Date:05/19/04ISR Number: 4360124-4Report Type:Expedited (15-DaCompany Report #PHFR2004GB01654
Age:74 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anaemia	Health Professional	Baclofen	PS	Novartis Sector: Pharma	ORAL	20 mg, TID	
	Duodenal Ulcer		Oxybutynin	C		ORAL	2.5 mg, BID	
	Haemorrhage		Rabeprazole	C		ORAL	10 mg/day	
	Nephrolithiasis		Ferrous Gluconate	C		ORAL	UNK, PRN	
			Lactulose	C		ORAL		

Date:05/19/04ISR Number: 4364533-9Report Type:Expedited (15-DaCompany Report #PHFR2004GB01886
Age: Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Atrioventricular Block	Health Professional Other	Baclofen (Baclofen) Unknown Dantrolene (Dantrolene)	PS C				

Date:05/28/04ISR Number: 4368551-6Report Type:Expedited (15-DaCompany Report #PHFR2004GB01886
Age:42 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Atrioventricular Block	Foreign	Baclofen					
	Cardiac Arrest	Health	(Baclofen)	PS		ORAL		
ORAL								
	Convulsion	Professional	Dantrolene					
	Electrocardiogram Pr	Other	(Dantrolene)	SS		ORAL		
ORAL								
	Prolongation							

Date:05/28/04ISR Number: 4369769-9Report Type:Expedited (15-DaCompany Report #20041849
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Chills	Health	Lioresal Intrathecal					
	Confusional State	Professional	(Baclofen Injection)	PS		INTRATHECAL	MCG, DAILY,	
	Drug Withdrawal Syndrome							
INTRATHECAL								
	Hallucination							
	Medication Error							
	Muscle Spasms							
	Pyrexia							

Date:06/02/04ISR Number: 4368570-XReport Type:Expedited (15-DaCompany Report #BE-JNJFOC-20040403804
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Drug Interaction	Foreign	Durogesic (Fentanyl)					
Hospitalization - Initial or Prolonged	Encephalitis Insomnia	Health Professional	Patch	PS		TRANSDERMAL	100 UG/HR, TRANSDERMAL	
	Meningitis		Lioresal (Baclofen)					
	Myalgia		Tablets	SS		ORAL	10 MG, 3 IN 1 DAY, ORAL	
	Refusal Of Treatment By Patient Refusal Of Treatment By Relative Respiratory Depression		Voltaren (Diclofenac Sodium)	C				

Date:06/02/04ISR Number: 4371696-8Report Type:Expedited (15-DaCompany Report #20041785
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Creatine Phosphokinase Increased Drug Withdrawal Syndrome Hypertonia Muscle Spasticity Pyrexia Tachycardia	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		INTRATHECAL	UNK MCG, DAILY; INTRATHECAL	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/02/04ISR Number: 4371993-6Report Type:Expedited (15-DaCompany Report #PHBS2004SE06272
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Blood Alkaline Phosphatase Increased	Health Professional	Lioresal (Baclofen)	PS				
	Transaminases Increased	Other						

Date:06/03/04ISR Number: 4369014-4Report Type:Expedited (15-DaCompany Report #PHNU2004DE01939
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hyponatraemia Inappropriate Antidiuretic Hormone Secretion		Lioresal	PS	Novartis Sector: Pharma	UNKNOWN		
	Pneumonia							

Date:06/03/04ISR Number: 4371662-2Report Type:Direct Company Report #CTU 220055
Age:60 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Implant Site Reaction		Baclofen	PS				
	Medication Error		Radiation	SS				

Date:06/04/04ISR Number: 4371402-7Report Type:Expedited (15-DaCompany Report #04-06-0788
Age:42 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Cardio-Respiratory Arrest	Foreign	Baclofen - Ipi					
	Convulsion	Other	Tablets	PS	Ipi	ORAL	ORAL	
	Electrocardiogram Pr Prolongation		Dantrolene	SS		ORAL	ORAL	

Date:06/07/04ISR Number: 4375669-0Report Type:Expedited (15-DaCompany Report #20041867
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Central Nervous System Infection	Health Professional	Lioresal (Baclofen Injection)	PS		INTRATHECAL	DAILY,	
	White Blood Cell Count Increased					INTRATHECAL		

Date:06/08/04ISR Number: 4374396-3Report Type:Direct Company Report #CTU 220306
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardiac Arrest		Baclofen	PS				
	Infusion Related Reaction							

Date:06/09/04ISR Number: 4375823-8Report Type:Direct Company Report #CTU 220433
Age:55 YR Gender:Male I/FU:I

Outcome
Hospitalization - Initial or Prolonged

Other

	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Multiple Drug Overdose		Morphine	PS				
			Baclofen	SS				

Date:06/09/04ISR Number: 4377999-5Report Type:Expedited (15-DaCompany Report #UKP04000167
Age:42 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Atrioventricular Block	Foreign	Dantrium (Dantrolene					
	Cardiac Arrest	Health	Sodium)	PS		ORAL	25 MG, 3/DAY,	
	Convulsion	Professional					ORAL	
	Electrocardiogram Pr	Other	Baclofen (Baclofen)	SS		ORAL	ORAL	
	Prolongation							

Date:06/10/04ISR Number: 4375216-3Report Type:Expedited (15-DaCompany Report #PHRM2004FR01508
Age:64 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dermatitis Exfoliative Erythema		Lioresal	PS	Novartis Sector: Pharma	ORAL	5 mg, TID	12960MIN
	Pruritus		Augmentin Injection	SS			INTRAVENOUS	1 g, TID 11520MIN
	Purpura		Pyostacine	SS		ORAL	1000 mg, BID	2880 MIN
	Rash Maculo-Papular		Gentalline	C			INTRAVENOUS	1 DF, TID 10080MIN
			Oflocet	C		ORAL	200 mg, BID	11520MIN
			Loxen	C		ORAL	150 mg/day	
			Insulatard	C			SUBCUTANEOUS	8640 MIN
			Humalog	C			SUBCUTANEOUS	8640 MIN

			Tenormine	C		ORAL
100 mg/day						
			Zestril	C		ORAL
20 mg/day						
			Mediatensyl	C		ORAL
60 mg/day						
			Esidrex	C		ORAL
			Lovenox	C		
SUBCUTANEOUS	20160MIN					

Date:06/10/04ISR Number: 4375217-5Report Type:Expedited (15-DaCompany Report #PHFR2004GB02316
Age:41 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Swollen Tongue		Baclofen	PS	Novartis Sector: Pharma	ORAL	5 mg, TID	5760 MIN

Date:06/10/04ISR Number: 4375566-0Report Type:Expedited (15-DaCompany Report #PHHO2004DE07738
Age:57 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blood Creatinine Increased	Health Professional	Baclofen	PS	Novartis Sector: Pharma	ORAL		
	Creatinine Renal Clearance Decreased		Sti 571 Vs Ifn-Alpha + Cytarabine	SS		ORAL	400 mg, QD	
			Diclo-Phlogont	SS		ORAL		
			Voltaren	SS		ORAL		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/10/04ISR Number: 4379335-7Report Type:Expedited (15-DaCompany Report #KII-2004-0011034
Age:39 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Aggression Blood Pressure Diastolic Decreased Blood Pressure Increased	Study Health Professional Other	Oxycontin Tablets (Oxycodone Hydrochloride) Cr Tablet	PS		ORAL		
	Heart Rate Increased Intentional Misuse		Other Hypnotics And Sedatives ()	SS		ORAL		
	Metabolic Acidosis Respiratory Acidosis		Neurontin (Gabapentin)	SS		ORAL		
	Respiratory Rate		Ssri()	SS		ORAL		
	Increased		Baclofen (Baclofen)	SS		ORAL		
	Urine Cannabinoids Increased		Trazodone (Trazodone)	SS		ORAL		
	Vomiting		Tetrahydrocannabinol (Tetrahydrocannabinol)	SS				

Date:06/15/04ISR Number: 4381680-6Report Type:Expedited (15-DaCompany Report #KII-2004-0011112
Age:52 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Abnormal Behaviour Aggression Agitation Anger	Study Health Professional Other	Oxycontin Tablets(Oxycodone Hydrochloride) Cr Tablet	PS		ORAL		
	Aspartate Aminotransferase Increased		Benzodiazepine Derivatives ()	SS		ORAL		
	Back Pain Blood Alkaline		Baclofen (Baclofen)	SS		ORAL		
			Docusate Sodium (Docusate Sodium)	SS		ORAL		

Phosphatase Increased		Marijuana (Cannabis)	SS
Blood Glucose Increased		Tricyclic Antidepressants()	SS
Blood Pressure Systolic Increased		Ultram (Tramadol Hydrochloride)	SS
Blood Urea Increased		Antiepileptics ()	SS
Body Temperature Decreased			
Convulsion			
Delirium			
Disorientation			
Drug Abuser			
Drug Withdrawal Syndrome			
Grunting			
Hyperhidrosis			
Loss Of Consciousness			
Moaning			
Overdose			
Patient Restraint			
Pupillary Reflex Impaired			
Somnolence			
Stupor			
Tremor			
Urinary Incontinence			
White Blood Cell Count Increased			
White Blood Cells Urine Positive			

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/15/04ISR Number: 4381949-5Report Type:Expedited (15-DaCompany Report #PHHO2004DE07738
Age:57 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blood Creatinine Increased	Foreign Study	Lioresal	PS		ORAL	400 MG, QD,	ORAL
	Creatinine Renal Clearance Decreased	Health Professional	Voltaren (Diclofenac Resinate)	SS		ORAL		ORAL
		Other	Baclofen (Baclofen)	SS		ORAL		ORAL
			Diclo-Phlogont (Diclofenac Sodium)	SS		ORAL		ORAL

Date:06/15/04ISR Number: 4382009-XReport Type:Expedited (15-DaCompany Report #PHNU2004DE01939
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hyponatraemia Inappropriate Antidiuretic Hormone Secretion Pneumonia	Health Professional Other	Lioresal (Baclofen)	PS				

Date:06/16/04ISR Number: 4378730-XReport Type:Expedited (15-DaCompany Report #PHNU2004DE01939
Age:56 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hyponatraemia Inappropriate Antidiuretic Hormone Secretion Pneumonia		Lioresal	PS	Novartis Sector: Pharma	ORAL	80mg/day	

Date:06/16/04ISR Number: 4382709-1Report Type:Expedited (15-DaCompany Report #D-04-023
Age:82 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Coordination Abnormal	Consumer	Baclofen 10 Mg; Usl	PS		ORAL	5 MG TID PO	
	Hallucination		Alprazolam	C				
	Loss Of Consciousness		Aricept	C				
	Pneumonia		Neurontin	C				
			Oxycontin	C				
			Trazdone 50 Mg Qhs (From Unk Contin)	C				
			Endocet	C				
			Morphine Pca Intrathecal (From Unk (Contin))	C				

Date:06/18/04ISR Number: 4380727-0Report Type:Expedited (15-DaCompany Report #PHBS2004BR07749
Age:25 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blood Creatine Phosphokinase Increased		Baclofen	PS	Novartis Sector: Pharma		UNKNOWN	
	Dystonia		Carbamazepine	SS			UNKNOWN	
	Viral Infection		Trihexyphenidyl	SS			UNKNOWN	
			Clonazepam	SS			UNKNOWN	
			Tetrabenazine	C			UNKNOWN	

				Flurazepam	C		
UNKNOWN							
				Clobazam	C		
				Pimozide	C		
UNKNOWN							

Date:06/18/04ISR Number: 4383581-6Report Type:Expedited (15-DaCompany Report #20040600315
Age:54 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Gastrointestinal Disorder	Health	Duramorph (Morphine					
Hospitalization -	Hypotension	Professional	Sulfate, Baxter)	PS	Baxter			
Initial or Prolonged	Mental Status Changes		Baclofen	SS				
Required	Overdose		Ambien	C				
Intervention to	Pneumonia Aspiration		Amitriptyline	C				
Prevent Permanent	Pyrexia		Coumadin	C				
Impairment/Damage	Respiratory Failure		Ocybutynin	C				
			Valium	C				
			Lipitor	C				
			Macrodantin	C				
			Neurontin	C				
			Prozac	C				
			Zanaflex	C				
			Miralax	C				
			Peri-Colace	C				

Date:06/21/04ISR Number: 4383929-2Report Type:Expedited (15-DaCompany Report #20041867
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Central Nervous System	Health	Lioresal					
	Infection	Professional	(Baclofen Injection)	PS				
INTRATHECAL							DAILY,	
INTRATHECAL								

Date:06/21/04ISR Number: 4385114-7Report Type:Expedited (15-DaCompany Report #PHNU2003DE04094
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Drug Ineffective	Foreign	Lioresal Intrathecal					
	Drug Withdrawal Syndrome	Health	(Baclofen)	PS				
INTRATHECAL	TEST DOSE;							
	Electroencephalogram	Professional						
INTRATHECAL								
	Abnormal	Other						
	Intracranial Pressure							
	Increased							
	Medical Device							
	Complication							
	Sudden Death							

Date:06/25/04ISR Number: 4387715-9Report Type:Expedited (15-DaCompany Report #20041897
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Headache	Health	Lioresal					
Initial or Prolonged	Intentional Misuse	Professional	Intrathecal(Baclofen					
	Suicide Attempt		Injection)	PS				
INTRATHECAL	UNK MCG,							
DAILY,								
INTRATHECAL								
			Oral Baclofen	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/25/04ISR Number: 4387721-4Report Type:Expedited (15-DaCompany Report #20041895
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Coma Csf Culture Positive Culture Wound Positive Meningitis Sepsis Staphylococcal Infection Streptococcal Infection	Health Professional	Lioresal Intrathecal(Baclofen Injection)	PS		INTRATHECAL	UNK MCG, DAILY, INTRATHECAL	

Date:06/25/04ISR Number: 4387723-8Report Type:Expedited (15-DaCompany Report #20041903
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Burning Sensation Dysgeusia Hypoaesthesia Oedema Peripheral Pain	Health Professional	Lioresal Intrathecal(Baclofen Injection)	PS		INTRATHECAL	UNK MCG, DAILY, INTRATHECAL	
			Dilaudid	C				

Date:06/25/04ISR Number: 4387724-XReport Type:Expedited (15-DaCompany Report #20041860
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Catheter Related Complication Confusional State Convulsion	Health Professional	Lioresal Intrathecal(Baclofen Injection)	PS		INTRATHECAL	UNK MCG, DAILY,	

	Enterococcal Sepsis
INTRATHECAL	
	Headache
	Hypertonia
	Hypotension
	Medication Error
	Post Procedural
	Complication
	Pruritus
	Self-Medication
	Urinary Tract Infection

Date:06/25/04ISR Number: 4388266-8Report Type:Expedited (15-DaCompany Report #PHHO2004US00786
Age:55 YR Gender:Male I/FU:I

Outcome	PT
Death	Confusional State
Hospitalization -	Crepitations
Initial or Prolonged	Decreased Appetite
	Dehydration
	Dyspnoea
	Hyperkalaemia
	Hyponatraemia
	Hypotension
	Hypoxia
	Infection
	Malignant Neoplasm
	Progression
	Neurological Symptom

	Oral Intake Reduced Renal Failure Acute Respiratory Distress	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Somnolence Urinary Tract Infection Enterococcal Urine Output Decreased	Study	Baclofen (Baclofen, Baclofen) Glivec (Sti571/Cgp57148b T35717+Caps) Capsule	PS SS		ORAL	500 MG, QD ORAL
			Remeron (Mirtazapine) Lovenox (Heparin-Fraction, Sodium Salt) Thorazine (Chlorpromazine Hydrochloride) Paxil (Paroxetine Hydrochloride)	SS C C C			

Date:06/28/04ISR Number: 4389093-8Report Type:Expedited (15-DaCompany Report #US-SHR-03-019043
Age:62 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Coma Injection Site Cellulitis	Consumer	Betaseron (Interferon Beta-1b) Injection, 250mcg	PS		SUBCUTANEOUS	8 MIU, EVERY 2D, HS, SUBCUTANEOUS
			Baclofen (Baclofen)	SS			

Date:06/28/04ISR Number: 4390332-8Report Type:Expedited (15-DaCompany Report #2004040267
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration

Hospitalization - Initial or Prolonged	Abdominal Pain Upper	Consumer	Neurontin (Gabapentin)	PS	ORAL
ORAL Other 25 MG (2 IN 1 D)	Abnormal Behaviour				
	Condition Aggravated		Diazepam (Diazepam)	SS	
	Drug Ineffective				
	Drug Interaction		Baclofen (Baclofen)	SS	
	Drug Withdrawal Syndrome		All Other Therapeutic Products (All Other Therapeutic Products)	SS	
	Feeling Abnormal				
	Hallucination				
	Medication Error				
	Mental Disorder				
	Pyrexia		Oxybutynin Hydrochloride (Oxybutynin Hydrochloride)	C	
			Warfarin Sodium (Warfarin Sodium)	C	
			Potassium (Potassium)	C	
			Fluticasone Propionate (Fluticasone Propionate)	C	
			Combivent (Ipratropium		

			Bromide, Salbutamol Sulfate)	C		

Date:07/08/04ISR Number: 4392851-7Report Type:Expedited (15-DaCompany Report #PHBS2004JP08731
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Deep Vein Thrombosis		Lioresal	PS	Novartis Sector: Pharma			

Date:07/13/04ISR Number: 4395433-6Report Type:Expedited (15-DaCompany Report #PHRM2004FR02278
Age:66 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Arrhythmia Bradycardia	Health Professional	Lioresal	PS	Novartis Sector: Pharma	ORAL	35 mg/day	
	Dyspnoea							

Date:07/13/04ISR Number: 4395441-5Report Type:Expedited (15-DaCompany Report #PHBS2004JP08731
Age: Gender: I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Deep Vein Thrombosis	Health Professional	Lioresal	PS	Novartis Sector: Pharma			

Date:07/16/04ISR Number: 4406641-XReport Type:Expedited (15-DaCompany Report #REFE00204002334
Age:60 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Blood Pressure Decreased	Foreign	Cannador (Cannador)	PS		ORAL	10 MG DAILY	
	Circulatory Collapse	Study					PO, 10 MG	

	Pulse Absent	Health				
DAILY PO						
	Sinus Bradycardia	Professional	Baclofen (Baclofen)	SS		ORAL
30 MG DAILY						
		Other				
PO						

Date:07/16/04ISR Number: 4406642-1Report Type:Expedited (15-DaCompany Report #DRON00204002327
Age:50 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Circulatory Collapse	Foreign	Marinol (Dronabinol)	PS		ORAL
2.5 MG BID,						
	Confusional State	Study				
PO						
	Somnolence	Health	Amitripytline			
	Speech Disorder	Professional	(Amitriptyline)	SS		ORAL
200 MG DAILY						
		Other				
PO						
			Baclofen (Baclofen)	SS		ORAL
70 MG DAILY						
PO						
			Tizanidine			
			(Tizanidine)	SS		ORAL
32 MG DAILY						
PO						

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/20/04ISR Number: 4402845-0Report Type:Direct Company Report #CTU 223124
Age:78 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Abnormal Dreams		Baclofen	PS		ORAL	5 MG PO TID X	
	Coma						3 D , 10 MG	
	Dysphagia						TID X 3D, 20	
	Hallucination						MG TID X 2 D	
	Oral Intake Reduced		Sinemet	C				
	Physical Examination Abnormal		Zoloft	C				
	Speech Disorder							

Date:07/21/04ISR Number: 4403689-6Report Type:Expedited (15-DaCompany Report #PHFR2004GB02844
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Peptic Ulcer		Baclofen	PS	Novartis Sector: Pharma		20 mg, BID	

Date:07/26/04ISR Number: 4407380-1Report Type:Expedited (15-DaCompany Report #PHBS2004US09673
Age:32 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Haemoglobin Decreased	Health Professional	Baclofen	PS	Novartis Sector: Pharma			
Other	Haemolysis		Zanaflex $El	SS		ORAL	36 mg/d	
			Neurontin	C			UNKNOWN	
			Ditropan	C			UNKNOWN	

Date:07/29/04ISR Number: 4413959-3Report Type:Expedited (15-DaCompany Report #PHBS2004JP08731
Age: Gender: I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Deep Vein Thrombosis	Health Professional Other	Lioresal (Baclofen)	PS				

Date:07/29/04ISR Number: 4414463-9Report Type:Expedited (15-DaCompany Report #2004-DE-03937GD
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Congenital Anomaly	Drug Exposure During Pregnancy	Foreign Literature	Ibuprofen (Ibuprofen)	PS		INTRA-UTERINE	IU	
	Ventricular Septal Defect		Paracetamol (Paracetamol)	SS		INTRA-UTERINE	IU	
			Diazepam (Diazepam)	SS		INTRA-UTERINE	IU	
			Baclofen (Baclofen)	SS		INTRA-UTERINE	IU	

Date:07/29/04ISR Number: 4414651-1Report Type:Expedited (15-DaCompany Report #20031586
Age:9 YR Gender:Male I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Bruxism Catheter Related Complication Device Failure

		Granuloma Muscle Rigidity					
			Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
			Health Professional	Lioresal Intrathecal(Baclofen Injection)	PS		
INTRATRACHEAL	DAILY, INTRATHECAL						

Date:07/29/04ISR Number: 4414672-9Report Type:Expedited (15-DaCompany Report #20041759
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Required Intervention to Prevent Permanent INTRATHECAL Impairment/Damage	Meningitis	Health Professional	Lioresal Intrathecal(Baclofen Injection)	PS		

Date:07/29/04ISR Number: 4414673-0Report Type:Expedited (15-DaCompany Report #20041923
Age:20 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Death	Health Professional	Lioresal Intrathecal9baclofen Injection)	PS		
INTRATHECAL DAILY, INTRATHECAL						

Date:08/05/04ISR Number: 4422425-0Report Type:Expedited (15-DaCompany Report #PHBS2004US09673
Age:32 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Life-Threatening	Glucose-6-Phosphate Dehydrogenase Deficiency	Foreign Health	Zanaflex $El (Tizanidine			

	Haemoglobin Decreased	Professional	Hydrochloride)	PS		ORAL
36 MG/D						
	Haemolysis	Other	Baclofen (Baclofen)	SS		
			Neurontin (Gabapentin)	C		
			Ditropan (Oxybutynin Hydrochloride)	C		

Date:08/10/04ISR Number: 4425814-3Report Type:Expedited (15-DaCompany Report #2004033685
Age:43 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Completed Suicide	Foreign	Neurontin			
Other	Drug Level Above	Health	(Gabapentin)	PS		ORAL
ORAL						
	Therapeutic	Professional	Baclofen (Baclofen)	SS		
	Intentional Misuse					
	Muscle Relaxant Drug Level Above Therapeutic					
	Victim Of Homicide					

Date:08/12/04ISR Number: 4426046-5Report Type:Expedited (15-DaCompany Report #04-08-1139
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Peptic Ulcer	Foreign	Baclofen	PS	Ipi	ORAL	20MG BD	
		Health Professional Other						

Date:08/18/04ISR Number: 4431484-0Report Type:Expedited (15-DaCompany Report #20041951
Age:32 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	Drug Ineffective Drug Tolerance Decreased Fluid Retention Muscle Spasms Pyrexia Seroma	Health Professional	Lioresal Intrathecal(Baclofen Injection)	PS			45 MCG, DAILY, INTRACHECAL	

Date:08/19/04ISR Number: 4429617-5Report Type:Expedited (15-DaCompany Report #PHRM2004FR02278
Age:66 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Arrhythmia Bradycardia		Lioresal	PS	Novartis Sector: Pharma	ORAL	45 mg/day	
	Dyspnoea		Lioresal	SS	Novartis Sector: Pharma	ORAL	30 mg/day	

Date:08/23/04ISR Number: 4433088-2Report Type:Expedited (15-DaCompany Report #ZANA001328
Age:69 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Amnesia Blood Creatine Phosphokinase Increased Carotid Artery Stenosis Confusional State Delirium Encephalopathy Mental Status Changes Overdose Pain In Extremity Urinary Tract Infection	Health Professional Other	Zanaflex (Tizanidine Hydrochloride) Copaxone (Glatiramer Acetate) Baclofen (Baclofen)	PS SS SS		ORAL SUBCUTANEOUS ORAL	4 MG 20 MG DAILY, 14 TO 20 MG	

Date:08/24/04ISR Number: 4431077-5Report Type:Expedited (15-DaCompany Report #PHBS2004IE10906
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dyskinesia Infection Muscle Spasticity		Lioresal Lioresal	PS SS	Novartis Sector: Pharma Novartis Sector: Pharma	ORAL ORAL	240 mg/day 180 mg/day	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/26/04ISR Number: 4434050-6Report Type:Expedited (15-DaCompany Report #PHHO2004DE07738
Age:57 YR Gender:Unknown I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blood Creatinine Increased Creatinine Renal Clearance Decreased		Baclofen	PS	Novartis Sector: Pharma	ORAL		
			Sti 571 Vs Ifn-Alpha + Cytarabine	SS		ORAL	400 mg, QD	
			Diclo-Phlogont	SS		ORAL		
			Voltaren	SS		ORAL		

Date:09/02/04ISR Number: 4440038-1Report Type:Expedited (15-DaCompany Report #PHBS2004ZA11247
Age:14 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agitation Circulatory Collapse Coordination Abnormal Extraocular Muscle Disorder Nystagmus Overdose Respiratory Disorder		Lioresal	PS	Novartis Sector: Pharma			

Date:09/02/04ISR Number: 4441115-1Report Type:Direct Company Report #CTU 226232
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Convulsion		Baclofen 10 Mg Tablet	PS		ORAL	10 MG TID PO	

Date:09/03/04ISR Number: 4440504-9Report Type:Expedited (15-DaCompany Report #PHBS2004GB11400
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Other	Drug Exposure During Pregnancy		Baclofen	PS	Novartis Sector: Pharma	
TRANSPLACENTAL						
	Foetal Distress Syndrome		Diazepam	SS		
TRANSPLACENTAL						

Date:09/03/04ISR Number: 4440511-6Report Type:Expedited (15-DaCompany Report #PHBS2004US11398
Age:16 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Depressed Level Of Consciousness	Health Professional	Baclofen	PS	Novartis Sector: Pharma	
UNKNOWN						
	Dizziness		Tizanidine Hydrochloride	SS		
	Tachycardia					
UNKNOWN						
			Nortriptyline Hydrochloride	SS		
UNKNOWN						
			Gabapentin	SS		
UNKNOWN						
			Phenelzine	SS		
UNKNOWN						
			Ketorolac	SS		
UNKNOWN						
			Bethanechol	SS		
UNKNOWN						
			Olanzapine	SS		
UNKNOWN						

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/07/04ISR Number: 4442884-7Report Type:Direct Company Report #CTU 226404
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Mental Status Changes		Baclofen	PS				

Date:09/07/04ISR Number: 4444808-5Report Type:Direct Company Report #CTU 226505
Age:28 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Psychotic Disorder		Baclofen	PS		ORAL	20 MG TID PO	

Date:09/13/04ISR Number: 4448171-5Report Type:Expedited (15-DaCompany Report #PHRM2004FR02721
Age:50 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Alanine Aminotransferase Increased		Lioresal	PS	Novartis Sector: Pharma	ORAL	20 mg, TID	7200 MIN
	Aspartate Aminotransferase Increased		Di-Hydan	SS		ORAL	100 mg, 5QD	17280MIN
	Blood Alkaline Phosphatase Increased							
	Cytolytic Hepatitis							
	Gamma-Glutamyltransferase Increased							

Date:09/14/04ISR Number: 4448423-9Report Type:Expedited (15-DaCompany Report #PHBS2004ZA11247
Age:14 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Hospitalization - Initial or Prolonged	Agitation Blood Chloride Increased Blood Lactate Dehydrogenase Increased Blood Sodium Decreased Blood Urea Decreased Circulatory Collapse Coma Coordination Abnormal Excitability Extraocular Muscle Disorder Nystagmus Overdose Pco2 Decreased Respiratory Disorder		Lioresal Benzodiazepines Barbiturates Tricyclic Antidepressants	PS SS SS SS			UNK, ONCE/SINGLE 1440 MIN

Date:09/14/04ISR Number: 4450378-8Report Type:Expedited (15-DaCompany Report #PHNU2004DE02865
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Pyrexia	Health Professional Other	Lioresal Intrathecal (Baclofen) Unknown	PS		INTRATHECAL	600 NG/DAY; 150 NG/DAY; INTRATHECAL	

Valproate Sodium (Valproate Sodium)	C
Topamax (Topiramate)	C
Sodium Chloride (Sodium Chloride)	C

Date:09/14/04ISR Number: 4450580-5Report Type:Expedited (15-DaCompany Report #20041964
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to	Convulsion Muscle Spasticity	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		INTRATHECAL	MCG, DAILY,	
Prevent Permanent Impairment/Damage	Sepsis					INTRATHECAL		

Date:09/16/04ISR Number: 4454305-9Report Type:Direct Company Report #CTU 227407
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Mental Status Changes		Baclofen	PS				

Date:09/23/04ISR Number: 4457242-9Report Type:Expedited (15-DaCompany Report #PHFR2004GB03536
Age:4 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Extrapyramidal Disorder Facial Spasm		Baclofen	PS	Novartis Sector: Pharma		20 mg, TID	
Other	Muscle Spasms		Benzhexol	C				

Date:09/28/04ISR Number: 4462221-1Report Type:Expedited (15-DaCompany Report #04-09-1315
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Exposure During Pregnancy Foetal Distress Syndrome Forceps Delivery Pregnancy	Foreign Health Professional Other	Baclofen Diazepam	PS SS	Ipi	TRANSPLACENTAL TRANSPLACENTAL	TRANSPLANCENTAL TRANSPLACENTAL	

Date:10/04/04ISR Number: 4465123-XReport Type:Expedited (15-DaCompany Report #PHBS2002CL09569
Age:41 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Abdominal Distension Abdominal Pain Upper Chest Wall Pain Fatigue Flatulence Haematochezia		Lioresal Lioresal Lioresal Diazepam Omeprazole	PS SS SS C C	Novartis Sector: Pharma Novartis Sector: Pharma Novartis Sector: Pharma	ORAL ORAL ORAL	1 tablet/day 2 tablets/day 4 tablets/day UNKNOWN UNKNOWN	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/04/04ISR Number: 4468030-1Report Type:Direct Company Report #CTU 228709
Age:92 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Confusional State		Baclofen	PS				
	Somnolence							
	Tremor							

Date:10/06/04ISR Number: 4471331-4Report Type:Expedited (15-DaCompany Report #M2004-1416
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Complication Of Delivery	Foreign	Diazepam	PS		TRANSPLACENTAL	TRANS-PLACENTAL	
	Drug Exposure During Pregnancy	Other						
			Baclofen	SS				
	Foetal Distress Syndrome							
	Pregnancy							

Date:10/06/04ISR Number: 4471369-7Report Type:Expedited (15-DaCompany Report #20042012
Age:47 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Rigidity	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		INTRATHECAL	MCG, DAILY,	
Required Intervention to Prevent Permanent Impairment/Damage	Arrhythmia							
	Cyanosis							
	Device Failure							
	Drug Withdrawal Syndrome							
	Hypertension							
	Pyrexia							
	Tachycardia							

Date:10/06/04ISR Number: 4471376-4Report Type:Expedited (15-DaCompany Report #231317K04USA
Age:69 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Myocardial Infarction	Consumer Health Professional	Rebif (Interferon Beta)	PS				
			Baclofen (Baclofen)	SS				
			Beta Blocker (Beta Blocking Agents)	C				
			Aspirine (Acetylsalicylic Acid)	C				

Date:10/07/04ISR Number: 4471401-0Report Type:Expedited (15-DaCompany Report #04-09-1381
Age:19 YR Gender:Female I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Condition Aggravated
	Decreased Activity
	Device Failure
	Dyspnoea
	Dystonia
	Hyperreflexia
	Hypertonia
	Muscle Spasms
	Post Procedural Complication

	Respiratory Distress Stridor Vocal Cord Disorder	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
		Literature	Baclofen	PS		
INTRATHECAL 165-180U/DAY						
		Health				
INTRATHECAL 8 MON						
		Professional				

Date:10/12/04ISR Number: 4476484-XReport Type:Expedited (15-DaCompany Report #2004070485
Age:19 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Completed Suicide	Literature	Gabapentin			
	Intentional Misuse	Health	(Gabapentin)	PS		ORAL
ORAL						
		Professional	Baclofen (Baclofen)	SS		ORAL
ORAL						
			Oxybutynin			
			(Oxybutynin)	SS		ORAL
ORAL						

Date:10/13/04ISR Number: 4505129-5Report Type:Periodic Company Report #D-04-023
Age:82 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Coordination Abnormal	Consumer	Baclofen 10 Mg; Usl	PS		ORAL
5 MG TID; PO						
Initial or Prolonged	Hallucination		Alprazolam	C		
	Loss Of Consciousness		Aricept	C		
	Pneumonia		Neurontin	C		
			Oxycontin	C		
			Trazadone	C		
			Endocet	C		
			Morphine Pca			
			Intrathecal	C		

Date:10/13/04ISR Number: 4505130-1Report Type:Periodic Company Report #DCC 04-005
Age:8 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Withdrawal Syndrome	Consumer	Baclofen	PS		ORAL	ORAL	4 YR

Date:10/18/04ISR Number: 4480401-6Report Type:Expedited (15-DaCompany Report #20042004
Age:14 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Medical Device Complication Meningitis	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		INTRATHECAL	INTRATHECAL	DAILY,

Date:10/18/04ISR Number: 4480402-8Report Type:Expedited (15-DaCompany Report #20042004
Age:14 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Incision Site Complication Medical Device Complication Meningitis Wound Drainage	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		INTRATHECAL	INTRATHECAL	DAILY,

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/20/04ISR Number: 4483529-XReport Type:Direct Company Report #CTU 230115
Age:63 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Convulsion		Baclofen	PS		INTRATHECAL	75 MG ONCE IT	
	Respiratory Distress							

Date:10/25/04ISR Number: 4483836-0Report Type:Expedited (15-DaCompany Report #PHRM2004FR03161
Age:13 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Pancreatitis		Lioresal	PS	Novartis Sector: Pharma	ORAL	10 mg, TID	1460 DAY
			Depakine	SS		ORAL	500 mg, TID	
			Theralene	SS		ORAL	10 mg, QD	365 DAY
			Smecta	SS		ORAL		
			Duphalac	SS		ORAL		
			Efferalgan	C		ORAL		
			Mopral	C		ORAL	10 mg, QD	

Date:10/25/04ISR Number: 4485343-8Report Type:Direct Company Report #CTU 230381
Age:44 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dysarthria		Lioresal Intrathecal 2000mcg/Ml					
	Lethargy		Medtrinoc	PS	Medtrinoc	INTRATRACHEAL	INTRATRACH	

Date:10/25/04ISR Number: 4487674-4Report Type:Expedited (15-DaCompany Report #20042026
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Catheter Related Infection	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		INTRATHECAL	MCG,	DAILY,
	Csf Culture Positive					INTRATHECAL		
	Lung Infection							
	Meningitis							
	Staphylococcal Infection							
	White Blood Cell Count Increased							

Date:10/26/04ISR Number: 4488597-7Report Type:Expedited (15-DaCompany Report #20042018
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Catheter Related Infection	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		INTRATHECAL	DAILY,	
	Implant Site Infection					INTRATHECAL		
	Meningitis							
	Staphylococcal Infection							

Date:10/28/04ISR Number: 4488183-9Report Type:Expedited (15-DaCompany Report #PHNU2004DE03651
Age:58 YR Gender:Male I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Bradycardia
	Bradypnoea

		Hypotonia Intentional Misuse Loss Of Consciousness	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
		Myoclonic Epilepsy Sopor		Lioresal	PS	Novartis Sector: Pharma	ORAL
15 DF,							
ONCE/SINGLE	1440 MIN						

Date:10/29/04ISR Number: 4492023-1Report Type:Expedited (15-DaCompany Report #PHNU2004DE03427
Age:43 YR Gender:Female I/FU:I

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
		Drug Withdrawal Syndrome Medication Error	Health Professional	Lioresal Intrathecal (Baclofen) Unknown	PS		
INTRATHECAL	750 NG, QD						
		Pyrexia	Other	Beta Blocking Agents (No Ingredients/Substances)	C		

Date:11/01/04ISR Number: 4491269-6Report Type:Direct Company Report #CTU 230853
Age:22.5 YR Gender:Male I/FU:I

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Life-Threatening		Apnoea		Baclofen	PS		ORAL
40 MG PO Q 6							
Required		Oxygen Saturation					
H [2 DOSES]							
Intervention to		Decreased		Clonazepam	SS		ORAL
1.5 MG PO Q6							
Prevent Permanent		Procedural Complication					
H [2 DOSES]							
Impairment/Damage		Respiratory Depression Scar					

Date:11/01/04ISR Number: 4492086-3Report Type:Expedited (15-DaCompany Report #2004081136
Age: Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Diabetes Mellitus Fibromyalgia Multiple Sclerosis	Consumer	Neurontin (Gabapentin)	PS				
			Fentanyl (Fentanyl)	SS				
			Oxycocet (Oxycodone Hydrochloride, Paracetamol)	SS				
			Lidocaine (Lidocaine)	SS				
			Baclofen (Baclofen)	SS				
			Amantadine Hydrochloride (Amantadine Hydrochloride)	SS				
			All Other Therapeutic Proudcts (All Other Therapeutic Products)	SS				
			Insulin (Insulin)	SS				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/02/04ISR Number: 4492884-6Report Type:Expedited (15-DaCompany Report #PHBS2004NO12570
Age:26 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Decreased Appetite Device Failure	Health Professional	Lioresal Intrathecal (Baclofen) Ampoule	PS		INTRATHECAL	SEE IMAGE	
	Dyskinesia Muscle Spasticity Pyrexia Rash Generalised Rash Pruritic Respiratory Rate Decreased Sleep Disorder	Other	Rivotril (Clonazepam) Tablet	SS				

Date:11/02/04ISR Number: 4493386-3Report Type:Expedited (15-DaCompany Report #20042048
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Clonus Convulsion	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		INTRATHECAL	DAILY, INTRATHECAL	
	Hyperhidrosis Intestinal Obstruction Medication Error Muscle Spasms Pyrexia							

Date:11/05/04ISR Number: 4498419-6Report Type:Expedited (15-DaCompany Report #2004083821
Age:53 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Glucose Fluctuation Diabetes Mellitus	Foreign Health	Neurontin (Gabapentin)	PS		ORAL	1200 MG (1 D), ORAL	
	Dizziness Drug Ineffective	Professional	Lisinopril					

		Drug Interaction	(Lisinopril)	SS
20 MG (1 D)				
		Fall	Hydrochlorothiazide (Hydrochlorothiazide)	SS
		Grand Mal Convulsion		
		Hypoglycaemia		
12.5 MG (1 D)				
		Status Epilepticus	Baclofen (Baclofen)	SS
5 MG (1 D)				
			Pantoprazole Sodium (Pantoprazole Sodium)	SS
20 MG (1 D)				
			Interferon Beta (Interferon Beta)	SS
SUBCUTANEOUS	1 AMPULE (2			
D),				
SUBCUTANEOUS				
			Amitriptyline Hydrochloride (Amitriptyline Hydrochloride)	C
			Carbamazepine (Carbamazepine)	C
			Zopiclone (Zopiclone)	C

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/10/04ISR Number: 4500929-XReport Type:Expedited (15-DaCompany Report #20042061
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Meningitis	Health Professional	Lioresal Intrathecal(Baclofen Injection)	PS		INTRATHECAL	MCG, DAILY,	
						INTRACHECAL		

Date:11/11/04ISR Number: 4499277-6Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20040908837
Age:51 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Blood Pressure Abnormal		Tylenol 3	PS		OROPHARINGEAL		
	Cardio-Respiratory Arrest		Acetaminophen/Hydrocodone	SS		OROPHARINGEAL		
	Coma							
	Completed Suicide		Acetaminophen/Hydrocodone	SS		OROPHARINGEAL		
	Heart Rate Increased							
	Intentional Misuse		Amitriptyline	SS		OROPHARINGEAL		
	Loss Of Consciousness		Baclofen	SS				
	Oxygen Saturation Decreased		Zolpidem	SS				
	Pupil Fixed		Valdecoxib	SS				
	Status Epilepticus		Escitalopram	SS				
			Fentanyl	SS				
			Orphenadrine	SS				
			Pantoprazole	SS				

Date:11/11/04ISR Number: 4499278-8Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20040908836
Age:61 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Apnoea		Tylenol 3	PS		OROPHARINGEAL		

	Blood Pressure Increased		Morphine	SS			
OROPHARINGEAL							
	Coma		Lorazepam	SS			
OROPHARINGEAL							
	Completed Suicide		Baclofen	SS			
	Heart Rate Increased		Ibuprofen	SS			
	Hypothermia		Antacid Aluminum				
	Intentional Misuse		Magnesium Hydroxide	SS			
	Miosis		Cocaine	SS			
	Pulse Absent						
	Respiratory Rate Increased						

Date:11/16/04ISR Number: 4501993-4Report Type:Expedited (15-DaCompany Report #PHHO2004AU04534
Age:29 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Encephalopathy		Baclofen	PS	Novartis Sector: Pharma			
	Loss Of Consciousness							
	Metabolic Encephalopathy		Glivec	SS		ORAL	600 mg, QD	397 DAY
	Pneumonia Aspiration							
	Sepsis							
	Somnolence							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/17/04ISR Number: 4506997-3Report Type:Expedited (15-DaCompany Report #2004-BP-11398YA
Age:41 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Alanine Aminotransferase Increased	Foreign Health Professional Other	Harnal (Tamsulosin)	PS		ORAL	0.2 MG PO	
	Aspartate Aminotransferase Increased		Dantrium (Dantrolene Sodium)	SS		ORAL	25 MG PO	
	Blood Bilirubin Increased		Lioresal (Dantrolene Sodium)	SS		ORAL	5 MG PO	
	Blood Lactate Dehydrogenase Increased		Ternelin (Tizanidine Hydrochloride)	SS		ORAL	1 MG PO	
	Gamma-Glutamyltransferase Increased		Vitamedin (Benfotiamine/B6/B12)	C		ORAL		
	Hepatic Function Abnormal		Diazepam (Diazepam)	C				

Date:11/22/04ISR Number: 4506572-0Report Type:Expedited (15-DaCompany Report #PHRM2004FR03161
Age:13 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Distension		Lioresal	PS	Novartis Sector: Pharma	ORAL	10 mg, TID	1460 DAY
	Blood Amylase Increased		Depakine	SS		ORAL	500 mg, TID	
	C-Reactive Protein		Theralene	SS		ORAL	10 mg, QD	365 DAY
	General Physical Health Deterioration		Smecta	SS		ORAL		
	Leukocytosis		Duphalac	SS		ORAL		
	Lipase Increased		Efferalgan	C		ORAL		
	Pancreatic Necrosis		Mopral	C		ORAL	10 mg, QD	
	Pancreatitis							
	Pyrexia							

Date:11/29/04ISR Number: 4514790-0Report Type:Direct Company Report #CTU 233075
Age:77 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Asthenia		Baclofen	PS				
	Confusional State							
	Hypotension							

Date:11/30/04ISR Number: 4512867-7Report Type:Expedited (15-DaCompany Report #FR-ABBOTT-04P-056-0279415-00
Age:13 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	General Physical Health Deterioration		Depakine Tablets	PS		ORAL	.05% Syrup	1 YR
			Baclofen	SS		ORAL	4	YR
	Pancreatitis		Alimemazine Tartrate	SS		ORAL	Powder	
			Smectite	SS		ORAL		
			Omeprazole	C		ORAL	INTRAVENOUS	
			Omeprazole	C				
			Paracetamol	C		ORAL	INTRAVENOUS	
			Paracetamol	C				
			Paracetamol	C		ORAL		
			Lactulose	C		ORAL		
			Phenobarbital	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/30/04ISR Number: 4513292-5Report Type:Expedited (15-DaCompany Report #PHBS2004NL15786
Age:64 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Aortic Occlusion		Lioresal	PS	Novartis Sector:			
Hospitalization -	Hepatic Encephalopathy				Pharma	ORAL		
Initial or Prolonged	Hepatic Enzyme Increased		Nitrofuranaoine	SS				
	Nausea		Acenocoumarol	C				
	Somnolence		Paracetamol	C				
			Simvastatin	C				
			Paroxetin	C				

Date:12/06/04ISR Number: 4519660-XReport Type:Expedited (15-DaCompany Report #PHFR2004GB04326
Age:51 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Periorbital Oedema		Baclofen	PS	Novartis Sector:			
					Pharma	ORAL	10 mg, BID	5760 MIN
			Pregabalin	SS		ORAL	75 mg, BID	
			Trazodone	C			UNKNOWN	350mg nocte
			Tramadol	C			UNKNOWN	50 mg, TID
			Cetirizine	C			UNKNOWN	
			Omeprazole	C			UNKNOWN	20mg/day
			Lactulose	C			UNKNOWN	15ml nocte
			Naproxen	C			UNKNOWN	1-2 bid
			Gabapentin	C			300 mg, TID	
			Nefopam	C			UNKNOWN	600 mg, TID

Date:12/06/04ISR Number: 4519688-XReport Type:Expedited (15-DaCompany Report #PHNU2004DE03876
Age:74 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Cerebrovascular Accident Communication Disorder		Lioresal	PS	Novartis Sector: Pharma	ORAL	10mg/day	4320 MIN
	Disturbance In Attention		Mst	C				
	Speech Disorder		Neurontin	C				
			Tetra-Saar	C				
			Saroten "Bayer Vital"	C				

Date:12/08/04ISR Number: 4521297-3Report Type:Expedited (15-DaCompany Report #PHBS2004US16080
Age:73 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Catheter Related Complication		Lioresal Intrathecal	PS	Novartis Sector: Pharma		INTRATHECAL	1985 mcg/day
	Drug Ineffective		Lioresal Intrathecal	SS	Novartis Sector: Pharma		INTRATHECAL	270 mcg/day

Date:12/08/04ISR Number: 4521298-5Report Type:Expedited (15-DaCompany Report #PHBS2004US16083
Age:50 YR Gender:Male I/FU:I

Outcome	PT
Other	Chills
	Device Failure
	Diarrhoea
	Dysgeusia
	Hyperhidrosis

		Lacrimation Increased Nausea Pain	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
		Parosmia Yawning		Lioresal Intrathecal	PS	Novartis Sector: Pharma	
INTRATHECAL	129.6 ug/day						
				Morphine	C		

Date:12/08/04ISR Number: 4521299-7Report Type:Expedited (15-DaCompany Report #PHBS2004US16084
Age: Gender:Unknown I/FU:I

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Other		Hypertonia Speech Disorder		Lioresal Intrathecal	PS	Novartis Sector: Pharma	
INTRATHECAL							

Date:12/08/04ISR Number: 4521303-6Report Type:Expedited (15-DaCompany Report #PHBS2004US16086
Age: Gender:Unknown I/FU:I

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Other		Device Failure Drug Withdrawal Syndrome		Lioresal Intrathecal	PS	Novartis Sector: Pharma	
INTRATHECAL							

Date:12/08/04ISR Number: 4521304-8Report Type:Expedited (15-DaCompany Report #PHBS2004US16088
Age:49 YR Gender:Female I/FU:I

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Other		Anxiety Hyperhidrosis		Lioresal Intrathecal	PS	Novartis Sector: Pharma	
INTRATHECAL							
		Irritability Muscle Spasticity					

Date:12/09/04ISR Number: 4522627-9Report Type:Expedited (15-DaCompany Report #PHHO2004AU04534
Age:29 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Coma Encephalopathy Loss Of Consciousness Pneumonia Aspiration Sepsis Somnolence	Health Professional	Glivec Clofen	PS SS		ORAL	600 mg, QD	397 DAY

Date:12/13/04ISR Number: 4525886-1Report Type:Expedited (15-DaCompany Report #PHNU2004DE04093
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Condition Aggravated Confusional State		Lioresal	PS	Novartis Sector: Pharma	ORAL	5 mg, BID	
	Nausea Vomiting		Lioresal	SS	Novartis Sector: Pharma	ORAL	2.5 mg, BID	
			Trileptal "Novartis"	C			900mg/day	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/13/04ISR Number: 4525888-5Report Type:Expedited (15-DaCompany Report #PHBS2004PL16417
Age:40 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Acute Respiratory Failure Blood Creatine Phosphokinase Increased Bradycardia Coma Hypertension Intentional Misuse Suicide Attempt		Baclofen	PS	Novartis Sector: Pharma		UNKNOWN	1500 mg/day

Date:12/13/04ISR Number: 4525895-2Report Type:Expedited (15-DaCompany Report #PHBS2004PL16419
Age:19 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Acute Respiratory Failure Blood Creatine Phosphokinase Increased Bradycardia Coma Hypertension Intentional Misuse Suicide Attempt		Baclofen	PS	Novartis Sector: Pharma		UNKNOWN	500 mg/day

Date:12/13/04ISR Number: 4525898-8Report Type:Expedited (15-DaCompany Report #PHBS2004PL16418
Age:16 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Acute Respiratory Failure Blood Creatine Phosphokinase Increased Bradycardia Coma Intentional Misuse Suicide Attempt		Baclofen	PS	Novartis Sector: Pharma		UNKNOWN	1250 mg/day

Date:12/14/04ISR Number: 4526300-2Report Type:Expedited (15-DaCompany Report #PHBS2004PL16420
Age:18 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Acute Respiratory Failure Bradycardia Coma Intentional Misuse Suicide Attempt		Baclofen	PS	Novartis Sector: Pharma		UNKNOWN	400 mg/day

Date:12/14/04ISR Number: 4526301-4Report Type:Expedited (15-DaCompany Report #PHBS2004PL16422
Age:41 YR Gender:Female I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Acute Respiratory Failure Blood Creatine Phosphokinase Increased Coma Hypertension Intentional Misuse

	Suicide Attempt						
		Report Source	Product	Role	Manufacturer	Route	Dose Duration
			Baclofen	PS	Novartis Sector: Pharma		
UNKNOWN	300 mg/day						

Date:12/14/04ISR Number: 4526304-XReport Type:Expedited (15-DaCompany Report #PHBS2004PL16423
Age:15 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Coma Intentional Misuse Suicide Attempt		Baclofen	PS	Novartis Sector: Pharma		
UNKNOWN	250 mg/day						

Date:12/14/04ISR Number: 4526314-2Report Type:Expedited (15-DaCompany Report #PHBS2004PL16424
Age:55 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Acute Respiratory Failure Blood Creatine Phosphokinase Increased Coma Intentional Misuse Suicide Attempt		Baclofen	PS	Novartis Sector: Pharma		
UNKNOWN	250 mg/day						

Date:12/14/04ISR Number: 4526315-4Report Type:Expedited (15-DaCompany Report #PHBS2004PL16431
Age:28 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Blood Creatine Phosphokinase Increased Coma Intentional Misuse		Baclofen	PS	Novartis Sector: Pharma		
UNKNOWN	200 mg/day						

		Suicide Attempt					

Date:12/14/04ISR Number: 4526316-6Report Type:Expedited (15-DaCompany Report #PHBS2004PL16430
Age:16 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Coma Intentional Misuse Suicide Attempt		Baclofen	PS	Novartis Sector: Pharma		UNKNOWN	240 mg/day

Date:12/14/04ISR Number: 4526317-8Report Type:Expedited (15-DaCompany Report #PHBS2004PL16433
Age:25 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Creatine Phosphokinase Increased Coma Intentional Misuse Suicide Attempt		Baclofen	PS	Novartis Sector: Pharma		UNKNOWN	200 mg/day

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/14/04ISR Number: 4528903-8Report Type:Expedited (15-DaCompany Report #20042095
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Asthenia Lethargy Mental Status Changes	Health Professional	Lioresal Intrathecal (Baclofen Injection) 2000mcg/Ml	PS		INTRATHECAL	524.7 MCG,	DAILY,
	Pyrexia					INTRATHECAL		

Date:12/15/04ISR Number: 4527203-XReport Type:Expedited (15-DaCompany Report #PHBS2004PL16435
Age:30 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Creatine Phosphokinase Increased		Baclofen	PS	Novartis Sector: Pharma	UNKNOWN	200 mg/day	
	Coma Hypertension Intentional Misuse Suicide Attempt Therapeutic Agent Toxicity							

Date:12/15/04ISR Number: 4527204-1Report Type:Expedited (15-DaCompany Report #PHBS2004PL16436
Age:48 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Acute Respiratory Failure Blood Creatine Phosphokinase Increased		Baclofen	PS	Novartis Sector: Pharma	UNKNOWN	200 mg/day	
	Bradycardia Coma Hypotension Intentional Misuse Suicide Attempt							

Therapeutic Agent
Toxicity

Date:12/15/04ISR Number: 4527206-5Report Type:Expedited (15-DaCompany Report #PHBS2004PL16437
Age:48 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Acute Respiratory Failure Blood Creatine Phosphokinase Increased Coma Intentional Misuse Suicide Attempt		Baclofen	PS	Novartis Sector: Pharma		UNKNOWN	200 mg/day

Date:12/15/04ISR Number: 4527208-9Report Type:Expedited (15-DaCompany Report #PHBS2004PL16438
Age:53 YR Gender:Male I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Acute Respiratory Failure Blood Creatine Phosphokinase Increased Bradycardia Coma

		Intentional Misuse Suicide Attempt					
			Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
				Baclofen	PS	Novartis Sector: Pharma	
UNKNOWN	200 mg/day						

Date:12/15/04ISR Number: 4527209-0Report Type:Expedited (15-DaCompany Report #PHBS2004PL16439
Age:21 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization - Initial or Prolonged	Coma Intentional Misuse		Baclofen	PS	Novartis Sector: Pharma	
UNKNOWN	150 mg/day					
	Suicide Attempt					

Date:12/15/04ISR Number: 4527210-7Report Type:Expedited (15-DaCompany Report #PHBS2004PL16440
Age:58 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization - Initial or Prolonged	Blood Creatine Phosphokinase Increased		Baclofen	PS	Novartis Sector: Pharma	
UNKNOWN	150 mg/day					
	Bradycardia Coma Hypertension Intentional Misuse Suicide Attempt					

Date:12/15/04ISR Number: 4527211-9Report Type:Expedited (15-DaCompany Report #PHBS2004PL16443
Age:48 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization - Initial or Prolonged	Acute Respiratory Failure Blood Creatine		Baclofen	PS	Novartis Sector: Pharma	
UNKNOWN						
	Phosphokinase Increased					

	Coma					
	Hypertension					
	Intentional Misuse					
	Suicide Attempt					

Date:12/15/04ISR Number: 4527216-8Report Type:Expedited (15-DaCompany Report #PHRM2004FR03660
Age:34 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Bradycardia		Lioresal	PS	Novartis Sector:			
Hospitalization -	Coma				Pharma	ORAL	300 mg,	
Initial or Prolonged	Intentional Misuse						ONCE/SINGLE	
	Mydriasis							
	Suicide Attempt							

Date:12/15/04ISR Number: 4527520-3Report Type:Expedited (15-DaCompany Report #PHBS2004PL16421
Age:19 YR Gender:Male I/FU:I

Outcome	PT
Hospitalization -	Blood Creatine
Initial or Prolonged	Phosphokinase Increased
	Coma
	Intentional Misuse

Psychotic Disorder
Suicide Attempt

		Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
			Baclofen	PS	Novartis Sector: Pharma	
UNKNOWN	400 mg/day					

Date:12/16/04ISR Number: 4528559-4Report Type:Expedited (15-DaCompany Report #PHNU2004DE04185
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Other	Ammonia Increased		Lioresal	PS	Novartis Sector: Pharma	ORAL
10 mg, TID						
	Depressed Level Of Consciousness		Tetrazepam	C		
	Gamma-Glutamyltransferase Increased		Antibiotics	C		
	Hepatic Enzyme Increased		Heparin	C		
	Hepatocellular Damage					

Date:12/20/04ISR Number: 4535940-6Report Type:Expedited (15-DaCompany Report #20042105
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization - Initial or Prolonged	Meningitis	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		
INTRATHECAL	MCG, DAILY,					
Other						
INTRATHECAL						

Date:12/21/04ISR Number: 4532668-3Report Type:Expedited (15-DaCompany Report #PHRM2004FR03639
Age:55 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Other	Abasia		Tegretol	PS	Novartis Sector: Pharma	
	Drug Interaction					
200 mg, BID						

	Facial Palsy		Lioresal	SS		ORAL

Date:12/21/04ISR Number: 4532686-5Report Type:Expedited (15-DaCompany Report #PHRM2004FR03670
Age:53 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Arthritis Convulsion		Lioresal	PS	Novartis Sector: Pharma	ORAL	30 mg, TID	
	Pneumonia Aspiration		Athymil	SS		ORAL	60 mg/day	
	Sepsis Subileus		Lioresal	SS	Novartis Sector: Pharma	ORAL	60 mg/day	
			Urbanyl	C		ORAL		
			Keppra	C		ORAL		
			Imovane	C		ORAL	7.5 mg, QD	
			Rifadine	C		ORAL	600 mg, BID	
			Bactrim Forte	C			INTRAVENOUS	
			Lovenox	C				
			Tazocilline	C			INTRAVENOUS	
			Ciflox	C			UNKNOWN	
			Perfalgan	C			INTRAVENOUS	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/23/04ISR Number: 4535895-4Report Type:Expedited (15-DaCompany Report #PHNU2003DE02314
Age:68 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Dizziness Drug Interaction		Esidrix	PS	Novartis Sector: Pharma	ORAL	25 mg, QD
	Eye Rolling		Baclofen	SS		ORAL	25 mg, UNK
	Fall		Benalapril	SS		ORAL	5 mg, QD
	Hypotension Orthostatic Hypotension		Benalapril Doxepin (Ngx)	SS SS		ORAL	75 mg, QD
	Tremor		Celebrex	C		ORAL	200 mg, PRN
			Metoclopramide	C		ORAL	30 gtt, PRN

Date:12/29/04ISR Number: 4542809-XReport Type:Expedited (15-DaCompany Report #2004-05265
Age:38 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged Other	Condition Aggravated Drug Ineffective For Unapproved Indication Muscle Spasticity Nephrolithiasis Paraesthesia	Consumer	Baclofen Nexium (Esomeprazole) Multivitamins	PS C C	Watson Labaoratories	ORAL	SEE IMAGE

Date:01/03/05ISR Number: 4544097-7Report Type:Expedited (15-DaCompany Report #PHNU2003DE02314
Age:68 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Dizziness Drug Interaction	Foreign Study	Esidrix(Hydrochlorothiazide) Tablet	PS		ORAL	25 MG, QD,
	Drug Interaction	Health				ORAL	

	Potentiation Eye Rolling	Professional Other	Baclofen (Baclofen, Baclofen)	SS		ORAL 25 MG, ORAL
	Fall Orthostatic Hypotension Tremor		Benalapril (Enalapril) Tablet, 5mg	SS		ORAL 5 MG, QD, ORAL
			Doxepin (Ngx) (Doxepin) Capsule	SS		ORAL 75 MG, QD, ORAL
			Celebrex (Celecoxib) Capsule	C		
			Metoclopramide (Metoclopramide) Solution	C		

Date:01/06/05ISR Number: 4546300-6Report Type:Expedited (15-DaCompany Report #PHBS2002CL09569
Age:41 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Other	Abdominal Distension Abdominal Pain		Lioresal	PS	Novartis Sector: Pharma	ORAL 1 tablet/day
	Abdominal Pain Upper Chest Wall Pain		Lioresal	SS	Novartis Sector: Pharma	ORAL 2 tablets/day
	Fatigue Flatulence		Lioresal	SS	Novartis Sector: Pharma	ORAL 4 tablets/day
	Haematochezia Somnolence		Lioresal	SS	Novartis Sector: Pharma	ORAL 20 mg/day
	Urinary Incontinence		Diazepam	C		UNKNOWN

				Losec	C		
UNKNOWN	PRN						

Date:01/07/05ISR Number: 4624543-0Report Type:Periodic Company Report #234705K04USA
Age:53 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Joint Swelling	Consumer	Rebif (Interferon Beta)	PS				
	Oedema Peripheral		Baclofen	SS				

Date:01/13/05ISR Number: 4552753-XReport Type:Direct Company Report #CTU 236599
Age:17 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Catheter Related		Intrathecal Baclofen					
Hospitalization - Initial or Prolonged	Complication		Pump 400 Mcg Per Day Medtronics	PS	Medtronics	INTRATHECAL	400 MCG	
Required	Drug Withdrawal Syndrome							
DAILY								
Intervention to INTRATHECA	Surgery							
Prevent Permanent Impairment/Damage								

Date:01/18/05ISR Number: 4555354-2Report Type:Direct Company Report #CTU 237033
Age:35 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blood Glucose Decreased		Novolog Novonordisk	PS	Novonordisk	SUBCUTANEOUS	66 UNITS OVER 24 HOURS	
	Drug Interaction							
SUBCUTANEOUS								
			Baclofen 10mg	SS		ORAL	10MG TID ORAL	

Date:01/18/05ISR Number: 4557689-6Report Type:Expedited (15-DaCompany Report #PHFR2004GB04658
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Coma Escherichia Infection Incoherent Pyrexia Therapy Non-Responder	Health Professional Other	Lioresal (Baclofen) Solution For Injection	PS				

Date:01/19/05ISR Number: 4555426-2Report Type:Expedited (15-DaCompany Report #PHBS2005US00800
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Arnold-Chiari Malformation		Tegretol	PS	Novartis Sector: Pharma		UNKNOWN	300 mg/day
	Brain Herniation		Baclofen Intrathecal	SS		INTRATHECAL		
	Drooling Dysarthria Facial Palsy Hypokinesia Joint Contracture Shunt Malfunction Surgery							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/19/05ISR Number: 4556071-5Report Type:Expedited (15-DaCompany Report #PHBS2005IE00673
Age: Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Mania		Lioresal	PS	Novartis Sector: Pharma	ORAL		

Date:01/19/05ISR Number: 4556072-7Report Type:Expedited (15-DaCompany Report #PHRM2005FR00544
Age:42 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Alanine Aminotransferase		Lioresal	PS	Novartis Sector:			
Hospitalization -	Increased				Pharma	ORAL	50 mg/day	
Initial or Prolonged	Aspartate		Bactrim Forte	SS		ORAL	117	DAY
	Aminotransferase		Viracept "Roche"	SS		ORAL		
	Increased		Combivir	SS		ORAL	1 DF, BID	300 DAY
	Blood Lactate		Lysanxia	SS		ORAL	10080MIN	
	Dehydrogenase Increased		Fumafer	SS		ORAL	10080MIN	
	Bone Marrow Depression		Depakine Chrono	SS		ORAL	500 mg, BID	214 DAY
	Prothrombin Level		Coversyl	SS		ORAL	4 mg/day	
	Decreased		Aspegic	C		ORAL		

Date:01/19/05ISR Number: 4558591-6Report Type:Expedited (15-DaCompany Report #2004056018
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Abnormal Behaviour	Consumer	Neurontin					
	Adverse Event	Health	(Gabapentin)	PS				
	Amnesia	Professional	Morphine (Morphine)	SS				
	Economic Problem		All Other					
	Feeling Hot		Non-Therapeutic					
	Granuloma		Products (All Other					
	Heart Rate Increased		Non-Therapeutic					

	Hot Flush		Products)	SS	
	Hyperhidrosis		Baclofen (Baclofen)	SS	
	Inadequate Analgesia				
	Insomnia				
	Loss Of Consciousness				
	Medical Device Complication				
	Nerve Injury				
	Oedema				
	Pain				
	Speech Disorder				
	Spinal Disorder				
	Weight Increased				

Date:01/21/05ISR Number: 4578905-0Report Type:Periodic Company Report #PHBS2003US13735
Age:9 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Muscle Spasticity	Health Professional	Liorseal Intrathecal $Me(Baclofen) Ampoule	PS		INTRATHECAL	INTRATHECAL	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/21/05ISR Number: 4578906-2Report Type:Periodic Company Report #PHBS2004US01505
Age:44 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Meningitis Pyrexia Swelling	Health Professional	Liorseal Intrathecal $Me(Baclofen) Ampoule	PS		INTRATRACHEAL	INTRATHECAL	

Date:01/21/05ISR Number: 4578909-8Report Type:Periodic Company Report #PHBS2004US01509
Age:65 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Confusional State Drug Ineffective Drug Withdrawal Syndrome Hypertonia Pruritus	Health Professional	Liorseal Intrathecal $Me(Baclofen) Ampoule	PS		INTRATHECAL	INTRATHECAL	

Date:01/21/05ISR Number: 4578911-6Report Type:Periodic Company Report #PHBS2004US07423
Age:40 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Cerebrospinal Fluid Leakage Muscle Spasticity	Health Professional	Liorseal Intrathecal $Me(Baclofen) Ampoule	PS		INTRATHECAL	INTRATHECAL	

Date:01/21/05ISR Number: 4578912-8Report Type:Periodic Company Report #PHBS2004US07475
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Ineffective	Health Professional	Lioresal Intrathecal $Me(Baclofen) Ampoule	PS		INTRATHECAL	INTRATHECAL	

Date:01/21/05ISR Number: 4578913-XReport Type:Periodic Company Report #PHBS2004US07476
Age:45 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Muscle Spasticity	Health Professional	Lioresal Intrathecal $Me(Baclofen) Ampoule	PS		INTRATHECAL	INTRATHECAL	

Date:01/21/05ISR Number: 4578916-5Report Type:Periodic Company Report #PHBS2004US07483
Age:24 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Muscle Spasticity	Health Professional	Lioresal Intrathecal $Me(Baclofen) Ampoule	PS		INTRATHECAL	INTRATHECAL	

Date:01/21/05ISR Number: 4578918-9Report Type:Periodic Company Report #PHBS2004US07485
Age:16 YR Gender:Female I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Muscle Spasticity Musculoskeletal Stiffness

	Pruritus					
		Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
		Health Professional	Lioresal Intrathecal $Me(Baclofen) Ampoule	PS		
INTRATHECAL	INTRATHECAL					

Date:01/21/05ISR Number: 4578919-0Report Type:Periodic Company Report #PHBS2004US07572
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Other	Confusional State	Health Professional	Lioresal Intrathecal $Me(Baclofen) Ampoule	PS		
	Convulsion					
	Headache					
INTRATHECAL	INTRATHECAL					
	Hypertonia		Tegretol (Carbamazepine)	C		
	Hypotension					
	Infection		Valium (Diazepam)	C		
	Pruritus		Demerol (Pethidine Hydrochloride)	C		
	Urinary Tract Infection					

Date:01/21/05ISR Number: 4578920-7Report Type:Periodic Company Report #PHBS2004US08489
Age:34 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization - Initial or Prolonged	Condition Aggravated	Health Professional	Lioresal Intrathecal $Me(Baclofen) Ampoule	PS		
	Hypertonia					
	Muscle Spasticity					
INTRATHECAL	INTRATHECAL					
	Pain					

Date:01/21/05ISR Number: 4578921-9Report Type:Periodic Company Report #PHBS2004US08491
Age:47 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Other	Hypertonia	Health	Lioresal Intrathecal			

			Professional	$Me (Baclofen)			
				Ampoule	PS		
INTRATHECAL	INTRATHECAL						

Date:01/21/05ISR Number: 4578922-0Report Type:Periodic Company Report #PHBS2004US08492
Age:10 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hypertonia	Health	Lioresal Intrathecal					
	Muscle Rigidity	Professional	&Me(Baclofen)					
			Ampoule	PS				

Date:01/21/05ISR Number: 4578923-2Report Type:Periodic Company Report #PHBS2004US08555
Age:68 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Ineffective	Health	Lioresal Intrathecal					
	Muscle Spasticity	Professional	&Me(Baclofen)					
			Ampoule	PS				
INTRATHECAL	INTRATHECAL							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/21/05ISR Number: 4578924-4Report Type:Periodic Company Report #PHBS2004US08645
Age:14 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Overdose Respiratory Distress	Health Professional	Lioresal Intrathecal &Me(Baclofen) Ampoule	PS		INTRATHECAL	INTRATHECAL	

Date:01/21/05ISR Number: 4578925-6Report Type:Periodic Company Report #PHBS2004US08719
Age:47 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Ineffective Muscle Spasticity	Health Professional	Lioresal Inthratecal (Baclofen) Ampoule	PS		INTRATHECAL	INTRATHECAL	

Date:01/21/05ISR Number: 4578926-8Report Type:Periodic Company Report #PHBS2004US08720
Age:46 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Ineffective Muscle Spasticity	Health Professional	Lioresal Inthratecal (Baclofen) Ampoule	PS		INTRATHECAL	INTRATHECAL	

Date:01/21/05ISR Number: 4578927-XReport Type:Periodic Company Report #PHBS2004US08811
Age:50 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Ineffective	Health Professional	Lioresal Intrathecal &Me(Baclofen) Ampoule	PS		INTRATHECAL	200 UG/DAY, INTRATHECAL	

Date:01/21/05ISR Number: 4578928-1Report Type:Periodic Company Report #PHBS2004US08958
Age:32 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hypotonia	Health Professional	Lioresal Intrathecal &Me(Baclofen) Ampoule	PS		INTRATHECAL	INTRATHECAL	

Date:01/21/05ISR Number: 4578929-3Report Type:Periodic Company Report #PHBS2004US08961
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Muscle Spasticity	Health Professional	Lioresal Intrathecal &Me(Baclofen) Ampoule	PS		INTRATHECAL	INTRATHECAL	

Date:01/21/05ISR Number: 4578930-XReport Type:Periodic Company Report #PHBS2004US08965
Age:23 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dizziness Overdose	Health Professional	Lioresal Intrathecal &Me(Baclofen) Ampoule	PS		INTRATHECAL	INTRATHECAL	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/21/05ISR Number: 4578931-1Report Type:Periodic Company Report #PHBS2004US09117
Age:44 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Condition Aggravated Muscle Spasms Pain	Health Professional	Lioresal Intratecal (Baclofen) Ampoule	PS		INTRATHECAL	INTRATHECAL	

Date:01/21/05ISR Number: 4578932-3Report Type:Periodic Company Report #PHBS2004US09118
Age:11 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Lethargy Overdose Vomiting	Health Professional	Lioresal Intrathecal (Baclofen) Ampoule	PS		INTRATHECAL	INTRATHECAL	

Date:01/21/05ISR Number: 4578933-5Report Type:Periodic Company Report #PHBS2004US09253
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Ineffective	Health Professional	Lioresal Intrathecal $Me(Baclofen) Ampoule	PS		INTRATHECAL	INTRATHECAL	

Date:01/21/05ISR Number: 4578935-9Report Type:Periodic Company Report #PHBS2004US09254
Age:61 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Muscle Spasticity	Health Professional	Lioresal Intrathecal Me (Baclofen) Ampoule	PS		INTRATHECAL	INTRATHECAL	

Date:01/21/05ISR Number: 4578936-0Report Type:Periodic Company Report #PHBS2004US10136
Age:47 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Ineffective Overdose Sedation	Health Professional	Lioresal Intrathecal Me (Baclofen) Ampoule	PS		INTRATHECAL	INTRATHECAL	

Date:01/21/05ISR Number: 4578943-8Report Type:Periodic Company Report #PHBS2004US10137
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Ineffective	Health Professional	Lioresal Intrathecal Me (Baclofen) Ampoule	PS		INTRATHECAL	INTRATHECAL	

Date:01/21/05ISR Number: 4578944-XReport Type:Periodic Company Report #PHBS2004US10138
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Ineffective	Health Professional	Lioresal Intrathecal Me (Baclofen) Ampoule	PS		INTRATHECAL	975 UG/DAY, INTRATHECAL	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/21/05ISR Number: 4578945-1Report Type:Periodic Company Report #PHBS2004US10139
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Muscle Spasticity	Health Professional	Lioresal Intrathecal Me (Baclofen) Ampoule	PS		INTRATHECAL	600 UG/DAY,	
			Clonidine	C		INTRATHECAL		
			Dilaudid (Hydromorphone Hydrochloride)	C				

Date:01/21/05ISR Number: 4578946-3Report Type:Periodic Company Report #PHBS2004US10140
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Withdrawal Syndrome Loss Of Consciousness	Health Professional	Lioresal Intrathecal Me (Baclofen) Ampoule	PS		INTRATHECAL	INTRATHECAL	
			Dilaudid (Hydromorphone Hydrochloride)	C				

Date:01/21/05ISR Number: 4578949-9Report Type:Periodic Company Report #PHBS2004US10141
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Muscle Spasms	Health Professional	Lioresal Intrathecal Me (Baclofen) Ampoule	PS		INTRATHECAL	INTRATHECAL	

Date:01/26/05ISR Number: 4560776-XReport Type:Expedited (15-DaCompany Report #FR-SOLVAY-00205000157
Age:42 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Alanine Aminotransferase		Coversyl	PS		ORAL	Daily dose: 4	
Hospitalization -	Increased						milligram(s)	
Initial or Prolonged	Aspartate		Bactrim	SS		ORAL	Daily dose:	
	Aminotransferase						unknown	117 DAY
	Increased		Combivir	SS		ORAL	Daily dose: 2	
	Blood Lactate						dosage form	300 DAY
	Dehydrogenase Increased		Viracept	SS		ORAL	Daily dose:	
	Bone Marrow Depression						unknown	
	Prothrombin Level		Depakine	SS		ORAL	Daily dose:	
	Decreased						1000	
							milligram(s)	214 DAY
			Lioresal	SS			SUBCUTANEOUS	Daily dose:
							50	
							milligram(s)	
			Aspegic	C			SUBCUTANEOUS	Daily dose:
							unknown	
			Lysanxia	C		ORAL	Daily dose:	
							unknown	0 MON
			Fumafer	C		ORAL	Daily dose:	
							unknown	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/26/05ISR Number: 4561632-3Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0364763A
Age:42 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Alanine Aminotransferase		Combivir	PS	Glaxosmithkline	ORAL	1TAB Twice	
Other	Increased						per day	10 MON
	Anaemia		Viracept	SS		ORAL		
	Aspartate		Bactrim Fort	SS	Glaxosmithkline	ORAL	4	MON
	Aminotransferase		Depakine Chrono	SS		ORAL	500MG Twice	
	Increased						per day	7 MON
	Blood Lactate		Coversyl	SS		ORAL	4MG Per day	
	Dehydrogenase Increased		Lioresal	SS		ORAL	50MG per day	
	Bone Marrow Depression		Aspegic	C		ORAL		
	Leukopenia		Lysanxia	C		ORAL		
	Prothrombin Level Decreased		Fumafer	C	Glaxosmithkline	ORAL		
	Thrombocytopenia							

Date:01/26/05ISR Number: 4566398-9Report Type:Direct Company Report #CTU 238039
Age:15 MON Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Apnoeic Attack		Baclofen 1mg/1ml					
Hospitalization - Initial or Prolonged	Coma		Clinical Apothecaries	PS	Clinical Apothecaries		PARENTERAL	5MG TID
	Depressed Level Of Consciousness							
	Dry Mouth						PARENTERAL	
	Dyspnoea		Valium	C				
	Dysuria		Phenobarbital	C				
	Hypotonia		Pepcid	C				
	Lethargy							
	Mental Status Changes							
	Moaning							
	Oedema Peripheral							

	Pyrexia					
	Retching					
	Staring					

Date:01/27/05ISR Number: 4562762-2Report Type:Expedited (15-DaCompany Report #PHBS2004NL15786
Age:64 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Aortic Occlusion		Lioresal	PS	Novartis Sector:			
Hospitalization -	Autoimmune Hepatitis				Pharma	ORAL		
Initial or Prolonged	Hepatic Encephalopathy		Nitrofuranaoine	SS				
	Hepatic Enzyme Increased		Acenocoumarol	C				
	Nausea		Paracetamol	C				
	Somnolence		Simvastatin	C				
			Paroxetin	C				

Date:02/01/05ISR Number: 4601997-7Report Type:Periodic Company Report #ACO_0019_2004
Age:42 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Accidental Overdose	Consumer	Zanaflex	PS				
DF								
Initial or Prolonged	Coma		Baclofen	SS				
DF								
	Respiratory Distress		Xanax	SS				
DF								

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/02/05ISR Number: 4578098-XReport Type:Direct Company Report #CTU 238907
Age:58 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Oedema Peripheral		Baclofen 10mg	PS				

Date:02/07/05ISR Number: 4571548-4Report Type:Expedited (15-DaCompany Report #PHBS2003JP06722
Age:37 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Depressed Level Of Consciousness Muscular Weakness Sleep Apnoea Syndrome		Lioresal	PS	Novartis Sector: Pharma	ORAL		

Date:02/07/05ISR Number: 4576705-9Report Type:Expedited (15-DaCompany Report #20052152
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Convulsion	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS			INTRATHECAL	MCG, DAILY,
Hospitalization - Initial or Prolonged	Loss Of Consciousness Muscle Spasticity						INTRATHECAL	
Required Intervention to Prevent Permanent Impairment/Damage	Sepsis		Oral Baclofen	C				
	Treatment Noncompliance		Iv Valium	C				

Date:02/08/05ISR Number: 4575062-1Report Type:Expedited (15-DaCompany Report #PERI0020500157
Age:42 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Lactate Dehydrogenase Increased		Combivir Coversyl	PS SS	Glaxosmithkline	ORAL	300 DAY UNKNOWN	 4MG Per day

	Bone Marrow Depression		Bactrim	SS	Glaxosmithkline	
UNKNOWN						
	Prothrombin Level		Viracept	SS		
UNKNOWN						
	Decreased		Depakine Chrono	SS		
UNKNOWN						
	Transaminases Increased		Lioresal	SS		
UNKNOWN						

Date:02/09/05ISR Number: 4575417-5Report Type:Expedited (15-DaCompany Report #PHEH2005US01539
Age:42 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Alanine Aminotransferase Increased		Lioresal	PS	Novartis Sector: Pharma	
	Aspartate		Coversyl	SS		
4 mg, QD						
	Aminotransferase		Bactrim	SS		
	Increased		Viracept	SS		
	Blood Lactate		Combivir	SS		
	Dehydrogenase Increased		Depakine Chrono	SS		
	Bone Marrow Depression					
	Prothrombin Level					
	Decreased					

Date:02/09/05ISR Number: 4577751-1Report Type:Expedited (15-DaCompany Report #2004AL000561
Age:61 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death Hospitalization - Initial or Prolonged	Blood Pressure Increased Coma Completed Suicide Heart Rate Increased	Literature Health Professional	Kadian (Morphine Sulfate Sustained Release) Capsules, 100 Mg (Alpharma)	PS	Alpharma	ORAL	PO	
	Hypothermia Intentional Misuse		Lorazepam Tablets Usp, 2 Mg (Purepac)	SS	Purepac	ORAL	PO	
	Miosis Pulse Absent Respiratory Arrest Respiratory Rate Increased		Capital And Codeine Oral Suspension (Acetaminophen/Codeine Oral Suspension), 120/12 Per 5	SS	Alpharma	ORAL	PO	
			Ibuprofen Oral Suspension Usp, 100 Mg/5 Ml (Otc) (Alpharma)	SS	Alpharma	ORAL	PO	
			Ibuprofen Oral Suspension Usp, 100 Mg/5 Ml (Rx) (Alpharma)	SS	Alpharma	ORAL	PO	
			Baclofen	SS		ORAL	PO	
			Aluminium/Magnesioum Hydroxide	SS		ORAL	PO	
			Cocaine	SS		ORAL	PO	

Date:02/10/05ISR Number: 4579819-2Report Type:Expedited (15-DaCompany Report #2005022833
Age:42 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Alanine Aminotransferase Increased	Foreign Health	Viracept (Tablet) (Nelfinavir					

	Aplastic Anaemia	Professional	Mesilate)	PS	ORAL
ORAL					
	Aspartate Aminotransferase Increased		Bactrim (Sulfamethoxazole, Trimethoprim)	SS	ORAL
ORAL					
	Biopsy Bone Marrow Abnormal Blood Creatinine Abnormal Blood Lactate		Zidovudine W/Lamivudine (Lamivudine, Zidovudine)	SS	ORAL
2 IN 1 D,					
	Dehydrogenase Increased				
ORAL					
	Prothrombin Time Shortened Treatment Noncompliance		Ergenyl Chrono (Valproate Sodium, Valproic Acid)	SS	ORAL
2 IN 1 D,					
ORAL					
			Perindopril (Perindopril)	SS	ORAL
4 MG (4 MG, 1					
IN 1 D), ORAL					
			Baclofen (Baclofen)	SS	

Date:02/11/05ISR Number: 4578446-0Report Type:Expedited (15-DaCompany Report #FR-ABBOTT-05P-056-0289128-00
Age:42 YR Gender:Male I/FU:I

Outcome	PT
Life-Threatening	Alanine Aminotransferase Increased Aspartate Aminotransferase

		Increased Blood Lactate Dehydrogenase Increased					
		Bone Marrow Depression	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
		Prothrombin Time Ratio Decreased		Depakine Chrono Tablets	PS		ORAL
213	DAY						
				Bactrim	SS		ORAL
115	DAY						
				Nelfinavir Mesilate	SS		ORAL
				Nelfinavir Mesilate	SS		
				Nelfinavir Mesilate	SS		
				Nelfinavir Mesilate	SS		ORAL
				Zidovudine W/Lamivudine	SS		ORAL
				Zidovudine W/Lamivudine	SS		
				Perindopril	SS		ORAL
				Baclofen	SS		ORAL
				Acetylsalicylate Lysine	C		
UNKNOWN							
				Prazepam	C		ORAL
5	DAY						
				Ferrous Fumarate	C		ORAL
5	DAY						

Date:02/11/05ISR Number: 4583757-9Report Type:Expedited (15-DaCompany Report #20052173
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization - Initial or Prolonged Required	Drug Withdrawal Syndrome Muscle Spasticity Pruritus Pyrexia	Health Professional	Lioresal Intrathecal (Baclofen Injection) 720 Mcg/Ml	PS		
INTRATHECAL	180 MCG, DAILY, INTRATHECAL					
Intervention to Prevent Permanent Impairment/Damage			Morphine Sulfate	C		

Date:02/11/05ISR Number: 4583845-7Report Type:Expedited (15-DaCompany Report #2005022019
Age:29 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Cystitis	Consumer	Neurontin (Gabapentin)	PS			600 MG (200 MG, 3 IN 1 D)	
Other	Depression							
	Diarrhoea							
	Disturbance In Attention		Baclofen (Baclofen) (Baclofen)	SS			130 MG	
	Drug Interaction							
	Hallucination		Paracetamol	C				
	Hypotension		Ibuprofen	C				
	Insomnia		Vicodin (Hydrocodone Bitartrate, Paracetamol)	C				
	Neuralgia							
	Pain In Extremity							
	Psychotic Disorder							
	Sensory Disturbance							
	Social Avoidant Behaviour							
	Syncope							

Date:02/11/05ISR Number: 4583901-3Report Type:Expedited (15-DaCompany Report #20052158
Age: Gender:Female I/FU:I

Outcome
Required
Intervention to
Prevent Permanent

Impairment/Damage

	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Dysuria	Health	Lioresal Intrathecal					
	Medical Device	Professional	(Baclofen Injection)	PS			INTRATHECAL	DAILY,
	Complication						INTRATHECAL	
	Medication Error		Fentanyl	C				
	Muscle Spasms							
	Neck Pain							
	Pain							
	Pyrexia							

Date:02/15/05ISR Number: 4582767-5Report Type:Expedited (15-DaCompany Report #PERI0020500157
Age:42 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Alanine Aminotransferase		Combivir	PS	Glaxosmithkline	ORAL	300	DAY
Initial or Prolonged	Increased		Coversyl	SS			UNKNOWN	4MG Per day
	Aspartate		Bactrim	SS	Glaxosmithkline		UNKNOWN	
	Aminotransferase		Viracept	SS			UNKNOWN	
	Increased		Depakine Chrono	SS			UNKNOWN	
	Blood Lactate		Lioresal	SS			UNKNOWN	
	Dehydrogenase Increased							
	Bone Marrow Depression							
	Prothrombin Level							
	Decreased							
	Transaminases Increased							

Date:02/15/05ISR Number: 4587494-6Report Type:Expedited (15-DaCompany Report #2005024115
Age:42 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Hospitalization - Initial or Prolonged	Alanine Aminotransferase Increased	Health Professional	Viracept (Tablet) (Nelfinavir Mesilate)	PS
	Aspartate Aminotransferase Increased		Perindopril (Perindopril)	SS
4 MG				
	Blood Lactate Dehydrogenase Increased		Bactrim (Sulfamethoxazole, Trimethoprim)	SS
	Bone Marrow Depression		Zidovudine W/Lamivudine (Lamivudine, Zidovudine)	SS
	Prothrombin Level Decreased		Ergenyl Chrono (Valproate Sodium, Valproic Acid)	SS
			Baclofen (Baclofen)	SS

Date:02/16/05ISR Number: 4583868-8Report Type:Expedited (15-DaCompany Report #PHNU2005DE00955
Age:80 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Depressed Level Of Consciousness		Lioresal	PS	Novartis Sector: Pharma	ORAL	10 mg, QD	
							(pulverized)	1440 MIN
			Risperdal	SS		ORAL	1 mg, QD	
							(pulverized)	1440 MIN

			Durogesic	C			

Date:02/16/05ISR Number: 4583980-3Report Type:Expedited (15-DaCompany Report #PHBS2005US02308
Age:67 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Abdominal Mass		Baclofen	PS	Novartis Sector:			
Other	Confusional State				Pharma			
UNKNOWN								
	Death		Chlorpromazine	C				
	Drug Ineffective		Metoclopramide	C				
	Eructation		Senna	C				
	Faecaloma		Hydromorphone	C				
	Faeces Hard		Lidocaine	C				
	Haematemesis							
	Insomnia							
	Nausea							
	Small Intestinal Obstruction							
	Vomiting							

Date:02/16/05ISR Number: 4588914-3Report Type:Expedited (15-DaCompany Report #2004056018
Age:41 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Abnormal Behaviour	Consumer	Neurontin					
	Amnesia	Health	(Gabapentin)	PS			900 MG (1 D)	
	Dysstasia	Professional	Morphine (Morphine)	SS			INTRATHECAL	9 MG (1 D),
	Feeling Hot						INTRATHECAL	
	Granuloma		Baclofen (Baclofen)	SS				
	Heart Rate Increased		All Other					
	Hot Flush		Non-Therapeutic					
	Hyperhidrosis		Products (All Other					
	Insomnia		Non-Therapeutic					
	Loss Of Consciousness		Product)	SS				
	Medical Device		Bupivacaine					
	Complication		(Bupivacaine)	C				
	Mental Disorder							

Nerve Injury
Oedema
Pain
Speech Disorder
Unevaluable Event
Weight Increased

Date:02/17/05ISR Number: 4590494-3Report Type:Expedited (15-DaCompany Report #20052173
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Required	Condition Aggravated Drug Withdrawal Syndrome Muscle Spasticity	Health Professional	Lioresal Intrathecal (Baclofen Injection) 720 Mcg/Ml	PS		INTRATHECAL	180 MCG, DAILY,	
Intervention to Prevent Permanent Impairment/Damage	Pruritus Pyrexia		Morphine Sulphate	C		INTRATHECAL		

Date:02/18/05ISR Number: 4587005-5Report Type:Expedited (15-DaCompany Report #PHBS2005US02266
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Withdrawal Syndrome Muscle Spasticity		Baclofen Intrathecal	PS	Novartis Sector: Pharma		INTRATHECAL	180 ug/day
Other	Pruritus Pyrexia		Morphine Sulfate	C				

Date:02/18/05ISR Number: 4587088-2Report Type:Expedited (15-DaCompany Report #PHNU2005DE00987
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Cardiovascular Disorder Coma		Lioresal Intratecal	PS	Novartis Sector: Pharma		INTRATHECAL	50000 ug, ONCE/SINGLE
	Medication Error Respiratory Failure		Timonil Sirdalud	C C				

Date:02/22/05ISR Number: 4588705-3Report Type:Expedited (15-DaCompany Report #PHFR2005GB00884
Age:67 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Confusional State Medication Error		Baclofen	PS	Novartis Sector: Pharma	ORAL	10mg/day	8640 MIN
			Amitriptyline	C		ORAL	10 mg, QD	124 DAY
			Lansoprazole	C		ORAL	30 mg, QD	
			Alfacalcidol	C		ORAL	2 ug, QW2	

Date:02/22/05ISR Number: 4591070-9Report Type:Direct Company Report #CTU 240960
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 Myoclonus		Baclofe	PS		ORAL	20 MG PO TID	

Date:02/25/05ISR Number: 4596237-1Report Type:Expedited (15-DaCompany Report #20052206
Age:53 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Device Failure Pruritus Pyrexia Respiratory Depression	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		INTRATHECAL	DAILY, INTRATHECAL	

Date:02/25/05ISR Number: 4596238-3Report Type:Expedited (15-DaCompany Report #20052207
Age: Gender:Male I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Catheter Related Infection Csf Bacteria Identified Incision Site Complication

		Meningitis Staphylococcal Infection					
			Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
			Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		
INTRATHECAL	DAILY, INTRATHECAL						

Date:03/02/05ISR Number: 4598828-0Report Type:Expedited (15-DaCompany Report #230610K05USA
Age:32 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization - Initial or Prolonged	Convulsion Meningitis Chemical	Consumer	Rebif (Interferon Beta)	PS		
44 MCG, 3 IN						
	Muscle Spasms					
1 WEEKS						
	Thrombosis Urinary Tract Infection		Lioresal (Baclofen)	SS		

Date:03/02/05ISR Number: 4598968-6Report Type:Expedited (15-DaCompany Report #PHNU2004DE02948
Age:60 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					
Hospitalization - Initial or Prolonged	Apnoea Coma Device Failure	Health Professional Other	Baclofen Intrathecal (Baclofen) Solution For Infusion	PS		
INTRATHECAL	UNKNOWN; Hypotension					
INTRATHECAL						

(SEE IMAGE)

Date:03/03/05ISR Number: 4597250-0Report Type:Expedited (15-DaCompany Report #US-KINGPHARMUSA00001-K200500263
Age:42 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Alanine Aminotransferase Increased		Septra Tablets/Septra Ds Tablets	PS	King Pharmaceuticals, Inc.			
	Aspartate Aminotransferase Increased							
	Blood Lactate Dehydrogenase Increased		Combivir	SS		ORAL	UNK, UNK	
			Coversyl	SS			4 mg, qd	
	Bone Marrow Depression		Viracept "Agouron"	SS				
	Prothrombin Level Decreased		Depakine Chrono	SS				
			Lioresal "Ciba-Geigy"	SS				

Date:03/03/05ISR Number: 4598974-1Report Type:Expedited (15-DaCompany Report #PHFR2004GB04658
Age:56 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Hospitalization - Initial or Prolonged	Coma Escherichia Infection Incoherent	Health Professional Other	Lioresal Intrathecal (Baclofen) Solution For Injection	PS			INTRATHECAL	UNKNOWN ;
	Meningitis Bacterial						INTRATHECAL	

Date:03/03/05ISR Number: 4599601-XReport Type:Expedited (15-DaCompany Report #20052215
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Required	Catheter Related Infection Meningitis Muscle Spasticity Staphylococcal Infection	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		INTRATRACHEAL INTRATHECAL	DAILY,	
Intervention to Prevent Permanent Impairment/Damage								

Date:03/03/05ISR Number: 4600073-7Report Type:Expedited (15-DaCompany Report #PHNU2005DE00987
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Cardiovascular Disorder Coma	Health Professional	Lioresal Intratecal (Baclofen) Ampoule	PS			50000 UG,	
	Medication Error	Other						ONCE/SINGLE
	Respiratory Failure		Timonil (Carbamazepine) Sirdalud (Tizanidine Hydrochloride)	C C				

Date:03/04/05ISR Number: 4600418-8Report Type:Expedited (15-DaCompany Report #K200500263
Age:42 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 Lactate Dehydrogenase Increased Bone Marrow Depression	Health Professional Other	Septra Tablets/Septra Ds Tablets(Trimethoprim, Sulfamethoxazole) Tablet 80/400 Mg Combivir (Lamivudine, Zidovudine) Tablet	PS SS		ORAL		ORAL

	Prothrombin Level Decreased	Coversyl (Perindopril Erbumine) 4 Mg	SS	
4 MG, QD				
		Viracept "Agouron" (Nelfinavir Mesilate)	SS	Agouron
		Depakine Chrono (Valproate Sodium, Valproic Acid)	SS	
		Lioresal "Ciba-Geigy" (Baclofen)	SS	Ciba-Geigy

Date:03/07/05ISR Number: 4602460-XReport Type:Expedited (15-DaCompany Report #20052192
Age: Gender:Male I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Blister
	Blood Creatine Phosphokinase Increased
	Drug Withdrawal Syndrome
	Enzyme Abnormality
	Hepatic Enzyme Increased
	Hyperhidrosis

	Medical Device Complication Muscle Rigidity	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Pyrexia Tachypnoea	Health Professional	Lioresal Intrathecal(Baclofen Injection) 2000 Mcg/Ml	PS		INTRATHECAL	300 MCG DAILY, INTRATHECAL

Date:03/08/05ISR Number: 4603736-2Report Type:Direct Company Report #CTU 242303
Age:76 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Lethargy Mental Status Changes Treatment Noncompliance		Baclofen 20 Mg Lorazepam 1 Mg	PS SS		ORAL	20 MG PO QID 1 MG Q AM 2 MG Q HS

Date:03/08/05ISR Number: 4604280-9Report Type:Direct Company Report #CTU 242244
Age:54 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Life-Threatening	Loss Of Consciousness Suicide Attempt		Amitriptyline 25 Mg Baclofen	PS SS		ORAL	25 MG PO QHS

Date:03/09/05ISR Number: 4606114-5Report Type:Expedited (15-DaCompany Report #US014707
Age:39 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration

Hospitalization - Initial or Prolonged	Drug Interaction Grand Mal Convulsion	Study Consumer	Provigil Betaseron	PS SS		ORAL SUBCUTANEOUS
100 MG ORAL	8 MIU QOD					
						SUBCUTANEOUS
			Prednisone	SS		
15 MG						
			Baclofen	SS		
10 MG						
			Synthroid	C		

Date:03/10/05ISR Number: 4606722-1Report Type:Expedited (15-DaCompany Report #2005022019
Age:29 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Cystitis Depression	Consumer Health	Neurontin (Gabapentin)	PS		
UNKNOWN 600 MG (200 MG, 3 IN 1 D), UNKNOWN	Diarrhoea Disturbance In Attention	Professional				
UNKNOWN 130 MG (UNKNOWN)	Hallucination Hypotension Insomnia Social Avoidant Behaviour		Baclofen (Baclofen) Paracetamol (Paracetamol) Ibuprofen (Ibuprofen) Vicodin (Hydrocodone Bitartrate, Paracetamol) Ciprofloxacin (Ciprofloxacin)	SS C C C C		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/10/05ISR Number: 4608969-7Report Type:Expedited (15-DaCompany Report #2004-BP-11398YA
Age:41 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Alanine Aminotransferase Increased	Foreign Health Professional	Harnal (Tamsulosin)	PS		ORAL	0.2 MG (NR)	PO
Other	Aspartate Aminotransferase Increased		Dantrium (Dantrolene Sodium) (Nr)	SS		ORAL	25 MG (NR)	PO
	Blood Bilirubin Increased		Lioresal (Dantrolene Sodium) (Nr)	SS		ORAL	6 DF (NR)	PO
	Blood Lactate Dehydrogenase Increased		Ternelin (Tizanidine Hydrochloride) (Nr)	SS		ORAL	1 MG TID (NR,	TID) PO
	Gamma-Glutamyltransferase Increased		Vitamedin (Benfotiamine/B6/B12) (Nr)	C				
	Liver Disorder							
	Lymphocyte Stimulation Test Positive		Diazepam (Diazepam) (Nr)	C				
	Malaise							

Date:03/14/05ISR Number: 4609508-7Report Type:Direct Company Report #CTU 243164
Age:73 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Mental Status Changes		Baclofen	PS			10 MG TID	1-2 TID
			Dexamethasone	SS				
			Tramadol	SS				
			Oscal	C				
			Asa	C				
			Clonidine	C				
			Docusate	C				
			Guaifenesin	C				
			Isosorbide	C				
			Lisinopril	C				
			Zocor	C				
			Vitamin E	C				

			Metoprolol	C		

Date:03/15/05ISR Number: 4608733-9Report Type:Expedited (15-DaCompany Report #PHNU2005DE00955
Age:80 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Coma		Lioresal	PS	Novartis Sector:			
	Depressed Level Of				Pharma	ORAL	10 mg, BID	
	Consciousness		Risperdal	SS		ORAL	1 mg, QD	5760 MIN
			Risperdal	SS		ORAL		
			Durogesic	C			SUBCUTANEOUS	UNK, UNK
			Zolpidem	C		ORAL		
			Ramipril	C		ORAL		

Date:03/16/05ISR Number: 4612639-9Report Type:Expedited (15-DaCompany Report #20052232
Age: Gender:Male I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Abasia
Required Intervention to Prevent Permanent Impairment/Damage	Catheter Related Complication
	Drug Withdrawal Syndrome
	Granuloma
	Hypertonia

		Hypotonia Spinal Column Stenosis					
			Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
			Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		
INTRATHECAL	MCG, DAILY,						
INTRATHECAL							

Date:03/17/05ISR Number: 4615398-9Report Type:Expedited (15-DaCompany Report #2004070485
Age:19 YR Gender: I/FU:F

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Death		Completed Suicide Intentional Misuse	Literature Health	Gabapentin (Gabapentin)	PS		ORAL
ORAL							
			Professional	Baclofen (Baclofen) (Baclofen)	SS		ORAL
ORAL							
				Oxybutynin (Oxybutynin) (Oxybutynin)	SS		ORAL
ORAL							

Date:03/22/05ISR Number: 4614907-3Report Type:Expedited (15-DaCompany Report #PHBS2005TW03936
Age:70 YR Gender:Female I/FU:I

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Hospitalization - Initial or Prolonged		Confusional State Disorientation		Baclofen	PS	Novartis Sector: Pharma	ORAL
5 mg, TID	4320 MIN						
		Drug Toxicity Haemoglobin Decreased Leukoaraiosis Somnolence					

Date:03/22/05ISR Number: 4614909-7Report Type:Expedited (15-DaCompany Report #PHBS2005US03938
Age:38 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Cerebral Artery Embolism Headache Hyperacusis Photophobia		Baclofen	PS	Novartis Sector: Pharma			

Date:03/23/05ISR Number: 4622248-3Report Type:Direct Company Report #CTU 244040
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Medication Error		Baclofen	PS		INTRATHECAL	1250 MCG/DAY	
			Elavil	C		IT		
			Levoxyl	C				
			Cozaar	C				
			Lipitor	C				
			Protonix	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/24/05ISR Number: 4617756-5Report Type:Expedited (15-DaCompany Report #PHBS2005US03938
Age:38 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Cerebral Artery Embolism Headache Hyperacusis Photophobia		Baclofen Intrathecal	PS	Novartis Sector: Pharma	INTRATHECAL		

Date:03/24/05ISR Number: 4617784-XReport Type:Expedited (15-DaCompany Report #PHBS2005CA01725
Age:55 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Hypersensitivity Muscular Weakness		Lioresal	PS	Novartis Sector: Pharma	ORAL	20 mg/day	63360MIN
			Hydrochlorothiazide	C			UNKNOWN	25 mg, QD
			Diazepam	C		ORAL	5 mg, TID	20160MIN
			Didrocal	C				
			Calcium	C				

Date:03/24/05ISR Number: 4617871-6Report Type:Expedited (15-DaCompany Report #PHBS2005CA01725
Age:55 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Hypersensitivity Muscular Weakness		Lioresal	PS	Novartis Sector: Pharma	ORAL	20 mg/day	63360MIN
			Hydrochlorothiazide	C			UNKNOWN	25 mg, QD
			Diazepam	C		ORAL	5 mg, TID	20160MIN
			Didrocal	C				
			Calcium	C				

Date:03/28/05ISR Number: 4620061-4Report Type:Expedited (15-DaCompany Report #PHRM2005FR01124
Age:23 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardiac Failure		Lioresal	PS	Novartis Sector: Pharma	ORAL	100 mg/day	
	Chromaturia							
	Dyspnoea Exertional		Amfetamine	C				
	Nervous System Disorder		Morphine	C				
	Overdose							

Date:03/29/05ISR Number: 4621748-XReport Type:Expedited (15-DaCompany Report #PHRM2005FR01112
Age:52 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Alkaline Phosphatase Increased		Lioresal	PS	Novartis Sector: Pharma	ORAL	15 mg, TID	
	Blood Lactate Dehydrogenase Increased		Dafalgan	SS		ORAL	500 mg, 6QD	2880 MIN
			Fraxiparine	C		SUBCUTANEOUS	0.4 ml, QD	
	Gamma-Glutamyltransferase Increased		Duphalac	C		ORAL	10 g, 6QD	
	Hepatitis							
	Transaminases Increased							

Date:04/01/05ISR Number: 4628396-6Report Type:Expedited (15-DaCompany Report #20052246
Age: 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	Cystitis Drug Withdrawal Syndrome Failure Of Implant Heart Rate Increased Hypertonia Muscle Spasms Muscle Spasticity Pelvic Abscess Sepsis	Health Professional	Lioresal Intrathecan (Baclofen Injection)	PS		INTRATRACHEAL INTRATHECAL	MCG,	DAILY,

Date:04/04/05ISR Number: 4626071-5Report Type:Expedited (15-DaCompany Report #PHNU2005DE01513
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hypothyroidism		Lioresal	PS	Novartis Sector: Pharma	ORAL	Unknown	
			Lioresal	SS	Novartis Sector: Pharma	ORAL	100 mg/day	

Date:04/04/05ISR Number: 4628449-2Report Type:Expedited (15-DaCompany Report #20052265
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Muscle Spasticity Pyrexia Underdose	Health Professional	Lioresal Intrathecal(Baclofen Injection)500mcg/Ml	PS		INTRATHECAL	198 MCG, DAILY, INTRATHECAL	

Date:04/06/05ISR Number: 4628674-0Report Type:Expedited (15-DaCompany Report #20052265
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Muscle Spasticity Pyrexia Underdose	Health Professional	Lioresal Intrathecal (Baclofen Injection) 500 Mcg/Ml	PS		INTRATHECAL	198 MCG, DAILY, INTRATHECAL	

Date:04/08/05ISR Number: 4633308-5Report Type:Expedited (15-DaCompany Report #20052290
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Withdrawal Syndrome Erythema Implant Site Infection Muscle Spasticity Post Procedural Complication Pyrexia Staphylococcal Infection Swelling	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		INTRATHECAL	MCG, DAILY, INTRATHECAL	

Date:04/11/05ISR Number: 4632024-3Report Type:Expedited (15-DaCompany Report #PHBS2005JP04814
Age:63 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Depressed Level Of Consciousness		Lioresal	PS	Novartis Sector: Pharma	ORAL	15 mg/day	2880 MIN
			Lasix	C		ORAL	80 mg/day	
			Zantac	C		ORAL	150 mg/day	
			Amlodin	C		ORAL	10 mg/day	
			Anplag	C		ORAL	200 mg/day	
			Calcium Carbonate	C		ORAL	3 g/day	
			Neurovitan	C		ORAL	3 df/day	
			Renagel	C		ORAL	750 mg/day	
			Cilostate	C		ORAL	50 mg/day	
			Diovan	C		ORAL	80 mg/day	
			Alfarol	C		ORAL	0.5 ug/day	
			Tryptanol	C		ORAL	40 mg/day	
			Tegretol	C		ORAL	400 mg/day	

Date:04/11/05ISR Number: 4633096-2Report Type:Direct Company Report #CTU 245806
Age:46 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Chest Pain		Baclofen	PS		ORAL	20 MG 3 TIMES	
	Pain In Extremity						A DAY ORAL	
			Wellbutrin 300 Mg	SS		ORAL	300 MG 1 TIME	

A DAY ORAL

	Vioxx	C
	Celebrex	C
	Bextra	C

Date:04/11/05ISR Number: 4635229-0Report Type:Expedited (15-DaCompany Report #20052246
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Cystitis	Health Professional	Lioresal Intrathecal(Baclofen Injection)	PS				
Required	Drug Withdrawal Syndrome							
INTRATHECAL	Heart Rate Increased						DAILY,	
Intervention to Prevent Permanent Impairment/Damage	Hypertonia						INTRATHECAL	
	Medical Device Complication							
	Medication Error							
	Muscle Spasticity							
	Pelvic Abscess							
	Pyrexia							
	Urosepsis							

Date:04/13/05ISR Number: 4635614-7Report Type:Expedited (15-DaCompany Report #KII-2005-0015781
Age:36 YR Gender:Male I/FU:I

Outcome	PT
Life-Threatening	Acidosis
Hospitalization - Initial or Prolonged	Agitation
	Bowel Sounds Abnormal
Other	Bradycardia
	Cardiac Arrest
	Coma
	Disorientation
	Electrocardiogram Qt

		Prolonged Hypertension Intentional Misuse Mydriasis	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
		Pupillary Reflex Impaired Somnolence	Study Health Professional Other	Morphine Sulfate (Similar To Nd 19-516) (Morphine Sulfate) Unknown	PS		ORAL
ORAL							
				Clonazepam(Clonazepam)	SS		ORAL
ORAL							
				Baclofen(Baclofen)	SS		ORAL
ORAL							
				Methocarbamol(Methocarbamol)	SS		ORAL
ORAL							
				Gabapentin(Gabapentin)	SS		

Date:04/18/05ISR Number: 4638119-2Report Type:Expedited (15-DaCompany Report #PHRM2005FR01234
Age:70 YR Gender:Female I/FU:I

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Hospitalization - Initial or Prolonged		Abasia Alanine Aminotransferase		Lioresal	PS	Novartis Sector: Pharma	ORAL
10 mg, TID	15840MIN						
		Increased		Zaldiar	SS		ORAL
2 DF, TID							
		Aspartate		Xanax	C		ORAL
0.25 mg, TID							
		Aminotransferase		Anafranil	C		ORAL
25 mg, BID							
		Increased		Dafalgan	C		ORAL
		Cerebral Atrophy Confusional State Escherichia Urinary Tract Infection					

Date:04/21/05ISR Number: 4641288-1Report Type:Expedited (15-DaCompany Report #PHFR2005GB01495
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hallucination		Baclofen	PS	Novartis Sector: Pharma		UNKNOWN	
	Muscle Spasms							
	Paranoia		Dantrolene	C			UNKNOWN	

Date:04/22/05ISR Number: 4642762-4Report Type:Expedited (15-DaCompany Report #PHEH2005US04344
Age:17 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Mental Status Changes		Zelnorm	PS	Novartis Sector: Pharma			
			Klonopin	I				
			Keppra	I				
			Baclofen	I				
			Ativan	I			UNK, PRN	
			Depakote	I				
			Prevacid	I				

Date:04/25/05ISR Number: 4643634-1Report Type:Expedited (15-DaCompany Report #PHBS2005JP04814
Age:63 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Depressed Level Of Consciousness		Lioresal	PS	Novartis Sector: Pharma	ORAL	15 mg/day	2880 MIN

			Lasix	C		ORAL
80 mg/day						
			Zantac	C		ORAL
150 mg/day						
			Amlodin	C		ORAL
10 mg/day						
			Anplag	C		ORAL
200 mg/day						
			Calcium Carbonate	C		ORAL
3 g/day						
			Neurovitan	C		ORAL
3 df/day						
			Renagel	C		ORAL
750 mg/day						
			Cilostate	C		ORAL
50 mg/day						
			Diovan	C		ORAL
80 mg/day						
			Alfarol	C		ORAL
0.5 ug/day						
			Tryptanol	C		ORAL
40 mg/day						
			Tegretol	C		ORAL
400 mg/day						

Date:04/27/05ISR Number: 4648618-5Report Type:Expedited (15-DaCompany Report #2005022833
Age:42 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Alanine Aminotransferase Increased	Foreign Health Professional	Viracept (Tablet) (Nelfinavir Mesilate)	PS		ORAL	ORAL	
	Aplastic Anaemia							
	Aspartate Aminotransferase Increased		Bactrim (Sulfamethoxazole, Trimethoprim)	SS		ORAL	ORAL	
	Blood Creatinine Abnormal		Zidovudine W/Lamivudine (Lamivudine, Zidovudine)	SS		ORAL	(2 IN 1 D), ORAL	
	Blood Lactate Dehydrogenase Increased							
	Blood Urea Decreased							
	Bone Marrow Depression							

	Epilepsy		Ergenyl Chrono			
	Prothrombin Level Decreased		(Valproate Sodium, Valproic Acid)	SS		ORAL (2 IN 1 D),
	Prothrombin Time Shortened					ORAL
	Treatment Noncompliance		Perindopril (Perindopril)	SS		ORAL 4 MG (4 MG, 1 IN 1 D), ORAL
			Baclofen (Baclofen)	SS		

Date:04/28/05ISR Number: 4647182-4Report Type:Expedited (15-DaCompany Report #PHBS2005US05720
Age:39 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose Duration
Hospitalization - Initial or Prolonged	Delirium		Baclofen	PS	Novartis Sector: Pharma	ORAL 30 mg, QID
	Drug Withdrawal Syndrome					
	Heart Rate Increased		Gabapentin	C		ORAL 400 mg, TID
	Overdose		Oxycodone	C		ORAL 60 mg, TID
	Pyrexia		Celecoxib	C		ORAL 100 mg, BID
	Self-Injurious Ideation		Nifedipine	C		ORAL 60 mg/day
	Suicide Attempt		Omeprazole	C		ORAL 20 mg/day
			Tizanidine	C		ORAL 12 mg, TID

Date:04/28/05ISR Number: 4647183-6Report Type:Expedited (15-DaCompany Report #PHBS2002CL09569
Age:41 YR Gender:Male I/FU:F

Outcome	PT
Other	Abdominal Distension
	Abdominal Pain Upper
	Chest Wall Pain
	Choking Sensation

	Fatigue Flatulence Haematochezia	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Pigmentation Disorder Somnolence		Lioresal	PS	Novartis Sector: Pharma	ORAL	1 tablet/day
	Urinary Incontinence		Lioresal	SS	Novartis Sector: Pharma	ORAL	2 tablets/day
			Lioresal	SS	Novartis Sector: Pharma	ORAL	4 tablets/day
			Lioresal	SS	Novartis Sector: Pharma	ORAL	20 mg/day
			Diazepam	C			UNKNOWN
			Losec	C			UNKNOWN PRN

Date:05/02/05ISR Number: 4651510-3Report Type:Expedited (15-DaCompany Report #20052273
Age: 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	Catheter Related Complication Device Failure Dizziness Migration Of Implant Vision Blurred	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		INTRATHECAL	MCG, DAILY, INTRATHECAL

Date:05/02/05ISR Number: 4652397-5Report Type:Expedited (15-DaCompany Report #20052321
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Device Malfunction Respiratory Failure	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		INTRATHECAL	UNK MCG,

Required
DAILY,
Intervention to
INTRATHECAL
Prevent Permanent
Impairment/Damage

Date:05/02/05ISR Number: 4652462-2Report Type:Expedited (15-DaCompany Report #20052219
Age: Gender: I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Amnesia	Foreign	Lioresal Intrathecal					
Hospitalization -	Coma	Health	(Baclofen Injection)	PS				
INTRATHECAL							MCG,	DAILY,
Initial or Prolonged	Confusional State	Professional						
INTRATHECAL								
Required	Convulsion							
Intervention to	Hypertonia							
Prevent Permanent	Hypotension							
Impairment/Damage	Respiratory Disorder							
	Shock							

Date:05/02/05ISR Number: 4652855-3Report Type:Expedited (15-DaCompany Report #PHFR2005GB01495
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Hallucination	Health	Baclofen (Baclofen)	PS				
	Muscle Spasms	Professional	Dantrolene					
	Paranoia	Other	(Dantrolene)	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/02/05ISR Number: 4652864-4Report Type:Expedited (15-DaCompany Report #PHNU2005DE00987
Age:37 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Cardiovascular Disorder	Foreign	Lioresal Intratecal					
Hospitalization - Initial or Prolonged	Coma	Health Professional	(Baclofen) Ampoule	PS		INTRATHECAL	50000 UG, ONCE/SINGLE	
	Convulsion							
	Depressed Level Of Consciousness	Other						
	Disorientation		Timonil (Carbamazepine)	C				
	Hypotension		Sirdalud (Tizanidine Hydrochloride)	C				
	Incorrect Dose Administered							
	Memory Impairment							
	Muscle Spasticity							
	Respiratory Failure							

Date:05/02/05ISR Number: 4653037-1Report Type:Expedited (15-DaCompany Report #20052279
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Catheter Related Complication	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		INTRATHECAL	MCG, DAILY,	
	Device Failure							
	Drug Withdrawal Syndrome		Miralax	C				
	Haematemesis		Mobic	C				
	Lethargy							
	Melaena							
	Overdose							
	Pyrexia							

Date:05/12/05ISR Number: 4660527-4Report Type:Expedited (15-DaCompany Report #PHBS2002CL09569
Age:41 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Abdominal Distension		Lioresal	PS	Novartis Sector: Pharma	ORAL	1 tablet/day	
	Abdominal Pain Upper							
	Chest Wall Pain		Lioresal	SS	Novartis Sector: Pharma	ORAL	2 tablets/day	
	Choking Sensation							
	Fatigue		Lioresal	SS	Novartis Sector: Pharma	ORAL	4 tablets/day	
	Flatulence							
	Haematochezia		Lioresal	SS	Novartis Sector: Pharma	ORAL	20 mg/day	
	Pigmentation Disorder							
	Somnolence		Diazepam	C			UNKNOWN	
	Urinary Incontinence		Losec	C			UNKNOWN	PRN

Date:05/12/05ISR Number: 4660535-3Report Type:Expedited (15-DaCompany Report #PHNU2005DE01924
Age:48 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blood Chloride Decreased		Lioresal	PS	Novartis Sector: Pharma	ORAL	7200 MIN	
	Blood Sodium Decreased							
	Delusional Disorder, Persecutory Type		Detrusitol	C				
			Spasmex	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/12/05ISR Number: 4661366-0Report Type:Expedited (15-DaCompany Report #05-05-0802
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hallucination	Foreign	Baclofen	PS				
	Muscle Spasms	Other	Baclofen	SS				
	Paranoia		Dantrolene	C				

Date:05/20/05ISR Number: 4669855-XReport Type:Expedited (15-DaCompany Report #20052351
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Implant Site Reaction Inflammation Mass	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		INTRATHECAL	MCG, DAILY, INTRATHECAL	

Date:05/23/05ISR Number: 4669589-1Report Type:Expedited (15-DaCompany Report #PHNU2005DE01956
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hypothermia		Lioresal	PS	Novartis Sector: Pharma	ORAL	5 mg, TID	

Date:05/23/05ISR Number: 4672802-8Report Type:Expedited (15-DaCompany Report #PHBS2005BE06441
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Cholestasis	Foreign Health Professional Other	Lioresal (Baclofen) Ampoule	PS		INTRATHECAL	1 MG/KG/DAY, INTRATHECAL	

Date:05/24/05ISR Number: 4672877-6Report Type:Expedited (15-DaCompany Report #05-05-0914
Age:4 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Disability	Colitis	Foreign Other	Baclofen	PS		ORAL	2.5 MG MANE	

Date:05/24/05ISR Number: 4674153-4Report Type:Expedited (15-DaCompany Report #KII-2005-0016647
Age:30 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Agitation Bowel Sounds Abnormal Coma Disorientation Hypotension Mydriasis Tachycardia	Study Health Professional Other	Hydromorphone Hcl (Similar To Nda 21-044) (Hydromorphone Hydrochloride)	PS		ORAL	ORAL	
			Methadone (Methadone)	SS		ORAL	ORAL	
			Gabapentin (Gabapentin)	SS		ORAL	ORAL	
			Amitriptyline (Amitriptyline)	SS		ORAL	ORAL	
			Baclofen (Baclofen)	SS		ORAL	ORAL	

			Benzodiazepine Derivatives ()	SS		ORAL
ORAL						
			Antiepileptics()	SS		ORAL
ORAL						
			Warfarin (Warfarin)	SS		ORAL
ORAL						

Date:05/26/05ISR Number: 4674599-4Report Type:Expedited (15-DaCompany Report #PHFR2005GB01910
Age:4 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Colitis		Baclofen	PS	Novartis Sector: Pharma	ORAL	2.5mg Mane; 5mg Nocte	
Disability								

Date:05/26/05ISR Number: 4674600-8Report Type:Expedited (15-DaCompany Report #PHBS2005JP04814
Age:63 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Depressed Level Of Consciousness		Lioresal	PS	Novartis Sector: Pharma	ORAL	5 mg, TID	2880 MIN
			Lasix	C		ORAL	80 mg/day	
			Zantac	C		ORAL	150 mg/day	
			Amlodin	C		ORAL	10 mg/day	
			Anplag	C		ORAL	UNK, UNK	
			Calcium Carbonate	C		ORAL	UNK, UNK	
			Neurovitan	C		ORAL	3 df/day	
			Renagel	C		ORAL	UNK, UNK	
			Cilostate	C		ORAL	UNK, UNK	

			Diovan	C		ORAL
UNK, UNK						
			Alfarol	C		ORAL
UNK, UNK						
			Tryptanol	C		ORAL
UNK, UNK						
			Tegretol	C		ORAL
UNK, UNK						

Date:05/26/05ISR Number: 4674603-3Report Type:Expedited (15-DaCompany Report #PHFR2005GB01495
Age:15 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hallucination		Baclofen	PS	Novartis Sector: Pharma	ORAL	40 mg/day	
	Muscle Spasms							
	Paranoia		Senna	C			2 tabs nocte	
			Dantrolene	C			UNKNOWN	
			Valproate Sodium	C		ORAL	400 mg/day	

Date:05/27/05ISR Number: 4678272-8Report Type:Expedited (15-DaCompany Report #KII-2005-0016712
Age:54 YR Gender:Male I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Atrioventricular Block First Degree
Other	Blood Pressure Systolic Increased
	Convulsion
	Depressed Level Of Consciousness
	Drug Ineffective
	Hypokalaemia
	Hypotension
	Intentional Misuse

		Multiple Drug Overdose Simple Partial Seizures Sinus Bradycardia	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
			Study Health Professional Other	Morphine Sulfate (Similar To Nda 19-516) (Moprhine Sulfate) Other	PS		ORAL
60 MG, SEE TEXT, ORAL							
				Baclofen (Baclofen)	SS		ORAL
ORAL							

Date:06/02/05ISR Number: 4679421-8Report Type:Expedited (15-DaCompany Report #1996AS00236
Age:13 YR Gender:Male I/FU:F

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Other		Blood Pressure Decreased		Naropin	PS		
EPIDURAL	DOSE: 20 MG 1 DAY						
		Bundle Branch Block		Baclofen	SS		
		Cardiac Septal Defect		Imipramine Hydrochloride	SS		
		Convulsive Threshold Lowered		Diazepam	C		
		Drug Level Increased					
		Drug Toxicity					
		Grand Mal Convulsion					
		Incorrect Route Of Drug Administration					
		Sinus Tachycardia					
		Tachycardia					

Date:06/02/05ISR Number: 4679967-2Report Type:Expedited (15-DaCompany Report #PHNU2005DE01956
Age:45 YR Gender:Female I/FU:F

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Other		Drug Toxicity Hypothermia		Lioresal	PS	Novartis Sector: Pharma	ORAL
5 mg, TID							
		Leukopenia		Zoloft	SS		ORAL
50 mg/day							

	Thrombocytopenia		Acimethin	C		ORAL	1500 mg/day
			Pantozol	C		ORAL	40 mg/day
			Torem	C		ORAL	5 mg, QD
			Acetylsalicylic Acid	C		ORAL	100 mg, QD

Date:06/02/05ISR Number: 4679968-4Report Type:Expedited (15-DaCompany Report #PHFR2005GB01965
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Blood Creatinine		Baclofen	PS	Novartis Sector:			
Hospitalization -	Increased				Pharma	ORAL	40 mg, QD	
Initial or Prolonged	Drug Level Increased		Tizanidine	SS		ORAL	36mg/day	
Other	Epilepsy		Gabapentin	SS				
UNKNOWN							400 mg, BID	
	Glasgow Coma Scale		Bendrofluazide	C		ORAL	2.5mg/day	
	Abnormal							
	Hallucination							
	Loss Of Consciousness							
	Overdose							
	Renal Failure Acute							
	Urinary Tract Infection							

Date:06/03/05ISR Number: 4680697-1Report Type:Expedited (15-DaCompany Report #1999AU14180
Age:13 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Bundle Branch Block		Ropivacaine	PS			EPIDURAL	DOSE: 20 mg
	Grand Mal Convulsion		Baclofen	SS				
	Tachycardia		Imipramine	SS				

Date:06/03/05ISR Number: 4684546-7Report Type:Expedited (15-DaCompany Report #20052367
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Cardiac Enzymes Increased	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		INTRATHECAL	MCG, DAILY,
Required Intervention to Prevent Permanent Impairment/Damage	Loss Of Consciousness							
	Urosepsis	Company				INTRATHECAL		
		Representative						

Date:06/06/05ISR Number: 4682607-XReport Type:Expedited (15-DaCompany Report #PHNU2004DE04093
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Condition Aggravated		Lioresal	PS	Novartis Sector: Pharma	ORAL	5 mg, BID	
	Confusional State							
	General Physical Health Deterioration		Lioresal	SS	Novartis Sector: Pharma	ORAL	2.5 mg, BID	
	Nausea		Trileptal "Novartis"	C			900mg/day	
	Vomiting							

Date:06/07/05ISR Number: 4683825-7Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20050600391
Age:71 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dyskinesia Vomiting		Tramadol Hydrochloride	PS				
OROPHARINGEAL							6	DAY
			Tramadol Hydrochloride	SS				
OROPHARINGEAL							6	DAY
			Baclofen	SS				
OROPHARINGEAL							6	DAY
			Asprin	C				
OROPHARINGEAL								
			Frusemide	C				
OROPHARINGEAL								
			Senna	C				
OROPHARINGEAL								

Date:06/07/05ISR Number: 4683919-6Report Type:Expedited (15-DaCompany Report #PHFR2005GB02015
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Confusional State Creatinine Renal		Baclofen	PS	Novartis Sector: Pharma			
UNKNOWN							10 mg,	TID
	Clearance Decreased Renal Impairment Sedation							

Date:06/07/05ISR Number: 4684072-5Report Type:Expedited (15-DaCompany Report #PHBS2005IE07820
Age:42 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Asthenia		Lioresal	PS	Novartis Sector: Pharma	ORAL	5 mg	
	Bradycardia							
	Syncope		Lithium	C				

Date:06/07/05ISR Number: 4685227-6Report Type:Expedited (15-DaCompany Report #05-06-0968
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Confusional State	Foreign	Baclofen -Ipi	PS			10 MG TDS	
	Renal Impairment	Other						
	Sedation							

Date:06/08/05ISR Number: 4687999-3Report Type:Expedited (15-DaCompany Report #20052372
Age:17 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Required	Blood Pressure Decreased	Health Professional	Lioresal Intrathecal(Baclofen Injection)	PS			INTRATHECAL	MCG, DAILY,
Intervention to Prevent Permanent Impairment/Damage	Blood Test Abnormal						INTRATHECAL	
	Catheter Related							
	Complication							
	Device Failure							
	Drug Administration Error							
	Drug Withdrawal Syndrome							
	Heart Rate Increased							
	Hyperhidrosis							
	Infection							
	Pain In Extremity							

Date:06/13/05ISR Number: 4688716-3Report Type:Expedited (15-DaCompany Report #PHRM2005FR01742
Age:23 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Alanine Aminotransferase Increased		Lioresal	PS	Novartis Sector: Pharma	ORAL	UNKNOWN	
	Aspartate Aminotransferase Increased		Iuvacor	C			UNK, UNK	
	Asthenia		Oxygen	C				
	Blood Alkaline Phosphatase Increased		Seretide	C			UNK, UNK	
	Blood Bilirubin Increased		Ventoline	C				
	Chromaturia		Meteospasmyl	C		ORAL	PRN	
	Chronic Hepatitis							
	Cytolytic Hepatitis							
	Faeces Discoloured							
	Jaundice							
	Pruritus							

Date:06/15/05ISR Number: 4691421-0Report Type:Expedited (15-DaCompany Report #KII-2005-0016870
Age:63 YR Gender:Female I/FU:I

Outcome	PT
Other	Abnormal Behaviour
	Anger

		Cerebral Ischaemia Confusional State Drug Ineffective Hostility Hypertension Somnolence Thinking Abnormal	Report Source Study Health Professional Other	Product Oxycontin Tablet (Oxycodone Hydrochloride) Cr Tablet Flexeril (Cyclobenzaprine Hydrochloride) Amitriptyline (Amitriptyline) Baclofen (Baclofen)	Role PS SS SS SS	Manufacturer	Route ORAL ORAL ORAL ORAL
Dose	Duration						
HS, ORAL							
SEE TEXT,							
ORAL							
SEE TEXT,							
ORAL							
DAILY, ORAL							

Date:06/17/05ISR Number: 4695697-5Report Type:Direct Company Report #CTU 251410
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Drug Dispensing Error Medication Error		Baclofen	PS		

Date:06/20/05ISR Number: 4696318-8Report Type:Expedited (15-DaCompany Report #2005087341
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged Other	Blood Pressure Abnormal Chest Pain Drug Ineffective Heart Rate Irregular Hepatic Cyst Mobility Decreased Multiple Sclerosis	Consumer	Bextra (Valdecoxib) Celebrex (Celecoxib) Baclofen (Baclofen) Vioxx (Rofecoxib) Rebif (Interferon Beta) Biaxin	PS SS SS SS SS		

	Nausea		(Clarithromycin)	SS		
	Spinal Cord Injury		Skelaxin (Metaxalone)	SS		

Date:06/21/05ISR Number: 4698265-4Report Type:Expedited (15-DaCompany Report #20052321
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Required	Device Failure Respiratory Failure	Health Professional	Lioresal Intrathecal(Baclofen Injection)	PS				
INTRATHECAL							MCG, DAILY,	
Intervention to INTRATHECAL Prevent Permanent Impairment/Damage								

Date:06/22/05ISR Number: 4697061-1Report Type:Expedited (15-DaCompany Report #PHRM2005FR01836
Age:42 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Accidental Overdose Hypotonia		Lioresal	PS	Novartis Sector: Pharma	ORAL	150 mg	1440 MIN
	Salivary Hypersecretion Somnolence		Lioresal	SS	Novartis Sector: Pharma	ORAL	30 mg/day	

			Topalgic "Houde"	C		ORAL	
			Spasfon	C		UNKNOWN	
			Microlax	C		RECTAL	

Date:06/22/05ISR Number: 4698580-4Report Type:Expedited (15-DaCompany Report #20052367
Age: Gender:Unknown I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged Required	Autonomic Nervous System Imbalance Disease Progression Loss Of Consciousness Multiple Sclerosis Myocardial Infarction Orthostatic Hypotension Urosepsis	Health Professional Company Representative	Lioresal Intrathecal(Baclofen Injection)	PS		INTRATHECAL	DAILY, INTRATHECAL
Intervention to Prevent Permanent Impairment/Damage							

Date:06/22/05ISR Number: 4699427-2Report Type:Expedited (15-DaCompany Report #ACO_0169_2005
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Epilepsy	Foreign	Zanaflex	PS		ORAL	36 MG PO
	Glasgow Coma Scale	Health Professional	Gabapentin	SS		ORAL	800 MG PO
	Abnormal		Baclofen	SS		ORAL	40 MG PO
	Hallucination Intentional Misuse Loss Of Consciousness Overdose Renal Failure Acute Urinary Tract Infection	Other	Ciprofloxacin Bendrofluazide	C C			

Date:06/27/05ISR Number: 4700189-0Report Type:Expedited (15-DaCompany Report #PHBS2005JP04814
Age:63 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Depressed Level Of Consciousness		Lioresal	PS	Novartis Sector: Pharma	ORAL	5 mg, TID	2880 MIN
			Lasix	C		ORAL	80 mg/day	
			Zantac	C		ORAL	150 mg/day	
			Amlodin	C		ORAL	10 mg/day	
			Anplag	C		ORAL	200 mg/day	
			Calcium Carbonate	C		ORAL	3 g/day	
			Neurovitan	C		ORAL	3 df/day	
			Renagel	C		ORAL	750 mg/day	
			Cilostate	C		ORAL	100 mg/day	
			Diovan	C		ORAL	80 mg/day	
			Alfarol	C		ORAL	0.5 ug/day	
			Tryptanol	C		ORAL	40 mg/day	
			Tegretol	C		ORAL	400 mg/day	

Date:06/29/05ISR Number: 4702446-0Report Type:Expedited (15-DaCompany Report #PHRM2005FR01836
Age:42 YR Gender:Male I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Areflexia
	Drug Dispensing Error
Other	Dry Mouth

	Enuresis Medication Error Psychomotor Skills	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
	Impaired Somnolence		Lioresal	PS	Novartis Sector: Pharma	ORAL
150 mg 1440 MIN						
			Lioresal	SS	Novartis Sector: Pharma	ORAL
10 mg, 6QD						
			Topalgic "Houde"	C		ORAL
			Spasfon	C		ORAL
			Microlax	C		
RECTAL						
			Lovenox	C		

Date:07/06/05ISR Number: 4707038-5Report Type:Expedited (15-DaCompany Report #PHBS2005CN09312
Age:64 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Glaucoma		Lioresal	PS	Novartis Sector: Pharma	ORAL
120 to 160						
mg/day						

Date:07/07/05ISR Number: 4708591-8Report Type:Expedited (15-DaCompany Report #PHFR2005GB02359
Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Drug Withdrawal Syndrome Muscular Weakness		Lioresal	PS	Novartis Sector: Pharma	
80-100mg 274 DAY						
Other	Myalgia Tachycardia		Ginger	SS		

Date:07/07/05ISR Number: 4708621-3Report Type:Expedited (15-DaCompany Report #200512160FR
Age:14 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Convulsion		Rifadine	PS	Aventis Pharmaceuticals Inc.	ORAL		
	Drug Effect Decreased							
	Drug Level Below Therapeutic		Artane	SS		ORAL		
			Oflocet	SS		ORAL		
	Drug Level Decreased		Depakine	SS		ORAL		
	Postictal State		Lioresal	SS		INTRATHECAL		

Date:07/07/05ISR Number: 4708859-5Report Type:Expedited (15-DaCompany Report #2005087341
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Blood Pressure Fluctuation	Consumer Health Professional	Bextra (Valdecoxib)	PS				
	Chest Pain		Celebrex (Celecoxib)	SS				
	Drug Ineffective		Baclofen (Baclofen)	SS				
	Heart Rate Irregular		Vioxx (Rofecoxib)	SS				
	Hepatic Cyst		Rebif (Interferon Beta)	SS				
	Multiple Sclerosis		Biaxin (Clarithromycin)	SS				
	Nausea		Skelaxin					

				(Metaxalone)	SS		

Date:07/07/05ISR Number: 4709519-7Report Type:Expedited (15-DaCompany Report #2005087341
Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Pressure Fluctuation	Consumer	Bextra (Valdecoxib)	PS				
Other	Chest Pain	Health Professional	Celebrex (Celecoxib)	SS				
	Drug Ineffective		Baclofen (Baclofen)	SS				
	Heart Rate Irregular		Vioxx (Rofecoxib)	SS				
	Hepatic Cyst		Rebif (Interferon Beta)	SS				
	Multiple Sclerosis		Biaxin (Clarithromycin)	SS				
	Nausea		Skelaxin (Metaxolone)	C				

Date:07/11/05ISR Number: 4710613-5Report Type:Expedited (15-DaCompany Report #PHBS2005IE07820
Age:42 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Asthenia		Lioresal	PS	Novartis Sector: Pharma	ORAL		
	Bradycardia							
	Syncope		Lithium	C				

Date:07/11/05ISR Number: 4711302-3Report Type:Expedited (15-DaCompany Report #05-07-1153
Age:49 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	Baclofen - Ipi Tablets	PS		ORAL	10MG TID ORAL	
	Chest Pain							
	Hypoaesthesia Oral							
	Mitral Valve Prolapse							
	Palpitations							
	Paraesthesia Oral							

Date:07/12/05ISR Number: 4711987-1Report Type:Expedited (15-DaCompany Report #PHBS2005AT09514
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Adhesion		Lioresal	PS	Novartis Sector: Pharma	ORAL	25 mg, TID	
Disability	Asthenia							
	Motor Dysfunction		Lioresal Intrathecal	SS			INTRATHECAL	
	Oedema							

Date:07/13/05ISR Number: 4713077-0Report Type:Expedited (15-DaCompany Report #PHHO2005US10718
Age:81 YR Gender:Male I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Adrenal Adenoma
	Bladder Mass
	Dehydration
	Haematuria
	Hypotension
	Mental Status Changes

	Sedation Syncope Urinary Tract Infection	Report Source	Product	Role	Manufacturer	Route	Dose Duration
			Baclofen	PS	Novartis Sector: Pharma		
			Zoledronic Acid Vs Placebo	SS			
INTRAVENOUS	Double-blind						
			Ativan	SS			
			Pentoxifylline	SS			
			Lasix	SS			
			Calcium Carbonate	C			
			Vitamin D	C			

Date:07/13/05ISR Number: 4714224-7Report Type:Direct Company Report #CTU 253147
Age:45 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Difficulty In Walking Post Procedural Complication		Baclofen .	PS C			
			Neurontin	C			
			Tylenol	C			

Date:07/15/05ISR Number: 4715316-9Report Type:Expedited (15-DaCompany Report #FR-ABBOTT-05P-056-0305095-00
Age:14 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Convulsion		Depakine Tablets	PS		ORAL	
	Drug Effect Decreased		Rifampicin	SS		ORAL	
	Drug Interaction		Morphine	C			UNKNOWN
	Drug Level Decreased		Morphine	C			UNKNOWN
			Morphine	C			UNKNOWN
			Ofloxacin	I		ORAL	
			Baclofen	I			
INTRATHECAL	125 mg daily						

through

implantable

intrathecal

pump

				Trihexyphenidyl Hydrochloride	I	

Date:07/15/05ISR Number: 4715673-3Report Type:Direct Company Report #CTU 253397
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Device Failure		Lioresal	PS		INTRATHECAL	1400 MG OVER 24 HOURS	
Required Intervention to Prevent Permanent Impairment/Damage	Hypotension Lethargy Loss Of Consciousness Overdose Urinary Retention					INTRATHECA		

Date:07/19/05ISR Number: 4719507-2Report Type:Expedited (15-DaCompany Report #20052426
Age: Gender:Male I/FU:I

Outcome
Hospitalization - Initial or Prolonged

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Asthenia Diplegia Granuloma	Health Professional	Lioresal Intrathecal(Baclofen Injection) 2000 Mcg/Ml	PS			INTRATHECAL	MCG, DAILY, INTRATHECAL

Date:07/19/05ISR Number: 4720549-1Report Type:Expedited (15-DaCompany Report #20052419
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	Atrial Fibrillation Catheter Related Complication Drug Withdrawal Syndrome Dysphonia Fluid Retention Hallucination Mental Status Changes Muscle Spasticity Post Procedural Complication Pruritus Pulmonary Embolism Screaming	Health Professional	Lioresal	PS			INTRATHECAL	700-1100 MCG, DAILY, INTRATHEC

Date:07/22/05ISR Number: 4722538-XReport Type:Expedited (15-DaCompany Report #JP-JNJFOC-20050700852
Age:14 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Convulsion		Oflocet	PS		ORAL		
	Drug Interaction		Artane	SS		ORAL		
	Drug Level Below		Rifadine	SS		ORAL		

	Therapeutic		Lioresal	SS		
INTRATRACHEAL						
	Postictal State		Depakine	I		ORAL

Date:07/25/05ISR Number: 4726181-8Report Type:Expedited (15-DaCompany Report #20052437
Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Gait Disturbance	Foreign	Lioresal Intrathecal					
Initial or Prolonged	Generalised Oedema	Health	(Baclofen Injection)	PS				
DAILY,								
	Hypotonia	Professional						
INTRATHECAL								
	Laboratory Test Abnormal							

Date:07/25/05ISR Number: 4726243-5Report Type:Expedited (15-DaCompany Report #PHBS2005AT09514
Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Adhesion	Foreign	Lioresal Intrathecal					
Initial or Prolonged	Asthenia	Health	(Baclofen) Ampoule	PS				
INTRATHECAL	INTRATHECAL							
Disability	Brain Oedema	Professional	Lioresal (Baclofen)					
	Motor Dysfunction	Other	Tablet	SS		ORAL		
25 MG, TID								
	Muscular Weakness							
ORAL								
	Oedema							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/27/05ISR Number: 4725756-XReport Type:Expedited (15-DaCompany Report #PHNR2005AU01158
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Delusion		Lioresal	PS	Novartis Sector: Pharma	ORAL	100-150 mg,	daily
	Psychotic Disorder							

Date:07/27/05ISR Number: 4727384-9Report Type:Direct Company Report #CTU 254537
Age:66 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Toxicity		Baclofen	PS				[PAST WEEK]
	Mental Status Changes		Lipitor	C				
			Glipizide	C				
			Zemplar	C				
			Epogen	C				
			Insulin	C				
			Prevacid	C				
			Vicodin	C				
			Trazodone	C				
			Plavix	C				
			Pro-Med	C				

Date:07/27/05ISR Number: 4727426-0Report Type:Direct Company Report #CTU 254510
Age:67 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hypotension		Hydromorphone 20 Mg/Ml	PS		INTRATHECAL	20 MG/ML , 4 MG DAILY IT	[LONG TERM]
	Hypoventilation							
	Hypoxia							
	Lethargy							
	Respiratory Depression		Baclofen 140 Mg /Ml	SS		INTRATHECAL	28 MCG DAILY	

Sedation

IT [LONG

Somnolence

TERM]

Ambien	C
Propoxyphene	C
Singulair	C
Promethazine	C
Lamictal	C
Zanaflex	C
Paxil	C
Neurotin	C
Zetia	C
Nexium	C
Maxide	C
Dicyclomine	C
Patanol	C
Nasonex	C
Diazepam	C
Clarinex	C
Coumadin	C

Date:08/01/05ISR Number: 4730631-0Report Type:Expedited (15-DaCompany Report #PHHO2005US10718
Age:81 YR Gender:Male I/FU:F

Outcome
Hospitalization - Initial or Prolonged

PT
Adrenal Adenoma
Bladder Mass

	Dehydration						
	Haematuria						
	Hypotension	Report Source	Product	Role	Manufacturer	Route	Dose Duration
	Mental Status Changes		Baclofen	PS	Novartis Sector: Pharma		
	Sedation						
	Syncope		Zoledronic Acid Vs				
	Urinary Tract Infection		Placebo	SS			INTRAVENOUS Double-blind
			Ativan	SS			
			Pentoxifylline	SS			
			Lasix	SS			
			Calcium Carbonate	C			
			Vitamin D	C			

Date:08/01/05ISR Number: 4732408-9Report Type:Expedited (15-DaCompany Report #KII-2005-0017700
Age:56 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization - Initial or Prolonged	Body Temperature Increased	Study	Oxycodone Hydrochloride				
Other	Confusional State	Health Professional	(Similar To Nda 20-553) (Oxycodone				
	Hypertension	Other	Hydrochloride)	PS		ORAL	ORAL
	Lethargy		Tramadol (Tramadol)	SS		ORAL	ORAL
	Tremor		Acetaminophen With Propoxyphene (Acetaminophen With				
			Propoxyphene)	SS		ORAL	ORAL
			Baclofen (Baclofen)	SS		ORAL	ORAL

Date:08/01/05ISR Number: 4733088-9Report Type:Direct Company Report #CTU 254843
Age:80 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Dyskinesia		Baclofen	PS		ORAL	5 MG PO TID

Initial or Prolonged	Fall		Promethazine	SS		ORAL	60 MG PO Q 12
Required	Mental Status Changes						H
Intervention to	Pain		Diphenhydramine	SS			PRN
Prevent Permanent			Morphine	SS			
Impairment/Damage			Hydrocodone/Apap	C			

Date:08/01/05ISR Number: 4733092-0Report Type:Direct Company Report #CTU 254840
Age:49 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose Duration
Hospitalization -	Agitation		Baclofen	PS			
Initial or Prolonged	Headache		Buspirone	SS			
Required	Hyperhidrosis		Mirtazapine	SS			
Intervention to	Hypotension		Quetiapine	SS			
Prevent Permanent	Hypoxia		Sertraline	SS			
Impairment/Damage	Insomnia		Tramadol	SS			
	Pyrexia						
	Sepsis						
	Serotonin Syndrome						
	Tremor						

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/02/05ISR Number: 4735675-0Report Type:Expedited (15-DaCompany Report #2005-02654
Age:1 DY Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Convulsion Neonatal Drug Exposure During Pregnancy General Physical Health Deterioration Neonatal Respiratory Distress Syndrome Premature Baby	Health Professional	Baclofen (Watson Laboratories) (Baclofen) Tablet Vicodin (Paracetamol) Enbrel (Etanercept)	PS SS SS	Watson Laboratories			

Date:08/10/05ISR Number: 4741421-7Report Type:Expedited (15-DaCompany Report #PHHO2005US10718
Age:81 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death Hospitalization - Initial or Prolonged	Adrenal Adenoma Anaemia Bladder Cancer Bladder Mass Confusional State Dehydration General Physical Health Deterioration Haematocrit Decreased Haematuria Haemoglobin Decreased Hypokalaemia Hyponatraemia Hypotension Mental Status Changes Sedation Syncope Urinary Tract Infection		Baclofen Zoledronic Acid Vs Placebo Ativan Pentoxifylline Lasix Calcium Carbonate Vitamin D	PS SS SS SS C C	Novartis Sector: Pharma		INTRAVENOUS	Double-blind

Date:08/11/05ISR Number: 4742577-2Report Type:Expedited (15-DaCompany Report #PHBS2005JP11296
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Abdominal Distension Gastrointestinal Disorder		Lioresal	PS	Novartis Sector: Pharma		5 mg	
			Lioresal	SS	Novartis Sector: Pharma		5 mg TID	

Date:08/18/05ISR Number: 4747946-2Report Type:Expedited (15-DaCompany Report #US-ABBOTT-05P-163-0307987-00
Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Convulsion Convulsion Neonatal Drug Exposure During Pregnancy Neonatal Respiratory Distress Syndrome Premature Baby Premature Labour Respiratory Distress		Vicodin Baclofen Etanercept	PS SS SS				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Summary report for FOI selections:

Selection by inexact search of active ingredient: BACLOFEN%

Selection by inexact search of Tradename/Verbatim: LIORESAL%

Total number of reports: 1,270

From: 01-NOV-1997 To: Present