Freedom Of Information (FOI) Report

1						
Date:11/06/97ISR Numbe Age:40 YR Gender:Mal	er: 100000196Report Type:Expe .e I/FU:I	edited (15-DaCompany Re	eport #97-10-0745			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Life-Threatening	Heart Rate Decreased Hypotension	Consumer	Baclofen Tablets	PS	Zenith Goldine Pharm.	ORAL
10MG Q4-6HRS						
ORAL						
			Tylenol	C		
Date:11/10/97ISR Numbe Age:37 YR Gender:Mal	er: 100000225Report Type:Expe e I/FU:F	edited (15-DaCompany Re	eport #97F10891			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - DAILY, ORAL	Agitation	Foreign	Lioresal	PS		ORAL
Initial or Prolonged	Clonic Convulsion Confusional State Hallucination Overdose	Health Professional Other				
Date:11/12/97ISR Numbe Age:35 YR Gender:Fem	er: 3000337-7Report Type:Expe ale I/FU:I	edited (15-DaCompany Re	eport #970566			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization -	Bradycardia	Foreign	Lioresal			
Initial or Prolonged Required DAY	Hypertonia Mydriasis	Health Professional	Inthrathecal (Balcofen Injection)	PS		
Intervention to Prevent Permanent Impairment/Damage	Pulmonary Oedema Respiratory Arrest					
A						

	97ISR Number Gender:Fema	: 3038112-XReport Type:Periodic le I/FU:I	c Company Repor	t #97USA10819			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
		Paraesthesia Oral	Health	Lioresal Tablet	PS		ORAL
50 MG DAILY		Parosmia	Professional				
	97ISR Number Gender:Male	: 3038114-3Report Type:Periodic I/FU:I	c Company Repor	t #97USA10944			
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration	Urticaria	Consumer	Lioresal Tablet	PS		ORAL
20 MG, TID	6 YR	Ultitalia	Consumer	DIOLESAL TADICE	ΕIJ		UKAL
	97ISR Number Gender:Male	: 3038117-9Report Type:Periodic I/FU:I	c Company Repor	t #97USA11792			
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration	Pulmonary Congestion	Health	Lioresal Tablet	PS		ORAL
PO			Professional				
1							

			FDA – Adv	verse Event Reporting Sy	'stem (AERS)	
				dom Of Information (FOI)		
Date:11/19/ Age:16 MON		r: 3038120-9Report Type:Peric I/FU:I	odic Company F	Report #97USA11812		
Outcome Dose	Duration	PT	Report Source	Product	Role Manufacturer	Route
DOBE	Duración	Impaired Gastric Emptying	Health Professional	Lioresal Tablet	PS	ORAL
	/97ISR Numbe: Gender:Fema	r: 3038122-2Report Type:Peric ale I/FU:I	odic Company F	Report #96USA14950		
Outcome	Duration	РТ	Report Source	Product	Role Manufacturer	Route
Dose	DULACION	Dizziness Nausea Vomiting	Health Professional	Baclofen Tablet	PS	ORAL
Age:59 YR Outcome Dose	Gender:Fema Duration	РТ	Report Source	Product	Role Manufacturer	Route
10 MG, TID	12 YR	Coordination Abnormal Dizziness Fatigue Hypoaesthesia Multiple Sclerosis Nausea Palpitations Sedation Vision Blurred	Health Professional	Lioresal Tablet	ΡS	ORAL
Date:11/19/ Age:	/97ISR Numbe: Gender:Male	r: 3038605-5Report Type:Peric e I/FU:I	odic Company F	Report #96USA14623		
Outcome Dose	Duration	PT	Report Source	Product	Role Manufacturer	Route
20 MG, QID	2 YR	Abdominal Pain	Consumer	Lioresal Tablet	PS	
ZU MG, QID	Z IK	Dermatitis				

		Dysgeusia Insomnia Nasal Congestion Oedema Peripheral Vision Blurred				
Date:11/19/9 Age:	97ISR Number Gender:Fema	: 3038607-9Report Type:Periodia le I/FU:I	c Company Repor	t #96USA14953		
Outcome	Duration	PT	Report Source	Product	Role Manufacturer	Route
Dose	Duration	Alopecia	Health	Lioresal Tablet	PS	ORAL
PO			Professional			
	97ISR Number Gender:Male	: 3038608-0Report Type:Periodio I/FU:I	c Company Repor	t #97USA10672		
Outcome	Duration	PT	Report Source	Product	Role Manufacturer	Route
Dose	Duration	Confusional State	Health	Lioresal Tablet	PS	ORAL
20 MG, TID		Hypertonia	Professional	Nortriptyline Tablet	С	
4						

		FDA - Advers¢	e Event Reporting Syste	em (AERS)	
		Freedom (Of Information (FOI) Re	eport	
Date:11/19/97ISR Number Age:42 YR Gender:Male	r: 3038611-0Report Type:Periodi e I/FU:I	Company Report	rt #97USA10750		
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 Age: Gender:Male	r: 3004006-9Report Type:Expedit e I/FU:I	ced (15-DaCompany Repo	rt #970568		
Outcome	PT	Report Source	Product	Role Manufacturer	Route
Dose Duration Death INTRATHECAL UNKNOW	Blood Pressure Increased WN	Company	Lioresal Intrathecal	PS	
DOSE/FREQUENC	Cardiac Disorder	Representative			
Y;	Faecaloma				ļ
INTRATHECAL	Hyperthermia Malignant				
ROUTE	Hypertonia				
	Myocardial Infarction Pyrexia				
Date:12/03/97ISR Number Age: Gender:Male	r: 3006825-1Report Type:Direct e I/FU:I	Company Repor	rt #		
Outcome Dose Duration	PT	Report Source	Product	Role Manufacturer	Route
Hospitalization -	Bradycardia IV Q6		Baclofen	PS	
Initial or Prolonged HOURS	Diplopia				
Other	Lethargy Mental Disorder				

Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
20MG -5/DAY	Duración	Condition Aggravated		Baclofen	PS		
20MG -5/DAY		Drug Ineffective		Baclofen	SS		
		Hypertonia					
Date:12/24/9' Age:19 YR (: 3012858-1Report Type:Expedite le I/FU:F	ed (15-DaCompany Report	t #97F-10699			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalizat: DAILY, ORAL		Leukopenia	Foreign	Lioresal	PS		ORAL
Initial or P	rolonged	Thrombocytopenia	Health Professional	Methotrexate Fraxiparine	C C		
	7ISR Number Gender:Male	: 3049149-9Report Type:Periodio I/FU:I	c Company Report	t #ZANA0319970300			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other PER ORAL		Hepatitis	Health	Zanaflex	PS		ORAL
		Pyrexia Sedation	Professional	Baclofen Prozac Wellbutrin	SS C C		

Freedom Of Information (FOI) Report

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

Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Life-Threater Hospitalizati	ning Lon -	Heart Rate Decreased Hypotension	Consumer Health	Baclofen	PS	Zenith Goldline Pharm.	ORAL
10 MG Q4-6HRS Initial or Pr			Professional	Tylenol	С		

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 30.000	MCG				
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 Hospitaliza 30MG DAILY	Duration tion -	Confusional State	Foreign	Lioresal	PS	
Initial or 1	Prolonged	Depressed Level Of Consciousness Muscle Twitching Urinary Incontinence	Literature Health Professional	Hemodialysis	C	

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose Hospitalizati INTRATHECAL	Duration ion -	Accidental Overdose	Foreign	Lioresal	PS		
Initial or Pr	colonged		Health Professional				
	8ISR Number: Gender:Male	: 3020705-7Report Type:Expedite	ed (15-DaCompany Repor	t #970582			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalizati INTRATHECAL			Company	Lioresal	PS		
Initial or Pr		Overdose	Representative				
	8ISR Number: Gender:Male	: 3024237-1Report Type:Direct I/FU:I	Company Report	t #			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Dose Hospitalizati Initial or Pr	ion -		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 Role Manufacturer Outcome PTReport Source Product Route Dose Duration Life-Threatening Depressed Level Of Foreign Lioresal PS ORAL 10 MG DAILY, Consciousness Health ORAL Hyponatraemia Professional Dantrolene С Inappropriate Etizolam` С Antidiuretic Hormone Carmellose Sodium Unknown Secretion С Pantethine С Date:02/13/98ISR Number: 3063706-5Report Type:Direct Company Report # Aqe:72 YR Gender:Male I/FU:I Role Manufacturer Outcome PTReport Source Product Route Dose Duration Baclofen Life-Threatening Apnoea 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 Report Source Role Manufacturer Outcome PTProduct Route Dose Duration Hospitalization -Haemorrhage ORAL Foreign Lioresal PS 10 MG TID Initial or Prolonged Hepatic Cirrhosis Health ORAL Professional

Other

Varices Oesophageal

Non-Steroidal Anti-I C

			ort #98GB-10084	edited (15-DaCompany Re	: 3032698-7Report Type:Exp I/FU:I		Date:02/20/ Age:56 YR
Route	Manufacturer	Role	Product	Report Source	PT	Duration	Outcome Dose
ORAL		PS	Lioresal	Foreign	Blindness Transient		Other 10 MG, QID,
				Health	Vision Blurred	£/	ORAL
		C C	Ibuprofen Nifedipine	Professional Other			
			ort #98GB-10054	edited (15-DaCompany Re	: 3032709-9Report Type:Exp le I/FU:I		
Route	Manufacturer	Role	Product	Report Source	PT	Duration	Outcome Dose
ORAL		PS	Baclofen	Foreign	Convulsion	alization -	Hospitaliza DAILY, ORAL
		C	Tamoxifen	Health Professional Other	Hypothermia Respiratory Acidosis Respiratory Arrest	or Prolonged	
			ort #970584	edited (15-DaCompany Re	: 3036481-8Report Type:Exp I/FU:I	2/24/98ISR Number Gender:	Date:02/24/ Age:
Route	Manufacturer	Role	Product	Report Source	PT	Duration	Outcome Dose
		PS	Lioresal	Foreign	Overdose		Death INTRATHECAL
				Company Representative			

Freedom Of Information (FOI) Report

Date:02/24/98ISR Number: 3036483-1Report Type:Expedited (15-DaCompany Report #970581 Age: Gender:Male I/FU:F Outcome PTReport Source Product Role Manufacturer Route Dose Duration Hospitalization -Accidental Overdose Foreign Lioresal Intrathecal PS INTRATHECAL DAILY DOSE Initial or Prolonged Depressed Level Of Health UNKNOWN Consciousness Professional AMOUNT Dyspnoea INTRATHECAL Renal Failure Acute Date:02/27/98ISR Number: 3037747-8Report Type:Expedited (15-DaCompany Report #98F--10125 Aqe:40 YR Gender:Male I/FU:I Role Manufacturer Outcome PTReport Source Product Route Dose Duration Life-Threatening Hepatic Enzyme Increased Foreign Lioresal PS ORAL 30 MG, DAILY, Hepatitis Health 2 YR ORAL Corticoids ORAL Professional SS ORAL Other Date:02/27/98ISR Number: 3037749-1Report Type:Expedited (15-DaCompany Report #98F--10124 Age:67 YR Gender:Female I/FU:I Role Manufacturer Outcome PTReport Source Product Route Dose Duration Hospitalization -Alanine Aminotransferase ORAL Foreign Lioresal PS 10 MG, BID, Initial or Prolonged Increased Health ORAL 11 DAY Aspartate Professional Di-Antalvic С Aminotransferase Other Dafalgan С Increased Hepatitis

Age:8 YR Gender:Mal	er: 3056638-XReport Type:Dire Le I/FU:I	ect Company Re	eport #		
Outcome Dose Duration	PT	Report Source	Product	Role Manufacturer	Route
Hospitalization - 50 MG AM, 25	Crying	Health	Topiramate	PS	
Initial or Prolonged MG PM 3-4	Irritability	Professional			
MONTHS	Oliguria				
1 MG PO, 3-4			Glycopyrrolate	SS	
MONTHS			Baclofen	SS	
Date:03/17/98ISR Numbe Age: Gender:Fer Outcome	er: 3056245-9Report Type:Expendence nale I/FU:I PT	edited (15-DaCompany Re Report Source	eport #98GB-10188 Product	Role Manufacturer	
Dose Duration					Route
Hospitalization -	Agitation	Foreign	Lioresal	PS	Route ORAL
	Agitation Brain Stem Infarction Fall	Foreign Health Professional Other	Lioresal Sinemet Bromocriptine Oxybutynin	PS C C C	

Life-Threatening Required Intervention to

Freedom Of Information (FOI) Report

Prevent Permanent Impairment/Damage

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

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

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Company Report #

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

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 -	11	Foreign	Lioresal	PS	
INTRAVENOUS 1200 M Initial or Prolonged INTRATHECAL	CQ/DAY; Muscle Spasms	Literature			
INIRAIMECAL	1	Health Professional			

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

Outcome Dose	Duration	РТ	Report Source	Product	Role Manufacturer	Route
Other 10 MG, TID,	Duración	Agitation	Foreign	Baclofen	PS	ORAL
ORAL	1 D	Bronchospasm AY	Health			
		Disorientation Loss Of Consciousness	Professional s Other			

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

OutcomePTReport SourceDeathDeathForeignLiterature

Freedom Of Information (FOI) Report

		Health Professional			
		PLOLESSIONAL	Product	Role Manufacturer	Rout
Dose Duration					
INTRATHECAL (INJEC			Lioresal	PS	
INTRATHECAL (INJEC	(TION)				
	r: 3063444-9Report Type:Expedi	ted (15-DaCompany Repo:	rt #970590		
Age:65 YR Gender:Fema	ale I/FU:I				
Outcome Dose Duration	PT	Report Source	Product	Role Manufacturer	Route
Hospitalization - INTRATHECAL 1100 M	Hyperhidrosis MCG	Foreign	Lioresal	PS	
Initial or Prolonged (INJECTION)/D	Muscle Spasms	Literature			
	Pyrexia	Health			
АУ	Tachycardia Tachypnoea	Professional			
Date:04/09/98ISR Number Age: Gender:Male Outcome	r: 3073686-4Report Type:Expedi e I/FU:I PT	ted (15-DaCompany Repor Report Source	rt #970592 Product	Role Manufacturer	Route
Dose Duration	a	** 1 + 1-	+ ' T	50	
Hospitalization - INTRATHECAL 2000 M	Coma MCG/ML	Health	Lioresal	PS	
Initial or Prolonged INTRATHECAL	Medication Error	Professional			
Required Intervention to Prevent Permanent Impairment/Damage	Overdose				
	r: 3065703-2Report Type:Expedi ale I/FU:I	ted (15-DaCompany Repor	rt #98USA10515		
Outcome Dose Duration	PT	Report Source	Product	Role Manufacturer	Rout

Hospitalizati DAILY ORAL	on -	Small Intestinal	Health	Lioresal	PS	ORAL
Initial or Pr	olonged	Obstruction	Professional			
	ISR Number ender:Male	: 3070742-1Report Type:Exped I/FU:I	ited (15-DaCompany Re	eport #970588		
Outcome		PT	Report Source	Product	Role Manufacturer	Route
Dose	Duration					
Other		Haematemesis	Foreign	Lioresal	PS	
INTRATHECAL	700 MC	G/DAY,				
		Intestinal Functional	Health			
INTRATHECAL						
		Disorder Renal Impairment	Professional			
	ISR Number ender:Fema	: 3065841-4Report Type:Exped le I/FU:I	ited (15-DaCompany Re	eport #98USA10556		
-						
Outcome		PT	Report Source	Product	Role Manufacturer	Route
	Duration					
Other DAILY ORAL		Coma	Health	Lioresal	PS	ORAL
			Professional	Lescol Atenolol Ticlid	C C C	

FDA - Adverse Event Reporting System (AERS) Freedom Of Information (FOI) Report Date:04/24/98ISR Number: 3068804-8Report Type:Expedited (15-DaCompany Report #98F--10306 Age:45 YR Gender:Male I/FU:I Outcome PTReport Source Product Role Manufacturer Route Dose Duration Hospitalization -Alanine Aminotransferase Foreign Lioresal PS ORAL 60 MG Initial or Prolonged Health Increased (TABLET), Professional Hepatic Necrosis 9 DAILY WK Hepatitis Date:04/28/98ISR Number: 3073283-0Report Type:Expedited (15-DaCompany Report #970584 Gender: Aqe: I/FU:I ΡТ Report Source Role Manufacturer Product Route Outcome Dose Duration Death Overdose Foreign Lioresal PS Company Representative Date:04/28/98ISR Number: 3073284-2Report Type:Expedited (15-DaCompany Report #970566 Age:35 YR Gender:Female I/FU:I Role Manufacturer Outcome PTReport Source Product Route Dose Duration Death Bradycardia Foreign Lioresal PS INTRATHECAL 250MCG/DAY/IN Hospitalization -Health Coma TRATHECAL Initial or Prolonged Muscle Spasticity Professional Mydriasis Pulmonary Oedema Respiratory Arrest

Shock

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose Hospitalizat 500 MG,	Duration ion -	Agitation	Foreign	Lioresal	PS		ORAL
Initial or P ONCE,ORAL,	rolonged	Coma	Health				
TAB		Pneumonia Aspiration	Professional				
		Suicide Attempt	Distributor Other				
Date:04/30/9 Age:80 YR		: 3074374-0Report Type:Expedit	ed (15-DaCompany Repor	t #98USA10617			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Life-Threate 5 MG, TID,	ning	Confusional State	Health	Lioresal	PS		ORAL
ORAL, TAB		Feeling Jittery	Professional				
		Status Epilepticus Tongue Discolouration					
Date:05/01/9 Age:54 YR		: 3073162-9Report Type:Direct I/FU:I	Company Repor	t #			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
		Agitation		Baclofen	PS		
10 MG TID X DAYS	5	Confusional State					

Freedom Of Information (FOI) Report

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

Outcome Dose Duration	PT	Report Source	Product	Role Manufacturer	Route
Other	Apallic Syndrome CCG/DAY,	Foreign	Lioresal	PS	
INTRATHECAL	Autonomic Neuropathy	Health			
	Bladder Disorder Gastrointestinal Disorder Haematemesis	Professional			
Date:05/05/98ISR Numbe Age:74 YR Gender:Fem	er: 3073597-4Report Type:Exped male I/FU:F	ited (15-DaCompany Re	≥port #98USA10515		
Outcome Dose Duration	PT	Report Source	Product	Role Manufacturer	Route
Dose Duration Hospitalization - (TABLET)	Small Intestinal	Health	Lioresal	PS	ORAL
Initial or Prolonged DAILY	Obstruction	Professional			
Date:05/15/98ISR Numbe Age: Gender:Mal	r: 3079236-0Report Type:Exped e I/FU:I	ited (15-DaCompany Re	≥port #970597		
Outcome Dose Duration	PT	Report Source	Product	Role Manufacturer	Route
Hospitalization - INTRATHECAL 30 MG	Accidental Overdose	Foreign	Lioresal	PS	
Initial or Prolonged MG/30 ML	Disorientation	Health			
INTRATHECAL	Drug Withdrawal Syndrome Hypotension	Professional			
	Medication Error				
1					

Outcome		PI	Report Source	Product	ROIE Manulactulei	Roule
Dose Other	Duration	Cerebrovascular Accident		Fluoxetine	PS	
20 MG NG QD		Dystonia		Baclofen	SS	
5-15 MG TID						
NG		Encephalopathy				
мG		Hallucination				
		Hypertonia				
		Muscle Rigidity				/
		Staring Tremor				
Date:05/28/9 Age:84 YR		r: 3084737-5Report Type:Exped: e I/FU:I	ited (15-DaCompany Rep	ort #98D-10328		
Outcome		PT	Report Source	Product	Role Manufacturer	Route
Dose	Duration					
Death		Arrhythmia	Foreign	Lioresal	PS	ORAL
1 DF, BID, Life-Threate	ning	Atrial Flutter	Health			
ORAL						
Hospitalizat		Phlebothrombosis	Professional	Euglucon N	SS	ORAL
3 DE, DAILY, Initial or P		Pneumonia				
ORAL	IUIUIIgea	Pileumonita				
		Rash Erythematous		Adumbran	SS	ORAL
1 DF, DAILY,		Charberlandersel Congig				
ORAL		Staphylococcal Sepsis				
		Urinary Tract Infection		Heparin	SS	
INTRAVENOUS	25000	I.E.				
DAILY						
INTRAVENOUS				_		
40 MG, DAILY	1			Sotalex	SS	ORAL
ORAL						
				Sotalex	SS	ORAL
2 DF, DAILY						
ORAL						
10 MC DATIV				Hypnomidate Ampoule	SS	
10 MG, DAILY						
22-Aug-2005 Page: 10	12:15 PM					

Report Source

Product

Role Manufacturer

Route

Outcome

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		FDA – Adve	erse Event Reporting Sys	<pre>stem (AERS)</pre>	
		Freedo	om Of Information (FOI)	Report	
			Tramal Drops	SS	ORAL
15 DRP,			-		
DAILY, ORAL					
2 DF, DAILY			Tambocor Ampoule	SS	
30 DRP, DAILY			Novalgin Drops	SS	ORAL
ORAL					
Date:06/04/98ISR Number Age:49 YR Gender:Fema	r: 3090258-6Report Type:Direc ale I/FU:I	t Company Re	eport #		
Outcome Dose Duration	РТ	Report Source	Product	Role Manufacturer	Route
Dose Duration Life-Threatening INTRATHECAL INTRAT Required 10 MG	Cardiac Arrest THECAL Coma		Baclofen	PS	
It MG Intervention to Prevent Permanent Impairment/Damage	Hypotension Lethargy		Asa Tylenol	C C	
Date:06/04/98ISR Number Age:84 YR Gender:Male	r: 3091096-0Report Type:Exped e I/FU:I	ited (15-DaCompany Re	eport #199811483HPD		
Outcome Dose Duration	PT	Report Source	Product	Role Manufacturer	Route
Death	Pneumonia	Foreign	Novalgin	PS	
Life-Threatening 2-1-0 U QD PO	Skin Disorder	Study	Euglucon N	SS	ORAL
Hospitalization - 2-1-0 U QD PO	Staphylococcal Sepsis	Health	Azuglucon	SS	ORAL
Initial or Prolonged	Stevens-Johnson Syndrome IU/DAY Toxic Epidermal	Professional	Heparin	SS	
IV	Necrolysis		Augmentan Tramal Adumbran Lioresal	SS SS SS SS	

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

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 Durat Life-Threatening DAILY, ORAL	tion Coma	Health	Liorseal	PS	ORAL
Hospitalization - Initial or Prolong Other		Professional	Lescol Capsule Atenolol Tablet Ticlid Tablet	С С С	

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

Freedom Of Information (FOI) Report

Dose	Duration	Hypertension Hypertonia Myocardial Infarction Pyrexia	Report Source Company	Product Lioresal Intrathecal		Manufacturer	Route
INTRATHECAL	UKNOWN	DOSE	Representative				
	8ISR Number Gender:Male	: 3098110-7Report Type:Exped: I/FU:I	ited (15-DaCompany Repo	ort #970600			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
		Unevaluable Event	Foreign Health Professional	Lioresal	PS		
	8ISR Number Gender:Male	: 3098117-XReport Type:Exped:	ited (15-DaCompany Repo	ort #98510034			
Outcome Dose	Duration	I/FU:I PT	Report Source	Product	Role	Manufacturer	Route
		PT Pruritus	Report Source Foreign		Role PS	Manufacturer	Route
Dose Hospitalizat	ion - 338 MC	PT Pruritus	-	Product		Manufacturer	Route
Dose Hospitalizat INTRATHECAL Initial or P	ion - 338 MC	PT Pruritus G,	Foreign	Product		Manufacturer	Route
Dose Hospitalizat INTRATHECAL Initial or P DAILY,	ion - 338 MC	PT Pruritus G, Rash Generalised	Foreign	Product		Manufacturer	Route
Dose Hospitalizat INTRATHECAL Initial or P DAILY, INTRATHECAL Date:06/24/9	ion - 338 MC rolonged	PT Pruritus G, Rash Generalised Toxic Skin Eruption : 3098123-5Report Type:Exped:	Foreign Other	Product Lioresal Propavan	PS	Manufacturer	Route
Dose Hospitalizat INTRATHECAL Initial or P DAILY, INTRATHECAL Date:06/24/9	ion - 338 MC rolonged 8ISR Number	PT Pruritus G, Rash Generalised Toxic Skin Eruption : 3098123-5Report Type:Exped:	Foreign Other	Product Lioresal Propavan	PS C	Manufacturer	Route

	: 3098128-4Report Type:Exped:	ited (15-DaCompany Rep	ort #98D10348			
Age:49 YR Gender:Fema	le I/FU:I					
Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Flushing	Foreign	Lioresal	PS		
INTRATHECAL 500 MC	G,					
	Suicidal Ideation	Consumer				
DAILY,						
-		Other				
INTRATHECAL 5 MON	ſ					
l l						
l l						
Date:06/24/98ISR Number	: 3098130-2Report Type:Exped:	ited (15-DaCompany Rep	ort #98D10348			
Age:49 YR Gender:Fema						
Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration	- -	Report Bource	liodaee	ROIC	hanalaeearer	nouce
Hospitalization -	Flushing	Foreign	Lioresal	PS		
INTRATHECAL DAILY,		roreign	LIUIESAI	ED		
		Conguman				
Initial or Prolonged	Hypertonia	Consumer				
INTRATHECAL 5 MON						
Other	Pruritus					
	Suicidal Ideation					
I						
	: 3098736-OReport Type:Direct	Company Rep	ort #			
Age:63 YR Gender:Fema	le I/FU:I					
Outcome	PT					
Life-Threatening	Clonic Convulsion					
	Depressed Level Of					
	Consciousness					
	Pain In Extremity					
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Freedom Of Information (FOI) Report

Dose Duration	Renal Failure Chronic Stupor Tachypnoea	Report Source	Product Baclofen	Role Manufacturer PS	Route ORAL
10 MG PO 1700			Bactoren	ES	UIAL
AND 2300			Isordil Lepovir Dorvil Estrogen Regulin	C C C C	
Date:06/29/98ISR Numb Age:71 YR Gender:Ma	er: 3100132-4Report Type:Exped le I/FU:I	ited (15-DaCompany Re	Ancef eport #970606	C	
Outcome	PT	Report Source	Product	Role Manufacturer	Route
Hospitalization - INTRATHECAL 2000	Atrioventricular Block MCG/DAY,	Foreign	Lioresal	PS	
Initial or Prolonged INTRATHECAL 17 D	Complete AY	Health			
Required Intervention to Prevent Permanent Impairment/Damage	Blood Pressure Decreased Bradycardia Drug Effect Decreased Muscle Spasms	Professional	Atropine Diazepam Fentanyl Urapidil Midazolam Dopamine Pancuronium	C C C C C C C C C C C C C C C C C C C	
Date:06/29/98ISR Numb Age:41 YR Gender:Fe	er: 3100466-3Report Type:Exped male I/FU:I	ited (15-DaCompany Re	eport #970609		
Outcome Dose Duration	PT	Report Source	Product	Role Manufacturer	Route
Hospitalization - INTRATHECAL 2000 Initial or Prolonged	Condition Aggravated MCG/DAY; Drug Effect Decreased	Foreign Literature	Lioresal	PS	
INTRATHECAL Required Intervention to	Musculoskeletal Stiffness Sedation	Health Professional	Pancuronium Diazepam	C C	

Prevent Permanent Impairment/Damage	Trismus		Flumanezil	С	
Date:06/29/98ISR Number Age:52 YR Gender:Fema	r: 3100467-5Report Type:Expe ale I/FU:I	edited (15-DaCompany Re	eport #970608		
Outcome	PT	Report Source	Product	Role Manufacturer	Route
Dose Duration					
Hospitalization - INTRATHECAL 500 MG	Hypopnoea CG/DAY,	Foreign	Lioresal	PS	
Initial or Prolonged INTRATHECAL	Sedation	Literature			
Required		Health	Diazepam	С	
Intervention to		Professional	Pancuronium	С	
Prevent Permanent			Flumazenil	C	
Impairment/Damage					
Date:06/29/98ISR Number	r: 3100468-7Report Type:Expe	dited (15-DaCompany R	2007t #970607		
Age:66 YR Gender:Fema		alled (15 bacompany in	2port #970007		
Outcome Dose Duration	PT	Report Source	Product	Role Manufacturer	Route
Life-Threatening INTRATHECAL VARIOU	Drug Effect Decreased US;	Foreign	Lioresal	PS	
Required INTRATHECAL 54 DAY	Hypotension	Literature			
Intervention to		Health	Midazolam	С	
Prevent Permanent		Professional	Pancuromium	C	
Impairment/Damage			Atropine	C	
			-		

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Freedom Of Information (FOI) Report

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 Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Life-Threatening	Bradycardia Cardiac Arrest	Foreign Health	Lioresal Intrathecal (Baclofen Injection)	PS		
INTRATHECAL 40 M	G, DAILY, Electrocardiogram St	Professional				
INTRATHECAL 16 M	ON	1101000101101				
	Segment Elevation Heart Rate Irregular Hypotension Hypothermia Hypoventilation Loss Of Consciousness Medication Error Myocardial Infarction		Aspirin Glyceril Trinitrate ???	C C C		
	Respiratory Failure					
Date:06/29/98ISR Numb Age:59 YR Gender:Fe	er: 3100951-4Report Type:Exped:		ort #98GB-10607			
Age:59 YR Gender:Fe Outcome	er: 3100951-4Report Type:Exped: male I/FU:I PT	ited (15-DaCompany Repo Report Source	ort #98GB-10607 Product	Role	Manufacturer	Route
Age:59 YR Gender:Fe Outcome Dose Duration Life-Threatening	er: 3100951-4Report Type:Exped: male I/FU:I PT Bradycardia G DAILY	Report Source Foreign		Role PS	Manufacturer	Route
Age:59 YR Gender:Fe Outcome Dose Duration Life-Threatening INTRATHECAL 40 M	er: 3100951-4Report Type:Exped: male I/FU:I PT Bradycardia	Report Source	Product		Manufacturer	Route

Dutcome Dose Dura	ation	PT	Report Source	Product	Role	Manufacturer	Route
Other Dura		Antinuclear Antibody	Foreign	Tegretal			
600 MG,		Positive	Health	(Carbamazepine)	PS		ORAL
		Drug Toxicity	Professional				
DAILY, ORAL 89		Hepatic Haemorrhage		Lioresal (Baclofen)	SS		ORAL
50 MG DAILY,		Reparte naemorrinage		HINIGSAL (BACINICH)	22		
		Hepatic Necrosis					
ORAL 67		Hepatotoxicity		Jarsin Sugar-Coated	С		
		Liver Function Test Abnormal		Dytide H	С		
Date:07/07/98ISR Age:40 YR Gende	Number:	Abnormal : 3102583-0Report Type:Expe	edited (15-DaCompany Re		C		
Age:40 YR Gende: Outcome	Number: er:Male	Abnormal : 3102583-0Report Type:Expe	edited (15-DaCompany Re Report Source		-	Manufacturer	Route
Age:40 YR Gende: Outcome	Number: er:Male ation	Abnormal : 3102583-0Report Type:Expe I/FU:I		eport #98F-10529	-	Manufacturer	Route ORAL
Age:40 YR Gende Outcome Dose Dura Other 2.5 MG, TID,	Number: er:Male ation	Abnormal : 3102583-0Report Type:Expe I/FU:I PT	Report Source	eport #98F-10529 Product	Role	Manufacturer	
Age:40 YR Gende Outcome Dose Dura Other 2.5 MG, TID, ORAL	Number: er:Male ation	Abnormal : 3102583-OReport Type:Expe I/FU:I PT Coma Hypoglycaemia	Report Source Foreign	eport #98F-10529 Product	Role	Manufacturer	
Age:40 YR Gende Outcome Dose Dura Other 2.5 MG, TID, ORAL	Number: er:Male ation	Abnormal : 3102583-OReport Type:Expe I/FU:I PT Coma Hypoglycaemia	Report Source Foreign Health	eport #98F-10529 Product Lioresal	Role PS	Manufacturer	

Freedom Of Information (FOI) Report

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					
Hospitalizati	ion –	Pyrexia	Health	Lioresal	PS	ORAL
DIALY, ORAL						
Initial or Pr	colonged		Professional			

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

Outcome Dose	Duration	PT	Report Source	Product	Role Manufacturer	Route
	-	Dermatitis	Foreign	Lioresal	PS	ORAL
75 MG,DAILY,		Pyrexia	Health			
ORAL			Professional	Tegretol	SS	ORAL
800 MG,			Other			
DAILY, ORAL						
INTRAVENOUS	2G, DAI	ILY		Vancomycin	SS	
	- ,			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 Life-Threate 200 MG, ONCE	-	Blood Creatine	Foreign	Lioresal	PS	ORAL
Hospitalizat ORAL		Phosphokinase Increased	Health			
Initial or P	rolonged	Depressed Level Of Consciousness	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 Required 170MCG BOLUS,	Duration	Hypertension	Health	Lioresal	PS		
Intervention INTRATHECAL		Medication Error	Professional				
Prevent Perma Impairment/Da		Overdose					
	BISR Number: Gender:Femal	: 3108325-7Report Type:Direct le I/FU:I	Company Report	- #			

Outcome	PT	Report Source	Product	Role Manufacturer	Route
Dose Duration Hospitalization - 5MG 4 X DAILY	Amnesia		Baclofen	PS	
Initial or Prolonged	Confusional State		Famvir	С	
	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 Gender:Male Aqe:46 YR I/FU:I Outcome PTReport Source Product Role Manufacturer Route Dose Duration Hospitalization -Depressed Level Of Foreign Lioresal PS ORAL 20 MG DAILY Initial or Prolonged Consciousness Health ORAL Respiratory Disorder Professional Date:07/27/98ISR Number: 3109297-1Report Type:Expedited (15-DaCompany Report #970617 Age: Gender:Male I/FU:I Report Source Role Manufacturer Outcome PTProduct Route Duration Dose Condition Aggravated Lioresal Intrathecal PS Death Company INTRATHECAL APPROX. Hypertonia Representative 2000MCG/DAY, Procedural Site Reaction INTRATHECAL Date:07/30/98ISR Number: 3111411-9Report Type:Expedited (15-DaCompany Report #970588-2 Aqe:21 YR Gender:Male I/FU:F Outcome PTReport Source Product Role Manufacturer Route Dose Duration Other Bladder Disorder Foreign Lioresal PS INTRATHECAL 700 MCG/DAY, Haematemesis Health INTRATHECAL Intestinal Functional Professional Disorder Date:07/30/98ISR Number: 3111415-6Report Type:Expedited (15-DaCompany Report #970615-1 Age:4 YR Gender:Female I/FU:F PTReport Source Product Role Manufacturer Outcome Route Dose Duration

Required	Accidental Overdose	Health	Lioresal	PS	
INTRATHECAL 170 MC					
Intervention to BOLUS,	Hypotension	Professional			
Prevent Permanent INTRATHECAL	Respiratory Depression				
Impairment/Damage	Sedation				
Date:07/31/98ISR Number Age:15 YR Gender:Unkr	r: 3111269-8Report Type:Exp nown I/FU:I	edited (15-DaCompany Re	eport #98GB-10641		
Outcome Dose Duration	PT	Report Source	Product	Role Manufacturer	Route
Hospitalization - 40 MG, DAILY,	Hypothermia	Foreign	Baclofen	PS	ORAL
Initial or Prolonged ORAL		Health			
		Professional	Pro-Banthine Cephradine Prednisolone Ranitidine	С С С	
Date:08/05/98ISR Number Age:49 YR Gender:Male	: 3115239-5Report Type:Exp I/FU:I	edited (15-DaCompany Re	eport #98GB-10787		
Outcome Dose Duration	PT	Report Source	Product	Role Manufacturer	Route
Other 25 MG DAILY,	Liver Function Test	Foreign	Baclofen	PS	ORAL
ORAL	Abnormal	Health			
		Professional			

			FDA - A	dverse Event Reporting Syst	cem (AEF	RS)	
			Fre	edom Of Information (FOI) F	Report		
Date:08/05/ Age:37 YR	/98ISR Number Gender:Male	: 3226195-3Report Type:Period I/FU:I	lic Company	Report #98-03-0039			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other		Blood Insulin Increased Hepatic Function Abnormal	Consumer	Baclofen - Zenith Goldline Pharm.			
60MG/DAY OF	τΛ	Hypoglycaemia		Tablets	PS		ORAL
OUMG/DAI OF	(AL)			Vicodin	С		
l				Tenoretic	C		
				Cytotec	C		
				Naproxen	С		
				Tagamet	С		
Age:61 YR Outcome	Gender:Male	: 3226201-6Report Type:Period I/FU:I PT	lic Company Report Source	Report #97-10-0729 Product	Role	Manufacturer	Route
Dose Other	Duration	Muscular Weakness Pollakiuria	Consumer	Baclofen - Zenith Goldline Pharm.			
10MG 1/2QHS	5			Tablets	PS		ORAL
ORAL				Prednisone Therapy	С		
				Fredhisone merapy	C		
	/98ISR Number Gender:Male	: 3226206-5Report Type:Period I/FU:I	lic Company	Report #97-12-0815			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other	Duración	Dizziness Headache	Consumer	Baclofen - Zenith Goldline Pharm.			
		Muscle Rigidity		Tablets	PS		ORAL
10MG BID OF	RAL						
		Muscle Spasms					
		Paraesthesia					
		Tremor					

	98ISR Number Gender:Fema	r: 3226211-9Report Type:Perio ale I/FU:I	dic Company Re	eport #98-04-0096			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other		Heart Rate Increased Paraesthesia Sedation	Consumer	Baclofen - Zenith Goldline Pharm Tablets	PS		ORAL
40-60 MG/DAY	Y	Bedation		TUDICED	10		01412
10 00 110, 211	1	Sleep Apnoea Syndrome					
ORAL		Dicep inpliced 27-102 cmc					
				Paxil Flexeril	C C		
1				Ambien	C		
1				Morphine Sulfate	С		
1				Clonidine Patch	С		
	98ISR Number Gender:Male	r: 3226215-6Report Type:Perio e I/FU:F	dic Company Re	eport #97-05-0385			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other	Duración	Cerebrovascular Accident Vomiting	Health Professional	Baclofen - Zenith Goldline Pharm.			
1		-	Other	Tablets	PS		ORAL
5MG TID ORAL	⊔						
1				Asa	C		
1				Coumadin	C		
l				Centrum	C		

Freedom Of Information (FOI) Report

Zoloft

С

Date:08/05/98ISR Number: 3226758-5Report Type:Periodic Company Report #98-01-0003 Age:49 YR Gender:Female I/FU:I ΡТ Report Source Role Manufacturer Outcome Product Route Dose Duration Baclofen Other Asthenia Consumer Bladder Disorder Other Tablets-Zenith Constipation Goldline Pharm. Zenith Goldline PS Hypersomnia Pharm. ORAL 20MG TID ORAL Increased Appetite Ms Contin С Muscle Spasms Klonopin С Urinary Retention Soma С Urinary Tract Disorder Vision Blurred Date:08/05/98ISR Number: 3226759-7Report Type:Periodic Company Report #97-12-0818 Gender:Female Age:26 YR I/FU:I Report Source Product Role Manufacturer Outcome PTRoute Dose Duration Drug Ineffective Health Baclofen Zenith Goldline Other PS Professional 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 \mathbf{PT} Report Source Product Role Manufacturer Route Dose Duration Hospitalization -Respiratory Depression Foreign Lioresal PS Initial or Prolonged Sedation Health

Professional

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

Outcome Dose Duration	PT	Report Source	Product	Role Manufacturer	Route
Hospitalization - Initial or Prolonged	Bradycardia Coma Hypotension Overdose Respiratory Depression	Foreign Health Professional Distributor	Lioresal	PS	
Date:08/14/98ISR Numbe Age:46 YR Gender:Mal	r: 3117305-7Report Type:Expe e I/FU:F	dited (15-DaCompany Re	eport #98J-10271		
Outcome Dose Duration	РТ	Report Source	Product	Role Manufacturer	Route
Dose Duration Hospitalization -		Report Source Foreign	Product Lioresal	Role Manufacturer PS	Route ORAL
Dose Duration	PT Depressed Level Of Consciousness				

Freedom Of Information (FOI) Report

Lioresal

Dantrium

SS

SS

ORAL

ORAL

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 Life-Threater 200 MG ONCE	Duration ning	Blood Creatine	Foreign	Lioresal	PS	ORAL
		Phosphokinase Increased	Health			
ORAL						
		Depressed Level Of Consciousness Hypotonia Rhabdomyolysis Sedation Suicide Attempt	Professional			
Date:08/18/98	BISR Number	: 3118773-7Report Type:Expedite	ed (15-DaCompany Report	t #FLUV001980094		
Age:30 YR (Gender:Fema	le I/FU:I				
Outcome Dose	Duration	PT	Report Source	Product	Role Manufacturer	Route
Hospitalizat: PER ORAL	ion -	Prothrombin Time		Floxyfral	PS	ORAL
Initial or Pr PER ORAL	rolonged	Shortened		Sermion	SS	ORAL

PER 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	e	Product	Role	Manufacturer	Route
Dose Other 600 MG DAILY	Duratio		nuclear Antibod	Y	Foreign		Tegretal	PS		ORAL
ORAL	89	Posi DAY	tive		Health					

	Hepatic Haemorrhage	Professional	Lioresal	SS	ORAL
50 MG DAILY					
ORAL 67 DAY	Hepatic Necrosis	Other			
URAL UT DR.	Liver Function Test Abnormal		Jarsin Sugar-Coated Tablet	с	
			Dytide H	С	
	r: 3242793-5Report Type:Per	iodic Company Re	eport #970545		
Age:44 YR Gender:Fema	ale I/FU:I				
Outcome Dose Duration	PT	Report Source	Product	Role Manufacturer	Route
Hospitalization -	Bradycardia	Foreign	Lioresal Intrathecal		
Initial or Prolonged BOLUS DOSE OF	Confusional State	Literature	(Baclofen Injection)	PS	
	Dyspnoea	Health			
0.2 ML OF 500	Hypertonia	Professional			
MCG/ML	нурегопта	PLOLESSIONAL			
	Hypotonia Sedation				
	r: 3242797-2Report Type:Per	iodic Company Re	eport #970546		
Age:38 YR Gender:Male	e I/FU:I				
Outcome Dose Duration	PT	Report Source	Product	Role Manufacturer	Route
Hospitalization -	Convulsion	Foreign	Lioresal Intrathecal		
Initial or Prolonged 100 MCG BOLUS		Literature	(Baclofen Injection)	PS	
		Health			
DOSE		Professional			

				FDA – Adve	erse Event Reporting Syste	em (AEF	RS)	
					om Of Information (FOI) Re			
Date:08/20 Age:	0/98ISR Number Gender:Unkn	r: 3242806-0Report Type:Pe nown I/FU:I	riodic	Company Re	eport #970547			
Outcome Dose Other	Duration	PT Hypotonia	Report Literat Health Profess	ture	Product Lioresal Intrathecal (Baclofen Injection)		Manufacturer	Route
Date:08/20 Age:	0/98ISR Number Gender:Unkn	r: 3242810-2Report Type:Pe nown I/FU:I	riodic	Company Re	eport #970548			
Outcome Dose Other	Duration	PT Hypotonia	Report Literat Health Profess	ture	Product Lioresal Intrathecal (Baclofen Injection)		Manufacturer	Route
Date:08/20 Age:	0/98ISR Number Gender:Unkn	r: 3242813-8Report Type:Pe nown I/FU:I	riodic	Company Re	eport #970549			
Outcome Dose Other	Duration	PT Hypotonia	Report Literat Health Profess	ture	Product Lioresal Intrathecal (Baclofen Injection)		Manufacturer	Route
Date:08/20 Age:	0/98ISR Number Gender:Unkn	r: 3242815-1Report Type:Pe nown I/FU:I	riodic	Company Re	eport #970550			
Outcome Dose Other	Duration	PT Urinary Retention	Report Literat Health Profess	ture	Product Lioresal Intrathecal (Baclofen Injection)		Manufacturer	Route

	PT	Report Source	Product	Role	Manufacturer	Route
Duration						
	Urinary Retention	Literature Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		
		odic Company Repo	ort #970552			
Duration	PT	Report Source	Product	Role	Manufacturer	Route
	Urinary Retention	Literature Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		
		odic Company Repo	ort #970553			
Duration	PT	Report Source	Product	Role	Manufacturer	Route
	Dizziness Nausea Sedation	Literature Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		
	8ISR Number Gender:Unkr Duration 8ISR Number Gender:Unkr	Duration Urinary Retention 8ISR Number: 3242819-9Report Type:Perio Gender:Unknown I/FU:I PT Duration 8ISR Number: 3242820-5Report Type:Perio Gender:Unknown I/FU:I PT Duration PT Duration PT Duration	Duration Urinary Retention Literature Health Professional 8ISR Number: 3242819-9Report Type:Periodic Gender:Unknown I/FU:I PT PT PT PT Report Source Health Professional 8ISR Number: 3242820-5Report Type:Periodic Gender:Unknown I/FU:I PT PT PT PT Report Source Health Professional 8ISR Number: 3242820-5Report Type:Periodic Company Report Company Report Company Report PT PT PT PT PT Report Source Health Professional 8ISR Number: 3242820-5Report Type:Periodic Company Report Company Report Company Report PT PT PT PT Report Source Literature Health PT PT Report Source Health	Duration Urinary Retention Literature Health Health (Baclofen Injection) Professional 8ISR Number: 3242819-9Report Type:Periodic Company Report #970552 Gender:Unknown I/FU:I PT	DurationUrinary RetentionLiterature Health ProfessionalLioresal Intrathecal (Baclofen Injection)PS8ISR Number:3242819-9Report Type:Periodic Gender:Unknown I/FU:ICompany Report #970552PSDurationPT Urinary RetentionReport SourceProductRole (Baclofen Injection)0PT ProfessionalLiterature Health ProfessionalLioresal Intrathecal (Baclofen Injection)PS8ISR Number:3242820-5Report Type:Periodic IFU:ICompany Report #970553PS8ISR Number:3242820-5Report Type:Periodic IFU:ICompany Report #970553RoleDurationPT Dizziness NauseaReport SourceProductRoleDizziness NauseaLiterature HealthLioresal Intrathecal (Baclofen Injection)PS	Duration Urinary Retention Literature Health Professional Lioresal Intrathecal (Baclofen Injection) PS 8ISR Number: 3242819-9Report Type:Period: Company Report #970552 Product Role Manufacturer Duration PT Report Source Product Role Manufacturer Urinary Retention Literature Health Professional Lioresal Intrathecal (Baclofen Injection) PS 8ISR Number: 3242820-5Report Type:Period: Company Report #970553 PS 8ISR Number: 3242820-5Report Type:Period: Company Report #970553 PS Buration PT Report Source Product Role Manufacturer Duration PT Report Source Product Role Manufacturer Duration PT Report Source Product Role Manufacturer Duration Dizziness Literature Health Product Role Manufacturer

			FDA - Adverse	e Event Reporting Syste	em (AEI	RS)	
			Freedom (Df Information (FOI) Re	port		
Date:08/20/9 Age:	98ISR Number Gender:Unkn	: 3242822-9Report Type:Periodi own I/FU:I	C Company Repo	rt #970554			
Outcome Dose Other	Duration	PT Confusional State Hypotonia	Report Source Foreign Literature Health Professional	Product Lioresal Intrathecal (Baclofen Injection)		Manufacturer	Route
Date:08/20/9 Age:	98ISR Number Gender:Fema	: 3242824-2Report Type:Periodi le I/FU:I	c Company Repo	rt #970555			
Outcome Dose Other 390 MCG/DAY OF 2000	Duration	PT Condition Aggravated Hypertonia	Report Source Health Professional	Product Lioresal Intrathecal (Baclofen Injection)		Manufacturer	Route
MCG/ML Date:08/20/9 Age:	98ISR Number Gender:Male	: 3242826-6Report Type:Periodi I/FU:I	c Company Repo	ct #970556			
Outcome Dose Other INTRATHECAL	Duration	PT Hypotonia	Report Source Company Representative	Product Lioresal Intrathecal (Baclofen Injection)		Manufacturer	Route
INTRATHECAL							
Date:08/20/9 Age:	98ISR Number Gender:Male	: 3242828-XReport Type:Periodi I/FU:I	C Company Repor	rt #970558			
Outcome Dose Hospitalizat	Duration tion -	PT Hypertonia	Report Source Foreign	Product Lioresal Intrathecal	Role	Manufacturer	Route

Initial or Prolonged		Health	(Baclofen Injection)	PS		
INTRATHECAL 250 MC	G/DAY					
		Professional				
INTRATHECAL						
	: 3242829-1Report Type:Periodi	c Company Repor	t #970562			
Age: Gender:Fema	le I/FU:I					
Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Urinary Incontinence	Health	Lioresal Intrathecal			
		Professional	(Baclofen Injection)	PS		
INTRATHECAL UNKNOW	N DOSE,					
INTRATHECAL						
DELIVERY						
Dete:00/20/00TGD Numbers	· 2040021 WDomout Three Dominal					
Age:4 YR Gender:Male	: 3242831-XReport Type:Periodi I/FU:I	c Company Repor	10 #970567			
Age: 4 II. Gender Mare	1/10.1					
Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration		-				
Hospitalization -	Convulsion	Health	Lioresal Intrathecal			
Initial or Prolonged		Professional	(Baclofen Injection)	PS		
INTRATHECAL 48 MCG						
INTRATHECAL						
TNIVATURCAT						

BOLUS

				erse Event Reporting Syste		RS)	
			110000		POLC		
Date:08/20/9 Age:	98ISR Number Gender:Fema	: 3242832-1Report Type:Peri le I/FU:I	odic Company Re	eport #970569			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other	105 40	Condition Aggravated Hypertonia	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		
INTRATHECAL	105 MC	G/DAY,					
INTRATHECAL							
Date:08/20/9 Age:	98ISR Number Gender:Male	: 3242833-3Report Type:Peri I/FU:I	odic Company Re	eport #970570			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other		Condition Aggravated Hypertonia	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		
INTRATHECAL	264 MC	G/DAY,					
INTRATHECAL							
Date:08/20/9 Age:	98ISR Number Gender:Fema	: 3242835-7Report Type:Peri le I/FU:I	odic Company Re	eport #970571			
Outcome Dose	Duration	РТ	Report Source	Product	Role	Manufacturer	Route
Other		Condition Aggravated Hypertonia	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		
INTRATHECAL	638 MC						
INTRATHECAL							
Date:08/20/9 Age:	98ISR Number Gender:Male	: 3242837-0Report Type:Peri I/FU:I	odic Company Re	eport #970572			
Outcome	Durati	PT	Report Source	Product	Role	Manufacturer	Route
Dose Other	Duration	Condition Aggravated Hypertonia	Health Professional	Lioresal Intrathecal (Baclofen Injection)	DC		
INTRATHECAL	161 MC		PIOLESSIONAL	(Bacioren injection)	РЭ		

INTRATHECAL

Date:08/20/9 Age:	98ISR Number Gender:Male	: 3242840-0Report Type:Peri I/FU:I	iodic Company Re	port #970573			
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose Other	Duration	Hypertonia	Health Professional	Lioresal Intrathecal (Baclofen Injection)	DC		
INTRATHECAL	508 MC	G/DAY,	FIOLESSIONAL	(Bacioren injection)	PD		
INTRATHECAL							
Date:08/20/9 Age:	98ISR Number Gender:Male	: 3249289-5Report Type:Peri I/FU:I	iodic Company Re	port #970574			
Age	Gender · Mare	1/F0.1					
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other		Hypertonia	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		
831 MCG/DAY	1		1101000101141		10		
INTRATHECAL							
Date:08/20/9 Age:	98ISR Number Gender:Male	: 3249303-7Report Type:Peri I/FU:I	iodic Company Re	port #970575			
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration		TT 1.1.				
Other		Condition Aggravated Hypertonia	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		
830 MCG/DAY	,			,			
INTRATHECAL							
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FDA - Adverse Event Reporting System (AERS) Freedom Of Information (FOI) Report Date:08/20/98ISR Number: 3249307-4Report Type:Periodic Company Report #970576 Gender:Male Age: I/FU:I Outcome PTReport Source Product Role Manufacturer Route Duration Dose Other Condition Aggravated Health Lioresal Intrathecal Hypertonia Professional (Baclofen Injection) PS 260 MG/DAY, INTRATHECAL Company Report #970577 Date:08/20/98ISR Number: 3249311-6Report Type:Periodic Age: Gender: Female I/FU:I Report Source Role Manufacturer Outcome ΡТ Product Route Duration Dose Hospitalization -Lioresal Intrathecal Sedation Literature Initial or Prolonged (Baclofen Injection) PS Health 400 MCG/DAY, Professional INTRATHECAL Date:08/20/98ISR Number: 3249353-0Report Type:Periodic Company Report #970578 Age:19 YR Gender:Male I/FU:I Role Manufacturer Outcome PTReport Source Product Route Dose Duration Hospitalization -Sedation Literature Lioresal Intrathecal (Baclofen Injection) PS Initial or Prolonged Health 200 MCG/DAY, Professional INTRATHECAL Date:08/20/98ISR Number: 3249361-XReport Type:Periodic Company Report #970580 Age: Gender:Female I/FU:I PTReport Source Product Role Manufacturer Route Outcome Dose Duration Hypertonia Health Lioresal Intrathecal Other Pruritus Professional (Baclofen Injection) PS 500 MCG/DAY,

	Sedation					
INTRATHECAL			Oral Baclofen, Dose Unknown	С		
Date:08/20/98ISR Number Age: Gender:Fema	: 3249369-4Report Type:Periodi le I/FU:I	c Company Repor	t #970585			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - Initial or Prolonged DOSE UNKNOWN,	Hypotonia	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		
INTRATHECAL						
ROUTE						
Date:08/20/98ISR Number Age: Gender:Male	: 3249375-XReport Type:Periodi I/FU:I	c Company Repor	t #970586			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
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 PTReport Source Product Role Manufacturer Route Duration Dose Hypotonia Study Lioresal Intrathecal Other Urinary Incontinence (Baclofen Injection) PS Health UNKNOWN DOSE; Professional INTRATHECAL ROUTE Date:08/20/98ISR Number: 3249383-9Report Type:Periodic Company Report #970593 Gender:Female I/FU:I Age: Report Source Role Manufacturer PTProduct Route Outcome Dose Duration Hypotonia Lioresal Intrathecal Hospitalization -Health Initial or Prolonged Vomiting Professional (Baclofen Injection) PS 330 MG BOLUS, INTRATHECAL Date:08/20/98ISR Number: 3249387-6Report Type:Periodic Company Report #970594 Gender:Female Age: I/FU:I Outcome PΤ Report Source Product Role Manufacturer Route Dose Duration Sedation Health Lioresal Intrathecal Other Professional (Baclofen Injection) PS UNKNOWN, INTRATHECAL Date:08/20/98ISR Number: 3249392-XReport Type:Periodic Company Report #970595 Gender:Female I/FU:I Age: PTReport Source Role Manufacturer Outcome Product Route Duration Dose Hospitalization -Vomiting Lioresal Intrathecal Company

Initial or P: 87, MCG/DAY,	rolonged		Representative	(Baclofen Injection)	PS	
INTRATHECAL						
	8ISR Number: Gender:Male	3249395-5Report Type:Pe I/FU:I	eriodic Company Re	port #970596		
Outcome	Duration	PT	Report Source	Product	Role Manufac	turer Route
Dose Other		Hypotonia Sedation	Health Professional	Lioresal Intrathecal (Baclofen Injection)	סק	
UNKNOWN DOSE	;	Sedation	1101055101141		FD	
INTRATHECAL						
ROUTE						
	8ISR Number: Gender:Male	3249398-0Report Type:Pe I/FU:I	eriodic Company Re	port #970598		
Outcome Dose	Duration	PT	Report Source	Product	Role Manufac	turer Route
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 PTReport Source Product Role Manufacturer Route Duration Dose Hypotonia Study Lioresal Intrathecal Other (Baclofen Injection) PS Health UNKNOWN DOSE; Professional INTRATHECAL ROUTE Date:08/20/98ISR Number: 3249405-5Report Type:Periodic Company Report #970601 Gender:Male I/FU:I Aqe: Report Source Role Manufacturer PTProduct Route Outcome Dose Duration Lioresal Intrathecal Other Dyspnoea Other (Baclofen Injection) PS 900 MG/DAY, INTRATHECAL Date:08/20/98ISR Number: 3249408-0Report Type:Periodic Company Report #970603 Gender:Male Age: I/FU:I Role Manufacturer Outcome PTReport Source Product Route Dose Duration Muscle Twitching Other Lioresal Intrathecal Other (Baclofen Injection) PS 2 MCG/HOUR, INTRATHECAL Date:08/20/98ISR Number: 3249414-6Report Type:Periodic Company Report #970604 Age: Gender:Male I/FU:I PTReport Source Role Manufacturer Outcome Product Route Duration Dose Condition Aggravated Health Lioresal Intrathecal Other

		Hypertonia	Professional	(Baclofen Injection)	PS		
UNKNOWN DOS	SE,						
INTRATHECAL	L						
ROUTE							
Date:08/20/ Age:	98ISR Number Gender:Unkn	: 3249417-1Report Type:Per own I/FU:I	riodic Company Re	port #970610			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other		Medical Device Complication	Foreign Company Representative	Lioresal Intrathecal (Baclofen Injection)	PS		
Date:08/20/ Age:	98ISR Number Gender:Fema	: 3249420-1Report Type:Per le I/FU:I	riodic Company Re	port #970611			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Death		Convulsion	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		
UNKNOWN;							
INTRATHECAL				Trazadone Deserel Depakote	C C C		

Outcome Dose PT Report Source Product Role Manufacturer Route Other Drug Ineffective Health Professional Lioresal Intrathecal (Baclofen Injection) PS 375 MCG BOLUS AT TRIAL TRIAL PT Report Source Product Role Manufacturer Route Art TRIAL Company Report #970613 I/FU:I Company Report #970613 State State State State Route Outcome PT Report Source Product Role Manufacturer Route Outcome Duration State State Lioresal Intrathecal (Baclofen Injection) PS UNKNOWN: Health Literature (Baclofen Injection) PS Route Date: 08/21/981SR Number: 3120458-8Report Type: Expedited (15-DaCompany Report #98P10715 State Route Date: 08/21/981SR Number: 91/2458-8Report Type: Expedited (15-DaCompany Report #98P10715 State Route Date: 08/21/981SR Number: 91/2458-8Report Type: Expedited (15-DaCompany Report #98P10715 State Route Date: 08/21/981SR Number: 91/2458-8Report Type: Expedited (15-DaCompany Report #98P10715 Route Route Date: 08/21/981SR Number: 91/2458-8Report Type: Expedited (e Event Reporting Syste		
Dose Duration Other Drug Ineffective Health Professional (Baclofen Injection) 375 MCG BOLUS AT TRIAL Date:06/20/98ISR Number: 3249426-2Report Type:Periodic Company Report #970613 Age: Gender:Male I/FU'I Outcome Duration Dose Duration Dose Duration Disculation Disorder Foreign Lioresal Intrathecal Exectile Dysfunction Literature (Baclofen Injection) Date:06/21/98ISR Number: 3120458-BReport Type:Expedited (15-DaCompany Report #96F10715 Age: 30 VR Gender:remale I/FU'I Date:06/21/98ISR Number: 3120458-BReport Type:Expedited (15-DaCompany Report #96F10715 Age: 30 VR Gender:remale I/FU'I Dutcome Duration Dose Durat			c Company Repor	t #970612		
Age: Gender:Male I/FU:I Outcome PT Report Source Product Role Manufacturer Route Other Fjaculation Disorder Foreign Lioresal Intrathecal Erectile Dysfunction Literature (Baclofen Injection) PS UNKNOWN; Health NTRATHECAL Health Professional Date:08/21/98ISR Number: 3120458-8Report Type:Expedited (15-DaCompany Report #98F10715 Age:30 YR Gender:Female I/FU:I Outcome PT Report Source Product Role Manufacturer Route Dose Duration Hospitalization - Prothrombin Time Foreign Lioresal PS ORAL AGUE WK Initial or Prolonged Shortened Health Sermion SS ORAL ORAL 3 MON ORAL ORAL ORAL	Dose Duration Other 375 MCG BOLUS		Health	Lioresal Intrathecal		Route
Dose Duration Other Ejaculation Disorder Foreign Lioresal Intrathecal Erectile Dysfunction UNKNOWN: INTRATHECAL Date:08/21/98ISR Number: 3120458-8Report Type:Expedited (15-DaCompany Report #98F10715 Age:30 YR Gender:Female I/FU:I Outcome PT Report Source Product Role Manufacturer Route Dose Duration Hospitalization - Prothrombin Time Foreign Lioresal PS ORAL Ality ORAL 4 WK DAILY ORAL 4 WK ORAL 3 MON OUTCOME DAILY ORAL ORAL ORAL ORAL ORAL ORAL ORAL			c Company Repor	t #970613		
Age:30 YR Gender:Female I/FU:I Outcome PT Report Source Product Role Manufacturer Route Dose Duration Hospitalization - Prothrombin Time Foreign Lioresal PS ORAL DAILY ORAL 4 WK Initial or Prolonged Shortened Health Sermion SS ORAL ORAL 3 MON Professional Dantrium SS ORAL ORAL ORAL ORAL	Dose Duration Other UNKNOWN;	Ejaculation Disorder	Foreign Literature Health	Lioresal Intrathecal		Route
Dose Duration Hospitalization - Prothrombin Time Foreign Lioresal PS ORAL DAILY ORAL 4 WK Initial or Prolonged Shortened Health Sermion SS ORAL ORAL 3 MON Professional Dantrium SS ORAL 300 MG DAILY ORAL ORAL ORAL 5 ORAL			ed (15-DaCompany Repor	t #98F10715		
Hospitalization - DAILY ORALProthrombin TimeForeignLioresalPSORALDAILY ORAL4WKInitial or Prolonged ORALShortenedHealthSermionSSORALORAL3MONProfessionalDantriumSSORAL300 MG DAILYFloxyfralSSORAL		PT	Report Source	Product	Role Manufacturer	Route
Initial or Prolonged Shortened Health Sermion SS ORAL ORAL 3 MON Professional Dantrium SS ORAL 300 MG DAILY ORAL Floxyfral SS ORAL	Hospitalization -	Prothrombin Time	Foreign	Lioresal	PS	ORAL
Professional Dantrium SS ORAL ORAL Floxyfral SS ORAL	Initial or Prolonged		Health	Sermion	SS	ORAL
Floxyfral SS ORAL			Professional	Dantrium	SS	ORAL
				Floxyfral	SS	ORAL

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose Other 20 MG BID,	Duration	Drug Ineffective		Baclofen	PS		ORAL
ORAL							0.5.1.5
200 MG TID,				Tegretol	SS		ORAL
ORAL				Oxycodone/Acetaminop hen Alendronate Sodium Bisacodyl	C C C		
	8ISR Number Gender:Fema	: 3127343-6Report Type:Expedite le I/FU:I	ed (15-DaCompany Repor	t #970623			
Outcome	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Dose Life-Threate INTRATHECAL	Duration ning INTRAT	Confusional State HECAL	Health	Lioresal Intrathecal	PS		
Hospitalizat ROUTE	ion -	Convulsion	Professional				
Initial or P	rolonged	Drug Withdrawal Syndrome Hypertension Muscle Spasticity					
	8ISR Number Gender:Male	: 3127618-0Report Type:Expedit	ed (15-DaCompany Repor	t #970626			
Outcome Required Intervention Prevent Perm							
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Freedom Of Information (FOI) Report

Impairment/Damage

Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
	Duración	Asthenia	Health	Lioresal	PS		
DOSE,		Drug Withdrawal Syndrome	Professional				
INTRATHECAL		Dyspnoea					
DELIVERY		Hypertonia Medication Error Overdose Paraesthesia Pruritus					
Age:74 YR (
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalizat Initial or P	ion -	Accidental Overdose Bradycardia Bradypnoea Coma Drug Level Above Therapeutic Hypotension Hypothermia Respiratory Depression	Foreign Health Professional Other	Lioresal Benzodiazepine	PS SS		
Date:09/25/9 Age:65 YR (r: 3135394-0Report Type:Expedit e I/FU:I	ted (15-DaCompany Repor	:t #96-01870			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalizat. INTRAVENOUS		Abdominal Pain G;	Study	Camptosar	PS		
Initial or P: INTRAVENOUS	rolonged	Asthenia	Health				
Other INTRAVENOUS	1020 MG	Deep Vein Thrombosis MG	Professional	Adrucil	SS		

		Hyperbilirubinaemia			
WEEKLY		Hypotension			
INTRAVENOUS					
INTRAVENOUS	40 MG W	Pulmonary Embolism NEEKLY	Leucovorin	SS	
INTRAVENOUS					
10 MILLIGRAMS			Baclofen	SS	ORAL
TID ORAL					0.5.1.5
50 MILLIGRAMS			Amitriptyline	SS	ORAL
ONCE DAILY					
ORAL					
			Prevacid	C	
			Propulsid	С	
			Carafate	C	
			Paxil	C	
			Megace	C	
			Prilosec	С	
			Axid	С	
			Advil Duragogia Datah	С	
			Duragesic Patch Acyclovir	C	
			Indocin	C 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 Aqe:49 YR Gender:Male I/FU:I PTRole Manufacturer Outcome Report Source Product Route Dose Duration Hospitalization -Abnormal Behaviour Health Baclofen PS ORAL 10MG TID ORAL 2 DAY Initial or Prolonged Mental Impairment Professional Fosinopril С Nifedipine Extended Tremor Release С Date:09/29/98ISR Number: 3136285-1Report Type:Expedited (15-DaCompany Report #970628 Aqe: Gender: Female I/FU:I Report Source Product Role Manufacturer Outcome PTRoute Dose Duration Health Lioresal Hospitalization -Coma PS INTRATRACHEAL 229 MCG/DAY, Initial or Prolonged Professional Dizziness 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 Role Manufacturer Outcome PTReport Source Product 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	PARENT	ERAL		Nutrition)	SS	
	8ISR Number Gender:Fema	: 3137393-1Report Type:Exp le I/FU:I	pedited (15-DaCompany Re	eport #98GB-10868		
Outcome Dose	Duration	PT	Report Source	Product	Role Manufacturer	Route
Other 10 MG, TID,	Duración	Liver Function Test	Foreign	Lioresal	PS	ORAL
		Abnormal	Health			
UNAL			Professional Other	Amitriptyline Antibiotics	C C	
Age: Outcome	Gender:Male	: 3138377-XReport Type:Exp I/FU:F PT	pedited (15-DaCompany Re Report Source	eport #970617 Product	Role Manufacturer	Route
Dose Death	Duration	Death	Company	Lioresal	PS	
INTRATHECAL MCG/DAY,	APPROX	. 2000	Representative			
INTRATHECAL						
Date:10/15/9 Age:63 YR		: 3142510-3Report Type:Exp I/FU:I	pedited (15-DaCompany Re	eport #98J-10368		
Outcome Hospitalizat Initial or P		PT Depressed Level Of Consciousness	Report Source Foreign Health Professional			
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Freedom Of Information (FOI) Report

			Other			
Dose	Duration			Product	Role Manufacturer	Route
	Duración			Lioresal	PS	ORAL
10 MG, DAIL	Υ,					
ORAL	2 DAY					
				Landsen Lendormin	C	
				Lendormin	С	
	98ISR Number Gender:Male	: 3145451-0Report Type:Expo I/FU:I	edited (15-DaCompany R	eport #500691		
Outcome Dose	Duration	PT	Report Source	Product	Role Manufacturer	Route
Hospitaliza	tion -	Electroencephalogram	Foreign	Macrodantin	PS	ORAL
150 MG DAIL		-1 -1	TT].].			
Initial or ; ORAL	Prolonged	Abnormal	Health			
20 MG DAILY	;	Epilepsy	Professional	Lioresal	SS	ORAL
20 MG DAILI	,	Loss Of Consciousness				
ORAL						
		Monoparesis Movement Disorder		Lioresal	C	
		Tremor				
		Urinary Incontinence				
	98ISR Number Gender:Male	: 3245512-1Report Type:Per I/FU:I	iodic Company R	eport #9830427		
Outcome		PT	Report Source	Product	Role Manufacturer	Route
Dose Other	Duration	Drug Ineffective	Consumer	Viagra Tablets	PS	ORAL
50.00 MG			Combanier	Viagia Tabietb	10	Oldin
TOTAL:PRN:O	RA	Erectile Dysfunction				
L						
ORAL				Baclofen	SS	ORAL
				Betaseron	С	

			Amantidine	С		
			Desyrel	С		
Date:10/28/98ISR Number Age: Gender:	: 3148398-9Report Type:Exped: I/FU:I	ited (15-DaCompany R	eport #R98-063			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - Initial or Prolonged TID	Complications Of Maternal Exposure To Therapeutic	Health Professional	Baclofen	PS	Watson Laboratories Inc. Miami	
(28TH-29TH	Drugs					
	Foetal Movements					
WEEK -30TH	Decreased					
WEEK OF	Intraventricular					
PREGNANCY)						
	Haemorrhage Neonatal Premature Baby Small For Dates Baby		Hydrocortisone Tylenol #3	C 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 - Complications Of Maternal Initial or Prolonged Exposure To Therapeutic Congenital Anomaly Drugs Foetal Movements Decreased Intraventricular

Freedom Of Information (FOI) Report Haemorrhage Neonatal Premature Baby Role Manufacturer Report Source Product Route Duration Dose Health Cortef PS Professional Baclofen SS ORAL ORAL Tylenol With Codeine SS Company Representative Date:11/04/98ISR Number: 3152476-8Report Type:Expedited (15-DaCompany Report #98F--10882 Age:71 YR Gender:Male I/FU:I ΡТ Role Manufacturer Outcome Report Source Product Route Dose Duration Hospitalization -ORAL Agitation Foreign Lioresal PS DAILY, ORAL Initial or Prolonged Confusional State Health Convulsion Professional Other Date:11/04/98ISR Number: 3152478-1Report Type:Expedited (15-DaCompany Report #98HQ-10387 Aqe:71 YR Gender:Male I/FU:I PTRole Manufacturer Report Source Product Outcome Route Dose Duration Hospitalization -Abdominal Pain Foreign Baclofen PS ORAL 30 MG, DAILY, Initial or Prolonged Cerebral Atrophy Literature ORAL Cerebral Infarction Health Hemodialysis С Confusional State Professional Difficulty In Walking Other Encephalopathy Hypotonia Muscular Weakness Neurological Symptom Sedation

FDA - Adverse Event Reporting System (AERS)

Outcome Deserve	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration Hospitalization - 15 MG, DAILY,	Atrophy	Foreign	Baclofen	PS		ORAL
Initial or Prolonged ORAL	Brain Stem Infarction	Literature				
	Cheyne-Stokes Respiration Coma Confusional State	Health Professional Other	Hemodialysis	С		
D_{2}		tod (15 Declements Dec				
Age:48 YR Gender:Fem				Role	Manufacturer	Route
		Report Source	port #98-10-0239 Product	Role	Manufacturer	Route
Age:48 YR Gender:Fem Outcome Dose Duration Hospitalization - Initial or Prolonged	ale I/FU:I			Role PS	Manufacturer Zenith Goldline Pharm.	Route ORAL
Age:48 YR Gender:Fem Outcome Dose Duration Hospitalization -	nale I/FU:I PT Eye Disorder	Report Source	Product		Zenith Goldline	
Age:48 YR Gender:Fem Outcome Dose Duration Hospitalization - Initial or Prolonged	ale I/FU:I PT Eye Disorder Motor Dysfunction	Report Source	Product		Zenith Goldline	
Age:48 YR Gender:Fem Outcome Dose Duration Hospitalization - Initial or Prolonged 10 MG BID	ale I/FU:I PT Eye Disorder Motor Dysfunction	Report Source	Product		Zenith Goldline	

Freedom Of Information (FOI) Report

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

Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization -	Coma	Foreign	Lioresal Tablet			
Initial or Prolonged DAILY, ORAL	Epilepsy	Health	(Baclofen)	PS		ORAL
,	Hypertonia	Professional	Vastarel Tablet			
	Overdose		(Trimetazidine			
	Status Epilepticus		Dihydrochloride)	SS		ORAL
ORAL			-			
	Suicide Attempt					
Age: Gender:Fema Outcome Dose Duration Hospitalization - Initial or Prolonged INTRA-UTERINE INTRA	r: 3154708-9Report Type:Expedi ale I/FU:I PT Complications Of Maternal Exposure To Therapeutic UTERINE Drugs Intraventricular UTERINE Haemorrhage Neonatal Premature Baby	ited (15-DaCompany Rep Report Source Health Professional	ort #981104-107014347 Product Tylenol With Codeine #3 Hydrocortisone Baclofen	Role PS SS SS	Manufacturer	Route
Date:11/10/98ISR Number Age: Gender:Male Outcome Dose Duration Other ORAL	r: 3155630-4Report Type:Expedi e I/FU:I PT Arrhythmia	Report Source Foreign	Product Dantrium	PS	Manufacturer	Route ORAL
		Health Professional	Lioresal	SS		

Outcome	PT	Report Source	Product	Role Manufacturer	Route
Dose Duration					
Hospitalization - DAILY ORAL	Coma	Health	Baclofen	PS	ORAL
Initial or Prolonged	Dyspnoea Facial Palsy Hemiparesis Hypertension Tongue Oedema	Professional	Procardia Capsule Compazine Tablet	C C	
Date:11/18/98ISR Number Age:63 YR Gender:Male	r: 3160814-5Report Type:Expe e I/FU:I	dited (15-DaCompany Re	eport #98F11010		
Outcome Dose Duration	РТ	Report Source	Product	Role Manufacturer	Route
Hospitalization - 15 MG, TID,	Condition Aggravated	Foreign	Lioresal	PS	ORAL
Initial or Prolonged ORAL	Extrapyramidal Disorder	Health			
60 MG, DAILY,	Hemiplegia	Professional	Mestinon	SS	ORAL
ORAL		Other	Fonzylane	SS	ORAL
600 MG,			FolizyTalle	00	UITE
DAILY, ORAL			Prozac	SS	ORAL
20 MG, DAILY,					
ORAL			Kardegic	SS	ORAL
300 MG,					
DAILY, ORAL			Glucor	SS	ORAL
300 MG, DAILY, ORAL					
,					
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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 Dose Dur	ation	PT	Report Source	Product	Role	Manufacturer	Route
Other	acion	Electrolyte Imbalance	Foreign	Lioresal	PS		
DAILY			Health Professional Other	Klistier	SS		
	Number er:Fema	: 3161642-7Report Type:Expedi le I/FU:I	ited (15-DaCompany Repo	ort #98USA11687			
Outcome Dose Dur	ation	РТ	Report Source	Product	Role	Manufacturer	Route
Hospitalization 5 MG, TID,		Aspiration	Health	Baclofen	PS		ORAL
Initial or Prolonged ORAL	nged	Respiratory Failure	Professional				
		Sedation		Epogen Solution For			
				Injecti	С		
				Prilosec	С		
				Trovan	С		
	Number er:Male	: 3163511-5Report Type:Expedi I/FU:F	ited (15-DaCompany Repo	ort #98USA11651			
Outcome Dose Dur	ation	РТ	Report Source	Product	Role	Manufacturer	Route
Life-Threatening 5 MG, TID,		Asthenia	Health	Baclofen	PS		ORAL
Hospitalization	– 4 HR	Blood Pressure Increased	Professional				
Initial or Prolo	nged	Coma		Prozac	С		
Disability		Dyspnoea		Catapres	С		
		Facial Palsy Hypotension		Procardia Capsules Erythromycin	C		
		Loss Of Consciousness Nausea Stridor		Solution For Infusion Regular Insulin	С		
		Tongue Oedema		Suspension	С		
		Toligue Oedellia		Compazine Tablet	C		
				Compazine Tablet	C		/

	8ISR Number Gender:Male	: 3163510-3Report Type:Expedit I/FU:I	ed (15-DaCompany Repor	t #98F-11034			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalizat 30 MG, DAILY	ion -	Conduction Disorder	Foreign	Lioresal (Baclofen)	PS		ORAL
Initial or P: ORAL	rolonged	Myocardial Infarction	Health				
		Ventricular Tachycardia	Professional	Tenormine (Atenolol)	SS		ORAL
ORAL							
				Dantrium (Dantrolene Sodium)	SS		ORAL
ORAL							
				Lexomil Fonzylane	C C		
	8ISR Number Gender:Male	: 3164084-3Report Type:Direct I/FU:I	Company Repor	t #			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other	Duración	Urinary Retention		Baclofen Insulin Reg Human Acetaminophen/Codein	PS C		
				e Clindamycin	C C		
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Freedom Of Information (FOI) Report

Terazosin	С
Petrolatum	С
Camphor 0.5%/Menthol	
0.5%	С
Cetirizine	С
Insulin Lente Human	С
Lansoprazole	С
Dorzolamide	С
Timolol	С
Ferrous Sulfate	С
Calcium Carbonate	С
Furosemide	С
Nitroglycerin	С
Bisacodyl	С
Albuterol	0000000000000000000
Acertaminophen	С
Hydroxyzine Hcl	С
Silver Sulfadiazine	С
Finasteride	С
Selenium Sulf	С
Petrolatum	
Hydrophilic	С
Neutrogena Soap	C C C
Ketoconazole	С
Casanthranol/Docusat	
e	С
Aspirin Ec	C C
Nifedipine (Adalat	
Cc)	С

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

Outcome Dose	Duration	PT	Report Source	Product	Role Manufacturer	Route
Hospitalizatio		Coma	Foreign	Lioresal	PS	ORAL
Initial or Pro 10 DF, ONCE	olonged	Hypertonia	Health	Adalate	SS	ORAL
			Professional Other			

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

Freedom Of Information (FOI) Report

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

Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other 50MG DAILY	Duración	Arrhythmia	Foreign	Dantrium	PS		ORAL
		Myocardial Infarction	Health	Lioresal	SS		ORAL
30MG DAILY			Professional	Ditropan Fonzylane Lexomil Lioresal Tenormine	C C C C C C C		
	98ISR Number Gender:Fema	: 3168692-5Report Type:Expedit le I/FU:I PT	ed (15-DaCompany Repor Report Source	t #R98-068 Product	Role	Manufacturer	Route
Dose	Duration		Report Bource	1104400	1010		nouce
Hospitalizat Initial or H 2 QID		Convulsion Medication Error	Consumer Other	Baclofen	PS	Watson Laboratories, Miami Div.	
2 UIU				Amantidine	С		
Date:12/14/9 Age:	98ISR Number Gender:Fema	: 3170601-XReport Type:Expedit le I/FU:I	ed (15-DaCompany Repor	t #970629			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Death		Pyrexia	Health	Lioresal	PS		
INTRATHECAL	INTRAT	HECAL	D				
ROUTE			Professional				

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

Death		Convulsion	Health	Lioresa	PS		
INTRATHECAL	INTRATH	HECAL					
ROUTE			Professional				
	ISR Number: ender:Male	r: 3171745-9Report Type:Expedi e I/FU:I	.ited (15-DaCompany Re	eport #98CDN10565			
Outcome Dose Di	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other 7MG ONCE ORAL	dracion	Respiratory Arrest	Foreign	Lioresal	PS		ORAL
			Health Professional Other				
Outcome Dose Di	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Age:58 YR Gei	ender:Male						
Life-Threatenin		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			001102	Dantrium			
50 MG DAILY				(Dantrolene Sodium)	SS		ORAL
ORAL							
				Lexomil Ditropan Fonzylane	C C C		
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Freedom Of Information (FOI) Report

: 3176750-4Report Type:Direct le I/FU:I	Company Re			
PT	Report Source	Product	Role Manufacturer	Route
Sedation		Baclofen	PS	
		Procan Sr	С	
		Coumadin	C	
		Dig	С	
		Perd Colace	С	
		Premarine	С	
		Provera	C	
		Fosomax	C	
		Zantac	С	
	PT	PT Report Source	PT Report Source Product Sedation Procan Sr Coumadin Dig Perd Colace Premarine Provera Fosomax	PT Report Source Product Role Manufacturer Sedation PS Source Process Commadin Construction Commander Comments Process Commadin Comments C

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

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

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Aphasia	Consumer	Baclofen	PS	Zenith Goldline	
Initial or Prolonged 10MG BID ORAL	Bladder Disorder				Pharm.	ORAL
	Eyelid Disorder		Darvocet-N	С		
	Faecal Incontinence		Arthotec	С		
	Feeling Abnormal					
	Hearing Impaired					
	Irritable Bowel Syndrome					
	Paralysis					
Age:35 YR Gender:Fema Outcome Dose Duration	ale I/FU:I PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization -	Blood Bilirubin Increased	Foreign	Rivotril			
Initial or Prolonged	Cholestasis	Health	(Clonazepam) 2.5			
	Jaundice	Professional	Mg/Ml	PS		ORAL
ORAL						
	Pruritus	Other	Azantac (Ranitidine)	SS		ORAL
DAILY ORAL						
			Di-Antalvic			
			(Acetaminophen/Propo			
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	FDA - Adverse Event	Reporting System	FDA - Adverse Event Reporting System (AERS)				
	Freedom Of Info	rmation (FOI) Rep	port				
6 DOSE FORM	xypher Hydrod		SS	ORAL			
DAILY ORAL 2 DOSE DORM	Imure (Azatl		SS	ORAL			
DIALY ORAL 1 DOSE FORM		ril (Ethinyl diol/Levonorges	SS	ORAL			
DAILY ORAL 30 MG DAILY	Liore: 10 Mg	sal (Baclofen)	SS	ORAL			

ORAL

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

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

Outcome Dose Duration	PT	Report Source	Product	Role Manufacturer	Route
Hospitalization - DAILY ORAL	Nephrosclerosis	Health	Lioresal	PS	ORAL
Initial or Prolonged ORAL	Nephrotic Syndrome	Professional	Ibuprofen	SS	ORAL
	Scar				
Date:01/12/99ISR Number Age:18 MON Gender:Male	: 3180803-4Report Type:Exp I/FU:F	pedited (15-DaCompany Re	eport #99USA10012		
Outcome Dose Duration	PT	Report Source	Product	Role Manufacturer	Route
Hospitalization - 20 MG, DAILY,	Cerebral Palsy	Health	Lioresal	PS	ORAL
Initial or Prolonged ORAL	Glomerulonephritis	Professional			
ORAL	Hyperbilirubinaemia		Ibuprofen	SS	ORAL
	Kernicterus Nephrosclerosis Nephrotic Syndrome Scar				
Date:01/21/99ISR Number Age: Gender:Male	r: 3203026-9Report Type:Exp e I/FU:I	pedited (15-DaCompany Re	eport #98F-11092		
Outcome Dose Duration	PT	Report Source	Product	Role Manufacturer	Route
Hospitalization - Initial or Prolonged	Ileus Paralytic	Foreign Health Professional	Lioresal (Baclofen) Solution For Injection	PS	
INTRATHECAL 140 MC	CG DAILY				
INTRATHECAL					
22 Aug 2005 12115 DM					

FDA - Adverse Event Reporting System (AERS) Freedom Of Information (FOI) Report Date:01/21/99ISR Number: 3387083-5Report Type:Periodic Company Report #97USA11985 Aqe:54 YR Gender:Male I/FU:I Outcome PTReport Source Product Role Manufacturer Route Dose Duration Liver Function Test Health Lioresal Tablet 10mg Abnormal Professional (Baclofen) PS ORAL 10 MG, TID, ORAL 4 DAY Date:01/21/99ISR Number: 3387088-4Report Type:Periodic Company Report #97USA12197 Aqe:78 YR Gender:Male I/FU:I Report Source Role Manufacturer Outcome PTProduct Route Duration Dose Confusional State Health Lioresal Tablet 10 Sedation Professional Mg (Baclofen) PS ORAL 10 MG, QID, ORAL Nitro С Diuretics С Potassium С Date:01/21/99ISR Number: 3387091-4Report Type:Periodic Company Report #98USA10469 Aqe:54 YR Gender:Female I/FU:I Role Manufacturer Outcome PTReport Source Product Route Dose Duration Nasal Oedema Health Lioresal Tablet 10 Parosmia Professional Mg (Baclofen) ORAL PS 10 MG, TID, ORAL Date:01/21/99ISR Number: 3387095-1Report Type:Periodic Company Report #98USA10780 Aqe:25 YR Gender:Female I/FU:I Outcome PTReport Source Product Role Manufacturer Route Dose Duration

		Blood Prolactin Increased	Health	Lioresal Tablet		
DAILY, ORAL			Professional	(Baclofen)	PS	ORAL
	99ISR Number: Gender:Male	: 3387097-5Report Type:Periodi I/FU:I	ic Company Report	t #98USA10779		
Outcome	Duration	PT	Report Source	Product	Role Manufacturer	Route
Dose		Abnormal Faeces	Health Professional	Lioresal Tablet 5mg (Baclofen)	PS	ORAL
5 MG, TID,						
ORAL						
	99ISR Number: Gender:Male	: 3387100-2Report Type:Periodi I/FU:I	ic Company Report	t #98USA10794		
Outcome Dose	Duration	PT	Report Source	Product	Role Manufacturer	Route
		Dystonia Eye Movement Disorder	Health Professional	Lioresal Tablet (Baclofen)	PS	ORAL
DAILY, ORAL		Hyperhidrosis Pain				

			FDA - Advei	rse Event Reporting Syste	em (AER	2S)	
			Freedon	n Of Information (FOI) Re	port		
	SR Number: ender:Femal	3387102-6Report Type:Periodic Le I/FU:I	c Company Rep	oort #98USA11248			
Outcome Dose D	Ouration	PT	Report Source	Product	Role	Manufacturer	Route
20 MG, QD,		Pollakiuria	Consumer	Lioresal Tablet 20mg (Baclofen)	PS		ORAL
ZU MG, QD,							
ORAL				Imipramine Tablet Diflucan Zantac	C C C		
Date:01/21/99I Age:65 YR Ge		3387103-8Report Type:Periodic e I/FU:I	c Company Rep	oort #98USA11305			
Outcome Dose D	Ouration	PT	Report Source	Product	Role	Manufacturer	Route
	Juracion	Sedation	Health Professional	Lioresal Tablet 10 Mg (Baclofen)	PS		
10 MG, BID,							
ORAL							
	SR Number: ender:Femal	3387107-5Report Type:Periodic Le I/FU:I	c Company Rep	oort #98USA11316			
Outcome Dose D	Ouration	PT	Report Source	Product	Role	Manufacturer	Route
		Dystonia	Health Professional	Lioresal Tablet (Baclofen)	PS		ORAL
DAILY, ORAL							
Date:01/21/991 Age:43 YR Ge		3387108-7Report Type:Periodic Le I/FU:I	c Company Rep	oort #98USA11326			
Outcome Dose D	Ouration	PT	Report Source	Product	Role	Manufacturer	Route
LOBE L	uraciuli	Drug Ineffective	Health	Lioresal Tablet			

		Loss Of Libido	Professional	(Baclofen)	PS		ORAL
DAILY, ORAL				Betaseron	С		
	99ISR Number Gender:Male	r: 3387111-7Report Type:Per e I/FU:I	ciodic Company Re	eport #98USA11375			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Dose 20 MG, TID,		Liver Function Test Abnormal	Health Professional	Lioresal Tablet 20 Mg (Baclofen)	PS		ORAL
ORAL							
				Compazine Solution For Injection Amitriptyline Tablet Carafate Tablet Zanaflex Tablet Amitriptyline Tablet Motrin Tablet Ultram Tablet	000000		
	99ISR Number Gender:Male	r: 3387112-9Report Type:Per e I/FU:I	ciodic Company Re	eport #97USA12443			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
		Hepatitis	Health Professional	Baclofen Tablet Unknown (Baclofen)	PS		ORAL
DAILY, ORAL	7 DAY		Other	Tizanidine			
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							,
				Hydrochloride (Tizanidine Hydrochloride)	SS		ORAL
ORAL				Prozac Wellbutrin	C C		
		c: 3387114-2Report Type:Periodi	ic Company Repo	rt #98USA10706			
Age:47 YR	Gender:Male	e I/FU:I					
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~		Convulsion Hallucination	Health Professional	Baclofen Tablet (Baclofen)	PS		
DAILY				Ditropan	С		
Age:6 YR Outcome Dose	Gender:Male	e I/FU:I PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration	Haematuria	Health Professional	Baclofen Tablet (Baclofen)	PS		ORAL
DAILY, ORAL			FIOLODDIONAL	(Dattoren)	10		Ordin
	99ISR Number Gender:Fema	r: 3387120-8Report Type:Periodi ale I/FU:I	.c Company Repoi	rt #98USA11428			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
		Nocturia Pollakiuria	Health Professional	Baclofen Tablet 20 Mg (Baclofen)	PS		ORAL
20 MG, TID,		Urinary Incontinence					
ORAL				Valium Tablet Ditropan Tablet Na	C C C		

	9ISR Number Gender:Male	: 3387123-3Report Type:Period I/FU:I	lic Company Repo	ort #98USA11708			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
		Abnormal Behaviour Lethargy	Health Professional	Baclofen Tablet (Baclofen)	PS		ORAL
DAILY, ORAL		Tongue Disorder		Remeron Tablet Prilosec Tablet Valium Tablet	С С С		
	9ISR Number Gender:Male	: 3384582-7Report Type:Period I/FU:I	lic Company Repo	ort #R98-017			
Outcome Dose Duration	Duration	PT	Report Source	Product	Role	Manufacturer	Route
	Coordination Abnormal	Health Professional	Baclofen Tablets, (Strength Unknown) Watson, Miami	PS	Watson, Miami		
1/2 (10 MG				Watson, Miami	22	Watson, Miami	
TID)	2 DAY			Procardia Xl Cardura Zoloft Leukeran Nephrovit Qd Quinidine Ambien	C C C C C C C		
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FDA - Adverse Event Reporting System (AERS) Freedom Of Information (FOI) Report Ticlid С Date:01/22/99ISR Number: 3384588-8Report Type:Periodic Company Report #R98-024 Aqe:39 YR Gender:Male I/FU:I \mathbf{PT} Report Source Role Manufacturer Outcome Product Route Duration Dose Paraesthesia Health Baclofen Tablets, 10 Professional 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 Gender:Female Age:46 YR I/FU:I Outcome PTReport Source Product Role Manufacturer Route Dose Duration Drug Ineffective Consumer Baclofen Tablets, 10 PS Watson Miami Mq, Watson Miami QHS С Ridaura С Naprosyn Seldane С Potassium С Methotrexate С С Leucovorin Oral Contraceptive (Ortho Novum 777) С Prednisone С Date:01/22/99ISR Number: 3384594-3Report Type:Periodic Company Report #R98-065 Age: Gender:Female I/FU:I Outcome PTReport Source Product Role Manufacturer Route Dose Duration Dermatitis Consumer Baclofen Tablets, 10 Hypoaesthesia Mq, Watson Miami PSWatson Miami 10AM, 1 NOON,

1/2 QPM, 1/2						
QHS						
			Valium 80 Mg	С		
			Darvon-N	С		
Date:01/22/99ISR Number Age: Gender:Fema	r: 3384595-5Report Type:Perio ale I/FU:I	dic Company Re	eport #R98-067			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
	Chronic Fatigue Syndrome	Health	Baclofen Tablets, 10	Þa		
1 OD (1/2	Epistaxis	Professional	Mg, Watson Miami	PS	Watson Miami	
1 OD (1/2	Eye Haemorrhage					
TAB)	Eye naemorrnage					
	Vaginal Haemorrhage		Chlortrimeton Qd	С		
			Entex	С		
			Berroca Plus	С		
			Qd V &C 500 Mg			
			(Ester-C) Qd	С		
			Locithin Qd	С		
			Vitamin E (Several			
			X/Week) Zinc Prn	С		
			Betacarotene (Prn)	C		
			Garlic (Prn)	C		
			Siberian Ginseng	С		

Freedom Of Information (FOI) Report

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 Role Manufacturer PTReport Source Product Outcome Route Dose Duration Baclofen Hospitalization -Accidental Overdose Health PS ORAL DAILY , ORAL Initial or Prolonged Aggression Professional Drug Ineffective Medication Error Date:01/25/99ISR Number: 3185448-8Report Type:Expedited (15-DaCompany Report #99USA10037 Gender:Female Age:40 YR I/FU:I Role Manufacturer Outcome PTReport Source Product Route Dose Duration Hospitalization -Gastrointestinal Health Lioresal PS ORAL 10 MG , Q8H, Initial or Prolonged Obstruction Professional ORAL Peritonitis Dilantin С Synthroid С Sepsis Date:01/26/99ISR Number: 3194364-7Report Type:Periodic Company Report #9830427 Age:44 YR Gender:Male I/FU:F Role Manufacturer Outcome PTReport Source Product Route Dose Duration Drug Ineffective Viagra Tablets Other Consumer PS ORAL 50 MG TOTAL Erectile Dysfunction Health PRN ORAL Professional Baclofen SS ORAL ORAL Betaseron С Amantidine С Desyrel С

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 - 300 MG QD	Epilepsy	Foreign	Videx	PS	ORAL
Initial or Prolonged ORAL		Health			
		Professional	Baclofen	SS	
30 MG QD					
		Other	Bactrim Forte	C	
			Viracept	С	
			Viramune	С	
1				С	
				С	
1				С	
1				С	
				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 -	Appetite Disorder
Initial or Prolonged	Convulsion
	Difficulty In Walking
	Disturbance In Attention

Freedom Of Information (FOI) Report

		Medication Error Nausea Sedation	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						nouce
			Consumer Other	Baclofen	PS	Watson Labs, Miami Div.	
2 QID TABLET	S			Amantidine	С		
		: 3188604-8Report Type:Expedito	ed (15-DaCompany Repor	t #98J-10423			
Age:12 MON	Gender:	I/FU:F					
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
	Duración	Rectal Prolapse	Foreign	Lioresal Unknown (Baclofen)	PS		ORAL
5 MG, DAILY,							
ORAL							
				Ternelin Unknown (Tizanidine)	SS		ORAL
1 MG, DAILY,							
ORAL							
	9ISR Number: Gender:Male	: 3199029-3Report Type:Periodio I/FU:I	c Company Repor	t #990637			
Outcome	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Dose Hospitalizat Initial or P INTRATHECAL	ion -	Hypotonia Paraesthesia G/DAY Spinal Disorder	Consumer	Lioresal Intrathecal (Baclofen Injection)	PS		
Date:02/01/9 Age:47 YR		: 3188925-9Report Type:Direct I/FU:I	Company Repor	t #			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route

Hospitalization - INTRATHECAL IT	Respiratory Distress	Health	Baclofen	PS	
Initial or Prolonged	Vomiting	Professional			
Date:02/08/99ISR Number Age:51 YR Gender:	r: 3198526-4Report Type:Direct I/FU:I	Company Repor	rt #		
Outcome Dose Duration	РТ	Report Source	Product	Role Manufacturer	Route
Hospitalization - 10MG PO	Coordination Abnormal		Baclofen 10mg	PS	ORAL
Initial or Prolonged	Dysarthria		Humulin L	С	/
	Insomnia		Colace Qd	С	
	Sedation		Niferex Forte	С	
4	Tremor		Ecasa	C	
1			Coumadin	C	
4			Nephrocaps	C	
			Nahco3	C	ļ
4			Phoslo	С	ł
			Catapress	С	I
			Synthroid	С	I

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

Freedom Of Information (FOI) Report

		Jaundice Pruritus					
Dose	Duration		Report Source	Product	Role	Manufacturer	Route
			Foreign Health	Lioresal Tablet (Baclofen)	PS		ORAL
30 MG, DAILY	,		Professional				
ORAL	12 MON	ſ	Prolessional				
			Other	Imurel Tablet (Azathioprine)	SS		ORAL
100 MG,							
DAILY, ORAL	9 YR						
				Di-Antalvic Capsule (Aporex)	SS		ORAL
6 DF, DAILY,				(ADOLEY)	20		UKAL
ORAL							
UKAL				Rivotril Solution			
ORAL				(Clonazepam)	SS		ORAL
UKAL				Minidril Tablet			
1 DF, DAILY,				(Neovlar 21)	SS		ORAL
L DF, DAIDI,							
ORAL							
				Azantac Unknown (Ranitidine			
				Hydrochloride)	SS		ORAL
1 DF, DAILY,							
ORAL	7 MON	1					
Date:02/17/9 Age:30 YR (r: 3200636-XReport Type:Expedite ale I/FU:I	ed (15-DaCompany Report	t #98D10901			
Outcome	· · · · ·	PT	Report Source	Product	Role	Manufacturer	Route
Dose Life-Threate INTRATHECAL	Duration ning DAILY,	Condition Aggravated	Foreign	Lioresal Solution	PS		
		Dysphagia	Health				
INTRATHEKAL		Paralysis Flaccid	Professional	Bactrim Mylepsinum	C C		
		Quadriplegia		myrepsrnnum	C		

Akatinol Memantine C

Dutcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration Life-Threatening INTRATHECAL DAILY	Dysphagia	Health	Lioresal	PS		
INTRATHECAL	Paralysis Flaccid	Professional				
	Paresis Quadriplegia					
Date:02/18/99ISR Numbe Age:46 YR Gender:Mal	er: 3203378-XReport Type:Ex .e I/FU:F	pedited (15-DaCompany Re	eport #99USA10036			
Dutcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - Initial or Prolonged	Accidental Overdose Aggression	Health Professional	Baclofen Tablet 10 Mg (Baclofen)	PS		ORAL
000 MG, DAILY, ORAL	Confusional State					
	Convulsion Drug Ineffective					
	er: 3203023-3Report Type:Ex Specifil/FU:I	pedited (15-DaCompany Re	eport #990633			
Dutcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
	Spastic Paralysis	Other	Lioresal Intrathecal (Baclofen Injection)	PS		
Hospitalization - Initial or Prolonged						
Hospitalization -	ICG,					

Freedom Of Information (FOI) Report

DAILY,

INTRATHECAL

Date:02/25/99ISR N Age:13 YR Gender	umber: 3208015-6Report Type: :Female I/FU:I	Expedited (15-DaCompany Re	eport #200701		
Outcome Dose Durat:	PT	Report Source	Product	Role Manufactu	urer Route
Hospitalization - ORAL	Confusional State	Foreign	Naproxen (Naproxen)	PS	ORAL
Initial or Prolonge 10 DOSE FORM	ed Illusion	Other	Baclofen (Baclofen)	SS	ORAL
	Overdose				
ORAL	Psychotic Disorder				
- · · · 00 /05 /00 - 00					
	umber: 3211358-3Report Type: :Female I/FU:I	Periodic Company Re	eport #9805405		
Outcome Dose Durat:	PT ion	Report Source	Product	Role Manufactu	urer Route
Other 50.00 MG	Drug Dependence	Consumer	Zoloft Tablets	PS	ORAL
TOTAL;DAILY;O	Hypertonia				
ד א רו	Influenza Like Illness	1			
RAL	Insomnia		Baclofen Ambien Provera Climara	SS SS C C	
Date:03/05/99ISR N Age:11 YR Gender	umber: 3212283-4Report Type: :Male I/FU:I	Direct Company Re	eport #		
Outcome Dose Durat:	PT	Report Source	Product	Role Manufactı	arer Route
Hospitalization -	Medication Error 85 MCG/DAY		Baclofen	PS	
1					

Initial	or	Prolonged
INTRATH	CAI	J

Date:03/15/99ISR Number Age: Gender:Fema	r: 3220879-9Report Type:Exp ale I/FU:F	pedited (15-DaCompany Re	port #99USA10037			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - Initial or Prolonged 10 MG, Q8H,	Gastrointestinal Obstruction	Health Professional	Lioresal Tablet 10 Mg (Baclofen)	PS		ORAL
	Peritonitis					
ORAL	Sepsis		Dilantin Tablet Synthroid Tablet	C C		
Date:03/16/99ISR Number Age:55 YR Gender:Fema Outcome	r: 3222091-6Report Type:Exp ale I/FU:I PT	pedited (15-DaCompany Re Report Source	eport #001-0945-990140 Product	Role	Manufacturer	Route
Age:55 YR Gender:Fema Outcome Dose Duration	ale I/FU:I PT	Report Source	Product	Role	Manufacturer	Route
Age:55 YR Gender:Fema Outcome Dose Duration Death Hospitalization -	ale I/FU:I		-	Role PS	Manufacturer	Route
Age:55 YR Gender:Fema Outcome Dose Duration Death	ale I/FU:I PT Drug Interaction	Report Source Health	Product Neurontin Capsules		Manufacturer	Route

Freedom Of Information (FOI) Report

1						
			Niacin (Nicotinic			ļ
			Acid)	SS		
			Dilaudid			I
I			(Hydromorphone			Ţ
			Hydrochloride)	SS		Ţ
			(Alprazolam)	SS		
			(Losartan)	SS		
			(Atenolol)	SS		ľ
			(Diltiazem)	С		
22/12/2270D Number						
Date:03/19/99ISR Numbe Age: Gender:Mal	er: 3223446-6Report Type:Period le I/FU:I	ic Company kep	port #98F11092			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Ileus Paralytic	Foreign	Lioresal Solution			ľ
Initial or Prolonged		Health	For Injection	- ~		ľ
Other 140 M		Professional	(Baclofen)	PS		, , , , , , , , , , , , , , , , , , ,
INTRATHECAL 140 M	.CG,					I
		Other				ļ
DAILY,						
INTRATHECAL						
1			Lioresal Tablet			I
4			(Baclofen)	SS		ORAL
ORAL						
	er: 3223690-8Report Type:Expedi	ited (15-DaCompany Reg	port #98J10368			
Age:63 YR Gender:Mal	le I/FU:F					
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization -	Asthenia	Foreign	Lioresal Tablet			
Initial or Prolonged	Depressed Level Of	Health	(Baclofen)	PS		ORAL
10 MG ONCE	-		· · · · · · · · · · · · · · · · · · ·			
4	Consciousness	Professional				
ORAL						ł
	Disorientation		Calcium Carbonate	C		
4	Dry Mouth		Tegretol	C		ļ
4	Insomnia		Zantac	C		ł
1	Sedation		Landesen	C		!
4			Lendormin	C		ł
1			Norvasc	C		
						P

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

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 - Initial or Prolonged DAILY, ORAL	Ileus Paralytic	Health Professional	Lioresal Tablet (Baclofen)	PS	ORAL
			Ditropan Reglan Megace	C C C	

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

Outgomo		<u>سر</u>	Donest	Course	Dwoduczt			Manufactures	Doute
Outcome Dose Dura	ation	PT	Report :	Source	Product		коте	Manufacturer	Route
Life-Threatening 5 MG DAILY,		Anorexia	Health		Lioresal	(Baclofen)	PS		ORAL
Hospitalization - ORAL 3	- DAY	Apathy	Profess	ional					
Other	1 DF, 1	Fatigue	Other		Travad		SS		
RECTAL 8	DAY	Gastrooesophageal Reflux Disease Hypernatraemia Hypokalaemia Metabolic Alkalosis Oral Intake Reduced Pyrexia Screaming			Rivotril Antra		C C		
Date:04/14/99ISR Age:70 YR Gende		: 4515941-4Report Type:Direct I/FU:I		Company Report	t #USP 5224	13			
Outcome Dose Dura	ation	PT	Report :	Source	Product		Role	Manufacturer	Route
TABLET		Gastrointestinal			Baclofen		PS	Goldline	
TABLET		Haemorrhage			Lotensin		SS	Novartis	
		Haemorrhage Medication Error Myocardial Infarction							
Date:04/22/99ISR Age:70 YR Gende		: 3244511-3Report Type:Direct I/FU:I		Company Report	t #				
Outcome	ation	PT	Report :	Source	Product		Role	Manufacturer	Route
Dose Dura Life-Threatening	acton	Encephalopathy	Health		Baclofen				

PS	ORAL	10 MG PO TID 2 DAY	ζ		
Hospitalization - 300MG MWF 10 DAY	Multiple Sclerosis	Professional	Neurontin	SS	
Initial or Prolonged	Respiratory Acidosis		Synthroid	С	ľ
-	Sepsis		Colace	С	ľ
	-		Phos-Lo	С	l l l l l l l l l l l l l l l l l l l
			Nephron Caps	C	ľ
			Cortisone	С	l l l l l l l l l l l l l l l l l l l
			Senokot	С	l l l l l l l l l l l l l l l l l l l
			Prevacid	С	l l l l l l l l l l l l l l l l l l l
			Restoril	C	l l l l l l l l l l l l l l l l l l l
			Ventolin	C	l l l l l l l l l l l l l l l l l l l
			Atrovent	C	l l l l l l l l l l l l l l l l l l l
			Calcitonin	C	l l l l l l l l l l l l l l l l l l l
			Vicodin	C	ľ
Date:04/22/99ISR Number Age:53 YR Gender:Fema	: 3244513-7Report Type:Direct le I/FU:I	Company Repor	:t #		
Outcome	PT	Report Source	Product	Role Manufacturer	Route
Dose Duration					ľ
Life-Threatening 10 MG BID PRN	Aphasia	Health	Baclofen	PS	ORAL
Hospitalization - BUT PATIENT	Confusional State	Professional			
Initial or Prolonged ONLY TOOK 3	Encephalopathy				
PILLS TOTAL 3 DAY	Grand Mal Convulsion				
	Mental Impairment				/

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

	9ISR Number Gender:	: 3246969-2Report Type:Direct I/FU:I	Company Repor	rt #			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
		Gastrointestinal Haemorrhage		Baclofen Lotensin	PS	Goldline	
		Haemorrhage Medication Error Myocardial Infarction		(Benazepril)	SS	Novartis	
	9ISR Number Gender:Fema	: 3247009-1Report Type:Expedit le I/FU:I	ted (15-DaCompany Repor	rt #R99-014			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalizat	ion -	Convulsion	Health	Baclofen Tablets			
Initial or P		Depressed Level Of	Professional	(Strength Unk)			
Other		Consciousness		Watson Labs.,Miami	PS	Watson Labs.,Miami	
Required				Megace	С		
Intervention	to			Tums	С		
Prevent Perm	anent			Norvasc (Prn			
Impairment/D	amage			Hypertension)	С		
				Synthroid	С		
				Epogen	С		
				Ativan Qhs	С		
				Prozac (Qhs)	С		
	9ISR Number Gender:Fema	: 3249987-3Report Type:Expedit le I/FU:F	ted (15-DaCompany Repor	rt #001-0945-990140			
Outcome Dose	Duration	РТ	Report Source	Product	Role	Manufacturer	Route
Dose Death	Duración	Drug Interaction	Health	Neurontin Capsules			
Hospitalizat	ion -	Hepatic Necrosis	Professional	300 Mg (Gabapentin)	PS		
900 MG (300	1011	nepatit Neciosis	FIOLESSIONAL	Soo Mg (Gabapenein)	FD		
Initial or P MG, TID)	rolonged	Hepatotoxicity					
		Multi-Organ Failure		Ciclosporin	SS		
22-Aug-2005 Page: 47	12:15 PM						

Freedom Of Information (FOI) Report

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	С
Aspirin	С
Dicyclomine	С
Lasix	C C C C C C C C C
Lonox	С
Nizoral	С
Vitamin E	С
Niaspan	C C
Erythromycin	
Tylenol	С

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

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

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 22-Aug-2005 12:15 PM Page: 48

Freedom Of Information (FOI) Report

	Meningitis Pyrexia					
	-	Report Source	Product	Role	Manufacturer	Route
Dose Duration		Health Professional	Lioresal (R) Intrathecal (Baclofen Injection)	PS		
INTRATHECAL UNK,	DAILY,					
INTRATHECAL						
Date:05/03/99ISR Numbe Age: Gender:Mal	er: 3252141-2Report Type:Expe le I/FU:I	dited (15-DaCompany Re	eport #990665			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - Initial or Prolonged	Csf Culture Positive Mechanical Complication Of Implant	Health Professional	Lioresal (R) Intrathecal (Baclofen Injection)	PS		
	DAILY, Meningitis					
INTRATHECAL	Pyrexia					
Age:61 YR Gender:Mal Outcome	er: 3252629-4Report Type:Expe le I/FU:I PT	dited (15-DaCompany Re Report Source	eport #98D10338 Product	Role	Manufacturer	Route
Dose Duration Hospitalization - Initial or Prolonged	Asthma Condition Aggravated	Foreign Health	Lioresal Tablet (Baclofen)	PS		ORAL
75 MG, DAILY, ORAL	Drug Interaction	Professional				
			Theophyllin Unknown (Theophyllin)	SS		
200 MG, DAILY			Catapressan (Clonidine Hydrochloride)	SS		

Date:05/04/99ISR Number	r: 3256747-6Report Type:Expedi	ited (15-DaCompany Re	≥port #99F10373		
Age:62 YR Gender:Male	e I/FU:I				
Outcome	PT	Report Source	Product	Role Manufacturer	Route
Dose Duration					
Hospitalization -	Encephalopathy	Foreign	Lioresal Tablet		
Initial or Prolonged	Personality Change Due To	Health	(Baclofen)	PS	ORAL
5 MG,					
	A General Medical	Professional			
DAILY,ORAL 6 DAY	Ζ				
	Condition	Other	Rifadine Capsule		
1			(Rifampicin)	SS	ORAL
ORAL			· L ·		
			Inh Tablet		
1			(Isoniazid)	SS	ORAL
ORAL			(,	22	-
onum			Rimifon Tablet		
1			(Isoniazid)	SS	ORAL
ORAL			(1001110210)	55	010111
OTAL			Amlor Capsule	С	I
1			Triatec Tablet	C	I
			IIIatet idditte	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 - Condition Aggravated Initial or Prolonged Muscle Rigidity Neutrophil Count Increased Pyrexia Staphylococcal Sepsis

Freedom Of Information (FOI) Report

		White Blood Cell Count					
		Increased					
	Duration		Report Source	Product	Role	Manufacturer	Route
Dose	Duration		Health	Baclofen Tablet 5 Mg			
			Professional	(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	С		
	9ISR Number Gender: Duration	r: 3264030-8Report Type:Expedi I/FU:I PT Respiratory Arrest	ited (15-DaCompany Rep Report Source Foreign Health Professional	Product Product Efexor Tablets (Venlafaxine Hydrochloride) Baclofen Tablets	Role PS SS	Manufacturer	Route ORAL ORAL
ORAL				Bacioren indrees			UIAL
				Temazepam	SS		
				Unspecified			
				Medications	С		
		r: 3265938-XReport Type:Expedi e I/FU:I	ited (15-DaCompany Rep	oort #G99-245 (99F-10373)			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalizati	ion –	Coma	Foreign	Lioresal Tablet			
Initial or Pr		Confusional State	Health	(Baclofen)	PS		ORAL
5 MG DAILY							

ORAL 6 DAY

	Abnormal	Other	Rifadine Capsules		
	Encephalopathy		(Rifampicin)	SS	ORAL
ORAL			—		
	Overdose		Inh Tablet		
	Personality Change Due To		(Isoniazid)	SS	ORAL
ORAL					
	A General Medical		Rimifan Tablet		
	Condition		(Isoniazide)	SS	ORAL
ORAL					
			Amlor Capsule	С	
			Triatec Tablet	С	
Date:05/19/99ISR Numb Age: Gender:Fe	er: 3330432-4Report Type:Peri male I/FU:I	odic Company Re	port #5833/20771		
Age: Gender:Fe Outcome		odic Company Re Report Source	port #5833/20771 Product	Role Manufacturer	Route
Age: Gender:Fe	male I/FU:I PT	Report Source	Product		
Age: Gender:Fe Outcome	male I/FU:I PT	Report Source Consumer	Product Detrol Tablets	PS	Route ORAL
Age: Gender:Fe Outcome	male I/FU:I PT	Report Source Consumer Company	Product		
Age: Gender:Fe Outcome	male I/FU:I PT	Report Source Consumer	Product Detrol Tablets	PS	
Age: Gender:Fe Outcome Dose Duration	male I/FU:I PT	Report Source Consumer Company Representative	Product Detrol Tablets Baclofen	PS	

Outcome Death Hospitalization -

Freedom Of Information (FOI) Report

Initial or Prolonged

Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
		Encephalopathy	Health	Baclofen Tablets	PS		ORAL
10MG TID ORA	AL	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	С		
Outcome Dose Life-Threate Hospitalizat Initial or F	cion -	PT Grand Mal Convulsion Mental Impairment Speech Disorder	Report Source Health Professional	Product Baclofen - Zenith Goldline Pharm. Tablets	Role PS	Zenith Goldline	Route ORAL
10MG BID ORA		: 3268966-3Report Type:Direct	Company Repor	+ #			
	Gender:Fema		company nepor				
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Life-Threate Hospitalizat DAILY	-	Hypersensitivity Malaise	Health Professional	Propulsid 10mg & Premarin 0.625mg	PS		
Initial or H		Mechanical Complication					

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

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

Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Life-Threater Hospitalizati	ning	Coma Haemodialysis	Health Professional	Lioresal Tablet (Baclofen)	PS		ORAL
DAILY, ORAL Initial or Pr	rolonged	Hypothermia Overdose Respiratory Failure					
	9ISR Number Gender:	: 3269925-7Report Type:Expedite I/FU:I	ed (15-DaCompany Report	z #			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other		Overdose	Health Professional	Baclofen (Unknown Strenght) Watson			
	10.15 53						

Freedom Of Information (FOI) Report

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 Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Dose Death	Duration	Back Pain Encephalopathy	Health Professional	Neurontin (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	J	Sepsis		Colace (Docusate			
				Sodium) Phoslo (Calcium	С		
				Acetate) (Cortisone)	C C		
				Nephrocaps (Folic Acid, Vitamins Nos) Prevacid	С		
				(Lansoprazole) Restoril (Temazepam)	C C		
				(Calcitonin) Vicodin	C		
				(Paracetamol, Hydrocodone			
				Bitartrate) Senokot (Senna	С		
				Fruit) Ventolin	С		
				(Salbutamol) Atrovent	С		
				(Ipratropium Bromide) Synthroid	С		
				(Levothyroxine Sodium)	С		
				Cordarone (Amiodarone Hydrochloride)	С		

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

D	D	PT	Report Source	Product	Role	Manufacturer	Route
Dose Other	Duration	Complications Of Maternal Exposure To Therapeutic	Foreign Health	Lioresal Unknown (Baclofen)	PS		
DAILY		5					
		Drugs Convulsion Neonatal Drug Withdrawal Convulsions	Professional Other				
	99ISR Number Gender:Male	: 3274347-9Report Type:Exped	ited (15-DaCompany R	eport #99F-10446			
Age:75 YR		e I/FU:I		eport #99F-10446			
	Gender:Male		lited (15-DaCompany R Report Source Foreign	eport #99F-10446			
Age:75 YR Outcome	Gender:Male	e I/FU:I PT	Report Source	eport #99F-10446			

Freedom Of Information (FOI) Report

		Ot	ther			
Dogo	Durati	ion		Product	Role Manufacturer	Route
Dose	Durati	-01		Lioresal Tablet (Baclofen)	PS	ORAL
15 MG, DAILY,	,					
ORAL	12	DAY				
				Topalgic Capsule (Tramadol		ODAI
300 MG,				Hydrochloride)	SS	ORAL
DAILY, ORAL	10	WK				
				Lipur Tablet	C	
				Stilnox Tablet Spasfon Unknown	C C	

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

ORAL
ORAL

Date:06/07/99ISR Number Age:65 YR Gender:Male	: 3277800-7Report Type:Expedit I/FU:F	ed (15-DaCompany Repor	:t #99F10373		
Outcome Dose Duration	PT	Report Source	Product	Role Manufacturer	Route
Hospitalization -	Coma	Foreign	Lioresal Tablet		ļ
Initial or Prolonged 5 MG, DAILY,	Confusional State	Health	(Baclofen)	PS	ORAL
	Dialysis	Professional			l
ORAL 6 DAY	-				I
Date:06/09/99ISR Number Age:56 YR Gender:Male	Electroencephalogram Abnormal Encephalopathy Personality Change Due To A General Medical Condition : 3279012-XReport Type:Direct I/FU:I	Company Repor	Rifadine Capsule Mopral Capsule Amlor Capsule Inh Tablet Pirilene Tablet Triatec Tablet Fozitec Tablet		
-					
Outcome Dose Duration	PT	Report Source	Product	Role Manufacturer	Route
Hospitalization - 25MG PO Q 6H	Accident At Home		Baclofen	PS	ORAL
Initial or Prolonged 300MG PO TID	Fall		Gabapentin	SS	
	Sedation				

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 Dose Duration	PT	Report Source	Product	Role Manufacturer	Route
Hospitalization - Initial or Prolonged PER ONE DOSE	Depression Dyspnoea	Health Professional	Valium Tablets (Diazepam)	PS	ORAL
ORAL	Intentional Misuse				
PER ONE DOSE	Lethargy		Baclofen (Baclofen)	SS	ORAL
ORAL	Suicide Attempt				
1 PER ONE			Ativan (Lorazepam)	SS	ORAL
DOSE ORAL					
			Glyburide (Glyburide)	SS	ORAL
1 PER ONE					
DOSE ORAL			Glatiramer Acetate		
SUBCUTANEOUS 20 MG	DAILY		(Glatiramer Acetate)	SS	
SUBCUTANEOUS 56 DAY			Trazodone (Trazodone		
1 PER ONE			Hydrochloride)	SS	ORAL
DOSE ORAL					
DOSE ORAL			Doxazosin Mesilate Fosinopril Sodium Naproxen	C C 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	ther	Complications Of Maternal Exposure To Therapeutic	Foreign Health	Baclofen Unknown (Balcofen)	PS		
				(

DAILY

	Drugs Premature Baby	Professional Other	Hydrocortisone Unknown (Hydrocortisone) Tylex Unknown (Paracetamol + Codeine)	SS SS		
Date:06/11/99ISR Number Age: Gender:Fema	r: 3281482-8Report Type:Exp ale I/FU:I	pedited (15-DaCompany Re	port #685/9866			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration	Intraventricular Haemorrhage	Foreign Consumer Company Representative	Solu-Cortef Sterile Powder Codeine Phosphate Baclofen	PS SS SS		
Date:06/11/99ISR Number Age:51 YR Gender:Male	r: 3281491-9Report Type:Exp e I/FU:I	pedited (15-DaCompany Re	port #1895/17498			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - ORAL	Dyspnoea	Consumer	Micronase Tablets	PS		ORAL
Initial or Prolonged	Intentional Misuse		Baclofen	SS		
Other	Lethargy		Ativan	SS		
Required	Suicide Attempt		Valium	SS		
Intervention to			Trazadone	SS		
Prevent Permanent Impairment/Damage			Copaxone	С		

Freedom Of Information (FOI) Report

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 M	Manufacturer	Route
Dose Other	Duration	Intraventricular Haemorrhage	Foreign	Tab Hydrocortone (Hydrocortisone) Codeine Baclofen	PS SS SS		ORAL
	JISR Number Gender:Fema	r: 3282517-9Report Type:Exped: ale I/FU:I	ited (15-DaCompany Re	eport #99GB-10361			
Outcome		РТ	Report Source	Product	Role M	Manufacturer	Route
	Duration						
Other		Complications Of Maternal	Foreign Health	Baclofen Unknown	PS		
TRANSPLACENT	אד דיאוע ד	Exposure To Therapeutic DAILY,	Health	(Baclofen)	25		
IRANSPLACENIA	ALI UNK, I	Drugs	Professional				
TRANSPLACENTA	7	Drugs	TIOLOSSIONAL				
	-	Intraventricular	Other				
L							
		Haemorrhage Neonatal		Hydrocortisone			
		Premature Baby		Unknown			
				(Hydrocortisone)	SS		
TRANSPLACENTA	L UNK, U	JNK ,					
TRANSPLACENT	ł						
L							
				Codeine Phosphate			
				Unknown (Codeine			
TRANSPLACENT	AL UNK, U	JNK ,		Phosphate)	SS		
TRANSPLACENT	f						
L							

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 Age:34 YR Gender:Male	: 3288113-1Report Type:Expe I/FU:I	edited (15-DaCompany Re	port #99F10510			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration		noporo bodroc		11010		
Hospitalization -	Mouth Ulceration	Foreign	Lioresal Tablet			
Initial or Prolonged		Health	(Baclofen)	PS		ORAL
10 MG, BID,						
		Professional				
ORAL						
			Brexin Tablet			
			(Piroxicam Beta			
			Cyclodextrin)	SS		ORAL
40 MG, DAILY,						
oral 14 mon	T					
Date:06/22/99ISR Number Age:51 YR Gender:Male	: 3290028-XReport Type:Expe I/FU:I	edited (15-DaCompany Re	port #199912638HMRI			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization -	Depression		Glyburide	PS		ORAL
PO 1 DAY	-			10		oruin
Initial or Prolonged	Dyspnoea		Copaxone	SS		
	Intentional Misuse		Baclofen	SS		
1 DAY						
	Lethargy		Lorazepam	SS		
1 DAY	51		-			
	Suicide Attempt		Diazepam (Valium)	SS		
1 DAY	-		•			
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Freedom Of Information (FOI) Report

Prozac

Detrol Demerol

Voltaren

Macrodantin

С

С

C C

С

Route

1 DAY		Trazodone	SS	
1 DAY		Doxazosin Mesilate	С	
		Naproxen	С	
		Fosinopril	С	
Date:06/23/99ISR Number: 3292386-9Re Age:40 YR Gender:Female I/FU:I	ort Type:Periodic Company Repor	t #108820USA		
Outcome PT	Report Source	Product	Role	Manufacturer
Dose Duration				
Hospitalization - Dysphagia	Consumer	Copaxone (Glatiramer		
Initial or Prolonged Headache		Acetate)	PS	
SUBCUTANEOUS 20 MILLIGRAMS				
Hypertonia				
QD				
Neck Pain				
SUBCUTANEOUS				
		Baclofen	SS	
		Neurontin	С	
		Baclofen	С	
		Zanaflex	С	
		Prevacid	С	

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

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

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					
Hospitaliza	ition -	Overdose	Foreign	Lioresal Tablet		
Initial or	Prolonged		Health	(Baclofen)	PS	ORAL
UNK, DAILY,						
			Professional			I
ORAL						
			Other			

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 -	Eosinophilia	Foreign	Dantrium Capsules,		
Initial or Prolonged		Health	Dose Unspecified		
		Professional	(Dantrolene Sodium)	PS	ORAL
ORAL					
			Lioresal (Baclofen)	SS	ORAL
ORAL					
			Tegretol		
			(Carbamazepine)	SS	ORAL
1200 MG					
DAILY; ORAL				~	
			• • •	C	
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Freedom Of Information (FOI) Report

Trazodone (Trazodone

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

1							
Outcome	Provention	PT	Report Source	Product	Role	Manufacturer	Route
Dose I Death	Duration	Arrhythmia	Foreign	Lioresal Tablet			
Life-Threaten:	ina	Malaise	Health	(Baclofen)	PS		ORAL
60 MG, DAILY,			11042011	(Daolocion,	- ~		···
		Pulmonary Embolism	Professional				
ORAL							
			Other	Tanakan Tablet			
				(Ginkgo Tree Leaves	SS		ORAL
120 MG,				Extract)	66		ORAL
120 110,							
DAILY, ORAL							
				Avonex Solution For			
				Injection			
				(Interferon Beta)	SS		
INTRAMUSCULAR	INTRAM	USCULAR					
Outcome Dose I Other	Duration	PT Haemorrhage Intracranial Haemorrhagic Stroke	Report Source Foreign Other	Product Tab Hydrocortone (Hydrocortisone)	Role PS	Manufacturer	Route ORAL
PO							
		Intraventricular		Codeine	SS		
		Haemorrhage		Baclofen	SS		
	ISR Number ender:Male	: 3297918-2Report Type:Expedi I/FU:I	ted (15-DaCompany Repo	rt #208768			
Outcome Dose I	Duration	РТ	Report Source	Product	Role	Manufacturer	Route
Hospitalizatio		Depression	Other	Valium (Diazepam)	PS		ł
Initial or Pro		Dyspnoea	O CIICE	Glyburide	÷~		l
	01010	Lethargy		(Glyburide)	SS		ł
					~~		
		Suicide Attempt		Baclofen (Baclofen)	SS		
1		Suicide Attempt		Baclofen (Baclofen) Ativan (Lorazepam)	SS SS		

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

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

Outcome Dose	Duratio		PT	Report Source	Product	Role	Manufacturer	Route
Hospital Initial	.ization - or Prolonged DAILY		Convulsion Electroencephalogram	Foreign Health	Lioresal Tablet (Baclofen)	PS		ORAL
			Abnormal	Professional				
ORAL 300 MG			Epilepsy Pain Pneumonia		Bi-Profenid Tablet (Ketoprofen)	SS		ORAL
DAILY 50 MG	ORAL 4 1 DAILY	DAY	Pneumonia Aspiration		Anafranil Tablet (Clomipramine Hydrochloride)	SS		ORAL
50 MG	DAILI							
ORAL					Topalgic Capsule (Tramadol Hydrochloride)	SS		ORAL
300 MG						22		01012
DAILY	ORAL							

Freedom Of Information (FOI) Report

	er: 3298147-9Report Type:Exped:	ited (15-DaCompany R	eport #WAES 99065036			
Age: Gender:	I/FU:I					
Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Complications Of Maternal	Foreign	Tab Hydrocortisone	~		
50	Exposure To Therapeutic	Other	(Hydrocortisone)	PS		ORAL
PO	Drugs		Acetaminophen/Codein			
	Haemorrhage Intracranial		e Phosphate	SS		
l	Premature Baby		Baclofen	SS		
Doto 07/07/00ISB Number	r: 3298833-0Report Type:Exped:	Vited (15-DeCompany R				
Age:60 YR Gender:Male		ILEA (19-Dacompany in	3DOLC #0-22710-1214			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration		- L				
Hospitalization - 150 MG TWICE	Blood Creatinine	Foreign	Orudis (Ketoprofen)	PS		ORAL
Initial or Prolonged DAILY ORAL	Increased	Health				
	Blood Potassium Increased	Professional	Baclofen	SS		
	Convulsion		Clomipramine			
	Electroencephalogram		Hydrochloride	SS		ORAL
50 MG DAILY	_					
	Abnormal					
ORAL			— · · ·			
	Pneumonia Aspiration		Tramadol			
			Hydrochloride Injection	SS		
300 mg dose			INJECTION	66		
	er: 3300471-8Report Type:Exped:	ited (15-DaCompany R	eport #001-0945-990421			
Age:70 YR Gender:Male						
Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Alanine Aminotransferase	Health	Neurontin (Gabay antin)			
	Increased	Professional	(Gabapentin)	PS		
300 MG ON						
MON, WED, &	Aspartate					
MON, WED, &						

	Aminotransferase				
FRI					
	Increased		(Baclofen)	SS	ORAL
30 MG (10 MG,					
	Encephalopathy				
TID), PER					
	Mental Impairment				
ORAL	Respiratory Acidosis		Colace	0	
ı	Respiratory Acidosis Sepsis		Phoslo	C C	
I	Зерата		Cortisone	C	
I			Nephrocaps	C	
1			Prevacid	C	
1			Restoril		
			(Calcitonin)	C C	
l			(Calcitonin) Vicodin	C	
			Senokot	C	
			Ventolin		
				C	
			Atrovent	C	
1			Synthroid Cordarone	C C	
			Cordarone	C	
Date:07/12/99ISR Numbe Age:60 YR Gender:Mal	er: 3301916-XReport Type:Exp .e I/FU:I	edited (15-DaCompany R	eport #PRIUSA1999003300		
Outcome Dose Duration	PT	Report Source	Product	Role Manufacturer	Route
Hospitalization -	Convulsion	Foreign	Ultram (50 Mg		
Initial or Prolonged	Pneumonia Aspiration	Health	Tablet) (Tramadol		
inicial of fiolonyca	incumonita inspiración	Professional	Hydrochloride)	PS	ORAL
300 MG,		TIOLOSSIONAL	ng ar contor rac (10	oran
DAILY, ORAL					
			Clomipramine		
			(Clomipramine)	SS	ORAL
50 MG, ORAL					
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Freedom Of Information (FOI) Report

				Ketoprofen (Ketoprofen)	SS		ORAL
300 MG , ORA	AL .			Baclofen (Baclofen)	SS		ORAL
60 MG, 1 IN	1			bactoren (bactoren,	00		
DAILY, ORAL							
				Ultram (50 Mg Tablet) (Tramadol			
	200			Hydrochloride)	SS		
INTRAVENOUS	300 M	NG, IV					
Date:07/19/9 Age:63 YR		er: 3306499-6Report Type:Exped male I/FU:I	ited (15-DaCompany Re	eport #99USA10808			
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose Other	Duration	Apallic Syndrome	Health	Baclofen Tablet 10			
Other		Coma	Professional	Mg (Baclofen)	PS		ORAL
10 MG, BID,							-
ORAL	5 YR	2					
	91SR Numbe Gender:Fem	er: 3306720-4Report Type:Exped male I/FU:F	ited (15-DaCompany Re	eport #99GB-10342			
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration	Complications Of Maternal		Lioresal Unknown			
Other		Exposure To Therapeutic	Foreign Health	(Baclofen)	PS		
UNK, DAILY,		Exposure to merapeaste	nearch		10		
		Drugs	Professional				
UNKNOWN			211				
		Convulsion Neonatal Drug Withdrawal Syndrome Neonatal	Other				
D_{2} to $(02/02)$	OTCD Numbe	x. 2222107 2Depart Time. Derie	dia Company B				

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

Outcome		PT	Report Source	Product	Role Manufacturer	Route
Dose Du Life-Threatenin 10MG BID	ration g	Drug Withdrawal Syndrome	Consumer	Baclofen Tablets	PS	ORAL
ORAL						
Date:08/06/99IS Age:13 YR Gen		3320399-7Report Type:Expe I/FU:I	dited (15-DaCompany Re	eport #19990700899		
Outcome Dose Du	ration	PT	Report Source	Product	Role Manufacturer	Route
Other EPIDURAL	20 MG 1	Acquired Cardiac Septal	Foreign	Naropin	PS	
EPIDURAL 20 MG		Defect Atrioventricular Block Drug Level Above Therapeutic Grand Mal Convulsion Medication Error Tachycardia	Literature Other	Baclofen Imipramine	SS SS	
	R Number: der:Male	3324846-6Report Type:Expe I/FU:I	dited (15-DaCompany Re	eport #99GB-10503		
Outcome Dose Du	ration	PT	Report Source	Product	Role Manufacturer	Route
Hospitalization Initial or Prol 2.5 MG,	-	Muscular Weakness Respiratory Depression	Foreign Health	Baclofen Unknown (Baclofen)	PS	ORAL
Other DAILY, ORAL			Professional			
			Other	Rifampicin Folic Acid	C C	

Freedom Of Information (FOI) Report

Sytron	С
Ciprofloxacin	С
Prozac	С
Teicoplanin	С
Clexane	С

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

Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalizat		Suicide Attempt	Foreign	Lioresal Tablet			
Initial or H DAILY, ORAL	2	Toxicologic Test Abnormal	Health	(Baclofen)	PS		ORAL
			Professional				

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 10 MG, DAILY,	Asthma Condition Aggravated	Foreign Health	Lioresal Tablet (Baclofen)	PS	ORAL
	Drug Interaction	Professional			
ORAL	Sedation	Other	Theophyllin (Theophylline)	SS	ORAL
200 MG,					I
DAILY, ORAL					I
			Catapressan (Clonidine		
			Hydrochloride)	SS	
			Aponal	C	
1			Zyrtec	C	
1			Bronchoretard Mite	C	
			Mono-Embolex	C	
1			Euphylong	C	
1			Bronchorcort	C	

Outcome .	PT	Report Source	Product	Role Manufacturer	Route
Dose Duration					
Hospitalization -	Convulsion	Foreign	Dantrium Capsules,		
Initial or Prolonged	Drug Level Below Therapeutic	Health Professional	100mg (Dantrolene Sodium)	PS	ORAL
300 MG DAILY;					
	Medication Error				
ORAL					
			Floxyfral		
			(Fluvoxamine		
			Maleate)	SS	ORAL
100 MG DAILY;					
ORAL					
ORAL			Lioresal (Baclofen)	SS	ORAL
40 MG DAILY;				55	014
ORAL					
			Tegretol		
			(Carbamazepine)	SS	ORAL
400 MG DAILY;					
ORAL					
ord m			Tiapridal (Tiapride)	SS	ORAL
200 MG DAILY;					
ORAL					
ORAL			Floxyfral	С	
			Lioresal	C	
			Stablon	C	
			Tegretol	C	
			Tiapridal	C	

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

Age:73 YR Gender:Male

I/FU:I

Outcome	PT	Report Source	Product	Role Manufacturer	Route
Dose Duration Hospitalization -	Petechiae	Foreign	Valium (Diazepam) 1%	PS	ORAL
4 DROP DAILY Initial or Prolonged ORAL	Vascular Purpura	Other			
			Lutheran (Chlormadinone		
5 MG DAILY			Acetate) 5 Mg	SS	ORAL
ORAL					
			Depakine (Valproate Sodium)	SS	ORAL
ORAL			Lioresal (Baclofen)	22	
30 MG 3 PER			10 Mg	SS	ORAL
DAY ORAL			/		
			Forlax (Polyethylene Glycol)		
30 GRAM DAILY			10gram	SS	ORAL
ORAL					
Date:09/20/99ISR Number Age:50 YR Gender:Male	r: 3352151-0Report Type:Direct e I/FU:I	Company Repor	't #		
Outcome	PT	Report Source	Product	Role Manufacturer	Route
Dose Duration Hospitalization - 20MG QID PO	Hallucination		Baclofen	PS	ORAL
Initial or Prolonged	Mental Impairment				
Date:09/21/99ISR Number	: 3352953-OReport Type:Direct	Company Repor	:t #		

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration Hospitalization - 30MG QID PO	Confusional State		Baclofen	PS		ORAL
	Dyspnoea		Dantrolene	SS		ORAL
~	Hallucination					
	: 3356209-1Report Type:Expedit	ed (15-DaCompany Report	= #97F10835			
Age:80 YR Gender:Femal	le I/FU:I					
Outcome Dose Duration	РТ	Report Source	Product	Role	Manufacturer	Route
Hospitalization -	Agitation	Foreign	Lioresal Tablet			
Initial or Prolonged ORAL 2 DAY	Confusional State	Health	(Baclofen)	PS		ORAL
		Professional Other				
Date:09/27/99ISR Number;	: 3359188-6Report Type:Expedit	ed (15-DaCompany Report	- #99D10869			
Age:40 YR Gender:Femal			- π//μ 1000/			
Outcome Dose Duration	РТ	Report Source	Product	Role	Manufacturer	Route
Hospitalization - Initial or Prolonged	Bacterial Infection Pyrexia	Foreign Health	Lioresal Unknown (Baclofen)	PS		
100 MG DAILY		Professional	Keltican	С		

Freedom Of Information (FOI) Report

Luteran Tablet

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

Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - Initial or Prolonged 40 MG, ONCE,	Ventricular Tachycardia	Health Professional	Lioresal Tablet (Baclofen)	PS		ORAL
ORAL						
Date:09/30/99ISR Numbe Age:70 YR Gender:Mal	er: 3362069-5Report Type:Exped: Le I/FU:I	ited (15-DaCompany Rep	ort #99HQ-10414			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other	Convulsion Delirium	Foreign Literature	Baclofen Unknown (Baclofen)	PS		ORAL
100 MG DAILY	'					
ORAL	Drug Ineffective	Health				
	Loss Of Consciousness Sedation	Professional Other	Diazepam Unknown (Diazepam)	SS		ORAL
20 MG DAILY						
ORAL						
			Dantrolene Unknown (Dantrolene)	SS		ORAL
400 MG DAILY						
ORAL						
Date:10/01/99ISR Numbe Age:48 YR Gender:Fem	er: 3362835-6Report Type:Exped: male I/FU:I	ited (15-DaCompany Rep	ort #99F10832			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - Initial or Prolonged 30 MG DAILY	Vascular Purpura	Foreign Health	Lioresal Tablet (Baclofen)	PS		ORAL
		Professional				
ORAL		_				

Other

			(Chlormadinone		
			Acetate)	SS	ORAL
5 MG DAILY					
ORAL					
			Depakine Solution		
			(Valproate Sodium)	SS	ORAL
1 DF, DAILY					
ORAL					
Data:10/14/0015P Number	: 3371020-3Report Type:Direct	Company Repor	+ #		
Age:50 YR Gender:Male	I/FU:I	Company repor	L #		
	_/				
Outcome	PT	Report Source	Product	Role Manufacturer	Route
Dose Duration Death	Sudden Death	Health	Naltrexone	PS	
SUBCUTANEOUS SUBCUTA		Health	Naitrexone	25	
		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	
4			-		

Ketamine Hcl

Clonidine

Naltrexone

Enalapril Maleate

Diazepam

SS

С

С

С

С

Freedom Of Information (FOI) Report

PT Sudden Death CANEOUS	Report Source Health Professional	Product Naltrexone Baclofen	PS	Manufacturer	Route
	Professional	Baclofen			
		Citric Acid/Sodium	SS		
		Citrate	SS		
		Glycopyrrolate	SS		
		Ketamine Hcl	SS		
		Fentanyl	SS		
		Dexamethasone	SS		
	lited (15-DaCompany Re				
PT	Report Source	Product	Role	Manufacturer	Route
	Foreign	Lioresal Tablet			
White Blood Cell Count	Health	(Baclofen)	PS		ORAL
-					
Increased	Professional Other				
	ale I/FU:I	AleI/FU:IPTReport SourceThrombocytopeniaForeign HealthWhite Blood Cell CountHealthIncreasedProfessional	Midazolam Octreotide Acetate Vercuronium Trazodone Propofol Nalmefene Cefazolin Sodium Clonidine Droperidol Metoclopramide Hcl Naloxone Hcl Ondanstetron Hcl Ondanstetron Hcl PT Report Source Product Thrombocytopenia Foreign Lioresal Tablet White Blood Cell Count Health (Baclofen) Increased Professional	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 Ondanstetron Hcl C ST PT Report Source Product Role Thrombocytopenia Foreign Lioresal Tablet White Blood Cell Count Health (Baclofen) PS Increased Professional	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 SS Propofol SS Nalmefene SS Cefazolin Sodium C Clonidine C Droperidol C Metoclopramide Hcl C Naloxone Hcl C Ondanstetron Hcl C SS Propofol SS Nalmefene SS Cefazolin Sodium C Clonidine C Droperidol C Metoclopramide Hcl C Naloxone Hcl C Naloxone Hcl C SS Propofol SS Nalmefene SS Cefazolin Sodium C Clonidine C Droperidol C Metoclopramide Hcl C Naloxone Hcl C SS Propofol SS Nalmefene SS Cefazolin Sodium C Clonidine C Droperidol C Metoclopramide Hcl C Naloxone Hcl C SS Propofol SS Nalmefene SS Propofol SS Nalmefene SS Nalmefe

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

Route

OutcomePTReport SourceProductRole ManufacturerDoseDuration

Death		Death
SUBCUTANEOUS	1000MG	

SUBCUTANEOUS

Naltrexone	PS
------------	----

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	С
Cefazolin Sodium	С
Clonidine	С
Naltrexone	С

FDA - Adverse Event Reporting System (AERS) Freedom Of Information (FOI) Report Date:10/25/99ISR Number: 3382435-1Report Type:Expedited (15-DaCompany Report #99USA11187 Gender:Male I/FU:I Age: Report Source Role Manufacturer Outcome PTProduct Route Dose Duration Muscle Twitching Hospitalization -Consumer Lioresal Tablet 20 Initial or Prolonged Paraesthesia Mg (Baclofen) PS ORAL 80 MG, DAILY, Peripheral Nerve Injury ORAL Date:11/01/99ISR Number: 3386792-1Report Type:Expedited (15-DaCompany Report #99F--10775 Aqe:53 YR Gender:Male I/FU:F PTReport Source Product Role Manufacturer Outcome Route Duration Dose Hospitalization -Bradycardia Foreign Lioresal Tablet Initial or Prolonged Health (Baclofen) Coma PS ORAL UNK, DAILY, Hypothermia Professional ORAL Lung Disorder Other Theralene Drpos Suicide Attempt (Alimemazine Tartrate) SS UNK, DAILY, ORAL Lysanxia Tablet (Prazepam) SS ORAL UNK, UNK, ORAL Tegretol Tablet (Carbamazepine) ORAL SS 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 \mathbf{PT} Report Source Product Role Manufacturer Route Dose Duration Hospitalization -Abdominal Pain Upper Foreign Lioresal Suspension Initial or Prolonged Anorexia Health (Baclofen) PSORAL 5 MG, TID, Depression Professional Other ORAL 10 DAY Haloperidol Capsule Eye Excision Other С Intraocular Melanoma Daktarin Oral Gel Lethargy Gel С Malignant Melanoma Stage Lactulose Syrup С Bisacodyl Tablet С Iv Pain Prednisolone Tablet С Mst 60 Tablet 60 С С Normax Cyclizine С Date:11/01/99ISR Number: 3387232-9Report Type:Expedited (15-DaCompany Report #S9432751 Gender:Female Aqe: I/FU:I

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

Freedom Of Information (FOI) Report

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 -	Aphasia	Health	Baclofen Tablets			
Initial or Prolonged	Aspiration	Professional	10mg, Watson			
	Crying		Laboratories, Inc.,			
	Dyskinesia		Miami	PS	Watson Laboratories,	
	Euphoric Mood				Inc.,	ORAL
APPROX. 40						
	Intentional Misuse					
TABS ORAL						
	Memory Impairment		Klonopin	С		
	Mental Impairment		Prescription			
	Mood Altered		Antihistamines	С		
	Suicide Attempt					
	Tongue Disorder					
	Vomiting					

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

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

Outcome Dose Duration	PT	Report Source	Product	Role Manufacturer	Route
Dose Duration Hospitalization - Initial or Prolonged 25 MG	Pemphigoid	Foreign Health	Lioresal (Baclofen)	PS	ORAL
QID		Professional			
ORAL		Other			
UKAL			Antibiotics Sirdalud	C C	
Date:11/23/99ISR Number Age:73 YR Gender:Fema	r: 3405354-0Report Type:Direct ale I/FU:I	Company Repor	rt #		
Outcome Dose Duration	PT	Report Source	Product	Role Manufacturer	Route
Life-Threatening 2TABS BID Hospitalization -	Grand Mal Convulsion		Zanaflex 4mg	PS	ORAL
ORAL Initial or Prolonged 1 TAB TID			Lioresal 20mg	SS	ORAL
ORAL			Diltantin Prozac Kcl	C C C	
					/

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 Other UNKNOWN	Duration 1 TABL	Feeling Cold Hypoaesthesia Muscle Disorder Muscle Twitching Neck Pain ET QID Pain	Consumer	Baclofen 10 Mg Tablets, Watson Laboratories, Inc. (Miami)	PS	Watson Laboratories, Inc (Miami)	
UNKNOWN		Paraesthesia Peripheral Nerve Injury Radiculopathy		Ibuprofen & Nnaproxen Prazosin Aspirin Nabumetone Gabapentin Atenolol Methocarbamol Hydroxyzine Lansoprazole Tylenol #3 Hydrochlorothiazide Trazodone	000000000000		
Date:12/01/ Age:	99ISR Number Gender:Fema	: 3414799-4Report Type:Per le I/FU:I	iodic Company Re	port #AR-1295			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other 10 MG TID		Abdominal Pain Headache	Consumer	Baclofen Tablets, 10 Mg (Danbury/Schein)	PS	Danbury/Schein	ORAL
(ORAL),		Rash Papular					
INCREASED T	С						
10 MG BID							
(ORAL)				Wellbutrin Premarin	C C		

			Motrin	C	
			Ultram	C	
Date:12/06/99ISR Number Age:48 YR Gender:Male	r: 3414086-4Report Type:Exp e I/FU:I	pedited (15-DaCompany Re	eport #99F11057		
Outcome Dose Duration	PT	Report Source	Product	Role Manufacturer	Route
Hospitalization - Initial or Prolonged 80 MG, DAILY,	Dermatitis Bullous Eosinophilia	Foreign Health	Lioresal Tablet (Baclofen)	PS	ORAL
ORAL	Linear Iga Disease	Professional			
	Rash Macular Rash Pruritic	Other	Aspegic Powder (Lysine Acetylsalicylate)	SS	ORAL
ORAL			Xanax Tablet (Alprazolam)	SS	ORAL
ORAL			Tilcotil Tablet (Tenoxicam)	SS	ORAL
ORAL					oram
20 mg, daily,			Prozac Capsule (Fluoxetine)	SS	ORAL
ORAL					
			Ciflox Tablet (Ciprofloxacin Hydrochloride)	SS	ORAL
750 MG, BID,			nyaroonioriae,	55	01012
ORAL 10 DAY	ζ				
22-Aug-2005 12:15 PM Page: 66					

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 Gender:Male Age:70 YR I/FU:I Outcome PTReport Source Product Role Manufacturer Route Dose Duration Hospitalization -Confusional State Foreign Lioresal Tablet Initial or Prolonged Delirium Health PS ORAL (Baclofen) DAILY, ORAL Professional Other Date:12/17/99ISR Number: 3425536-1Report Type:Expedited (15-DaCompany Report #99B-10098 Aqe:53 YR Gender:Female I/FU:I Report Source Role Manufacturer Outcome PTProduct Route Duration Dose Haemoglobin Decreased Foreign Other Lioresal Unknown Health Pancytopenia (Baclofen) PS ORAL 55 MG, DAILY, Professional White Blood Cell Count ORAL Prothiaden Decreased С С Prepulsid Date:12/27/99ISR Number: 3431260-1Report Type:Expedited (15-DaCompany Report #99J--10474 Age:51 YR Gender:Female I/FU:I Outcome PΤ Report Source Product Role Manufacturer Route Dose Duration Life-Threatening Abdominal Pain Lower Foreign Lioresal Tablet Amnesia Health (Baclofen) ORAL PS45 MG, DAILY Professional Anxiety Blood Creatinine Other Increased Blood Urea Increased Chest Discomfort Condition Aggravated Delusion Difficulty In Walking Fall Hallucination

Hypoaesthesia

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						ļ
Hospitalization -	Affect Lability	Health	Baclofen Tablets 10			ſ
Initial or Prolonged	Aspiration	Professional	Mg, Watson			/
	Bradyphrenia		Laboratories, Inc.,			/
	Crying		Miami	PS	Watson Laboratories,	ſ
1	Dyskinesia				Inc., Miami	ORAL
APPROX. 15 TO						ſ
1	Euphoric Mood					/
20 TABS, ORAL						ļ
1	Intentional Misuse		Thyroid	С		/
1	Memory Impairment		Celexa	С		ļ
1	Sedation		Zyprexa	С		, j
1	Suicidal Ideation		Ibuprofen	С		
	Suicide Attempt		Klonopin	С		
	Tongue Disorder					
1	Vomiting					

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

Dutcome Dose Dura	ation	PT	Report Source	Product	Role	Manufacturer	Route
)ther		Confusional State Convulsion	Foreign Other	Valium Tablets (Diazepam)	PS		ORAL
20 MG DAILY			001102	(223-225)			0
ORAL		Delirium					
JKAL		Loss Of Consciousness		Baclofen (Baclofen)	SS		ORAL
100 MG DAILY							
DRAL		Sedation					
				Dantrolene (Dantrolene)	SS		ORAL
400 MG DAILY				(
ORAL							
	Number er:Male	: 3433661-4Report Type:Direct I/FU:I	Company Repor	rt #			
Outcome Dose Dura	ation	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - 40MG PO TID		Confusional State		Baclofen	PS		ORAL
Initial or Prolor /2 MONTHS	nged	Delirium					
PRIOR TO		Difficulty In Walking					
EVENT 2	MON	Dysarthria					
EVENI Z	MOIN	Paranoia		Zantac	С		
				Cardura	С		
				Atenolol	C		
				Naproxen	С		
	Number	: 3435538-7Report Type:Expedit	ed (15-DaCompany Repor	-+ #99TND10060			

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

Hospitalization - Initial or Prolonged	Dermatitis Hypersensitivity	Foreign Health	Lioresal Unknown (Baclofen)	PS	ORAL
10 MG TID			(Bactoren)	F 5	UIAL
ORAL	Oedema	Professional			
	Pruritus	Other	Promethazine Pacitane	C C	
Date:01/05/00ISR Numbe: Age:70 YR Gender:Fema	r: 3437781-XReport Type:Expec ale I/FU:I	lited (15-DaCompany Re	eport #99D11189		
Outcome Dose Duration	PT	Report Source	Product	Role Manufacturer	Route
Other	Coma	Foreign	Lioresal Tablet		
5 MG, BID,	Condition Aggravated	Health	(Baclofen)	PS	ORAL
S MG, DID,	Extrapyramidal Disorder	Professional			
ORAL					
	Haemodialysis Overdose Renal Impairment Sedation	Other	Altra	C	
Age:58 YR Gender:Mal					
Outcome Dose Duration	PT	Report Source	Product	Role Manufacturer	Route
Hospitalization - Initial or Prolonged Other	Burns Second Degree Dermatitis Exfoliative Erythema Multiforme	Health Professional	Temesta Tablet (Lorazepam) Deroxat (Paroxetine	PS	
	Pain Rash Erythematous		Hydrochloride) Klean-Prep (Macrogol, Potassium	SS	

Freedom Of Information (FOI) Report

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

LAVEMENT-PHOS

PHATE

(29-SEP-99),

STERCULIA

GOMME

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

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Hospitalizati Initial or Pr 40 MG, QID,	-			Baclofen Tablet 20 Mg (Baclofen)	PS		ORAL

ORAL	Coordination Abnormal					
OKAL	Hallucination		Amantadine Tablet	С		
Date:01/19/00ISR Num Age:43 YR Gender:Ma	ber: 3445217-8Report Type:Di ale I/FU:I	rect Company Re	eport #			
Outcome Dose Duration	PT	Report Source	Product	Role Manufacturer	Route	
Hospitalization - TITRATED AS	Coma	Health	Baclofen	PS	ORAL	
Initial or Prolonged ABOVE PO	Medication Error	Professional				
	Renal Failure Chronic		Norvasc Nephrocaps Insulin Capoten Calcium Acetate Tenex Aspirin	C C C C C C C		
Date:01/28/00ISR Num Age:70 YR Gender:Ma	ber: 3447828-2Report Type:Ex ale I/FU:F	pedited (15-DaCompany Re	eport #222988			
Outcome Other	PT Confusional State Convulsion Delirium					

Freedom Of Information (FOI) Report

Dose Duration	Localised Infection Loss Of Consciousness Respiratory Depression	Report Source	Product	Role	Manufacturer	Route
	Sedation	Foreign Other	Valium Tablets (Diazepam)	PS		ORAL
20 MG DAILY			· • • •			
ORAL			Baclofen (Baclofen)	SS		ORAL
100 MG DAILY			Dacioren (Dacioren)	50		UTAL
ORAL			Dentriclere			
400 MG DAILY			Dantrolene (Dantrolene)	SS		ORAL
ORAL						
			Hypnovel (Inj) (Midazolam			
	er: 3449090-3Report Type:Exp	edited (15-DaCompany Re	Hydrochloride) eport #99D11039	SS		
Date:01/31/00ISR Numb Age:59 YR Gender:Fe Outcome		edited (15-DaCompany Ro Report Source			Manufacturer	Route
Age:59 YR Gender:Fe Outcome Dose Duration	nale I/FU:F PT	Report Source	eport #99D11039 Product		Manufacturer	Route
Age:59 YR Gender:Fe Outcome Dose Duration Hospitalization - Initial or Prolonged	nale I/FU:F PT		eport #99D11039		Manufacturer	Route ORAL
Age:59 YR Gender:Fe Outcome Dose Duration Hospitalization -	male I/FU:F PT Autoimmune Disorder	Report Source Foreign	eport #99D11039 Product Lioresal Tablet	Role	Manufacturer	

Sirdalud C Fungizid-Ratiopharm C

Date:02/10	0/00ISR Number:	3456364-9Report	Type:Expedited	(15-DaCompany	Report	#00GB-10093
Age:	Gender:Female	e I/FU:I				

Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other	Daración	Bone Marrow Depression Hepatic Function Abnormal	Foreign Health	Baclofen Unknown (Baclofen)	PS		ORAL
40 MG, QD,		-		· ·			
ORAL		Liver Function Test	Professional				
		Abnormal Neutropenia Thrombocytopenia	Other	Amitriptyline Unknown (Amitriptyline)	SS		ORAL
50 MG, DAILY	,				22		0101E
ORAL							
				Amoxycillin	С		
				Erythromycine	С		
1				Paracetamol	С		

		FDA – Adv	erse Event Reporting Sy	stem (AERS)	
		Freed	om Of Information (FOI)	Report	
Date:02/11/00ISR N Age:67 YR Gender	umber: 3456482-5Report Type :Male I/FU:I	e:Direct Company R	eport #		
Outcome Dose Durat:	PT	Report Source	Product	Role Manufacturer	Route
Required 5MG PO BID Intervention to Prevent Permanent Impairment/Damage	Sedation		Baclofen	PS	ORAL
Date:02/14/00ISR N Age:82 YR Gender		e:Expedited (15-DaCompany R	eport #00D10137		
Outcome Dose Durat:	PT	Report Source	Product	Role Manufacturer	Route
Hospitalization -	Abdominal Pain	Foreign	Lioresal Unknown		
Initial or Prolonge 25 MG, TID,		Health	(Baclofen)	PS	
	Confusional State	Professional			
UNKNOWN	Extensor Plantar Resp Medication Error Muscle Contractions Involuntary Respiratory Disorder Restlessness Urinary Retention	ponse			
Date:02/22/00ISR N Age:29 YR Gender	umber: 3460039-XReport Type :Female I/FU:I	e:Direct Company R	eport #		
Outcome Dose Durat:	PT ion	Report Source	Product	Role Manufacturer	Route
Hospitalization - 175 MCG/24HR	Bradycardia		Baclofen	PS	
Initial or Prolonge IT	ed Ventricular Extrasyst	coles			
			Tavist	С	
			Motrin	С	
			Phenergan	C	
			Symmetral Feldene	C C	

Tylenol Extra Strength C

	01SR Number: Gender:Male	3462203-2Report I/FU:I	Type:Periodic	Company Re	port #9938788		
Outcome Dose	Duration	PT	Re	port Source	Product	Role Manufacture	r Route
Other 50.00 MG	Duración	Amnesia	Co	nsumer	Zoloft Tablets	PS	ORAL
TOTAL:DAILY:	0		Не	alth			
	0		Pr	ofessional			
RAL					Baclofen	SS	ORAL
80.00 MG							
TOTAL:DAILY:	0						
RAL					Zanaflex	С	
					Urex Vitamin C	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

Freedom Of Information (FOI) Report

Dose Duration	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	Sedation		(,		-
ORAL	Sedacton				
100 MG DAILY			Baclofen (Baclofen)	SS	ORAL
ORAL			Dantrolene		
400 MG DAILY			(Dantrolene)	SS	ORAL
ORAL					
URAL			Hypnovel (Inj) (Midazolam Hydrochloride)	SS	
Age:34 YR Gender:Ma	/	areed (15 Daeompany no	eport #00F-10154		
Outcome	Ale I/FU:I PT	Report Source	Product	Role Manufacturer	Route
Outcome Dose Duration Hospitalization -	PT			Role Manufacturer PS	Route ORAL
Outcome Dose Duration Hospitalization - 90 MG, DAILY, Initial or Prolonged	PT 1	Report Source	Product		
Outcome Dose Duration Hospitalization - 90 MG, DAILY, Initial or Prolonged ORAL	PT Blood Bilirubin Increased	Report Source Foreign	Product		
Outcome Dose Duration Hospitalization - 90 MG, DAILY, Initial or Prolonged	PT Blood Bilirubin Increased Hepatitis Cholestatic Jaundice Liver Function Test	Report Source Foreign Health Professional	Product Lioresal (Baclofen) Dantrium	PS	ORAL
Outcome Dose Duration Hospitalization - 90 MG, DAILY, Initial or Prolonged ORAL 150 MG,	PT Blood Bilirubin Increased Hepatitis Cholestatic Jaundice	Report Source Foreign Health Professional	Product Lioresal (Baclofen) Dantrium (Dantrolene Sodium)	PS	ORAL
Outcome Dose Duration Hospitalization - 90 MG, DAILY, Initial or Prolonged ORAL 150 MG,	PT Blood Bilirubin Increased Hepatitis Cholestatic Jaundice Liver Function Test Abnormal	Report Source Foreign Health Professional	Product Lioresal (Baclofen) Dantrium	PS	ORAL
Outcome Dose Duration Hospitalization - 90 MG, DAILY, Initial or Prolonged ORAL 150 MG, DAILY, ORAL 12 W 40 MG, DAILY,	PT Blood Bilirubin Increased Hepatitis Cholestatic Jaundice Liver Function Test Abnormal	Report Source Foreign Health Professional	Product Lioresal (Baclofen) Dantrium (Dantrolene Sodium) Prozac Solution	PS SS	ORAL
Outcome Dose Duration Hospitalization - 90 MG, DAILY, Initial or Prolonged ORAL 150 MG, DAILY, ORAL 12 W	PT Blood Bilirubin Increased Hepatitis Cholestatic Jaundice Liver Function Test Abnormal	Report Source Foreign Health Professional	Product Lioresal (Baclofen) Dantrium (Dantrolene Sodium) Prozac Solution	PS SS	ORA: ORA:

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

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 -	Dialysis	Health	Unasyn For Injection	PS	
Initial or Prolonged	Drug Level Above	Professional	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	С	
1 5			-		

			FDA – Adve	erse Event Reporting Syste	em (AEF	2S)	
			Freedo	om Of Information (FOI) Re	port		
)ISR Number Gender:Male	: 3478991-5Report Type:Exp I/FU:I	pedited (15-DaCompany Re	eport #00-0263			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalizat: Initial or P:	ion -	Hallucination Urinary Incontinence Vomiting	Health Professional	Baclofen Tablets 10 Mg, Watson Laboratories, Inc.			
10 400 575				Miami	PS	Watson Laboratories, Inc. Miami	ORAL
10 MG, BID,							
PO				Lopressor Zantac Nephro Caps Prinivil Aspirin Nitroglycerin Sublingual Isosorbide Dintirate	00000000		
)ISR Number Gender:Fema	: 3538615-5Report Type:Pe: le I/FU:I	ciodic Company Re	eport #USA012831			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
	Daración	Weight Increased	Consumer Other	Meridia	PS	Knoll Pharmaceutical Co Sub Basf Corp	ORAL
15 MG OD PO				Morphine Baclofen Hydrochlorothiazide Tylox Soma	SS SS C C C		
)ISR Number Gender:Fema	: 3482753-2Report Type:Exp le I/FU:F	pedited (15-DaCompany Re	eport #A005891			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalizat:		Depressed Level Of	Health	Unasyn For Injection	PS		

Initial or Prolonged 120.00 MG	Consciousness	Professional	Baclofen	SS	ORAL
Required TOTAL:DAILY:O	Dialysis				
Intervention to RAL	Drug Level Above				
Prevent Permanent ORAL	Therapeutic		Percocet	SS	ORAL
Impairment/Damage	Loss Of Consciousness Nephritis Interstitial Renal Failure		Ditropan	С	
Date:04/03/00ISR Numbe Age:19 YR Gender:Fem	r: 3483863-6Report Type:Exp ale I/FU:I	pedited (15-DaCompany R	eport #00GB-10239		
Outcome Dose Duration	PT	Report Source	Product	Role Manufacturer	Route
Life-Threatening	Agitation Cyanosis	Foreign Health	Baclofen Unknown (Baclofen)	PS	ORAL
80 MG QD,	Hypoxia	Professional			
ORAL	Respiratory Failure	Other	Dantrolene Unknown		
200 MG,			(Dantrolene)	SS	ORAL
DAILY, ORAL					
			Zanaflex Unknown (Tizanidine Hydrochloride)	SS	ORAL
10 MG DAILY,				55	ordin
ORAL			Voltarol	С	
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Freedom Of Information (FOI) Report

С

С

Bisacodyl

Lactulose

				Cefuroxime Temazepam Motilium Ephedrine Frusemide Glycerol Maxolon Morphine Paracetamol Potassium Chloride Senna Cyclizine			
Date:04/06 Age:	5/00ISR Number Gender:	: 3484628-1Report Type:Direct I/FU:I	Company Repor	rt #USP 52914			
Outcome Dose	Duration	РТ	Report Source	Product	Role	Manufacturer	Route
DOSE		Cardiac Arrest Depressed Level Of Consciousness Grand Mal Convulsion Hypothermia Medication Error Overdose Respiratory Arrest		Lioresal (Baclofen)	PS	Novartis	
Date:04/06 Age:	5/00ISR Number Gender:Fema	r: 3484728-6Report Type:Direct ale I/FU:I	Company Repor	rt #			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
10MG QD		Condition Aggravated	Health	Lioresal - Baclofen	PS		
1000 20		Muscle Spasms	Professional				
4							

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						ļ
Hospitaliza	.ation -	Anxiety	Consumer	Baclofen Tablets 10			, , , , , , , , , , , , , , , , , , ,
	r Prolonged	Chest Discomfort		Mg, Watson			, , , , , , , , , , , , , , , , , , ,
	-	Decreased Appetite		Laboratories, Inc.	PS	Watson Laboratories,	
		Disturbance In Attention				Inc.	
10 MG, TID	J						
		Fatigue		Celebrex	С		7
l		Insomnia		Advil	С		
l		Palpitations		Prilosec	С		, , , , , , , , , , , , , , , , , , ,
1		Panic Attack		Trazadone	С		
1		Restlessness		Ornade	C		ŗ
		Tinnitus					
Date:04/24/ Age:	4/00ISR Number Gender:	r: 3491470-4Report Type:Direct I/FU:I	Company Repor	rt #			
Age·	Gender .	1/10.1					ļ
Outcome	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration			- ' 7	Ъq		ļ
1		Condition Aggravated		Lioresal	PS		ľ
4		Muscle Spasms			C		ļ
1							1
4							r

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 -	Abdominal Distension	Consumer	Baclofen Tablets, 10			
Initial or Prolonged	Abdominal Pain Upper		Mg, Watson			
	Asthenia		Laboratories, Inc.			
	Blood Pressure Increased		Miami	PS	Watson Laboratories,	
	Diarrhoea				Inc., Miami	
1	Dyspnoea		Ultram 100mg,	SS	Ortho	
1	Extrasystoles				Pharmaceuticals	
6 TABS A DAY						
	Muscle Disorder		Klonopin	С		
	Nervousness		Diazepam	С		
			Vioxx	С		ļ
			Albuterol Inhaler	С		
			Methadone	С		l

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 -	Depression	Health	Baclofen Tablets 10			
Initial or Prolonged	Hallucination	Professional	Mg, Watson			/
	Paranoia	Other	Laboratories, Inc.			
	Psychotic Disorder		Miami	PS	Watson Laboratories,	
	Sedation				Inc., Miami	
5 MG						
	Speech Disorder					
INCREASED TO						/
10 MG						
						/
(UNKNOWN						/
						/
FREQUENCY)						
			Minoxidil	С		
			Lopressor	С		
			Zoloft	С		
			Renagel	С		

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

Outcome Dose Duratic	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - Initial or Prolonged	Abdominal Pain	Health Professional	Baclofen Tablets (Strength Unknown) Watson Laboratories Inc	PS	Watson Laboratories Inc	
120 MG QD	Depressed never of				IIIC	
	Consciousness Drug Toxicity Loss Of Consciousness Nephritis Interstitial Renal Failure Renal Impairment		Unasyn (Strength Unknown), Pfizer	SS	Pfizer	
Date:05/09/00ISR Num Age:42 YR Gender:M	ıber: 3497773-1Report Type:Exp Male I/FU:F	edited (15-DaCompany Re	eport #00-0365			
Outcome	PT					
Hospitalization -	Anxiety					
Initial or Prolonged						

Freedom Of Information (FOI) Report

		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					-	IIIC. MIAMI DIV.	
				Celebrex Advil Prilosec Trazadone Ornade	с с с с с с		
Date:05/16/0 Age:73 YR		: 3500940-1Report Type:Direct I/FU:I	Company Repor	t #			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalizat 10MG TID		Dizziness		Baclofen	PS		
Initial or E	Prolonged	Dyspnoea		Lipitor Reglain Lanoxin Pepecid Cardizem Flovet Coumadin Prednisone Combivant	C C C C C C C C C C		
)0ISR Number Gender:Male	: 3503501-3Report Type:Direct I/FU:I	Company Repor	t #			
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose Life-Threate 110 MG QID >		Angina Pectoris	Health	Baclofen/Lioreseal	PS		
Hospitalizat TO 120 MG QI	tion -	Myocardial Infarction	Professional				
Initial or F					С		

Required						
Intervention to						
Prevent Permanent						
Impairment/Damage						

Date:05/31/00ISR Number: Age:67 YR Gender:Male	: 3506698-4Report Type:Direct I/FU:I		Company Repor	t #			
Outcome Dose Duration	PT	Report	Source	Product	Role	Manufacturer	Route
Hospitalization - Initial or Prolonged	Hepatitis		Baclofen 20mg Tab Azathioprine 50 Mg	PS			
				Tab Interferon Beta 1b	SS		
				Vi Inj	С		
				Syringe 2.5-3ml/Ndl	С		
				Tuberculin Syringe	С		

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 Dose Duratior	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - Initial or Prolonged 5 MG, DAILY,	Aggression Agitation	Foreign Literature	Lioresal	PS	Novartis Pharmaceuticals Corp	ORAL
ORAL	Blood Bicarbonate	Health				
URAL	Increased Blood Creatinine Increased Blood Urea Increased Confusional State Diabetes Mellitus Electroencephalogram Abnormal Encephalopathy Haemoglobin Decreased Hyperglycaemia Infarction Muscle Rigidity Nervous System Disorder	Professional Other	Rifampicin Rimifon Pirilene Mopral Fozitec Hemodialysis	C C C C C C C C		
Date:06/06/00ISR Numk Age:42 YR Gender:Ma	per: 3508574-XReport Type:Expe ale I/FU:F	edited (15-DaCompany Re	eport #00-0469			
Outcome Dose Duratior	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - Initial or Prolonged 5 MG TID; 10	Cognitive Disorder Delusional Disorder,	Health Professional	Baclofen	PS	Watson Laboratories Inc	
MG TID	Persecutory Type	Other				
	Depression Hallucination Post-Traumatic Stress Disorder Psychotic Disorder Sedation Speech Disorder		Minoxidil Lopressor Zoloft Renagel	C C C C		

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 -	Abdominal Distension	Consumer	Baclofen	PS	Watson Laboratories	
Initial or Prolonged	Abdominal Pain Upper				Inc	
	Asthenia		Ultram	SS		
6 TABS A DAY						
	Blood Pressure Increased		Klonopin	С		
	Diarrhoea		Diazepam	С		
	Drug Dependence		Vioxx	С		
	Drug Withdrawal Syndrome		Albuterol	С		
	Dyspnoea		Methadone	С		
	Extrasystoles					
	Fatigue					
	Muscle Disorder					
	Nervousness					

Freedom Of Information (FOI) Report

Tegretol

(Carbamazepine)

SS

ORAL

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

-						
Outcome Dece	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duratio Hospitalization - Initial or Prolongeo 20 MG QID PO	Coma	Other	Baclofen	PS	Watson Laboratories Inc	ORAL
ZU MG QID FO	Hyperhidrosis Speech Disorder		Ultram 50 Mg Tablets,			
	-1		Ortho-Mcneil	SS	Ortho-Mcneil	ORAL
QD PO			Urecholine 25 Mg			
			Merck	SS	Merck	
25 MG TID			Dilantin	С		
			Gabatril	C		
			Ogen	C		
			Pepcid	С		
			Symmetrel	С		
Age:82 YR Gender: Outcome Dose Durati	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - Initial or Prolonged	Blister	Foreign Health	Lioresal	PS	Novartis Pharmaceuticals Corp	
45 MG, TID,		Professional Other	Furosemid	С		
Age:66 YR Gender:1 Outcome Dose Duratio Hospitalization -	Male I/FU:I PT	e:Expedited (15-DaCompany Re Report Source	port #WAES 00061841 Product	Role	Manufacturer	Route
Initial or Prolonged	Dyspnoea	Foreign Health	Zocor	PS	Merck Research Laboratories Div	
Initial or Prolonge	Dyspnoea	-	Zocor	PS		ORAL

Other

ge:52 YR Outcome	Gender:	I/FU:I PT	Report Source	Product	Role	Manufacturer	Route
ose	Duration	± ±	Report Bource	I I Oddet	ROIE	manaraccarer	Rouce
eath		Completed Suicide	Literature Health Professional	Tylenol	PS	Mcneil Consumer Products Co Div Mcneilab Inc	ORAL
1							
)				Baclofen	SS		ORAL
)				Methocarbamol	С		
)0ISR Number Gender:Fema	r: 3580989-3Report Type:Pe ale I/FU:I	riodic Company Re	eport #USA013334			
ge:40 YR		Ale I/FU:I PT	riodic Company Re	eport #USA013334			
ge:40 YR		Ale I/FU:I PT Chest Pain	riodic Company Re	eport #USA013334			
ge:40 YR		PT Chest Pain Decreased Appetite Dry Mouth	riodic Company Re	eport #USA013334			
		PT Chest Pain Decreased Appetite Dry Mouth Haemorrhoids	riodic Company Re	eport #USA013334			
ge:40 YR		PT Chest Pain Decreased Appetite Dry Mouth	riodic Company Re	eport #USA013334			

ORAL

Freedom Of Information (FOI) Report

		Nausea Pain In Extremity					
		Fain in Exclemicy	Report Source	Product	Role	Manufacturer	Route
Dose I	Duration		Consumer Other	Meridia	PS	Knoll Pharmaceutical Co Sub Basf Corp	
			0 CHCL	Generic Robitussin D	SS	co sub basi corp	
				Pro-Image	SS		
				Allegra	SS		
				Sudafed	SS		
				Benadryl	SS		
				Cardizem	SS		
					SS		ORAL
				Aspirin	22		ORAL
TAB UNK PO					00		
				Motrin	SS		
				Aleve	SS		
				Vioxx	SS		
				Naproxen	SS		ORAL
FAB UNK PO							
				Darvocet-N	SS		
				Vicodin	SS		
				Baclofen	SS		ORAL
TAB UNK PO							
				Phernilin-Forte			
				(50/650 Mg)	SS		ORAL
FAB UNK PO							
Age:66 YR Ge	ISR Number ender:Male						
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
	Duration						
Hospitalizatio		Dyspnoea	Foreign	Lioresal	PS	Novartis	
Initial or Pro	olonged	Pneumonia	Health			Pharmaceuticals Corp	ORAL
SMG, DAILY,							
			Professional				
DRAL			Others	magnatal mablet			
			Other	Tegretol Tablet			
				(Carbamazepine)	SS		ORAL
NK, DAILY,							
	0 1703-						
RAL	2 MON						
				Lodales Tablet			
				(Simvastatin)	SS		ORAL

ORAL

Date:07/20/00ISR Number Age:55 YR Gender:Fema	: 3532343-8Report Type:Direct le I/FU:I	Company Repor	't #		
Outcome Dose Duration	PT	Report Source	Product	Role Manufacturer	Route
Hospitalization - 30MG GT QD	Neutropenia		Prevacid	PS	
Initial or Prolonged 10MG TID	Pyrexia		Baclofen	SS	
			Insulin	C	I
1			Aspirin	C	
1			Vitamin C	С	
			Ativan	C	
1			Oscal With Vit D	С	
1			Pericolace	С	
1			Cipro Eye Drops	С	
1			Erythromycin	С	
1			Lopressor	C	
1			Nitro Patch	C	
			Robittusin Dm	C	

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 Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - Initial or Prolonged 1 DF, DAILY,	Blister Dermatitis Bullous	Foreign Health	Lioresal	PS	Novartis Pharmaceuticals Corp	
	Drug Eruption	Professional				
PERCUTANEOUS	TT		Deres a sector	a		
	Haemorrhage	Other	Furosemid	C C		
			· · · · · · ·	C		
			•••	C		
Date:08/03/00ISR Number Age:48 YR Gender:Fema	: 3543697-0Report Type:Periodi le I/FU:I	c Company Repor	t #99-08-0254			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration Hospitalization -	Nausea	Consumer	Baclofen	PS	Zenith Goldline	
Initial or Prolonged INTRATHECAL 525MEG	Respiratory Depression	Consumer	Bacioren	FD	Pharmaceuticals	
INTRATHECAL						
			Prozac	С		
			Prempro	С		
Date:08/03/00ISR Number Age: Gender:Fema	: 3543699-4Report Type:Periodi le I/FU:I	c Company Repor	t #00-04-0188			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other	Oedema Peripheral	Consumer	Baclofen	PS	Zenith Goldline Pharmaceuticals	ORAL
20 MG ORAL			Diuretics	С		

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration		-				
Other		Vision Blurred	Consumer	Baclofen	PS	Zenith Goldline Pharmaceuticals	ORAL
5MG TID ORAL							-
I				Hytrin	С		
				Verapamil	С		
		: 3541259-2Report Type:Direct	Company Repor	rt #			
Age:17 YR	Gender:Male	I/FU:I					
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalizat INTRATHECAL	ion - VARIES	Blood Creatinine		Baclofen	PS		
INTRATHECAL Initial or P PUMP		VIA Increased					
		Blood Urea Increased					
INTRATHECAL							
1		Dehydration		Bisacodyl	C		
1		Oedema		Lasix	C		
				Aldactone	С		
D	ATOD Number	: 3588659-2Report Type:Periodi	- Compony Popol				
Age:46 YR			IC сощрану керот	rt #USA013973			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
		Constipation	Consumer Other	Vicoprofen	PS	Knoll Pharmaceutical Co Sub Basf Corp	ORAL
1 TAB TID PO							
TAB PO				Baclofen	SS		ORAL
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Freedom Of Information (FOI) Report

Neurontin	С
Zocor	С
Avapro	С
Multivitamins	С

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

Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Life-Threate	ning	Coma Dyspnoea	Foreign Health	Neurontin	PS	Parke Davis Pharmaceuticals Ltd	ORAL
200 MG DAILY		Laryngeal Disorder	Professional				
PER ORAL		Lung Disorder Respiratory Depression		Laroxyl (Amitriptyline Hydrochloride)	SS		ORAL
25 MG DAILY				nyaroenioriae)	00		UKAL
PER ORAL				Lioresal (Baclofen)	SS		ORAL
15 MG DAILY							-
PER ORAL				Lexomil (Bromazepam)	99		ORAL
9 MG DAILY				lenomii (biomažepum)	66		OIUIE
PER ORAL							
				Levothyrox (Levothyroxine Sodium) Diffu-K (Potassium	С		
				Chloride)	С		

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						
Hospitalizat	ion -	Delusional Disorder,	Foreign	Lioresal	PS	Novartis	
Initial or P	rolonged	Persecutory Type	Health			Pharmaceuticals Corp	ORAL
7.5 MG DAILY							

Professional

Other	Diazepam	С
	Diclofenac	С
	Zopiclone	С
	Fluoxetine	С

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

Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Life-Threatening Hospitalization - 15 MG DAILY	Coma Depressed Level Of	Foreign Health	Lioresal	PS	Novartis Pharmaceuticals Corp	ORAL
Initial or Prolonged ORAL	Consciousness	Professional				
	Drug Interaction Dyspnoea	Other	Lexomil Tablet (Bromazepam)	SS		ORAL
9 MG DAILY						
ORAL	Laryngeal Disorder					
	Lung Disorder Overdose Respiratory Depression		Laroxyl Tablet (Amitriptyline Hydrochloride)	SS		ORAL
25 MG	Respiratory Disorder		<i>, al contol fac ;</i>	55		orum
DAILYORAL						
			Neurontin Capsule (Gabapentin)	SS		ORAL
200 MG DAILY			(
ORAL						
			Diffu-K Capsule Levothyrox Tablet	C C		

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ORAL

Freedom Of Information (FOI) Report

)0ISR Number Gender:Fema	: 3570383-3Report Type:Direct le I/FU:I	Company Repo	rt #			
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose Life-Threate 1 PO QD	Duration ening	Agitation		Metabolite	PS		ORAL
1 PO QD		Circulatory Collapse		Baclofen	SS		ORAL
1 10 00		Coma Convulsion Drug Abuser		St John'S Wort Melatonin	SS SS		
)0ISR Number Gender:Fema	: 3572537-9Report Type:Expedi le I/FU:I	ted (15-DaCompany Repo:	rt #HQ0900212SEP2000			
Outcome	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Dose Death ORAL	Duración	Activated Partial	Health	Robaxin	PS	Ah Robins Co	ORAL
Life-Threate ORAL	ening	Thromboplastin Time	Professional	Acetaminophen	SS		ORAL
Hospitalizat ORAL	ion -	Prolonged		Baclofen	SS		ORAL
Initial or H	Prolonged	Blood Bicarbonate Decreased Blood Pressure Fluctuation Coma Hypothermia Loss Of Consciousness Pco2 Decreased Po2 Increased Pupillary Reflex Impaired Suicide Attempt					
Date:09/22/(Age:)0ISR Number Gender:Fema	: 3578905-3Report Type:Expedi le I/FU:I	ted (15-DaCompany Repo:	rt #PHBS2000CA08880			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalizat		Cerebrovascular Accident	Foreign	Lioresal	PS	Novartis	

Initial or Prolonged 5 MG, TID,	Confusional State	Health			Pharmaceuticals Corp	ORAL
	Disorientation	Professional				
ORAL						
		Other				
Date:09/25/00ISR Num	ber: 3579462-8Report Type:Exp	edited (15-DaCompany R	eport #PHEH2000US08592			
Age:37 YR Gender:Ma			L			
			_	-	_	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration		~				
Other	Abdominal Pain Alanine Aminotransferase	Consumer	Lioresal	PS	Novartis Pharmaceuticals Corp	ORAL
30 MG, QID,						
	Increased					
ORAL						
	Aspartate		Valproic Acid	С		
	Aminotransferase		Phenobarbital	С		
	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 PTReport Source Product Role Manufacturer Route Dose Duration Hospitalization -Mental Impairment Baclofen PS Initial or Prolonged Date:10/04/00ISR Number: 3587645-6Report Type:Expedited (15-DaCompany Report #A032407 Gender:Male Age: I/FU:I Outcome PTReport Source Product Role Manufacturer Route Dose Duration Hospitalization -Pfizer Inc Aphasia Consumer Procardia PS 30.00 MG Initial or Prolonged Aspiration TOTAL: TID Disability Brain Contusion Guaifenesin/Phenylpr opanolamine Required Drug Interaction SS QID Intervention to Dysphagia Dantrium SS 75.00 MG Parenteral Nutrition Prevent Permanent TOTAL: TID Baclofen Impairment/Damage Pneumonia SS 80.00 MG Road Traffic Accident TOTAL: QID Skin Ulcer Zanaflex С Claritin T-Cell Lymphoma С Cranberry Juice С Date:10/06/00ISR Number: 3590703-3Report Type:Expedited (15-DaCompany Report #PHEH2000US08924 Gender:Female I/FU:I Aqe: Outcome PTReport Source Product Role Manufacturer Route Duration Dose Other Coma Health Lioresal PS Novartis Overdose Professional Pharmaceuticals Corp ORAL

100 MG, ORAL 1 DAY

Psychotic Disorder

Date:10/13/00ISR Number Age:84 YR Gender:Fema	: 3594850-1Report Type:Expedi le I/FU:I	ted (15-DaCompany Repor	t #PHEH2000US09173			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration Hospitalization - Initial or Prolonged 20 MG QID	Hallucination Psychotic Disorder	Health Professional	Lioresal	PS	Novartis Pharmaceuticals Corp	ORAL
ORAL						
Date:10/18/00ISR Number Age: Gender:Male	: 3597570-2Report Type:Expedi I/FU:F	ted (15-DaCompany Repor	t #A032407			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - 30.00 MG	Accident	Consumer	Procardia	PS	Pfizer Inc	
Initial or Prolonged TOTAL: TID	Aspiration	Health				
Disability Required QID	Brain Contusion Dysphagia	Professional	Guaifenesin/Phenylpr opanolamine	SS		
Intervention to 75.00 MG	Mutism		Dantrium	SS		
Prevent Permanent TOTAL: TID	Pneumonia					
Impairment/Damage 80.00 MG	Refusal Of Treatment By		Baclofen	SS		
TOTAL: QID	Relative					
	T-Cell Lymphoma Ulcer Vomiting		Zanaflex Claritin Cranberry Juice	C C C		

Freedom Of Information (FOI) Report

Date:10/20/00ISR Number: 3598920-3Report Type:Direct Company Report # Gender: Female Age: I/FU:I Outcome PTReport Source Product Role Manufacturer Route Dose Duration Required Confusional State Baclofen PS ORAL 1PO BID Euphoric Mood Intervention to Apap 650 Mg С Prevent Permanent Hypotension Asaec 81 Mg С Impairment/Damage Lethargy Levothyroxine 0.1 Mg С Memory Impairment С Hct/Triamterene Tc#3 1-2 Tab С Psychomotor Hyperactivity Baclofen С Date:10/23/00ISR Number: 3600637-3Report Type:Expedited (15-DaCompany Report #PHFR2000GB01595 Gender:Female I/FU:I Age:2 YR Role Manufacturer Outcome PTReport Source Product Route Dose Duration Life-Threatening Aphasia Foreign Lioresal PS Novartis Coma Health Pharmaceuticals Corp ORAL 2.5 ML, BID, Convulsion Professional ORAL (SEE Diarrhoea Other DAY IMAGE) 17 Face Oedema Sedation Date:10/24/00ISR Number: 3600288-0Report Type:Expedited (15-DaCompany Report #00-1458 Aqe:60 YR Gender:Male I/FU:I Role Manufacturer Outcome PTReport Source Product Route Dose Duration Hospitalization -Arrhythmia Health Baclofen PS Watson Laboratories Initial or Prolonged Depressed Level Of Professional Inc Consciousness Other Drug Interaction Hypotension Loss Of Consciousness Sinus Bradycardia Syncope

Date:10/24/00ISR Number Age:33 YR Gender:Male	: 3600465-9Report Type:Direct I/FU:I		Company Repor	t #			
Outcome Dose Duration	PT	Report	Source	Product	Role	Manufacturer	Route
Hospitalization - Initial or Prolonged Required INTRATHECAL 100MG Intervention to INTRATHECAL; Prevent Permanent 50MG Impairment/Damage INTRATHECAL	Confusional State Convulsion Headache Mental Impairment			Lioresal Intrathecal-Medtroni c	PS	Medtronic	
				Oxycodone	С		
Date:10/25/00ISR Number Age:84 YR Gender:Fema Outcome Life-Threatening Hospitalization - Initial or Prolonged Disability	: 3601207-3Report Type:Direct le I/FU:I PT Acute Psychosis Bradycardia Cardiac Arrest Condition Aggravated Confusional State Delirium		Company Repor	t #			
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Freedom Of Information (FOI) Report

Dose 20 MG QD RECEIVED X3 DOSES	Duration	Depressed Level Of Consciousness Dissociation Hallucination Mania Medication Error Speech Disorder	Report Source	Product Baclofen	Role PS	Manufacturer	Route
	0ISR Number Gender:Male	: 3605245-6Report Type:Expect I/FU:I	lited (15-DaCompany Re	port #PHRM2000FR01545	5		
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Life-Threater		Atrial Fibrillation	Foreign Health	Lioresal	PS	Novartis Pharmaceuticals Corp	ORAL
ORAL			Professional				
			TIOLOSSIONAL				
Age:84 YR (Outcome	Gender:Fema	r: 3605925-2Report Type:Exped ale I/FU:F PT		eport #PHEH2000US09173 Product		Manufacturer	Route
Age:84 YR (Outcome Dose Hospitalizati Initial or Pr	Gender:Fema Duration ion -	ale I/FU:F	dited (15-DaCompany Re			Manufacturer Novartis Pharmaceuticals Corp	Route ORAL
Age:84 YR (Outcome Dose Hospitalizati	Gender:Fema Duration ion -	Ale I/FU:F PT Acute Psychosis	dited (15-DaCompany Re Report Source Health	Product	Role	Novartis	

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 -	Arrhythmia	Health	Baclofen	PS	Watson Laboratories	
Initial or Prolonged	Blood Pressure Increased	Professional			Inc	
	Depressed Level Of	Other	Neurontin	С		
	Consciousness		Celebrex	С		
	Disorientation		Plavis	С		
	Dizziness		Zoloft	С		
	Drug Interaction		Sinequan	С		
	Heart Rate Decreased		Methadone	С		
	Hypotension		Aspirin	С		
	Loss Of Consciousness					
	Petit Mal Epilepsy					
	Sinus Bradycardia					
	Speech Disorder					
	Syncope					

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	Consumer	Neurontin	PS	Parke Davis Pharmaceuticals Ltd	ORAL
1800 MG (600	Decreased					
MG TID) PER	Disorientation					
ORAL	Drug Interaction		(Methadone)	SS		ORAL
PER ORAL				SS		
PER ORAL	Drug Level Above		Morphine			ORAL
PER ORAL	Therapeutic		Baclofen	SS		ORAL
	Hypertension Memory Impairment Migraine Muscle Contractions Involuntary Tachycardia Tremor		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	C		
			Edisylate)	С		

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

Freedom Of Information (FOI) Report

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

Health Professional	Lioresal	PS	Novartis	
			Pharmaceuticals Corp	ORAL
mogram	Hydroxyurea (Hydroxycarbamide Synthroid Nifedipine Flovent (Fluticas Propionate)	C C		
E C n	Emission omogram r nal	Emission omogram r nal	Emission omogram r	Emission omogram r nal

Age:53 YR Gender:Female I/FU:I

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

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

Freedom Of Information (FOI) Report

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

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
Hospitalization Initial or Prol 20 MG, QID,	Bradycardia Brain Stem Ischaemia	Health Professional	Lioresal	PS	Novartis Pharmaceuticals Corp	ORAL
Disability ORAL	Cardiac Arrest					
	Cerebrovascular Disorder Confusional State Delirium Depressed Level Of Consciousness Dissociation Hallucination Logorrhoea Mania Medication Error Pain In Extremity Psychotic Disorder Sick Sinus Syndrome Single Photon Emission Computerised Tomogram Abnormal Speech Disorder Thinking Abnormal		Hydroxyurea Synthroid Flovent Nifedipine-Slow Release	C C C		

Date:11/28/00ISR Number: 3618194-4Report Type:Expedited (15-DaCompany Report #HQ0900212SEP2000 Age:52 YR Gender:Female I/FU:F

 \mathbf{PT}

Death	Activated Partial	Literature	Robaxin	PS	Ah Robins Co	ORAL
ORAL						
Life-Threatening	Thromboplastin Time		Acetaminophen			
Hospitalization - ORAL	Prolonged		(Paracetamol)	SS		ORAL
Initial or Prolonged	Blood Bicarbonate		Baclofen (Baclofen,)	SS		ORAL
ORAL						
	Decreased					
	Blood Pressure					
	Fluctuation					
	Completed Suicide					
	Electroencephalogram					
	Abnormal					
	Haemorrhage					
	Hypothermia					
	Loss Of Consciousness					
	Pco2 Decreased					
	Po2 Decreased					

FDA - Adverse Event Reporting System (AERS) Freedom Of Information (FOI) Report Date:11/29/00ISR Number: 3618933-2Report Type:Expedited (15-DaCompany Report #PHFR2000GB01907 Gender:Male Age:5 YR I/FU:I Outcome PΤ Report Source Product Role Manufacturer Route Dose Duration Hospitalization -Renal Failure Foreign Lioresal PS Novartis Initial or Prolonged Health Pharmaceuticals Corp 700 UG/DAILY Professional Other Date:12/06/00ISR Number: 3622690-3Report Type:Expedited (15-DaCompany Report #00-1678 Age:77 YR Gender:Female I/FU:I Product Role Manufacturer Outcome PTReport Source Route Dose Duration Other Baclofen Watson Laboratories Other Anorexia PS Condition Aggravated Inc ORAL 5 MG, BID, Dysphagia PO; 2.5 MG, Failure To Thrive BID, PO Sedation Lopressor С Speech Disorder С Zantac Date:12/11/00ISR Number: 3626940-9Report Type:Expedited (15-DaCompany Report #PHRM2000FR01800 Gender:Male Age:80 YR I/FU:I PTRole Manufacturer Outcome Report Source Product Route Duration Dose Life-Threatening Confusional State Foreign Lioresal PS Novartis Memory Impairment Health Pharmaceuticals Corp ORAL 30 MG/DAY, Professional ORAL Other Comtan Tablet С Modopar (Levodopa, Benserazide Hydrochloride) Capsule С Requip (Ropinirole Hydrochloride)

			Tablet	C		
Date:12/12/00ISR Number Age:24 YR Gender:Male		Expedited (15-DaCompany Re	port #2000-12-0048			
Outcome Dose Duration	РТ	Report Source	Product	Role	Manufacturer	Route
Dose Duration Hospitalization - Initial or Prolonged INTRAVENOUS 5 MG QI	Convulsion D	Foreign Health	Polaramine	PS	Schering Corp Sub Schering Plough Corp	
INTRAVENOUS	-	Professional				
INTRAVENOUS 50 MG (QD	Other	Cortancyl Injectable	SS		
INTRAVENOUS			Lioresal Tablets	99		
2 QD ORAL				SS		ORAL
30 mg Qd oral			Skenan Capsules	SS		ORAL

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 Hospitalizat: Initial or Pr 5 MG, BID,	Drug Interaction International Normalised	Foreign Health	Lioresal	PS	Novartis Pharmaceuticals Corp	ORAL
	Ratio Increased	Professional				
ORAL		Other	Coumadine (Warfarin Sodium) Tablet	SS		ORAL
UNK, UNK,						

ORAL 4 DAY

Freedom Of Information (FOI) Report

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 Dose Duration	РТ	Report Source	Product	Role	Manufacturer	Route
Hospitalization - Initial or Prolonged 900 MG(300 MG	Arthralgia Asthenia	Consumer	Neurontin	PS	Parke Davis Pharmaceuticals Ltd	ORAL
Other TID):2400MG(8	Blood Potassium Decreased					
0 0 MG	Carpal Tunnel Syndrome					
TID):2100MG(7	Cholelithiasis					
00mg	Cholestasis					0.7.1.1
80 MG PER	Decreased Activity Dental Caries		Baclofen	SS		ORAL
ORAL	Depression		Ms Contin	SS		
1600 MG	Difficulty In Walking		Propulsid	SS		
2500 MG	Dry Mouth		Methadone	SS		
1 OR 2 (Q 4 H	Fall		Percocet	SS		
PRN)	Fatigue					
80 MG	Gallbladder Disorder		Valium	SS		
8 MG PER ORAL	Gallbladder Pain		Zanaflex	SS		ORAL
200 MG PER	Headache Hypoaesthesia		Zoloft	SS		ORAL
	11/ Poaco circo ra					

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	C						
		Dysphagia		Baclofen Tablets 10			
		Eating Disorder		Мд	SS		ORAL
5 MG BID PO							
		Failure To Thrive		Lopressor	С		
		Sedation		Zantac	С		
		Speech Disorder					

Freedom Of Information (FOI) Report

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 Other	Duration	Coma Convulsion	Literature Health	Lioresal	PS	Novartis Pharmaceuticals Corp	
120 MGDAY		Drug Interaction Drug Toxicity Electroencephalogram Abnormal Haemodialysis Lethargy	Professional	Unasyn(Sultamicillin)	SS		
)1ISR Number Gender:Male	: 3652741-1Report Type:Exped I/FU:F	ited (15-DaCompany Re	port #00-1458 FOL #2			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalizat Initial or H	cion -	Blood Pressure Increased Depressed Level Of	Health Professional	Baclofen	PS	Watson Laboratories Inc	
		Consciousness Dizziness Drug Interaction Hypotension Loss Of Consciousness Sinus Bradycardia Speech Disorder Syncope	Other	See B5 See B5	SS C		
Date:02/02/0 Age:)1ISR Number Gender:	: 3658416-7Report Type:Exped I/FU:I	ited (15-DaCompany Re	port #01-0081			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalizat Initial or P	cion -	Overdose	Health Professional	Baclofen	PS	Watson Laboratories Inc	
			Company Representative	Klonopin Tablets	SS	Hoffmann-Laroche	

	lISR Number: Gender:Femal	: 3660536-8Report Type:Periodic le I/FU:I	c Company Report	: #A009870			
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose Other 10 MG TOTAL	Duration	Headache	Consumer	Zyrtec	PS	Pfizer Inc	ORAL
		Pruritus					,
DAILY ORAL				Baclofen	SS		ORAL
20 MG TOTAL							Ţ
BID ORAL							I
BID NASAL				Flonase	SS		NASAL
Date:02/08/01 Age:76 YR (: 3662369-5Report Type:Direct I/FU:I	Company Report	τ #			
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose Hospitalizati Initial or Pr		Mental Impairment Vomiting		Baclofen	PS		

		FDA - Advers	e Event Reporting Syst	em (AEF	RS)	
		Freedom	Of Information (FOI) R	eport		
Date:02/08/01ISR Number Age:51 YR Gender:Male	: 3662373-7Report Type:Direct I/FU:I	Company Repo	rt #			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - Initial or Prolonged	Confusional State Hallucination		Baclofen	PS		
Date:02/15/01ISR Number Age:80 YR Gender:	: 3666007-7Report Type:Direct I/FU:I	Company Repo	rt #			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - 10MG TID	Confusional State		Baclofen	PS		
Initial or Prolonged	Disorientation		Naproxen Fluoxetine Levothyroxine Lisinopril Terazosin	C C C C C C C		
Date:02/28/01ISR Number Age:72 YR Gender:Fema	: 3671474-9Report Type:Expedi- ale I/FU:F	ted (15-DaCompany Repo	rt #001-0945-M0000462			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - Initial or Prolonged 900 MG (300	Aphonia Blood Glucose Increased Cellulitis	Health Professional	Neurontin	PS	Parke Davis Pharmaceuticals Ltd	ORAL
MG, TID), PER	Disturbance In Attention					
ORAL	Dizziness		Baclofen (Baclofen)	SS		ORAL
75 MG (25 MG,			bacioren (bacioren)	66		URAL
TID), PER	Headache					
ORAL	Nausea					
	Tremor Vision Blurred		(Insulin) Aleve (Naproxen Sodium)	C C		

Date:02/28/0 Age:	01ISR Number Gender:Fema	: 3672718-XReport Type:Per le I/FU:I	iodic Company	Report #A037642			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Life-Threate		Intentional Misuse Suicide Attempt	Other	Zoloft	PS	Pfizer Pharmaceuticals Inc	
1		-		Glyburide	SS		
I				Penicillin	SS		
l				Baclofen	SS		
I				Ibuprofen	С		
				Fluoxetine	С		
Date:03/01/0 Age:68 YR	01ISR Number Gender:Fema	: 3672327-2Report Type:Exp le I/FU:I	edited (15-DaCompany	Report #PHBS2001BE02018			
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration				PS		
Other		Body Temperature Increased	Foreign Health	Lioresal	PD	Novartis	ODAT
5 MG, TID,		Increased	Healui			Pharmaceuticals Corp	ORAL
S™G, IID,							

Loramet

D-Cure

Folc Acid

(Lormetazepam)

Dafalgan Codeine (Paracetamol) С

С

С

С

Professional

Other

ORAL

Freedom Of Information (FOI) Report

Date:03/01/01ISR Number: 3683080-0Report Type:Periodic Age:72 YR Gender:Female I/FU:I Company Report #2000AU04364

Outcome		РТ	Report Source	Product	Role	Manufacturer	Route
Dose Other	Duration	Dura Mauth	Other		DQ	7	
other		Dry Mouth Dry Skin	other	Plendil	PS	Astrazeneca Pharmaceuticals Lp	
		Dry Throat		Cozaar	SS	Filat maceuticats up	
		Glossodynia		Oxybutynin "Generics	22		
		Nasal Dryness		Uk"	SS		ORAL
5 MG TID PO		-					
		Pruritus		Baclofen	С		
				Insulin	С		
				Nitro Patch	C		
	lISR Number Gender:Fema	: 3674694-2Report Type:Direc le I/FU:I	ct Company Re	port #			
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Hospitalizat		Nausea		Baclofen Intrathecal			
Initial or P		Vomiting		Pump	PS		
INTRAVENOUS	2000MC	G/ML-20					
		Weight Decreased					
ML IV					a		
				Verapamil Premarin	C C		
				Omeprazole	C		
				Cisapride	C		
				Diazepam	C		
				Trazadone	C		
				iiuzudone	C		
		: 3674755-8Report Type:Expe	dited (15-DaCompany Re	port #PHEH2001US01929			
Age:2 YR (Gender:Male	I/FU:I					
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Hospitalizat		Accidental Overdose	Health	Lioresal	PS	Novartis	
Initial or Pr ORAL	rolonged	Coma	Professional			Pharmaceuticals Corp	ORAL
Required		Convulsion					

Intervention to Respiratory Depression Prevent Permanent

Dutcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
)ther	Duración	Body Temperature Increased	Foreign Health	Lioresal	PS	Novartis Pharmaceuticals Corp	ORAL
5 MG TID ORAI	L					-	
			Professional Other	Loramet (Lorametazepam) D-Cure Folic Acid Dafalgan Codeine (Paracetamol)	C C C		

Outcome PT Death Bronchitis Acute Cardiac Failure Congestive

Freedom Of Information (FOI) Report

		Collapse Of Lung Drug Interaction Drug Level Above	Report Source	Product	Role	Manufacturer	Route
Dose	Duration	Drug lever Above	Keport Bource	FIGURE	NOTC		Route
		Therapeutic	Consumer	Reglan	PS	Ah Robins Co	ORAL
ORAL		Dyspnoea Respiratory Depression Respiratory Failure		Baclofen Dantrium (Dantrolene Sodium)	SS SS		ORAL
FOUR TIMES		Sedation					0111
DAILY, ORAL							ľ
				Darvocet-N (Dextropropoxyphene/	~~		
ORAL				Paracetamol)	SS		ORAL
ORAL				Imipramine	SS		ļ
Date:03/19/0 Age: Outcome Dose	Gender: Duration	: 3684033-9Report Type:Direct I/FU:I PT Medication Error	Company Repor Report Source	rt # Product Baclofen Tegretol Estradiol	Role PS SS SS	Manufacturer Novartis	Route
)1ISR Number Gender:Male	r: 3684297-1Report Type:Expedit e I/FU:I	ted (15-DaCompany Repor	rt #PHEH2001US02375			
Outcome	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Dose Other	DULALION	Electrocardiogram Q Waves	Health Professional	Lioresal	PS	Novartis Pharmaceuticals Corp	ORAL
10 MG, QD							C
ORAL							

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose Death	Duration	Completed Suicide	Literature Health	Coumadin	PS	Dupont Merck Pharmaceutical Co	ORAL
РО			Professional	Ni (Amitriptyline)	SS		ORAL
PO				Ni (Baclofen)	SS		ORAL
PO				NI (Bacioten)	66		OIT
Date:03/26/(11TSR Number	: 3690183-3Report Type:Expedit	ted (15-DaCompany Repor	×+ #ס¤вс2001ве02884			I
	Gender:Femal		.eu (15 Dacompany	t #FND02001DE02001			ļ
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other		Ageusia Anosmia	Foreign Health	Lioresal	PS	Novartis Pharmaceuticals Corp	ORAL
5 MG, TID,			Professional				I
ORAL	2 DAY		Other				I
l							
)1ISR Number: Gender:Male	: 3699553-0Report Type:Periodi I/FU:I	ic Company Repor	:t #A013553			
Outcome	Description	PT	Report Source	Product	Role	Manufacturer	Route
Dose Other	Duration	Hypertonia	Consumer	Cardura	PS	Pfizer Laboratories Div Pfizer Inc	ORAL
2.00 MG						DIV FLIZET INC	UKAL
TOTAL: DAILY	::						
ORAL				Baclofen	SS		ORAL
60.00 MG				Bactoren	66		UKAL
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Freedom Of Information (FOI) Report

TOTAL: QID:

ORAL

Ativan	С
Macrodantin	С
Plendil	С

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 -	Aphasia	Foreign	Sandoglobulin Or			
Initial or Prolonged	Epilepsy	Study	Placebo (Placebo			
		Health	Placebo)	PS		
INTRAVENOUS QMO,						
		Professional				
INTRAVENOUS						
		Other	Baclofen (Baclofen) Ds-103-282	SS		
			(Tizanidine			
			(Hydrochloride)	SS		
			Orfiril (Valproate	55		
			Sodium)	С		
			Neuromet	C		
			(Oxiracetam)	С		
Date:04/02/01ISR Number Age: Gender:Fema	: 3694560-6Report Type:Expedi le I/FU:F	ted (15-DaCompany Repo	rt #PHBS2000CA08880			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Cerebrovascular Accident	Foreign	Lioresal	PS	Novartis	
Initial or Prolonged 5 MG, TID,	Confusional State	Health			Pharmaceuticals Corp	ORAL
	Disorientation	Professional				
ORAL						
		Other				

Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Life-Threater		Gastric Haemorrhage	Foreign Health	Lioresal	PS	Novartis Pharmaceuticals Corp	ORAL
60 MG/DAY, ORAL		Professional					
		Other					
		: 3696156-9Report Type:Expedite	ed (15-DaCompany Repor [.]	t #PHEH2001US01929			

Age:2 YR Gender:Male I/FU:F

Outcome Dose Durati	PT	Report Source	Product	Role	Manufacturer	Route
Dose Durati Life-Threatening Hospitalization - ORAL	Accidental Overdose Body Temperature	Health Professional	Lioresal	PS	Novartis Pharmaceuticals Corp	ORAL
Initial or Prolonge Required Intervention to Prevent Permanent Impairment/Damage	ed Decreased Bradycardia Coma Convulsion Drug Level Above Therapeutic Hypothermia Lethargy Respiratory Depression					

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 Dose Durat:	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - Initial or Prolonged 20 MG PO OID	Anorexia	Consumer	Baclofen	PS	Watson Laboratories Inc	
ZU MG PU QID	Dry Mouth		Baclofen	SS	Qualitest	ORAL
20 MG PO QID						
	Headache		Baclofen	SS	Schein	
	Multiple Sclerosis				Pharmaceuticals	ORAL
20 MG QID PO						
	Nausea		Topamax Ms	С		
	Paraesthesia		Tegretol & Klonopin	С		
			Fioriceet	С		
			Demerol	С		
			Phenergan	С		
			Ditropan	C		

Date:04/05/01ISR Number: 3699720-6Report Type:Expedited (15-DaCompany Report #PHBS2001GB03223 Age:36 YR Gender:Male I/FU:I

Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalizat	Hospitalization - Initial or Prolonged	Aspartate Aminotransferase	Foreign Literature	Lioresal	PS	Novartis Pharmaceuticals Corp	
		Increased	Health	Amitriptyline			
		Blood Creatine	Professional	(Amitriptyline)	SS		
50 MG/DAY							
		Phosphokinase Increased Blood Lactate Dehydrogenase Increased Depressed Level Of Consciousness Drug Withdrawal Syndrome Hyperhidrosis Leukocytosis Muscle Rigidity Neuroleptic Malignant Syndrome Pyrexia Tachycardia					

Date:04/05/01ISR Numbe Age:68 YR Gender:Mal	er: 3700147-9Report Type:Direc .e I/FU:I	ct Company Re	eport #			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization -	Hypoglycaemia		Phenytoin	PS		
Initial or Prolonged 10 MG TID	Lethargy		Baclofen	SS		
			Warfarin	С		
			Insulin	С		
			Gemfibrozil	С		
			Carvedilol	С		
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization -	Ammonia Increased	Health	Baclofen	PS	Watson Laboratories	
Initial or Prolonged 10 MG - 20 MG	Asthenia	Professional			Inc	
TID (SEE	Coma					
IID (SEE	Coma					
IID (SEE	Coma Difficulty In Walking					
TEXT)						
			Zoloft	С		
	Difficulty In Walking		Zoloft Prevacid	C C		
·	Difficulty In Walking Disorientation					

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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 ORAL	Aggression Choking	Foreign Consumer	Lioresal	PS	Novartis Pharmaceuticals Corp	ORAL
	Dysphagia Hallucination Tongue Oedema	Other	Diazepam Clonazepam Clonidine (Clonidine) Temazepam Sulfamethoxazole (Sulfamethoxazole) Duphalac Coloxyl With Senna (Sennoside A+B) Memantine (Memantine) Ergocalciferol Alendronate Serenase	0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0		

Date:04/30/01ISR Number: 3715017-XReport Type:Expedited (15-DaCompany Report #PHFR2001GB01322 Age:59 YR Gender:Male I/FU:I

Outcome	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Dose Other	Duracion	Condition Aggravated Drug Withdrawal Syndrome	Foreign Health	Lioresal	PS	Novartis Pharmaceuticals Corp	ORAL
30 MG, TID,		Ileus Paralytic	Professional				
ORAL		-					
		Paranoia	Other	Diazepam	С		
				Tramadol (Tramadol) Ranitidine	С		
				(Ranitidine)	С		
				Warfarin (Warfarin)	С		
				Carbamazepine	С		
				Dantrolene			
				(Dantrolene)	С		

Date:05/01/01ISR Nu Age:44 YR Gender	umber: 3714490-0Report Type:Direct :Male I/FU:I	Company Repor	rt #			
Outcome Dose Durat:	PT	Report Source	Product	Role	Manufacturer	Route
Other	Face Oedema Swelling		Baclofen (10mg Tab)	PS		
Date:05/10/01ISR Nu Age:38 YR Gender	umber: 3720659-1Report Type:Direct :Male I/FU:I	Company Repor	rt #			
Outcome Dose Durat:	PT	Report Source	Product	Role	Manufacturer	Route
Life-Threatening Hospitalization - Initial or Prolonge	Accidental Overdose Bradycardia		Lioresal Intrathecal / 10mg/ 20cc / Novartis For			
Required Intervention to	Hypotension Respiratory Disorder .17MCG.		Medtronic	PS	Novartis For Medtronic	
INTRATHECAL			Medtronic Synchromed Pump	С		

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

Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration Hospitalization - Initial or Prolonged 100 MG/DAY,	Aggression Choking	Foreign Health	Lioresal	PS	Novartis Pharmaceuticals Corp	ORAL
ORAL	Dysarthria	Professional				
	Dysphagia Hallucination Tongue Oedema	Other	Diazepam Clonazepam Clonidine (Clonidine) Temazepam Sulfamethoxazole (Sulfamethoxazole) Duphalac Coloxy With Senna (Sennoside A+B) Memantine (Memantine) Erogcalciferol Alendronate Serenase	С С С С С С С С С С С С С С С С С С С		
Date:05/14/01ISR Numbe Age: Gender:Mal	er: 3724028-XReport Type:Exp .e I/FU:I	pedited (15-DaCompany Re	eport #20010820			
Outcome Dose Duration	PT	Report Source	Product			
			1100000	Role	Manufacturer	Route
Hospitalization -	Coma 5 MCG,	Foreign	Lioresal	Role PS	Manufacturer Medtronic Inc	Route
Hospitalization - INTRATHECAL 0.025 Initial or Prolonged						Route
Hospitalization - INTRATHECAL 0.025	MCG, Hepatocellular Damage Renal Failure Acute	Foreign				Route

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 Dose I	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalizatic Initial or Pro 20 MG PO OID	on –	Anorexia Asthenia	Consumer	Baclofen	PS	Watson Laboratories Inc	ORAL
~		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 Nausea Pain Paraesthesia Weight Increased		Topamax Tegretol Klonopin Fioricet Demerol Phenergan	0000000		

Freedom Of Information (FOI) Report

Ditropan	С
Oxybutynin	С
Promethazine	С
Meperidine	С
Potassium	С
Furosemide	С
Alprazolam	С
	С
Pevacid	С
	С
Imitrex Injection	С
Neurontin	С

Date:05/21/01ISR Number: 3726917-9Report Type:Expedited (15-DaCompany Report #PHBS2001DE04906 Age:25 YR Gender:Male I/FU:I

								ľ
Outcome Dose	Duration	PT	Report	Source	Product	Role	Manufacturer	Route
Dose Other 40 MG/D	Duration	Overdose Sleep Apnoea Syndrome	Foreign Literat Health Profess Other	ture	Lioresal	PS	Novartis Pharmaceuticals Corp	
Age:44 YR				Company Repor			•• ···	
Outcome Dose Hospitalizat INTRATHECAL Initial or P INTRATHECAL	180MCG	PT Medication Error G 1 DAY	Report	Source	Product Lioresal 2000 Mcg/Ml		Manufacturer	Route
)1ISR Number Gender:Fema	r: 3727772-3Report Type:Direct ale I/FU:I		Company Repor	t #			
Outcome Dose	Duration	PT	Report	Source	Product	Role	Manufacturer	Route

Required 20MG BID GT	Alanine Aminotransferase		Baclofen (10mg)	PS	
Intervention to PRIOR TO	Increased				
Prevent Permanent ADMISSION	Aspartate				
Impairment/Damage	Aminotransferase Increased Blood Alkaline Phosphatase Increased Blood Creatine Phosphokinase Increased		Acetaminophen	С	
Date:05/23/01ISR Nuu Age:18 YR Gender:	mber: 3727773-5Report Type:Direc I/FU:I	ct Company Re	eport #		
Outcome	PT	Report Source	Product	Role Manufacturer	Route
Dose Duratio Required 10MG QID	on Alanine Aminotransferase		Baclofen 10mg	PS	
Intervention to	Increased		Solu-Medrol	C	
Prevent Permanent	Aspartate		Propranolol	С	
Impairment/Damage	Aminotransferase		Hazepam	C	
	Increased		Clonidine	C	
	Blood Lactate				
1	Dehydrogenase Increased				I

Freedom Of Information (FOI) Report

Date:05/29/01ISR Number: 3729550-8Report Type:Direct Company Report # Gender:Female Age: I/FU:I Outcome PTReport Source Product Role Manufacturer Route Dose Duration Hospitalization -Coma Baclofen PS ORAL DOSE UNKNOWN Initial or Prolonged Drooling PO X 1 Gabapentin Required Dyskinesia С Medication Error С Intervention to Clonazepam Buspirone С Prevent Permanent Speech Disorder Impairment/Damage Urinary Incontinence Alprazolam С Vomiting Diazepam С Date:06/04/01ISR Number: 3733094-7Report Type:Expedited (15-DaCompany Report #PHEH2001US02961 Age:15 YR Gender:Female I/FU:I Role Manufacturer Outcome PTReport Source Product Route Dose Duration Hospitalization -Extravasation Health Lioresal PS Novartis Initial or Prolonged Medication Error Professional 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 Role Manufacturer Outcome PTReport Source Product Route Dose Duration Baclofen (Lioresal Hospitalization -Coma Initial or Prolonged Medication Error 2000mg / Ml) PS Novartis INTRATHECAL 2000 MG/ML Other 4X5 ML AMPULES Lioresal 500mg/Ml (Baclofen) SS Novartis INTRATHECAL 500 MG/ML

Date:06/11/ Age:	/01ISR Number Gender:Male	r: 3737262-XReport Type:Per e I/FU:I	riodic Company Rep	eport #2000-09-1047			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
		Drug Interaction Skin Disorder	Consumer	Claritin	PS	Schering Corp Sub Schering Plough Corp	ORAL
10 MG/QD OF				Zanaflex (Tizanidine Hcl) Tablets	SS		ORAL
4-8 MG/PRN							I
ORAL				Dantrium	SS		
25 MG/TID				Procardia	SS		
10 MG/TID				Docusate Sodium	SS		ORAL
1/2-2 TSP/E	BID			DOCUSALE SOULUM	66		ULAI
ORAL							
				Senokot Baclofen	SS SS		
20 MG/QID				Milk Of Magnesia	SS		
2 TBS/Q3D				Simethicone	SS		
80-160 MG/Q	QID						
1/2 TAB/QII	D			Entex La Tablets	SS		
Date:06/11/ Age:	/01ISR Number Gender:Fema	r: 3740489-4Report Type:Per ale I/FU:I	ciodic Company Re	eport #20010823			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitaliza INTRATHECAL	ation -	Hypoventilation	Health	Lioresal	PS	Medtronic Inc	
Initial or DAILY,		Sedation	Professional				

Freedom Of Information (FOI) Report

INTRATHECAL

Date:06/15/01ISR Number Age:25 YR Gender:Male	r: 3740755-2Report Type:Expe e I/FU:F	dited (15-DaCompany Re	port #PHBS2001DE04906			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other	Nightmare	Foreign	Lioresal	PS	Novartis	ļ
	Overdose	Literature			Pharmaceuticals Corp	ļ
40 MG/D						I
	Sleep Apnoea Syndrome	Health				I
I	Sleep Attacks	Professional				1
	Sleep Disorder	Other				
Date:06/15/01ISR Number Age: Gender:	r: 3740882-XReport Type:Expe I/FU:I	edited (15-DaCompany Re	eport #PHEH2001US04787			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration		_	_ ' _			ſ
Disability	Anxiety	Consumer	Lioresal	PS	Novartis	1
Other	Emotional Disorder				Pharmaceuticals Corp	1
INTRATHECAL INTRAT	THECAL					ļ
	Injury Medication Error					I
	Medication Firor					
Date:06/20/01ISR Number Age:54 YR Gender:Fema	r: 3743119-0Report Type:Expe ale I/FU:F	edited (15-DaCompany R€	≥port #01-0396 FOL.#2			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization -	Anorexia	Consumer	Baclofen	PS	Watson Laboratories	I
Initial or Prolonged 20 MG PO QID	Anxiety			- - -	Inc	ORAL
	Asthenia		Baclofen Tablets 10			I
	Condition Aggravated		Mg, Qualitest	SS		ORAL
20 MG PO QID			mg, guarrocco			01011
	Drug Effect Decreased		Baclofen Tablets 20			1
	Dry Mouth		Mg, Schein			
	Face Oedema		Pharmaceuticals	SS	Schein	
	Headache			-	Pharmaceuticals	ORAL
20 MG QID PO						
-						

Multiple Sclerosis Nausea Paraesthesia Weight Increased

Topamax	С
Tegregol	С
Klonopin	С
Fioricet	С
Demerol	С
Phenergan	С
Ditropan	С
Oxybutynin	С
Promethazine	С
Meperidine	С
Potassium	С
Furosemide	С
Alprazolam	С
Baclofen	С
Prevacid	С
Clonazepam	С
Imitrex Injection	С
Neurontin	С

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

Freedom Of Information (FOI) Report

Professional

Dose Duration			Product	Role	Manufacturer	Route
			Neurontin	PS	Pfizer Inc	ORAL
PER ORAL			Baclofen (Baclofen)	SS		ORAL
PER ORAL						
Date:06/28/01ISR Number Age: Gender:Male	: 3749867-0Report Type:Exped I/FU:I	ited (15-DaCompany Rep	port #20010826			
Outcome Dose Duration	РТ	Report Source	Product	Role	Manufacturer	Route
Hospitalization -	Hypotonia G DAILY	Health	Lioresal	PS	Medtronic Inc	
Initial or Prolonged INTRATHECAL	Medication Error	Professional				
Required	Overdose					
Intervention to	Pocket Erosion					
Prevent Permanent Impairment/Damage						
Date:06/28/01ISR Number Age:80 YR Gender:Fema	: 3750110-7Report Type:Exped le I/FU:F	ited (15-DaCompany Rep	port #PHRM2000FR01837			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Life-Threatening Hospitalization - 15 MG/DAY,	Drug Interaction International Normalised	Foreign Health	Lioresal	PS	Novartis Pharmaceuticals Corp	ORAL
Initial or Prolonged ORAL	Ratio Increased	Professional				
Other		Other	Coumadine (Warfarin Sodium) Tablet	SS		ORAL
5 MG/DAY,						
ORAL 3 DAY			Gardenal "Specia" (Phenobarbital)Table			
50 MC/DAY			t	SS		ORAL

50 MG/DAY,

ORAL	3	DAY
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Date:06/29/01ISR Numbe: Age: Gender:Male	er: 3750713-XReport Type:Exped .e I/FU:I	lited (15-DaCompany Re	port #2012485			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other 40 MG PO	Coma	Health	Oxycontin	PS	Purdue Pharma Lp	ORAL
Required Intervention to		Professional Company	Baclofen (Lioresal)	SS		
Prevent Permanent Impairment/Damage		Representative				
	er: 3751328-XReport Type:Exped	lited (15-DaCompany Re	port #PHFR2001GB01825			
Date:07/02/01ISR Numbe: Age:82 YR Gender:Malo Outcome		lited (15-DaCompany Re Report Source	port #PHFR2001GB01825 Product	Role	Manufacturer	Route
Age:82 YR Gender:Mal Outcome Dose Duration	PT	Report Source	Product			Route
Age:82 YR Gender:Mal Outcome Dose Duration Hospitalization - Initial or Prolonged	e I/FU:I			Role PS	Manufacturer Novartis Pharmaceuticals Corp	Route
Age:82 YR Gender:Mal Outcome Dose Duration Hospitalization -	e I/FU:I PT Agitation	Report Source Foreign	Product		Novartis	

Freedom Of Information (FOI) Report

Date:07/13/01ISR Number: 3758525-8Report Type:Expedited (15-DaCompany Report #PHFR2001GB01980 Age:53 YR Gender:Female I/FU:I

Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Life-Threate		Apnoea Cheyne-Stokes Respiration Drug Interaction	Foreign Health Professional	Lioresal	PS	Novartis Pharmaceuticals Corp	ORAL
ORAL (SEE		Drug Interaction	Other				
IMAGE) Date:07/16/0 Age:35 YR	01ISR Number Gender:Fema	: 3759890-8Report Type:Expedit le I/FU:I		Enalapril (Enalapril) Atenolol Nortriptyline (Nortriptyline) Co-Dydramol (Dihydrocodeine Bitartrate, Paracetamol)	C C C		
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Disability ORAL	24240200	Optic Atrophy Papilloedema	Foreign Health	Lioresal	PS	Novartis Pharmaceuticals Corp	ORAL
			Professional Other	Neurontin (Gabapentin) Paroxetine Omeprazole Levothroid	C C C C		
Date:07/23/0 Age:59 YR	01ISR Number Gender:Fema	: 3763107-8Report Type:Periodi le I/FU:I	ic Company Repor	t #01-04-0187			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other	Durucion	Face Oedema	Consumer	Baclofen	PS	Zenith Goldline	

	Hypoaesthesia Oral				Pharmaceuticals	ORAL
20 MG BID						
ORAL	Polyuria					
	Sleep Disorder		Neurontin Prozac	C C		
			Prempro	С		
			Calcium Qd	C		
			Magnesium Qd Zinc Qd	C C		
			Multivitamins	C		
Date:07/23/01ISR Number: Age: Gender:Male	: 3763620-3Report Type:Exped I/FU:I	lited (15-DaCompany Re	port #034-0945-M0100007			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
100 MG TID,	Optic Atrophy	Foreign	Neurontin	PS	Pfizer Inc	ORAL
PER ORAL	Papilloedema	Health				
Other 10 MG TID,		Professional	Baclofen (Baclofen)	SS		ORAL
PER ORAL			Paroxetine			
			(Paroxetine)	SS		ORAL
20 MG (20 MG,						-
DAILY), PER						
ORAL			Omeprazol			
20 MG (20 MG,			(Omeprazole)	SS		ORAL
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ORAL

	Levothyroxine		
	(Levothyroxine)	SS	ORAL
100 MG (100			
MG, DAILY),			
PER ORAL			

Date:07,	/24/01	ISR Number:	3764144-XReport	Type:Expedited	(15-DaCompany	Report	#PHNU2001DE01547
Age:40 M	YR G	ender:Male	I/FU:I				

Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Life-Threatening	Coagulopathy Convulsion	Health Professional	Lioresal (Baclofen) Solution	PS		
	Drug Level Below	Other				
	Therapeutic					
DAY						
	Drug Withdrawal Syndrome		Insulin Basal			
	Medication Error		(Insulin Isophane			
	Multi-Organ Failure		Human Semisynthetic)	С		
	Muscle Spasms		Magnesium	С		
			Rivotril			
			(Clonazepam)	С		
			Benzodiazephines	С		

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 Dura	tion					
Life-Threatening	Coma	Health	Lioresal Intrathecal			
Hospitalization -	Drug Interaction	Professional	(Baclofen) Solution			
Initial or Prolonged		Other	For Injection	PS		
INTRATRACHEAL	0.05 MG, DAY;					

DAY; ORAL

Carbasalate Calcium Galenic/Amoxicillin/	С
Clavulanic Acid	
(Amoxicillin,	
Clavulanic Acid)	С
Fentanyl	С
Flucloxacillin	С
Nadroparin	С
Insulin	С
Morphine Sulfate	С
Paracetamol	С
Metoprolol	С
Morphine	С

Date:07/24/01ISR Number: 3764171-2Report Type:Expedited (15-DaCompany Report #20010833 Age: Gender:Male I/FU:I \mathbf{PT} Report Source Product Role Manufacturer Outcome Route Duration Dose Hospitalization -Decubitus Ulcer Health Lioresal (Baclofen Initial or Prolonged Drug Withdrawal Syndrome Professional Injection) Medtronic Inc ΡS INTRA-ARTICULAR MCG, DAILY, Required Implant Site Reaction INTRATHECAL Intervention to Mental Disorder Prevent Permanent Impairment/Damage 22-Aug-2005 12:15 PM

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FDA - Adverse Event Reporting System (AERS) Freedom Of Information (FOI) Report Date:07/24/01ISR Number: 3764173-6Report Type:Expedited (15-DaCompany Report #20010832 Gender: Age: I/FU:I Outcome PTReport 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 С Date:07/24/01ISR Number: 3764174-8Report Type:Expedited (15-DaCompany Report #20010831 Gender: I/FU:I Aqe: Role Manufacturer Route Outcome PTReport Source Product Dose Duration Lioresal Medtronic Inc Hospitalization -Coma Health PS INTRATHECAL 50 MCG, Initial or Prolonged Drug Interaction Professional DAILY, INTRATHECAL Date:07/24/01ISR Number: 3764270-5Report Type:Expedited (15-DaCompany Report #20010834 Gender:Female Age: I/FU:I \mathbf{PT} Role Manufacturer Outcome Report Source Product Route Duration Dose Complications Of Maternal Foreign Lioresal PS Medtronic Inc MCG, DAILY, INTRATHECAL Exposure To Therapeutic Health INTRATHECAL Drugs Professional Convulsion Neonatal Drug Withdrawal Syndrome Neonatal

Outcome	РТ	Report Source	Product	Role	Manufacturer	Route
Dose Duration Hospitalization -	Agitation	Foreign	Lioresal	PS	Novartis	
Initial or Prolonged 10 MG, BID,	Hepatitis	Health			Pharmaceuticals Corp	ORAL
	Vomiting	Professional				
ORAL		Other	Prepulsid (Cisapride)	SS		ORAL
10 MG, TID,						-
ORAL						
			Noctamid			
1 MG, QD,			(Lormetazepam)	SS		ORAL
ORAL						
30 MG, QD,			Ogast (Lansoprazole)	SS		ORAL
ORAL						
						ł

Date:07/26/01ISR Number: 3765465-7Report Type:Expedited (15-DaCompany Report #01-07-0392 Age:43 YR Gender:Male I/FU:I

Outcome Dose	Duration	РТ	Report Source	Product	Role	Manufacturer	Route
Other		Blood Creatine Phosphokinase Increased	Literature	Baclofen	PS	Zenith Goldline Pharmaceuticals	ORAL
ORAL 100MG HS ORAI		Oedema Peripheral		Doxepin Tablets	SS		ORAL
TOOMG IID ORAL	-	Pain In Extremity		Methadone Hydromorphone	C C		

Freedom Of Information (FOI) Report

Date:07/26/01ISR Number: 3766327-1Report Type:Expedited (15-DaCompany Report #031-0945-M0100017 Age: Gender:Female I/FU:F

Outcome	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Dose Other PER ORAL	Duration	Drug Interaction	Foreign	Neurontin	PS	Pfizer Inc	ORAL
PER ORAL		Loss Of Consciousness	Health	Baclofen	SS		ORAL
FER URAL				Insuline (Insulin Human) Dantroleen Morfine Sulfate Paracetamol Metoprolol Cabasalate Calcium Flucloxacilline Augmentin (Clavulanate Potassium, Amoxicillin Trihydrate) Nadroparine	000000		

Date:07/27/01ISR Number: 3766908-5Report Type:Expedited (15-DaCompany Report #2012485 Age: Gender:Male I/FU:F

Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Life-Threatening 40 MG 08H PO	Apnoea	Health	Oxycontin	PS	Purdue Pharma Lp	ORAL
Other 20 MG TID PO	Coma	Professional	Baclofen (Lioresal)	SS		ORAL
Required Intervention to Prevent Permanent Impairment/Damage	Delirium Drug Withdrawal Syndrome Hypotension	Company Representative	Paxil (Paroxetine) Lansoprazole Detrol La (Tolterodine Tartrate) Actos (Pioglitazone)	с с с		

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Death		Coma	Foreign	Lioresal	PS	Novartis	
Life-Threater	ning	Completed Suicide	Health			Pharmaceuticals Corp	ORAL
SEE IMAGE							
Hospitalizati		Depressed Level Of	Professional	Pentoxifylline			ļ
Initial or Pr		Consciousness Hypoxic Encephalopathy Intentional Misuse Pupillary Reflex Impaired Respiratory Arrest	Other	(Pentoxifylline)	С		
	Gender:	: 3768548-0Report Type:Expedit I/FU:I PT	ted (15-DaCompany Repor Report Source	rt #20010842 Product	Role	Manufacturer	Route
Age: (Outcome Dose Death	Gender: Duration	I/FU:I			Role PS	Manufacturer Medtronic Inc	Route
Age: (Outcome Dose	Gender: Duration	I/FU:I PT	Report Source Health	Product			Route
Age: (Outcome Dose Death	Gender: Duration	I/FU:I PT	Report Source	Product			Route
Age: (Outcome Dose Death 50 MCG TEST	Gender: Duration	I/FU:I PT	Report Source Health	Product			Route

FDA - Adverse Event Reporting System (AERS) Freedom Of Information (FOI) Report Date:08/06/01ISR Number: 3771463-XReport Type:Direct Company Report # Gender:Male Age:15 YR I/FU:I Outcome PTReport Source Product Role Manufacturer Route Dose Duration Life-Threatening Cardio-Respiratory Arrest Baclofen PS INTRATHECAL 1000MICRO DAY Hospitalization -Medication Error INTRATHECAL Initial or Prolonged Respiratory Depression Required Intervention to Prevent Permanent Impairment/Damage Date:08/08/01ISR Number: 3773296-7Report Type:Expedited (15-DaCompany Report #01-1110 Age:18 YR Gender:Male I/FU:I Role Manufacturer Outcome PTReport Source Product Route Dose Duration Required Coma Health Baclofen Tablets, Intervention to Professional Unknown Manufacturer/Strengt Prevent Permanent Impairment/Damage h PSAPPROXIMATELY 9 TABLETS Date:08/08/01ISR Number: 3783894-2Report Type:Direct Company Report # Age:48 YR Gender:Female I/FU:I Role Manufacturer Outcome PTReport Source Product Route Dose Duration 2000 Condition Aggravated Lioresal Failure Of Implant Mcg./Cc Medtronic PS Medtronic INTRATHECAL 350 MCG./ Hypertonia INTRATHECAL Pruritus Baclofen С Diazepam С Benadryl С Vistaril С Atarax С

r: 3773028-2Report Type:Direct ale I/FU:I	Company Repo	ort #			
PT	Report Source	Product	Role	Manufacturer	Route
Cough		Baclofen	PS		ORAL
		Mexitil	С		
r: 3775068-6Report Type:Expedi ale I/FU:I	ted (15-DaCompany Rep	ort #PHBS2001JP06832			
PT	Report Source	Product	Role	Manufacturer	Route
Constipation Eosinophilia	Foreign Health	Diovan	PS	Novartis Pharmaceuticals Corp	ORAL
					0
Face Oedema	Professional				
Haemorrhage Subcutaneous Headache	Other	Luvox(Fluvoxamine Maleate)	SS		ORAL
Hyponatraemia		·			
					00.11
Malaise		Evamyl(Lormetazepam)	SS		ORAL
			SS		ORAL
Malaise Nasal Congestion Petechiae		Evamyl(Lormetazepam) Lioresal (Baclofen, Baclofen) Unknown	SS		ORAL
Nasal Congestion Petechiae		Lioresal (Baclofen,			
Nasal Congestion		Lioresal (Baclofen,			
a. 7	ale I/FU:I PT Cough V c: 3775068-6Report Type:Expedit ale I/FU:I PT Constipation Eosinophilia Face Oedema Haemorrhage Subcutaneous Headache	Ale I/FU:I PT Report Source Cough Cough T: 3775068-6Report Type:Expedited (15-DaCompany Report Ale I/FU:I PT Report Source Constipation Foreign Eosinophilia Health Face Oedema Professional Haemorrhage Subcutaneous Other Headache	ale I/FU:I Report Source Product PT Report Source Baclofen Cough Mexitil *: 3775068-6Report Type:Expedited (15-DaCompany Report #PHBS2001JP06832 fle I/FU:I PT Report Source PT Report Source PT Report Source PT Product Constipation Foreign Eosinophilia Health Face Oedema Professional Haemorrhage Subcutaneous Other Luvox(Fluvoxamine Maleate)	PT Report Source Product Role Cough Cough The string of the string of th	PT Report Source Product Role Manufacturer Cough Cough Cough PS Mexitil C C Sale 1/FU:I PT Report Type:Expedited (15-DaCompany Report #PHBS2001JP06832 C PT Report Source Product Role Manufacturer PT Report Source Product Role Manufacturer Constipation Eosinophilia Foreign Health Face Oedema Professional Haemorrhage Subcutaneous Haemorrhage Subcutaneous Haemorrhage Subcutaneous

Freedom Of Information (FOI) Report

			Freedom C)f Information (FOI) Re	port		
				Carbonate) Ruefrien (Levoglutamide, Azulene) Danoil Sennosides A+B (Sennoside A+B)	C C C C		
)1ISR Number Gender:Fema	: 3777357-8Report Type:Expedit le I/FU:I	ed (15-DaCompany Repor	:t #20010844			
Outcome Dose	Duration	РТ	Report Source	Product	Role	Manufacturer	Route
Death INTRATHECAL	MCG, D	Completed Suicide AILY,	Health	Lioresal	PS	Medtronic Inc	
INTRATHECAL	1.00, 2.	FTTT ,	Professional				
)1ISR Number Gender:Fema	: 3781176-6Report Type:Expedit le I/FU:I	ed (15-DaCompany Repor	t #20010846			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Dose Death INTRATHECAL	975 MC	Cardiac Arrest	Health	Lioresal	PS	Medtronic Inc	
DAILY,		Vomiting	Professional				
INTRATHECAL				Oral Baclofen	С		
)1ISR Number Gender:Male	: 3783895-4Report Type:Direct I/FU:I	Company Repor	:t #			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalizat INTRATHECAL Initial or F INTRATHECAL	ion - 200MCG	Drug Withdrawal Syndrome /DAY Infected Skin Ulcer		Lioresal 2000 Mcg	PS		
Required Intervention	n to			Baclofen Diazepam	C C		

Prevent Permanent			Benadryl	С		
Impairment/Damage						
Date:08/29/01ISR Number Age: Gender:Male	: 3784137-6Report Type:Experies I/FU:I	dited (15-DaCompany Re	eport #20010852			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - Initial or Prolonged	Chills Decubitus Ulcer Heart Rate Increased	Foreign Health Professional	Lioresal (R) Intrathecal (Baclofen Injection)	PS		
INTRATHECAL MCG, D		FIOLESSIONAL	(Bactoren injection)	FD		
INTRATHECAL	Pruritus Pyrexia					
Date:09/06/01ISR Number Age:11 YR Gender:Male	: 3788553-8Report Type:Dire	ct Company Re	eport #			
Outcome Dose Duration	РТ	Report Source	Product	Role	Manufacturer	Route
Hospitalization - Initial or Prolonged INTRATHECAL INTRAT Required 50MCG	Body Temperature Increased HECAL Headache		Lioresal (Intrathecal)	PS		
Intervention to Prevent Permanent Impairment/Damage	Sedation Vomiting					
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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	Duration	PT	Report Source	Product	Role M	Manufacturer	Route
Dose Other	Duracion	Constipation Diabetes Mellitus	Foreign Health	Diovan (Valsartan) Tablet	PS		ORAL
80 MG/DAY,							Ĩ
ORAL		Dysuria	Professional				ļ
·		Eosinophilia Face Oedema	Other	Luvox(Fluvoxamine Maleate)	SS		ORAL
50MG/DAY,				1420402,	26		0
1		Gastritis					ľ
ORAL				T	20		~D A T
1 G/DAY, ORA	١ Τ.	Haemorrhage Subcutaneous		Evamyl(Lormetazepam)	SS		ORAL
I G/DAI, VILL	Ц	Hypertension Hypertonia		Lioresal(Baclofen, Baclofen) Unknown	SS		ORAL
10 MG/DAY,		пуретсопта		Dactoren, onniown	50		UKAL
		Hyponatraemia					ľ
ORAL		-					Ī
		Insomnia		Bufferin (Aluminium			ľ
		Malaise Nasal Congestion		Glycinate, Magnesium Carbonate)	С		ľ
1		Petechiae		Ruefrien	C		Ī
1		Pyrexia		(Levoglutamide,			Ī
1		White Blood Cell Count		Azulene)	С		Ī
1		Decreased		Daonil	C		Ī
1				Sennosides A+B			ļ
				(Sennoside A+B)	C		
)1ISR Number Gender:Fema	r: 3792940-1Report Type:Direct ale I/FU:I	Company Repor	rt #			
Outcome		PT	Report Source	Product	Role N	Manufacturer	Route
Dose	Duration		Report for the	1 2 0 0 0 2			
Other PO		Confusional State		Baclofen	PS		ORAL
		Delirium					
1		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	Dunation	PT	Report Source	Product	Role	Manufacturer	Route
Dose Other	Duration	Cerebral Infarction Constipation	Foreign Health	Diovan (Valsartan) Tablet	PS		ORAL
80 MG/DAY,							-
		Dermatitis	Professional				
ORAL		Diabetes Mellitus Dysuria	Other	Luvox (Fluvoxamine Maleate)	SS		ORAL
50 MG/DAY,				1.1.1.2.0.0.0,	22		01412
		Eosinophilia					
ORAL							
		Gastritis Haemorrhage Subcutaneous		Evamyl (Lormetazepam)	SS		ORAL
1 G/DAY, ORA	L						
		Headache Hemiplegia		Lioresal (Baclofen, Baclofen) Unknown	SS		ORAL
10 MG/DAY,							
		Hypertension					
ORAL							
		Hypertonia Hyponatraemia		Bufferin (Aluminium Glycinate, Magnesium			
		Insomnia Malaise		Carbonate) Ruefrien	С		
		Nasal Congestion		(Levoglutamide,			
		Pyrexia		Azulene)	С		
				Daonil	С		
				Sennosides A+B (Sennosides A+B)	С		

Freedom Of Information (FOI) Report

Age:56 YR Geno	der:Male	I/FU:I					
Outcome Dose Dui	ration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization 5 MG QID		Mental Disorder		Baclofen	PS		
Initial or Prolo	onged			Simavastatin	С		
				Prevacid	C		
				Metoprolol Levofloxacin	C C		
				Lorazepam(?)	C		
				Sertraline	C		
				Olanzapine(?)	C		
				Oxycontin	C		
				Oxycodone	С		
Outcome	der:Male ration MCG, Di	PT Cerebral Ischaemia Convulsion	Report Source Health Professional	Product Lioresal Intrathecal (Baclofen Injection) Tetracaine Morphine		Manufacturer	Route
		: 3809873-4Report Type:Exped le I/FU:F	ited (15-DaCompany Re	eport #2000COU1548			
Outcome Dose Dui	ration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization Initial or Prolo	-	Gastrooesophageal Reflux Disease International Normalised	Consumer	Coumadin (Crystalline Warfarin Sodium)	PS		ORAL
PO							
		Ratio Decreased		Neurontin			
Hospitalization		Disease	Consumer	(Crystalline	PS		

	Prothrombin Time	(Gabapentin)
	Shortened	Tegretol
	Transient Ischaemic	(Carbamazepine)
	Attack	Dilantin (Phenytoin
	Trigeminal Neuralgia	Sodium)
		Ni (Baclofen)
		Vioxx (Rofecoxib)
		Lanoxin (Digoxin)
		Ni Verapamil
		Lipitor
		(Atorvastatin
		Calcium)
		Ni Other (S) -
		Unspecified
$D_{2} = \frac{10}{10} \frac{10}{10} \frac{10}{100}$	Numbers, 2012154 (Demonstrations) distant (15	De Commercia Demente HDUDG2001 TD06022
Age:65 YR Gende	Number: 3812154-6Report Type:Expedited (15- er:Female I/FU:F	Dacompany Report #PHBS20010P06832
Age.65 IR Gende	er.Female I/FU.F	
Outcome	PT	
Other	Constipation	
	Dermatitis	
	Diabetes Mellitus	
	Dysuria	

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Freedom Of Information (FOI) Report

		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							ļ
		Haemorrhage Subcutaneous Hypertension	Professional Other	Luvox (Fluvoxamine Maleate)	SS		ORAL
50 MG/DAY,		Hypertonia					!
ORAL		Hyponatraemia		Evamyl(Lormetazepam)	SS		ORAL
1 G/DAY, ORAL	L						UKAL
		Insomnia Malaise		Lioresal(Baclofen, Baclofen)	SS		ORAL
10 MG/DAY,					22		0
ORAL		Nasal Congestion					
		Pyrexia White Blood Cell Count Decreased		Ruefrien (Levoglutamide, Azulene) Daonil Sennosides A+B (Sennoside A+B) Bufferin (Aluminium Glycinate, Magnesium Carbonate)	C C C		
	lISR Number Gender:Male	: 3811476-2Report Type:Direct I/FU:I	Company Report	t #			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalizat: 10MG PO Q8		Delirium		Baclofen	PS		ORAL
Initial or P	rolonged			Lansoprazole Oscal Codeine	C C C		

Outcome Dose Duration	PT	Report Source	Product	Role Manufacturer	Route
Hospitalization - Initial or Prolonged 300 MG, BID,	Sedation Urinary Incontinence	-	Trileptal (Trileptal T22413+) Unknown	PS	ORAL
ORAL		Health			
		Professional Other	Zoloft (Sertraline Hydrochloride) Lioresal (Baclofen) Unknown Mopral (Omeprazole)	SS SS 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 - C-Reactive Protein Initial or Prolonged Increased Depressed Level Of Consciousness Diarrhoea Hypertension Klebsiella Infection Proteus Infection Pulmonary Embolism Pyrexia

Freedom Of Information (FOI) Report

		Sedation White Blood Cell Count Increased	Report Source	Product	Role Manufacturer	Route
Dose	Duration	Incleased				Route
			Foreign Health	Lioresal (Baclofen) Tablet, 10 Mg	PS	ORAL
10 MG, TID,			Professional			
ORAL						
			Other	Tanakan (Ginkgo Biloba Extract)	SS	ORAL
1 DF, TID,				,		
ORAL						
				L-Thyroxin (Levothyroxine Sodium)	SS	ORAL
ORAL				Cacit (Citric Acid,		
				Calcium Carbonate)		
1 DF, QD,				Effervescent Tablet	SS	ORAL
ORAL						
				Isoptin (Verapamil Hydrochloirde)	~~	0.5.1.5
120 MG, TID,				Capsule	SS	ORAL
ORAL						
				Diovenor (Diosmin) Tablet	SS	ORAL
600 MG, QD,				TADIEC	55	URAL
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

Hospitalization - 120 MG TID PO	Depressed Level Of	Foreign	Isoptine	PS	ORAL
Initial or Prolonged 600 MG QD PO	Consciousness	Health	Diovenor	SS	ORAL
	Diarrhoea	Professional	Lioresal	SS	ORAL
1 UNK TID PO					
	Drug Tolerance Decreased	Other	Tanakan	SS	ORAL
1 UNK TID PO					
	Gait Disturbance		L Thyroxine	SS	
	Inflammation		Cacit D3	SS	ORAL
1 UNK PO					
	Klebsiella Infection		Pefloxacine	С	
	Proteus Infection				
	Pulmonary Embolism				
	Pyrexia				
	Sedation				
	Urinary Tract Infection				

Date:10/31/01ISR Number: 3818971-0Report Type:Expedited (15-DaCompany Report #2000COU1548 Age:59 YR Gender:Female I/FU:F

Outcome Description	PT	Report Source	Product	Role Manufacturer	Route
Dose Duration Hospitalization - Initial or Prolonged	Gastrooesophageal Reflux Disease International Normalised	Consumer	Coumadin (Crystalline Warfarin Sodium)	PS	ORAL
PO					
	Ratio Decreased		Neurontin		
	Medication Error		(Gabapentin)	SS	
	Prothrombin Time		Tegretol		
	Shortened		(Carbamazepine)	SS	
	Transient Ischaemic		Ni (Baclofen)	SS	
	Attack		Vioxx (Rofecoxib)	SS	
	Trigeminal Neuralgia		Lanoxin (Digoxin)	SS	
			Ni (Verapamil)	SS	

Freedom Of Information (FOI) Report

Lipitor(Atorvastatin						
Sodium)	SS					
Ni (Other (S) -						
Unspecified)	SS					
Ni(Baclofen)						
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 Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalizat 20 MG, TID,		Agitation	Foreign	Baclofen	PS		ORAL
Initial or H ORAL	Prolonged	Cerebral Atrophy	Literature				
		Confusional State Drug Withdrawal Syndrome Hallucination, Visual Renal Impairment	Health Professional Other	Lisinopril (Lisinopril) Fursemid Naproxen Allopurinol	C C C C		
Date:11/05/0 Age:48 YR	01ISR Number Gender:	: 3820744-XReport Type:Exped I/FU:I	ited (15-DaCompany Re	port #02657			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Death	Duración	Completed Suicide Intentional Misuse	Literature	Clonazepam Baclofen	PS SS		
Date:11/06/(Age:)1ISR Number Gender:Male	: 3820948-6Report Type:Exped I/FU:I	ited (15-DaCompany Re	port #20010866			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Death	Duración	Cardiac Arrest Condition Aggravated	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		
INTRATHECAL	380 MC			(,			

DAILY,

Hypertonia

INTRATHECAL	Meningitis Mental Impairment Sepsis	В	Baclofen	С
Date:11/12/01ISR Number Age: Gender:Male	r: 3823676-6Report Type:Expedited e I/FU:I	(15-DaCompany Report	#20010872	
Outcome Hospitalization - Initial or Prolonged	PT 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			

Freedom Of Information (FOI) Report

		Staphylococcal Infection Wound Infection					
I			Report Source	Product	Role	Manufacturer	Route
Dose	Duration		Health Professional	Lioresal (R) Intrathecal (Baclofen Injection)	PS		
INTRATHECAL	MCG, DA	AILY,					ļ
INTRATHECAL							
	ISR Number: ender:Femal	: 3825528-4Report Type:Direct le I/FU:I	Company Repor	-t #			
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
	Duration	-· · _	-		_		I
Life-Threaten INTRATHECAL	ing INTRATH	Medication Error HECAL		Morphine	PS		I
Hospitalizati	on –	Mental Impairment		Baclofen	SS		
Initial or Pr		Overdose					
		Respiratory Depression Toxicologic Test Abnormal					ľ
Age:50 YR G Outcome	ISR Number: ender:Femal Duration	: 3827865-6Report Type:Expedit le I/FU:I PT Sinus Bradycardia	ted (15-DaCompany Repor Report Source Foreign Health Professional Other	rt #PHRM2001FR02458 Product Lioresal(Baclofen) Tablet	Role PS	Manufacturer	Route ORAL
Age: G Outcome	ender:Male	: 3828566-0Report Type:Expedit I/FU:I PT No Adverse Drug Effect	ted (15-DaCompany Repor Report Source Health	rt #20010885 Product Lioresal Intrathecal	Role	Manufacturer	Route
1							

Initial or Prolonged MCG, DAILY,		Professional	(Baclofen Injection)	PS		
INTRATHECAL						
Date:11/26/01ISR Number Age:42 YR Gender:Male	r: 3828466-6Report Type:Expe e I/FU:I	edited (15-DaCompany R ϵ	eport #B0126849A			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - 150MG Per day	Multiple Sclerosis		Zyban	PS	Glaxo Wellcome	ORAL
Initial or Prolonged UNKNOWN			Interferon Beta	SS		
UNKNOWN			Lioresal	SS		
Date:11/26/01ISR Number Age:42 YR Gender:Male	r: 3828480-0Report Type:Expe e I/FU:I	edited (15-DaCompany R ϵ	eport #B0126849A			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - 150MG Per day	Multiple Sclerosis		Zyban	PS	Glaxo Wellcome	ORAL
Initial or Prolonged UNKNOWN			Interferon Beta	SS		
			Lioresal	SS		

UNKNOWN

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 Hospitalizat 150MG Per da		Multiple Sclerosis		Zyban	PS	Glaxo Wellcome	ORAL
Initial or H UNKNOWN	-			Interferon Beta	SS		
ONICIOWIN				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 Hospitalizat 150MG Per da		Multiple Sclerosis		Zyban	PS	Glaxo Wellcome	ORAL
Initial or P UNKNOWN	-			Interferon Beta	SS		
OINKIIOWIN				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 Sou	urce	Product	Role	Manufacturer	Route
Dose Du Hospitalization 150MG Per day	uration n -	Multiple Sclerosis			Zyban	PS	Glaxo Wellcome	ORAL
Initial or Prol UNKNOWN	longed				Interferon Beta	SS		
ONICIOWIN					Lioresal	SS		

UNKNOWN

Date:11/26/01ISR Number: 3829691-0Report Type:Expedited (15-DaCompany Report #20010894 Age: Gender:Male I/FU:I

Death	Blood Creatine	Health	Lioresal Intrathecal		
	Phosphokinase Increased	Professional	(Baclofen Injection)	PS	
INTRATRACHEAL 967 MC					
DAILY,	Blood Glucose Decreased				
DAILY,	Body Temperature				I
INTRATHECAL	body remperature				
	Increased Hypoaesthesia		See B5	С	
	Protein Total Increased				
Date:11/26/01ISR Number Age: Gender:Fema	: 3829700-9Report Type:Expedi le I/FU:F	ited (15-DaCompany Rep	ort #990710		
					l
Outcome Dose Duration	PT	Report Source	Product	Role Manufacturer F	Route
Hospitalization -	Agitation	Health	Lioresal Intrathecal		l
Initial or Prolonged INTRATRACHEAL DAILY,	Condition Aggravated	Professional	(Baclofen Injection)	PS	
	Csf White Blood Cell				l
INTRATHECAL					I
	Count Positive				I
	Hypertonia				I
	Procedural Site Reaction				l
					l
Date:11/26/01ISR Number Age: Gender:Fema	: 3830022-0Report Type:Expedi le I/FU:I	ted (15-DaCompany Rep.	ort #2001895		
Outcome	PT				
Life-Threatening	Agitation				l
Hospitalization -	Anxiety				
Initial or Prolonged	Confusional State Drug Withdrawal Syndrome				
	Hyperhidrosis				l
	Muscle Contractions				
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raye. IIJ					l

Freedom Of Information (FOI) Report

					-1		
		Involuntary Pyrexia Rhabdomyolysis					
Dece			Report Source	Product	Role	Manufacturer	Route
	iration		Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		
INTRATHECAL	DAILY,						
INTRATHECAL							
	SR Number nder:Male	: 3830035-9Report Type:Expedi I/FU:I	ted (15-DaCompany Repo	ort #20010890			
Outcome Dose Du	ration	PT	Report Source	Product	Role	Manufacturer	Route
Life-Threatenin Hospitalization INTRATHECAL	ng	Blood Creatine Phosphokinase Increased	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		
Initial or Prol INTRATHECAL	longed	Culture Urine Positive					
		Drug Withdrawal Syndrome Pyrexia Renal Impairment Rhabdomyolysis White Blood Cell Count Increased					
	SR Number ider:Male	: 3830067-0Report Type:Expedi I/FU:I	ted (15-DaCompany Repo	ort #20010892			
Outcome Dose Du	iration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization		Agitation	Health	Lioresal Intrathecal			
Initial or Prol INTRATHECAL	Longed 840 MCC	Blood Pressure Diastolic G, Increased	Professional	(Baclofen Injection)	PS		
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 \mathbf{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

Freedom Of Information (FOI) Report

Amitriptyline

SS

		Hypertonia Liver Function Test					
Dose	Duration	Abnormal	Report Source	Product	Role	Manufacturer	Route
Dose	Duración	Neuroleptic Malignant Syndrome Pyrexia	Health Professional	Lioresal Intrathecal(Baclofen Injection)	PS		
INTRATHECAL	350 MG				10		
		Rhabdomyolysis					
DAILY,							
		Streptococcal Infection					
INTRATHECAL		Swelling Tremor White Blood Cell Count Increased					
Age:70 YR)1ISR Number Gender:Male						
Outcome	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Dose Death ORAL	Duration	Cheyne-Stokes Respiration	Foreign	Lioresal (Baclofen)	PS		ORAL
		Hypotension	Health	Tramadol (Tramadol)	С		
		Respiratory Tract	Professional	Lorazepam	С		
		Infection Somnolence	Other	Naproxen	C		
)1ISR Number Gender:Male	: 3833761-0Report Type:Exped: E I/FU:I	ited (15-DaCompany Re	eport #11807			
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose Death	Duration	Cardiac Arrest Depressed Level Of	Literature Health	Oxybutynin Generic (Oxybutynin			
		Consciousness Grand Mal Convulsion Overdose	Professional	Chloride) Cyclobenzaprine Generic	PS		
				(Cyclobenzaprine) Clorazepate Propoxyphene	SS SS SS		

SS
SS

Route

)1ISR Number: Gender:Femal		Type:Expedite	ed (15-DaCompany Report	#20010903		
1190		1,10,1					
Outcome		PT		Report Source	Product	Role	Manufacturer
Dose	Duration						
Death		Coma		Health	Lioresal Intrathecal		
		Drug Withdrawal Sy	ndrome	Professional	(Baclofen Injection)	PS	
INTRATHECAL	220 MCC	, F					
		Somnolence					
DAILY,							
INTRATHECAL							

Freedom Of Information (FOI) Report

	lISR Number Gender:Fema	: 3837502-2Report Type:Dire le I/FU:I	ect Company Re	eport #			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other ONE PILL QHS		Abnormal Behaviour		Baclofen	PS		ORAL
ORAL		Hallucination		Junkien 10 Mar	99		
5-10 MG QHS		Psychotic Disorder Sleep Walking		Ambien 10 Mg	SS		ORAL
ORAL		Sieep warking		Hydrocodone	С		
				Synthroid Ultram	C C		
				Celexa Ibuprofen Premarin	С С С		
Outcome Dose Death Other 5 MG, BID,	Duration	PT Difficulty In Walking Hypotonia Myocardial Infarction	Report Source Foreign Literature Health	Product Baclofen (Baclofen) (Continued)	Role PS	Manufacturer	Route
UNKNOWN		Overdose	Professional Other				
	lISR Number Gender:Fema	: 3840494-3Report Type:Expe le I/FU:I	edited (15-DaCompany Re	eport #EMADSS2001007235			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other		Depressed Level Of Consciousness	Foreign Health	Risperdal (Tablet) (Risperidone)	PS		ORAL
1 MG, 1 IN 1		Drug Interaction	Professional				
DAY (S), ORA							

	Salivary Hypersecretion	Other	Lioseral (Baclofen)	SS		ORAL
5 MG, 3 IN 1						
DAY (S), ORAL						
Date:12/17/01ISR Number Age:42 YR Gender:Male	r: 3839290-2Report Type:Exped	lited (15-DaCompany Re	eport #B0126849A			
Age.42 IR Genuer.Mare						
Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration				Da		00.01
Hospitalization – 150MG Per day	Difficulty In Walking		Zyban	PS	Glaxo Wellcome	ORAL
Initial or Prolonged SUBCUTANEOUS	Faecal Incontinence		Interferon Beta	SS		
	Multiple Sclerosis		Lioresal	SS		ORAL
3UNIT per day						
100000 -	Urinary Incontinence		Paracetamol	С	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-Threaten	ning	Completed Suicide	Health	Omeprazole	SS	
		Depressed Level Of	Professional	Propoxyphene	SS	
		Consciousness		Clonazepam	SS	
1		Grand Mal Convulsion		Oxybutynin	SS	
1		Overdose		Cyclobenzaprine	SS	
		Toxicologic Test Abnormal		Baclofen	SS	
				Cisapride	SS	
				Diosmin	SS	

Freedom Of Information (FOI) Report

Glycopyrralate SS

	01ISR Number Gender:Male	: 3840807-2Report Type:Direct I/FU:I	Company Repor	t #			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalizat INTRATHECAL	tion -	Body Temperature HECAL		Lioresal Intrathecal	PS		
Initial or D 50 MCG	Prolonged	Increased					
Required		Headache					
Intervention	n to	Somnolence					
Prevent Perr		Vomiting					
Impairment/I	Damage						
Date:12/24/0 Age:	01ISR Number Gender:Male	: 3844508-6Report Type:Expedit I/FU:I	ed (15-DaCompany Repor	t #PHFR2001GB03410			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other 20 MG, TID,		Arrhythmia	Foreign	Lioresal(Baclofen)	PS		ORAL
ORAL		Drug Withdrawal Syndrome	Health				
		Gastric Haemorrhage Sepsis	Professional Other				
	01ISR Number Gender:	: 3847123-3Report Type:Expedit I/FU:I	ed (15-DaCompany Repor	rt #0311-01(0)			
Outcome Dose	Duration	РТ	Report Source	Product	Role	Manufacturer	Route
Disability		Deafness	Health	Baclofen 10 Mg			
-		Tinnitus	Professional	Tablets, Usp			
		Vertigo		(Unknown)	PS		ORAL
3 TABS DAIL	Y						

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 Dose	Duration	PT	Report Source	Product	Role Manufacturer	Route
Other	Duración	Asthenia Blood Pressure Increased	Foreign Consumer	Atorvastatin (Atorvastatin)	PS	ORAL
PER ORAL						
		Cerebrovascular Accident		(Acetylsalicylic		
		Drug Hypersensitivity		Acid)	SS	ORAL
PER ORAL						
		Fall		(Ranitidine)	SS	ORAL
PER ORAL		Mugglo Creama		(Continent of		
		Muscle Spasms Paraesthesia		(Conjugated	66	
PER ORAL		Paraestilesta		Estrogens)	SS	ORAL
FER ORAL		Pruritus		(Losartan)	SS	ORAL
PER ORAL		11 df f cab		(Lobar can)	55	01012
				(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,						
22-Aug-2005 12:15 PM						

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Freedom Of Information (FOI) Report

INTRATHECAL

Date:01/17/02ISR Number: 3854196-0Report Type:Expedited (15-DaCompany Report #200210022BFR Age:24 YR Gender:Female I/FU:I

Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - Initial or Prolonged 1000 MG DAILY	Bradycardia Drug Interaction	Health Professional	Ciflox (Ciprofloxacin)	PS		ORAL
ORAL	Hypotension	Other				
	Hypotonia Malaise		Sirdalud (Tizanidine Hydrochloride)	SS		ORAL
SEE IMAGE			Lioresal (Baclofen)	SS		ORAL
SEE IMAGE						
			Myolastan (Tetrazepam)	SS		ORAL
75 MG DAILY			(,			
ORAL						ſ
			Voltarene	C		
			Zyloric	C		ļ
			Verospiron	C		ľ
			Pantozol	C		ļ
			L!Snesium	C		ļ
			Melperon Zocor	C C		ļ
Date:01/18/02ISR Numb Age:46 YR Gender:Fe	per: 3855599-0Report Type:Period emale I/FU:I	lic Company Repo:	rt #PHBS2001US03558			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - Initial or Prolonged	Abdominal Pain Jejunostomy Nausea Vomiting	Consumer	Lioresal (Baclofen) Ampoule Betaseron (Albumin Human, Interferon	PS		
SUBCUTANEOUS SUBC	UTANEOUS		Beta)	SS		
SUBCUTAINEOUS SUBC	UTANEOUS		Verapamil (Verapamil)	С		

Trazadone	С
Imodium (Loperamide	
Hydrochloride)	С
Prilosec	
(Omeprazole)	С
Percocet (Oxycodone	
Hydrochloride,	
Paracetamol)	С
Robaxin	
(Methocarbamol)	С
Celexa (Citalopram	
Hydrobromide)	С
Valium	С
Neurontin	
(Gabapentin)	С
(Gabapentin) Urecholine	С
· -	С
Urecholine	C C
Urecholine (Bethanechol Chloride) Oxycontin (Oxycodone	C
Urecholine (Bethanechol Chloride)	C

		FDA – Adve	erse Event Reporting Syste	em (AERS)	
		Freedo	om Of Information (FOI) Re	eport	
Date:01/18/02ISR Number Age: Gender:Fema	r: 3855600-4Report Type:Peri le I/FU:I	iodic Company Re	eport #PHBS2001US05962		
Outcome	PT	Report Source	Product	Role Manufacturer	Route
Dose Duration Hospitalization - INTRATHECAL 2000 M	Accidental Overdose	Health	Lioresal Intrathecal	PS	
INITATHECAL 2000 M Initial or Prolonged INTRATHECAL	Hypoventilation	Professional			
INIKAINECAL	Somnolence				
Date:01/18/02ISR Number Age:14 YR Gender:Male Outcome	r: 3855871-4Report Type:Expe e I/FU:I PT	edited (15-DaCompany Re Report Source	eport #PHBS2002AU00570 Product	Role Manufacturer	Route
Dose Duration	7				
Hospitalization - Initial or Prolonged 500 MG,	Apnoea Bradycardia	Foreign Literature	Baclofen (Baclofen) Tablet	PS	ORAL
	Brain Oedema	Health			
ONCE/SINGLE,	Coma	Professional			
ORAL	Convulsion Depressed Level Of Consciousness Drug Screen Positive Encephalitis Headache Hyperhidrosis Hyperreflexia Hypertension Hyporeflexia Lethargy Nausea Overdose Pupil Fixed Vomiting	Other	Tramadol Hydrochloride (Tramadol Hydrochloride) Aspirine (Acetylsalicylic Acid)	SS SS	

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Death		Coma	Health	Lioresal Intrathecal			
		Drug Withdrawal Syndrome	Professional	(Baclofen Injection)	PS		
INTRATHECAL	220 MC						
		Pneumonitis					
DAILY,							
		Somnolence					
INTRATHECAL							
Date:01/23/0	2ISR Number	r: 3859515-7Report Type:Exped	lited (15-DaCompany Re	eport #20010846			
	Gender:Fema						
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration	1 1	Report Bource	TIOGGOU	ROIC	handracearer	Rouce
Death	Durución	Cardiac Arrest	Health	Lioresal			
Death		Clonic Convulsion	Professional	(Intrathecal			
		Medical Device		(Baclofen Injection)	PS		
INTRATHECAL	975 MC				10		
	<i>, , , , , , , , , , , , , , , , , , , </i>	Complication					
DAILY,		00mF1100010m					
,		Pneumonia					
INTRATHECAL							
		Vomiting		Baclofen	С		
Date:01/23/0 Age:45 YR		r: 3860015-9Report Type:Direc e I/FU:I	ct Company Re	eport #CTU 159872			
Age. 15 IK	Genuer · Mare	= 1/F0.1					
Outcome							
Life-Threate	ning						
Hospitalizat	-						
-							
22-Aug-2005	12:15 PM						
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Freedom Of Information (FOI) Report

Initial or Prolonged Disability

-						
Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duración	Cardio-Respiratory Arrest Coma		Lioresal 2000 Mcg./Cc Medtronic	PS	Medtronic	
INTRATRACHEAL 650 MC	CG DAY Convulsion					
INTRATRACHEAL						
	Drug Withdrawal Syndrome Muscle Spasticity Pyrexia		Valium	C		
Date:01/25/02ISR Number Age:24 YR Gender:Male	: 3860390-5Report Type:Expedi I/FU:I	ted (15-DaCompany Repor	rt #PHRM2002FR00519			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration		- ·				
Hospitalization - Initial or Prolonged 30 MG DAILY,	Bradypnoea Drug Interaction	Foreign Health	Lioresal(Baclofen)Ta blet	PS		ORAL
	Hypotension	Professional				
ORAL						
	Hypotonia Malaise	Other	Sirdalud(Tizanidine Hydrochloride)	SS		ORAL
12 MG DAILY,						
ORAL	Skin Infection					
ORAL			Myolastan(Tetrazepam			
)	SS		ORAL
75 MG PER						
DAY, ORAL						
			Ciflox(Ciprofloxacin)Tablet	SS		
1 G DAILY						
			Voltarene Lp (Diclofenac Sodium)	С		

Outcome Dose	Dunation	PT	Report Source	Product	Role	Manufacturer	Route
Dose Other	Duration	Depressed Level Of Consciousness	Foreign Health	Lioresal(Baclofen)Ta blet	PS		ORAL
10 MG,		Muscle Contractions	Professional				
ONCE/SINGLE,							
ORAL		Involuntary	Other				
ordine		Somnolence					
	2ISR Number Gender:Fema	: 3862026-6Report Type:Expedit le I/FU:I	ed (15-DaCompany Repor	t #PHBS2002AR01041			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other 10 MG,	Daración	Depressed Level Of	Foreign	Lioresal (Baclofen)	PS		ORAL
ONCE/SINGLE;		Consciousness	Health				
		Muscle Contractions	Professional				
ORAL		Involuntary Somnolence	Other				
Date:01/30/02 Age:16 YR (: 3862391-XReport Type:Expedit I/FU:I	ed (15-DaCompany Repor	t #PHEH2002US00956			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalizat: Initial or Pi	ion -	Pancreatitis	Health Professional	Lioresal (Baclofen)	PS		

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

Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - Initial or Prolonged ORAL	Phlebitis	Foreign Health	Lioresal (Baclofen) Tablet	PS		ORAL
		Professional Other	Lioresal Inthratecal (Baclofen) Solution For Injection	SS		
INTRATHECAL 80 MC	G/DAY,		FOI INJECTION	66		
INTRATHECAL						
			Previscan (Fluindione) Tablet Lysanxia (Prazepam)	С		
			Tablet Zyrtec (Cetirizine Hydrochloride)	C C		
Age:56 YR Gender:Mal	e I/FU:I					
Outcome Dose Duration	PT	Report Source	Product		Manufacturer	Route
	Asphyxia	Foreign	Product Baclofen (Baclofen)	Role PS	Manufacturer	Route
Dose Duration Death 2 G ONCE					Manufacturer	Route
Dose Duration Death 2 G ONCE SINGLE	Asphyxia	Foreign			Manufacturer	Route
Dose Duration Death 2 G ONCE SINGLE 20 G ONCE	Asphyxia Completed Suicide Cyanosis	Foreign Literature Health	Baclofen (Baclofen) Dipyrone (Metamizole	PS	Manufacturer	Route
Dose Duration Death 2 G ONCE SINGLE	Asphyxia Completed Suicide Cyanosis Drug Toxicity	Foreign Literature Health	Baclofen (Baclofen) Dipyrone (Metamizole Sodium) Oxybutynin	PS SS	Manufacturer	Route
Dose Duration Death 2 G ONCE SINGLE 20 G ONCE	Asphyxia Completed Suicide Cyanosis Drug Toxicity Intentional Misuse	Foreign Literature Health	Baclofen (Baclofen) Dipyrone (Metamizole Sodium)	PS	Manufacturer	Route
Dose Duration Death 2 G ONCE SINGLE 20 G ONCE SINGLE	Asphyxia Completed Suicide Cyanosis Drug Toxicity Intentional Misuse	Foreign Literature Health	Baclofen (Baclofen) Dipyrone (Metamizole Sodium) Oxybutynin	PS SS	Manufacturer	Route

SINGLE

			Laxatives (No Ingredients/Substanc es)	SS	ORAL
40 PILLS ONCE					012
SINGLE			Acetylsalicylic Acid (Acetylsalicylic		
3.3 G ONCE			Acid)	SS	
SINGLE			Defibrotide		
8.4 G ONCE			(Defibrotide)	С	
SINGLE					
Age:24 YR Gender:Male Outcome	r: 3867329-7Report Type:Exp = I/FU:F PT	Report Source	Product	Role Manufacturer	Route
Dose Duration Hospitalization - Initial or Prolonged 30 MG DAILY,	Bradycardia Drug Interaction	Foreign Health	Lioresal (Baclofen) Tablet	PS	ORAL
ORAL	Hypotension	Professional			
··	Hypotonia	Other			
	Malaise	Other	Sirdalud (Tizanidine Hydrochloride) Unknown	cc	ORAT,
12 MG DAILY,				SS	ORAL
12 MG DAILY, ORAL			Hydrochloride) Unknown	SS	ORAL
ORAL			Hydrochloride)	SS	ORAL
			Hydrochloride) Unknown Myolastan		-

Freedom Of Information (FOI) Report

Tablet SS

Voltarene Lp (Diclofenac Sodium) C

	ISR Number: ender:Male	3875557-XReport Type: I/FU:I	Periodic	Company Repor	t #2012150			
Outcome Dose D	Duration	PT	Report Se	ource	Product	Role	Manufacturer	Route
Death		Overdose	Health Professio Other	onal	Oxycodone Hydrochloride (Similar To Nda			
PO					20-553)	PS		ORAL
					Paroxetine	SS		ORAL
PO					Baclofen (Lioresal)	SS		
	ISR Number: ender:Male	3877776-5Report Type: I/FU:I	Periodic	Company Repor	t #2011912			
Age:46 YR Ge Outcome	ender:Male		Periodic (Report So		t #2011912 Product	Role	Manufacturer	Route
Age:46 YR Ge Outcome	ender:Male Duration	I/FU:I	Report So Health Professio	ource	Product Oxycontin Cr Tablets, 20 Mg	Role	Manufacturer	Route
Age:46 YR Ge Outcome Dose D	ender:Male Duration	I/FU:I PT	Report So Health Professio Company	ource onal	Product Oxycontin Cr Tablets, 20 Mg (Oxycodone		Manufacturer	
Age:46 YR Ge Outcome Dose D Death	ender:Male Duration	I/FU:I PT	Report So Health Professio	ource onal	Product Oxycontin Cr Tablets, 20 Mg	Role PS	Manufacturer	Route ORAL
Age:46 YR Ge Outcome Dose D	ender:Male Duration	I/FU:I PT	Report So Health Professio Company	ource onal	Product Oxycontin Cr Tablets, 20 Mg (Oxycodone Hydrochloride) Oxycontin Cr Tablets, 40 Mg		Manufacturer	
Age:46 YR Ge Outcome Dose D Death	ender:Male Duration	I/FU:I PT	Report So Health Professio Company	ource onal	Product Oxycontin Cr Tablets, 20 Mg (Oxycodone Hydrochloride) Oxycontin Cr		Manufacturer	
Age:46 YR Ge Outcome Dose D Death 20 MG BID PO	ender:Male Duration	I/FU:I PT	Report So Health Professio Company	ource onal	Product Oxycontin Cr Tablets, 20 Mg (Oxycodone Hydrochloride) Oxycontin Cr Tablets, 40 Mg (Oxycodone	PS	Manufacturer	ORAL

Date:02/19/02ISR Number: 3871971-7Report Type:Expedited (15-DaCompany Report #PHFR2002GB00742 Age:65 YR Gender:Female I/FU:I

1 G DAILY

Outcome	PT	Report Source	Product	Role Manufacturer	Route
Dose	Duration				

Other	Depressed Level Of	Foreign	Baclofen (Baclofen)		
	Consciousness	Health	Unknown	PS	ORAL
10 MG/DAY,					
	Hyperreflexia	Professional			
ORAL					
	Muscle Spasticity	Other	Gabapentin		
			(Gabapentin)	C	
			Tramadol (Tramadol)	C	
			Lisinopril		
l de la constante de la consta			(Lisinopril)	C	
			Ciprofloxacin		
			(Ciprofloxacin)	C	
Date:02/19/02ISR Numbe	er: 3872784-2Report Type:Ex	pedited (15-DaCompany Re	eport #20020950		
Age: Gender:Mal	.e I/FU:I				
Outcome	PT	Report Source	Product	Role Manufacturer	Route
Dose Duration					
Hospitalization -	Muscle Spasticity	Health	Lioresal		
Initial or Prolonged	Myalgia	Professional	Intrathecal	PS	
INTRATHECAL DAILY	· ,				
	Nausea				
INTRATHECAL					
	Syncope				

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 Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Death		Aortic Valve Stenosis Bronchitis Cerebral Ischaemia Cheyne-Stokes Respiration Hypotension Pyrexia Respiratory Tract Infection Somnolence	Foreign Health Professional Other	Lioresal (Baclofen) Tramadol Lorazepam Naproxen	PS C C C		ORAL
	2ISR Number Gender:Male	: 3875806-8Report Type:Expedit I/FU:I	ed (15-DaCompany Repor	t #PHFR2002GB00809			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalizat 2.5 MG/DAY,		Body Temperature	Foreign	Baclofen (Baclofen)	PS		ORAL
Initial or P ORAL	rolonged	Decreased	Health				
		Bradycardia Depressed Level Of Consciousness Hypotonia Somnolence	Professional Other				
	2ISR Number Gender:Fema	: 3890069-5Report Type:Periodi le I/FU:I	c Company Repor	rt #001-0945-M0100980			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other		Dry Mouth Libido Decreased Oedema Peripheral Overdose Pain Weight Increased	Consumer	Neurontin (Gabapentin) Baclofen Acetylsalicylic Acid, Caffeine Anhdyrous,	PS SS		

Chemotherapeutic Agent C

	2ISR Number Gender:Fema	: 3880297-7Report Type:Expedite le I/FU:I	ed (15-DaCompany Report	E #PHBS2002AU02650		
Outcome Dose	Duration	PT	Report Source	Product	Role Manufacturer	Route
Death ORAL		Completed Suicide	Foreign	Lioresal(Baclofen)	PS	ORAL
		Depression	Health Professional Other			
	2ISR Number Gender:Fema	: 3882125-2Report Type:Direct le I/FU:I	Company Report	t #CTU 163293		
Outcome Dose	Duration	PT	Report Source	Product	Role Manufacturer	Route
Other 10MG PO BID	Duración	Hallucination		Baclofen	PS	ORAL
75MCG Q 72H		Mental Status Changes		Duragesic Patch	SS	

FDA - Adverse Event Reporting System (AERS) Freedom Of Information (FOI) Report Date:03/12/02ISR Number: 3882919-3Report Type:Expedited (15-DaCompany Report #PHBS2002JP03106 Aqe:60 YR Gender:Female I/FU:I Role Manufacturer PTReport Source Product Route Duration Hospitalization -Eosinophilia Foreign Lioresal (Baclofen) Initial or Prolonged Lung Infiltration Health PS ORAL Tablet 1 TABLET/D, Pneumonia Professional Selegiline Other Hydrochloride С Herbal Extracts С Date:03/12/02ISR Number: 3882921-1Report Type:Expedited (15-DaCompany Report #PHRM2002FR00857 Age:52 YR Gender:Male I/FU:I Role Manufacturer PTReport Source Product Route Duration Amaurosis Fugax Foreign Lioresal Intrathecal Retinal Vein Thrombosis Health (Baclofen) Solution Professional For Injection PS INTRATHECAL 50 UG, Other ONCE/SINGLE, INTRATHECAL

Outcome

Dose

ORAL

Outcome

Dose

Other

Date:03/14/02ISR Number: 3886768-1Report Type:Periodic Company Report #2002087109US Age:42 YR Gender:Female I/FU:I Role Manufacturer Outcome PTReport Source Product Route Dose Duration Hospitalization -Health Solu-Medrol(Methylpr Delusion Initial or Prolonged Disorientation Professional ednisolone)Powder, Hallucination Sterile PS INTRAVENOUS IV Psychotic Disorder Baclofen SS Klonopin (Clonazepam) SS

Age: Gender:M	ale I/FU:I					
Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duratio						
Life-Threatening	Coma	Health	Lioresal			
Hospitalization -	Medication Error	Professional	Intrathecal(Baclofen			
Initial or Prolonged			Injection)	PS		
INTRATHECAL 100	MCG,					
Required						
DAILY,						
Intervention to						
INTRATHECAL						
Prevent Permanent						
Impairment/Damage						
Date:03/20/02ISR Num	ber: 3886160-XReport Type:F	Expedited (15-DaCompany R	eport #PHFR2002GB00491			
Age:73 YR Gender:M Outcome	ale I/FU:I	Expedited (15-DaCompany Ro Report Source	eport #PHFR2002GB00491 Product	Role	Manufacturer	Route
Age:73 YR Gender:M Outcome Dose Duratic	ale I/FU:I PT n	Report Source	Product	Role	Manufacturer	Route
Age:73 YR Gender:M Outcome	ale I/FU:I	Report Source Foreign	- Product Lioresal (Baclofen)		Manufacturer	Route
Age:73 YR Gender:M Outcome Dose Duratic Other	ale I/FU:I PT n	Report Source	Product	Role PS	Manufacturer	Route
Age:73 YR Gender:M Outcome Dose Duratic	ale I/FU:I PT n	Report Source Foreign Health	Product Lioresal (Baclofen) Tablet		Manufacturer	Route
Age:73 YR Gender:M Outcome Dose Duratic Other	ale I/FU:I PT n	Report Source Foreign Health Professional	Product Lioresal (Baclofen) Tablet Ranitidine	PS	Manufacturer	Route
Age:73 YR Gender:M Outcome Dose Duratic Other	ale I/FU:I PT n	Report Source Foreign Health	Product Lioresal (Baclofen) Tablet Ranitidine (Ranitidine)		Manufacturer	Route
Age:73 YR Gender:M Outcome Dose Duratic Other	ale I/FU:I PT n	Report Source Foreign Health Professional	Product Lioresal (Baclofen) Tablet Ranitidine (Ranitidine) Laxatives (No	PS	Manufacturer	Route
Age:73 YR Gender:M Outcome Dose Duratic Other	ale I/FU:I PT n	Report Source Foreign Health Professional	Product Lioresal (Baclofen) Tablet Ranitidine (Ranitidine) Laxatives (No Ingredients /	PS C	Manufacturer	Route
Age:73 YR Gender:M Outcome Dose Duratic Other	ale I/FU:I PT n	Report Source Foreign Health Professional	Product Lioresal (Baclofen) Tablet Ranitidine (Ranitidine) Laxatives (No Ingredients / Substances)	PS	Manufacturer	Route
Age:73 YR Gender:M Outcome Dose Duratic Other	ale I/FU:I PT n	Report Source Foreign Health Professional	Product Lioresal (Baclofen) Tablet Ranitidine (Ranitidine) Laxatives (No Ingredients / Substances) Bendrofluazide	PS C	Manufacturer	Route
Age:73 YR Gender:M Outcome Dose Duratic Other	ale I/FU:I PT n	Report Source Foreign Health Professional	Product Lioresal (Baclofen) Tablet Ranitidine (Ranitidine) Laxatives (No Ingredients / Substances)	PS C	Manufacturer	Route

Freedom Of Information (FOI) Report

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	Lioresal (Baclofen)			
			Health	Unknown	PS		
10 MG, TID,							
			Professional	Antiepileptics (No			
			Other	Ingredients /			
				Substances)	С		

Date:03/20/02ISR Number: 3886170-2Report Type:Expedited (15-DaCompany Report #PHBS2002AU02650 Age:47 YR Gender:Female I/FU:F

Outcome Dose	Duration	PT	Report Source	Product	Role Manufacturer	Route
Death	2 42 4 0 2 0 1	Completed Suicide Major Depression	Foreign Health	Lioresal (Baclofen) Tablet	PS	ORAL
20 MG/DAY,			Professional			
ORAL			Other	Cipramil	с	

Date:03/28/02ISR Number: 3890215-3Report Type:Expedited (15-DaCompany Report #309913 Aqe:69 YR Gender:Female I/FU:I

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Life-Threatening	ening	Coma		Rivotril	PS	Roche	
		Confusional State		Temesta	SS		
		Dyskinesia		Lioresal	SS		
		Hallucination					
		Medication Error					
		Memory Impairment					

	Number: er:Male	3891135-0Report Type:Perio I/FU:F	dic Company Re	eport #CIP00001154			
Outcome Dose Dur	ation	PT	Report Source	Product	Role	Manufacturer	Route
		Clonic Convulsion Cognitive Deterioration Condition Aggravated	Health Professional	Dantrium (Dantrolene Sodium) Capsule, Unknownmg	PS		ORAL
50 MG 3 TIMES				Ulikilowillig	гIJ		UKAL
DAILY; 25 MG		Confusional State					
3 TIMES		Drug Interaction					
DAILY; 30 MG		Dysarthria					
3 TIMES		Medication Error					
		Memory Impairment Muscle Spasms		Baclofen (Baclofen) Tablet	SS		ORAL
30 MG 3 TIMES		Somnolence					
DAILY, ORAL;		Speech Disorder					
20 MG 3 TIMES		Specon Diboraci					
DAILY				Norvasc (Amlodipine			
				Besilate) Norpramin	С		
				(Desipramine Hydrochloride)	С		

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	D	PT	Report Source	Product	Role Manufacturer	Route
Dose	Duration					
Life-Threaten	ing	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	INTRAVE	ENOUS				
		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 50.00 MG		Anorgasmia	Consumer	Viagra Tablets	PS	ORAL
Intervention TOTAL:PRN:OR		Ejaculation Failure				
Prevent Perm L	anent	Erectile Dysfunction				
Impairment/D 300.00 MG	Impairment/Damage	Hypoaesthesia		Doxepin	SS	
		Medication Error				
TOTAL						
		Overdose		Hydroxyzine	SS	
		Penis Disorder		Baclofen	SS	
		Priapism		Seroquel	С	
				Chloral Hydrate	С	
				Remeron	С	

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						
Hospitalizati	.on –	Asthenia	Foreign	Baclofen (Baclofen)			

Initial or Prolonged	Fear	Literature	Unknown	PS		
10 MG, BID Other	Loss Of Consciousness Nausea Poisoning Vomiting	Health Professional Other				
Date:04/08/02ISR Numbe Age:69 YR Gender:Fer	er: 3895870-XReport Type:Expe male I/FU:F	edited (15-DaCompany R^{i}	≥port #309913			
Outcome Dose Duration	PT	Report Source	Product	Role Manu	ufacturer	Route
Life-Threatening	Coma Confusional State Dyskinesia Hallucination Memory Impairment		Rivotril Temesta Lioresal	PS Roch SS SS	ne	
Date:04/08/02ISR Numbe Age:69 YR Gender:Fer Outcome Dose Duration	PT	pedited (15-DaCompany Re Report Source	eport #FR8947603APR2002 Product	Role Manu	ufacturer	Route
Dose Duration Life-Threatening ORAL	Coma Confusional State	Health Professional	Temesta (Lorazepam, Unspec, 0)	PS		ORAL
-	Hallucination OSE 50 Memory Impairment	Other	Lioresal (Baclofen)	SS		
DAY,	Muscle Contractions Involuntary					
INTRAVENOUS	1		Rivotril			
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Freedom Of Information (FOI) Report

5 DOSES

DAILY, ORAL

Age:69 YR Gender:Fen					
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 DOS					
	Medication Error				
TIMES PER DAY					
1	Memory Impairment		Rivotril		
1	Muscle Contractions		(Clonazepam)	SS	ORAL
5 DOSES DAILY					
1	Involuntary		Astrocytoma	C	
Date:04/10/02ISR Numbe Age:69 YR Gender:Fen	er: 3898469-4Report Type:Ex male I/FU:F	pedited (15-DaCompany Re	eport #309913		
		pedited (15-DaCompany Re Report Source	eport #309913 Product	Role Manufacturer	Route
Age:69 YR Gender:Fen	nale I/FU:F		-	Role Manufacturer	Route
Age:69 YR Gender:Fen Outcome	nale I/FU:F		-	Role Manufacturer	Route
Age:69 YR Gender:Fen Outcome Dose Duration	nale I/FU:F PT	Report Source	Product Rivotril	Role Manufacturer PS	Route ORAL
Age:69 YR Gender:Fen Outcome Dose Duration	nale I/FU:F PT Coma	Report Source Foreign	Product		
Age:69 YR Gender:Fen Outcome Dose Duration Life-Threatening	nale I/FU:F PT Coma Confusional State	Report Source Foreign	Product Rivotril		
Age:69 YR Gender:Fen Outcome Dose Duration Life-Threatening	nale I/FU:F PT Coma	Report Source Foreign	Product Rivotril		
Age:69 YR Gender:Fem Outcome Dose Duration Life-Threatening 5 UNIT DAILY	nale I/FU:F PT Coma Confusional State	Report Source Foreign	Product Rivotril		
Age:69 YR Gender:Fem Outcome Dose Duration Life-Threatening 5 UNIT DAILY	nale I/FU:F PT Coma Confusional State Dyskinesia	Report Source Foreign	Product Rivotril (Clonazepam)	PS	ORAL
Age:69 YR Gender:Fem Outcome Dose Duration Life-Threatening 5 UNIT DAILY ORAL	nale I/FU:F PT Coma Confusional State Dyskinesia	Report Source Foreign	Product Rivotril (Clonazepam)	PS	ORAL
Age:69 YR Gender:Fen Outcome Dose Duration Life-Threatening 5 UNIT DAILY ORAL ORAL	nale I/FU:F PT Coma Confusional State Dyskinesia Hallucination	Report Source Foreign	Product Rivotril (Clonazepam) Temesta (Lorazepam)	PS SS	ORAL

Memory Impairment

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Unevaluable Event	Foreign	Lioresal(R)			
Initial or Prolonged		Health	Intrathecal			
		Professional	(Baclofen Injection)	PS		
INTRATHECAL 100 M	ICG ONCE					
INTRATHECAL						
Date:04/15/02ISR Numbe Age:50 YR Gender:Mal	er: 3901520-6Report Type:Expe e I/FU:F	edited (15-DaCompany Ro	eport #A206119			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Required	Drug Effect Decreased	Consumer	Viagra Tablets	PS		ORAL
50.00 MG						
Intervention to	Ejaculation Disorder					
TOTAL:PRN:ORA						
Prevent Permanent	Erectile Dysfunction					
	_ ' '			~~		
Impairment/Damage 300.00 MG	Priapism		Doxepin	SS		
TOTAL						
			Hydroxyzine	SS		
			Baclofen	SS		
			Seroquel	С		
			Chloral Hydrate	С		
			Remeron (Subject			
			Drug)	С		
			-			

Date:04/16/02ISR Number: 3902278-7Report Type:Expedited (15-DaCompany Report #PHBS2002CL04226 Age:57 YR Gender:Male I/FU:I

OutcomePTOtherPulmonary Fibrosis

Report Source Foreign Consumer

Freedom Of Information (FOI) Report

		Other				
			Product	Role	Manufacturer	Route
Dose Duration			Lioresal(Baclofen) Tablet	PS		ORAL
SEE IMAGE 1095 DAY			Enalapril			0
			(Enalapril) Diazepam	C C		
Date:04/22/02ISR Number Age:69 YR Gender:Fema	r: 3903758-0Report Type:Expedit ale I/FU:F	ted (15-DaCompany Repor	t #309913			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration Life-Threatening	Coma		Rivotril	PS	Roche	I
	Confusional State Dyskinesia Hallucination Memory Impairment		Temesta Lioresal	SS SS		
Age:69 YR Gender:Fema Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Life-Threatening	Coma Confusional State	Foreign Other	Rivotril (Clonazepam)	PS		ORAL
5 UNIT DAILY	Dyskinesia					
ORAL	Hallucination		Temesta (Lorazepam)	SS		ORAL
INTRADISCAL	Memory Impairment		Lioresal (Baclofen)	SS		
(INTRASPINAL) 1 DOSE	C FORM 1					
per 50 day						
INTRADISCAL						

Date:04/26/02ISR Number: 3908528-5Report Type:Expedited (15-DaCompany Report #PHBS2002PL03764 Age:29 YR Gender:Female I/FU:F

Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - 10 MG, BID	Accommodation Disorder	Foreign	Baclofen(Baclofen)	PS		
Initial or Prolonged	Anxiety Asthenia Coma Dyspnoea Fear Hypoaesthesia Hypotonia Loss Of Consciousness Nausea Salivary Hypersecretion Somnolence Therapeutic Agent Toxicity Vomiting	Literature Health Professional Other				

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 Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalizat ORAL		Chromaturia	Consumer	Baclofen Tablets	PS	Ipi	ORAL
Initial or P Other	rolonged	Diabetes Mellitus Fatigue Hepatitis Hepatocellular Damage Liver Function Test Abnormal Pancreatic Disorder Pyrexia Swelling Weight Decreased		Bumex Ditropan Xl	C C		
	2ISR Number Gender:Fema	: 3912537-XReport Type:Expedite le I/FU:I PT	ed (15-DaCompany Report Report Source	2 #20021028 Product	Role	Manufacturer	Route
Dose	Duration		-		11010		
Required Intervention INTRATHECAL Prevent Perm INTRATHECAL Impairment/D	MCG, D. anent	Drug Withdrawal Syndrome AILY ,	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		
	2ISR Number Gender:Fema	: 3916451-5Report Type:Direct le I/FU:I	Company Report	: #CTU 167997			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalizat Initial or P	ion -	Hypersensitivity		Zanaflex Baclofen	PS SS		

Outcome	PT	Report Source	Product	Role Manufacturer	Route
	ation				
Hospitalization -		Foreign	Lioresal(Baclofen)		
Initial or Prolor 10 MG, QD,			Tablet	PS	ORAL
	Disorders	Professional			
ORAL		_			
	Hypotonia	Other	Neurontin		
	Multiple Sclerosis		(Gabapentin)	C	
	Relapse Nervous System Disord	er	Aldalix Capsule	С	
Age:52 YR Gende Outcome	Number: 3922404-3Report Type er:Male I/FU:F PT ation Amaurosis Fugax Hypotension Retinal Vein Thrombos 50 MG,	Report Source Foreign Health	Report #PHRM2002FR00857 Product Lioresal Intrathecal(Baclofer) Solution For Injection	Role Manufacturer	Route
ONCE/SINGLE,	,				
ONCE/ DINGLE,					
INTRATHECAL			Lioresal "Novartis"		
			(Baclofen) Tablet	SS	ORAL
75 MG/DAY,			(Bacioren) Tablet	66	UIAL
ORAL					
			Seropram(Citalopram		
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	FDA - Adverse Event Reporting System (AERS)	
	Freedom Of Information (FOI) Report	
20 MG/DAY,	Hydrovromide) Tablet SS	ORAL
ORAL 2 TABS/DAY,	Tardyferon(Ferrous Sulfate) Tablet SS	ORAL
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 Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - Initial or Prolonged	Angiogram Abnormal Angiogram Retina Abnormal Blindness	Literature	Mexiletine (Mexiletine Hydrochloride)	PS		ORAL
DAILY, PO						
	Conjunctival Hyperaemia Drug Toxicity		Clonidine (Clonidine)	SS		ORAL
PO						
	Eye Disorder		Morphine (Morphine)	SS		ORAL
PO	Fundoscopy Abnormal Maculopathy Retinogram Abnormal Retinopathy		Trazodine (Trazodine Hydrochloride) Pentosan Polysulfate (Pentosan Polysulfate) Gabapentin (Gabapentin) Lidocaine Hydrochloride (Lidocaine Hydrochloride)	SS SS SS		
INTRAVENOUS 385.	7 MG		nyaroenrorrae,	55		
(SINGLE DOSE						
INFUSION), IV						
DO			Baclofen (Baclofen)	SS		ORAL
PO			Methadone Hydrochloride (Methadone			

Hydrochloride)	SS
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

ORAL

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 -

Freedom Of Information (FOI) Report

Initial or Prolonged

		PT	Report Source	Product	Role	Manufacturer	Route
ose I	Duration						
		Aspiration Bronchial Blood Creatine	Foreign Health	Lioresal(Baclofen) Tablet, 25mg	PS		ORAL
000 MG,							
NCE/SINGLE,		Phosphokinase Increased	Professional				
RAL		Blood Creatine	Other				
JKAL		Phosphokinase Mb Coma Convulsion Intentional Misuse					
Age:38 YR Ge	ISR Number ender:Fema						-
Dutcome Dose I	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalizatio Initial or Pro		Blindness Retinal Degeneration Retinopathy Scotoma	Literature	Mexiletine (Mexiletine Hydrochloride) (Nr) (Mexiletine-Hcl)	PS		ORAL
20							
		Toxicologic Test Abnormal		Clonidine (Clonidine) (Nr) (Clonidine-Hcl)	SS		ORAL
20							
				Morphine (Morphine) (Nr) (Morphine-Hcl)	SS		ORAL
PO				Trazodone (Trazodone Hydrochloride) (Nr)			
				(Trazodone-Hcl) Pentosan Polysulfate	SS		
				(Pentosan Polysulfate) Gabapentin	SS		
				(Gabapentin) (Nr) Lidocaine Hydrochloride (Lidocaine	SS		

INTRAVENOUS	385.27 MG	Hydrochloride)	SS	
(SINGLE DOSE				
THERETON) TH				
INFUSION) IV		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	<u>aa</u>	
		Hydrochloride) Sucralfate	SS	
		(Sucralfate) (Nr)	SS	
		(Sucrarrate) (Nr)	66	

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 Dose Durati	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization -	Chromaturia	Consumer	Baclofen - Ipi			
Initial or Prolonge 10 MG ORAL	ed Diabetes Mellitus		Tablets	PS		ORAL
Other	Fatigue		Bumex	С		
	Gastrointestinal Disorder		Fluid Retention	С		ļ
	Hepatitis		Ditropan	С		ļ
	Hypertension Nasopharyngitis Pancreatic Disorder Pyrexia Swelling Urinary Tract Infection Weight Decreased		Cenestin	С		
Date:06/06/02ISR Nu Age: Gender: Outcome	umber: 3928907-XReport Type:Direct Male I/FU:I PT	Company Repo Report Source	ort #CTU 169646 Product	Role	Manufacturer	Route
Dose Durati	lon					
Hospitalization - INTRATHECAL 10	Agitation)OMCG/DAY		Baclofen	PS		
Initial or Prolonge CONTINOUS						
	Muscle Spasticity					
INTRATHECAL				a		ļ
	Pyrexia		Pediasure Mellaril	C C		ļ
			Albuterol	C		ļ
			Decadron	C		ļ
1			Mylicon	C		
1			Zyrtec	C		
1			Vancomycin	C		ļ
1			Aminophylline	C		
1			Tegretol	C		
1			Robanul	С		
1			Diamox	С		
1			Reglan	С		
1			Zantac	C		

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Durat:	-					
Hospitalization -	Eosinophilia	Foreign	Lioresal(Baclofen)			
Initial or Prolonge 5 MG/DAY,	ed Lung Infiltration	Health	Tablet	PS		ORAL
	Pneumonia	Professional				
ORAL						
		Other	Herbal Extracts Nos (No			
			Ingredients/Substanc			
			es)	SS		ORAL
ORAL						
			Selegilene			
			Hydrochloride	a		
			nyaroemioriae	С		
	umber: 3933087-0Report Type:E : I/FU:I	xpedited (15-DaCompany R	-	C		
Age:41 YR Gender	: I/FU:I	xpedited (15-DaCompany R	-	C		
Age:41 YR Gender Outcome	: I/FU:I PT		-	C		
Age:41 YR Gender Outcome	: I/FU:I PT Alanine Aminotransferas		-	C		
Age:41 YR Gender Outcome	: I/FU:I PT Alanine Aminotransferas Increased		-	C		
Date:06/12/02ISR Nu Age:41 YR Gender Outcome Other	: I/FU:I PT Alanine Aminotransferas		-	C		

Freedom Of Information (FOI) Report

		Aminotransferase Increased Gamma-Glutamyltransferase Increased	Report Source	Product	Role	Manufacturer	Route
Dose Du	ration				DO		0.0.0.1
10 MG, TID,			Foreign	Lioresal (Baclofen)	PS		ORAL
ORAL			Health				
			Professional Other				
	R Number: der:Femal	: 3933340-0Report Type:Expedit le I/FU:F	ed (15-DaCompany Repor	t #PHBS2002JP03106			
Outcome Dose Du	ration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization Initial or Prol 1 TABLET/D,	-	Eosinophilic Pneumonia Lung Infiltration	Foreign Health	Lioresal(Baclofen) Tablet	PS		ORAL
ORAL		Pneumonia	Professional				
			Other	Selegiline Hydrochloride (Selegiline Hydrochloride) Tablet	SS		ORAL
ORAL				Herbal Extracts Nos	22		01012
				(No Ingredients/Substanc			
ORAL				es)	SS		ORAL
Date:06/12/02IS Age:20 YR Gen		: 3933653-2Report Type:Expedit le I/FU:I	ed (15-DaCompany Repor	t #PHBS2002JP06406			
Outcome Dose Du	ration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization Initial or Prol 120 MG/D,	-	Hypercapnia	Foreign Health	Lioresal(Baclofen) Tablet	PS		ORAL
ORAL			Professional				

		Other	Phenobarbital(Phenob			
			arbital)	SS		ORAL
200 MG/D,						
ORAL						
			Depakene	С		
			Benzalin	C		
	· 2025505 ODerevet Tymo. Tymodi					
Age: Gender:Fema	: 3935686-9Report Type:Expedi le I/FU:I	ted (15-расотрану керо	prt #20021066			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization -	Medical Device	Health	Lioresal Intrathecal			
Initial or Prolonged INTRATHECAL UNK MC	Complication	Professional	(Baclofen Injection)	PS		
DAILY,						
INTRATHECAL						
Date:06/18/02ISR Number Age: Gender:Fema	: 3935689-4Report Type:Expedi le I/FU:I	ted (15-DaCompany Repo	ort #20021064			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration Hospitalization -	Csf Test Abnormal	Health	Lioresal Intrathecal			
Initial or Prolonged	CSI Test Abnormal Musculoskeletal Stiffness	Professional	(Baclofen Injection)	PS		
	, ONCE,	110100210101	(194010101111) ,	-~		
INTRATHECAL	Pain					
INIKAINECAL	Pyrexia					
	-					
00 7 000F 10.1F DM						

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		РТ	Report Source	Product	Polo	Manufacturer	Route
Dose	Duration		-		ROIE	Manuracturer	Route
Hospitalizat		Chromaturia	Health	Baclofen - Ipi			
Initial or F 10MG ORAL	rolonged	Dehydration	Professional	Tablets	PS	Ipi	ORAL
		Diabetes Mellitus		Bumex	С		
		Fatigue		Ditropan	С		
		Gastroenteritis		Cenestin	С		
		Hepatitis		Glucotrol Xl	С		
		Hepatocellular Damage		Quinine Sulfate	С		
		Hypertension					
		Inflammation					
		Muscle Spasms					
		Nasopharyngitis					
		Oedema					
		Pancreatic Disorder					
		Proteus Infection					
		Urinary Tract Infection					
		Weight Decreased					
	21SR Number Gender:Fema	r: 3940300-2Report Type:Exped ale I/FU:I	ited (15-DaCompany Re	port #PHNU2002DE01956			
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)	С		

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 -	Gastric Atony	Foreign	Lioresal Intrathecal			
Initial or Prolonged	Pancreatitis	Health	(Baclofen Injection)	PS		
INTRATHECAL 100 M	ACG,					

Professional

Required ONCE, Intervention to INTRATHECAL Prevent Permanent

Impairment/Damage

Sirdalud (Tizanidine 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	D	PT	Report Source	Product	Role Manufacturer	Route
Dose Death	Duration	Adrenoleukodystrophy Completed Suicide	Foreign Health	Lioresal(Baclofen) Tablet	PS	ORAL
10 MG, BID,		Depression	Professional			-
ORAL		Depression	TIOLOSSIONAL			
		Drug Toxicity Pulmonary Oedema Thyroid Disorder Toxicologic Test Abnormal	Other	Cipramil	C	

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 Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - Initial or Prolonged	Dehydration Grand Mal Convulsion	Foreign Health Professional	Dantrium (Dantrolene Sodium) Capsule, Unknown	PS		ORAL
150 MG DAILY,		Other				
ORAL		Other				
			Baclofen (Baclofen)	~~		0.5.3.5
60 MG DAILY,			Unknown, Unknown	SS		ORAL
ORAL						
			Tetrahydrocannabinol (Tetrahydrocannabino			
			l) Capsule, Unknown	SS		ORAL
8 DF DAILY,						

ORAL

	2ISR Number: Gender:Male	3945815-9Report Type:Direct I/FU:I		Company Report	: #CTU 171775			
Outcome Dose	Duration	PT	Report	Source	Product	Role	Manufacturer	Route
Disability		Drug Effect Decreased Drug Withdrawal Syndrome			Baclofen 10 Mg Watson	PS	Watson	ORAL
50 MG DAILY		Pharmaceutical Product						
ORAL		Complaint			Crixivan	С		
		00mp_20220			Combivir Albuterol	C C		
					Fosamax Nephrocaps	C C		

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged INTRATHECAL DAILY, Required INTRATHECAL Intervention to Prevent Permanent Impairment/Damage	Drug Ineffective Muscle Spasms	Health Professional	Lioresal Intrathecal (Baclofen Injection)	ΡS		
	: 3953478-1Report Type:Expe	dited (15-DaCompany P	Prost #2002111159CP			
Age:14 YR Gender:Fema		arred (15-Dacompany Re	eport #200211138GB			
Outcome Dose Duration	РТ	Report Source	Product	Role	Manufacturer	Route
Other	Anxiety	Foreign Health Professional	Cyklokapron (Tranexamic Acid) Solution, Sterile	PS		ORAL
ORAL		PIOLESSIONAL	Baclofen	SS		ORAL
			Mefenamic Acid	C		
Date:07/25/02ISR Number Age:72 YR Gender:Male	r: 3954880-4Report Type:Expe e I/FU:I	edited (15-DaCompany Re	eport #PHBS2002IT08366			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - 37.5 MG/DAY,	Drug Hypersensitivity	Foreign	Lioresal(Baclofen)	PS		ORAL
Initial or Prolonged ORAL	Generalised Erythema	Health				
7.5 MG/DAY,		Professional	Ditropan(Oxybutynin)	SS		ORAL
ORAL		Other				
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Freedom Of Information (FOI) Report

ORAL	Rivotril(Clonazepam)	SS	ORAL
	Omnic (Tamsulosin Hydrochloride)	SS	ORAL
OD N I			

ORAL

Date:08,	/01/0	02ISR Number:	3957636-1Report	Type:Expedited	(15-DaCompany	Report	#PHBS2002JP06406	
Age:20 Y	YR	Gender:Female	e I/FU:F					

Outcome Dose Duration	PT	Report Source	Product	Role Manufacturer	Route
Hospitalization - Initial or Prolonged	Convulsion Disease Recurrence	Foreign Health	Lioresal (Baclofen) Tablet	PS	ORAL
SEE IMAGE	Drug Level Changed Hypercapnia	Professional Other	Phenobarbital (Phenobarbital)	SS	ORAL
SEE IMAGE			· · ·		
	Pyrexia		Depakene	С	
	Respiratory Failure		Benzalin	C	
			Piracetam	C	
			Lactic Acid (Lactic		
			Acid)	C	
			Ambroxol		
			Hydrochloride		
			(Ambroxol		
			Hydrochloride)	С	

Date:08/01/02ISR Number: 3958288-7Report Type:Expedited (15-DaCompany Report #PHNU2002DE02465 Age: Gender:Female I/FU:I

Outcome Dose I	Duration	РТ	Report Source	Product	Role	Manufacturer	Route
Other	Duración	Oedema Peripheral	Health	Lioresal(Baclofen) Unknown Ribif (Interferon	PS		
			Other	Beta)	SS		

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose D	uration						
Other		Psychotic Disorder	Foreign	Baclofen(Baclofen)			
			Health	Unknown	PS		ORAL
180 MG, QD,							
0.5.1.5			Professional				
ORAL			0+h-m				
			Other				
Date:08/06/02T	SR Number	: 3959397-9Report Type:Expedi	ed (15-DaCompany Repor	+ #PHNU2002DE01956			
	nder:Femal		ted (15 bacompany nepor	. c #1111020020101930			
		10 1,101					
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose D	uration						
Other		Hypokalaemia	Foreign	Lioresal			
			Health	(Baclofen)	PS	Novartis	ORAL
2.5 MG, QID,							
			Professional				
ORAL; REGIMEN							
			Other				
2-8, SEE							
IMAGE					~		
				Topamax (Topiramate)	C		
					С		

FDA - Adverse Event Reporting System (AERS) Freedom Of Information (FOI) Report Date:08/14/02ISR Number: 3962179-5Report Type:Direct Company Report #CTU 174064 Gender:Female Age: I/FU:I Outcome PTReport Source Product Role Manufacturer Route Dose Duration Hospitalization -Coma Baclofen For Initial or Prolonged Intrathecal Use 6000 Hypotonia Required Medication Error Micrograms/Ml Muscle Spasticity Compound By Priorty Intervention to Prevent Permanent One PS Compound By Priorty Impairment/Damage One 1260 MCG/D INTRATHECAL INTRATHEAL Valium С Flagyl С Date:08/20/02ISR Number: 3965671-2Report Type:Expedited (15-DaCompany Report #20021138 Gender:Female Age: I/FU:I Outcome PTReport Source Product Role Manufacturer Route Dose Duration Drug Withdrawal Syndrome Lioresal Intrathecal Hospitalization -Health Initial or Prolonged Medical Device Professional (Baclofen Injection) PS INTRATHECAL MCG, DAILY, Complication INTRATHECAL Pharmaceutical Product Complaint Date:08/21/02ISR Number: 3966609-4Report Type:Expedited (15-DaCompany Report #PHNU2002DE02752 Gender:Female Aqe:65 YR I/FU:I Role Manufacturer Outcome PTReport Source Product Route Dose Duration Hospitalization -Accidental Overdose Foreign Lioresal (Baclofen) Initial or Prolonged Fatigue Health Tablet PS SEE IMAGE Hypertension Professional Other

Date:08/21/02ISR Numbe Age:59 YR Gender:Mal		Expedited (15-DaCompany Re	eport #PHBS2002BR09516			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other	Anorexia Paralysis	Foreign Consumer	Lioresal (Baclofen) Tablet	PS		ORAL
SEE IMAGE						-
	Vomiting	Other				
Date:09/03/02ISR Numbe Age:72 YR Gender:Fem Outcome		Expedited (15-DaCompany Re Report Source	port #WAES 0208CHE00033 Product	Role	Manufacturer	Route
Dose Duration	E 1	Report Dearee	1104400	1.010	Manuracearer	100400
Hospitalization -	Hypertension	Health	Vioxx	PS	Merck & Co., Inc	ORAL
Initial or Prolonged 3 DAY	Stupor	Professional	Baclofen	SS		ORAL
			Deflazacort	SS		ORAL
			Acetaminophen	С		ORAL
			Amlodipine Besylate	C		ORAL
			Aspirin	C		ORAL
			Indapamide	С		ORAL
			Calcium			
			(Unspecified) And Vitamin D			
			(Unspecified)	С		ORAL
			(onspectived) Cozaar	C		ORAL ORAL
			Hydrochlorothiazide	C		OITAL

Freedom Of Information (FOI) Report

And Losartan		
Potassium	C	ORAL

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Other		Burning Sensation	Health	Lioresal 2000 Mcg/Ml			
		Feeling Cold Hypoaesthesia	Professional	Intratheca (Baclofen Injectino)	PS		
INTRATHECAI	L 580 M			IIIJeccillo)	PS		
		Muscle Spasticity					
DAILY,							
INTRATHECAI							
Age:41 YR	02ISR Number Gender:Male			-			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitaliza		Leukopenia		Rivotril	PS	Roche	
8 DAY		-					
Initial or	Prolonged	Overdose		Deroxat	SS		
8 DAY		Renal Failure Acute		Methotrexate	SS		
DAILY.	8 DAY			Methotrexate	22		
		Thrombocytopenia		Lioresal	SS		
8 DAY				NT			
8 DAY				Neurontin	SS		
				Topalgic	SS		
8 DAY				Xanax	С		
				nallan			
Date:09/05/	02ISR Number	r: 3972264-XReport Type:Exp	pedited (15-DaCompany Re	eport #PHBS2002IT10106			
Age:52 YR	Gender:Male		· · · ·				
Outcome		PT	Report Source	Product	Polo	Manufacturer	Route

Hospitalization -	Erythema	Foreign	Lioresal (Baclofen)	PS	ORAL
75 MG/DAY Initial or Prolonged ORAL		Health			
		Professional Other	Ditropan (Oxybutynin)	SS	ORAL
7.5 MG/DAY,					
ORAL			Rivotril		
15 DROPS/DAY			(Clonazepam) Drops	SS	ORAL
ORAL					
URAL			Omnic (Tamsulosin Hydrochloride)	С	
					ļ
Date:09/05/02ISR Number Age: Gender:Fema	r: 3972269-9Report Type:Expe ale I/FU:I	edited (15-DaCompany Re	≥port #PHBS2002CH10098		
Outcome Dose Duration	PT	Report Source	Product	Role Manufacturer	Route
Dose Duration Hospitalization - 75 MG/DAY,	Hypertensive Crisis	Foreign	Lioresal (Baclofen)	PS	ORAL
Initial or Prolonged ORAL	Stupor	Health			
25		Professional	Vioxx (Rofecoxib)	SS	ORAL
		Other			
MG/DAY,ORAL			Calcort (Deflazacort)	SS	ORAL
15 MG/DAY,			(Dellalacele,	55	·
ORAL					
			Dafalgan (Paracetamol) Norvasc Aspirine Fludex (Indapamide) Calcimagon-D3 Cosaar (Losartan	C C C C	
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Freedom Of Information (FOI) Report

Potassium)	С			
Losartan Potassium				
W/Hydrochlorothiazid				
e (Losartan				
Potassium)	С			

Route

Date:09/05/02ISR Num Age:31 YR Gender:Ma		Type:Expedited (15-DaCompany	Report #PHNU2002DE02854	Ł	
Outcome	PT	Report Source	Product	Role	Manufacturer

Other 25 MG, TID,	Duration	Cholelithiasis	Foreign	Lioresal (Baclofen)	PS	ORAL
		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 Dose Duration	PT	Report Source	Product	Role Manufacturer	Route
Hospitalization - Initial or Prolonged 25 MG, BID,	Accidental Overdose Apathy	Foreign Health	Lioresal (Baclofen) Tablet	PS	ORAL
ORAL	Bradycardia	Professional			
	Clonic Convulsion Fatigue Medication Error	Other	Lioresal "Novartis" Tablet Botox (Botulinum Toxin Type A)	C C	

Date:09/05/02ISR Number: 3972283-3Report Type:Expedited (15-DaCompany Report #PHBS2002JP06406 Age:20 YR Gender:Female I/FU:F

Outcome		РТ	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Hospitalization - Initial or Prolonged SEE IMAGE		Pyrexia ged Respiratory Failure	Foreign Health	Lioresal (Baclofen) Tablet			ORAL
DEE IMAGE			Professional	Phenobarbital			

	Other	(Phenobarbital)	SS	ORAL
SEE IMAGE				
		Depakene	С	
		Benzalin	С	
		Lactic Acid (Lactic		
		Acid)	С	
		Ambroxol		
		Hydrochloride		
		(Ambroxol		
		Hydrochloride)	С	
		-		

Date:09/05/02ISR Number: 3972659-4Report Type:Expedited (15-DaCompany Report #PHBS2002JP08298 Age:73 YR Gender:Male I/FU:I

Outcome Dose Duration	PT	Report Source	Product	Role Manufacturer	Route
Life-Threatening	Drug Level Increased Loss Of Consciousness	Foreign Health	Lioresal (Baclofen) Tablet	PS	ORAL
10 то 20					
		Professional			
MG/DAY ORAL					
		Other	Primperan		
			(Metoclopramide)	С	
			Calcium Carbonate		
			Tablet	C	
			Pantosin		
			(Panthethine)	С	
			Nitorol Tablet	C	

Freedom Of Information (FOI) Report

Lasix	С		
Methycobal			
(Mecobalamin) Tablet	С		
Erispan			
(Fludiazepam) Tablet	С		
Halcion (Triazolam)			

Date:09	9/06/	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							
Hospitalizati	lon –		Leukopenia	Consumer	Rivotril	PS	Roche	
8 DAY Initial or Pi	rolonged		Overdose		Deroxat	SS		
8 DAY	orongeu		Overdose		Deroxat	55		
			Renal Failure Acute		Methotrexate	SS		
DAILY.	8 1	DAY						
0 531			Thrombocytopenia		Lioresal	SS		
8 DAY					Neurontin	SS		
8 DAY								
0 534					Topalgic (Tramadol)	SS		
8 DAY					Xanax	С		

Date:09/09/02ISR Number: 3973743-1Report Type:Expedited (15-DaCompany Report #20021156 Age: Gender:Female I/FU:I

Outcome Dose	Duration	РТ		Report Source	Product	Role	Manufacturer	Route
Death	Duración	Accidental	Overdose	Other	Lioresal? Intrathecal (Baclofen Injection)	PS		
INTRATHECAL	MCG, D	DAILY,						

INTRATHECAL

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Condition Aggravated	Health	Lioresal?			
Initial or Prolonged	Drug Withdrawal Syndrome	Professional	Intrathecal			
	Incoherent		(Baclofen Injection)	PS		
INTRATHECAL MCG, 1	DAILY,					
	Medical Device					
INTRATHECAL						
	Complication					
	Muscle Spasticity					
	Pyrexia					
Date:09/09/02ISR Number	r: 3973862-XReport Type:Exped	ited (15-DaCompany Re	eport #2002054640			
Age:77 YR Gender:Male		ited (is bacompany ite	2002051010			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Arrhythmia	Foreign	Norvasc (Amlodipine)	PS		ORAL
10 MG (BID),						
Initial or Prolonged	Atrial Fibrillation	Health				
ORAL						
Other	Cardiac Disorder	Professional	Carbamazepine			
	Dizziness	Other	(Carbamazepine)	SS		ORAL
600 MG (BID),						
	Drug Interaction					
ORAL						
	Drug Level Above		Lioresal (Baclofen)	SS		ORAL
25 MG			((
	Therapeutic					
(DAILY), ORAL						
,,	Drug Toxicity		Digitoxin	С		
	Vomiting		Ferroglycine Sulfate	~		
			Complex	С		
			Furosemide	C		
			Karvea Hct	C		
			Glibenclamide	C		
			GIIDENCIAIIIIGE	C		
			GTIDENCIUMITUE			

Freedom Of Information (FOI) Report

Pantoprazole Sodiu	m C
Budesonide	С
Oxitropium Bromide	С

Date:09/11/02ISR Number: 3974286-1Report Type:Expedited (15-DaCompany Report #PHNU2002DE02963 Age:77 YR Gender:Male I/FU:I

Dose Duration Hospitalization - Atrial D 25 MG, QD, Initial or Prolonged Blood P: ORAL	Flutter ressure Systolic	Foreign Study	Lioresal (Baclofen)	PS	ORAL
Initial or Prolonged Blood P:	ressure Systolic	Study			0.010
OKAL					
Increase Dizzine:	SS	Professional	Carbamazepine Azu(Carbamazepine)		0.0.0.1
300 MG, BID,	teraction	Other	200 Mg	SS	ORAL
Drug To: ORAL	CICILY				
Nausea Vertigo			Norvasc(Amlodipine Besilate)	SS	
5MG, BID,ORAL			Digitoxin Ferro "Sanol" (Ferroglycine	С	
			Sulfate Complex) Furorese	C C	
			Karvezide(Irbesartan	-	
) Maninil	C	
			"Berlin-Chemie" Pantozol (Pantoprazole	С	
			Sodium)	С	
			Pulmicort Ventilat (Oxitropium	C	
			Bromide)	С	
			Oxcarbazepine	С	

Outcome		РТ	Report Source	Product	Role Manufacturer	Route
Dose	Duration					
Life-Threate	ening	Depressed Level Of	Foreign	Lioresal (Baclofen)		
		Consciousness	Health	Tablet	PS	ORAL
10 TO 20						
		Drug Level Increased	Professional			
MG/DAY, ORAI	J					
			Other	Primperan		
				(Metoclopramide)	C	
				Calcium Carbonate	C	
				Pantosin		
				(Panthethine)	C	
				Nitorol	C	
				Lasix	C	
				Methycobal		
				(Mecobalamin)	C	
				Erispan		
				(Fludiazepam)	C	
				Halcion (Triazolam)	C	

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

1							
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalizat		Leukopenia	Foreign	Paxil Tablet			
Initial or F		Overdose		(Paroxetine			
		Renal Failure Acute		Hydrochloride)	PS		ORAL
20 MG ORAL				my ar comportance,	10		0101-
20 110 01012		Thrombocytopenia		Tramadol			
		millioneou, copenia		Hydrochloride			
				(Formulation			
				Unknown) (Tramadol			
							
0.5.3.T				Hydrochloride)	SS		ORAL
ORAL				~ 1			
1				Gabapentin			
1				(Formulation			
				Unknown)			
				(Gabapentin)	SS		ORAL
ORAL							
				Clonazepam Injection			
				(Clonazepam)	SS		
INTRAVENOUS	INTRAV	VENOUS		· _			
				Baclofen Tablet			
				(Baclofen)	SS		ORAL
ORAL				(1240101011)	65		01111
				Methotrexate Tablet			
				(Methotrexate)	SS		ORAL
ORAL				(Metholiexale)	GG		UKAL
ORAL				⁷	~		
				Alprazolam	С		
	0						
		: 3977332-4Report Type:Exped:	ited (15-DaCompany Repor	rt #PHNU2002DE03089			
Age:	Gender:	I/FU:I					
					- 1		
Outcome		PT	Report Source	Product	Ro⊥e	Manufacturer	Route
Dose	Duration						
Other		Drug Interaction	Foreign	Lioresal(Baclofen)			
		Muscle Spasticity	Health	Tablet	PS		ORAL
ORAL							
			Professional	Dronabinol			
			Other	(Dronabinol)	SS		
1							

	r: 3978402-7Report Type:Exped:	ited (15-DaCompany Re	eport #20021182			
Age: Gender:Male	e I/FU:I					
Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Dyskinesia	Consumer	Lioresal?			
Initial or Prolonged	Feeling Hot	Health	Intrathecal			
	Hypoaesthesia	Professional	(Baclofen Injection)	PS		
INTRATHECAL MCG, I	DAILY,					
	Injection Site					
INTRATHECAL						
	Inflammation					
	Injection Site Oedema					
	Joint Stiffness					
	Muscular Weakness					
	Neck Pain					
	Paraesthesia					
	Pyrexia					
	-					
Date:09/18/02ISR Number	r: 3978403-9Report Type:Exped:	ited (15-DaCompany Re	eport #20021185			
Age: Gender:Fema	ale I/FU:I					
Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Meningitis Staphylococcal	Health	Lioresal?			
Initial or Prolonged		Professional	Intrathecal			
_			(Baclofen Injection)	PS		
MCG, DAILY,			<u> </u>			
INTRATHECAL						
-						

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

PT	Report Source	Product	Role Manufacturer	Route
Hepatotoxicity	Foreign	Baclofen (Baclofen)	PS	ORAL
	Literature Health Professional Other			
: 3977960-6Report Type:Expedit I/FU:F	ted (15-DaCompany Repor	rt #PHBS2002IT10106		
PT	Report Source	Product	Role Manufacturer	Route
Erythema	Foreign	Lioresal (Baclofen)	PS	ORAL
	Health			
	Professional Other	Ditropan (Oxybutynin)	SS	ORAL
		Rivotril (Clonazenam) Drons	22	ORAL
		(cronazepam) brops	55	UIAL
		Omnic (Tamsulosin	a	
	ted (15-DaCompany Repor			
	Report Source	Product	Role Manufacturer	Route
	Hepatotoxicity : 3977960-6Report Type:Expedia I/FU:F PT Erythema	Hepatotoxicity Foreign Literature Health Professional Other : 3977960-6Report Type:Expedited (15-DaCompany Report I/FU:F PT Report Source Erythema Foreign Health Professional Other : 3977967-9Report Type:Expedited (15-DaCompany Report I/FU:F	HepatotoxicityForeign Health Professional OtherBaclofen (Baclofen)Literature Health Professional OtherLiterature HealthPTReport SourceProductErythemaForeignLioresal (Baclofen)Health Professional OtherDitropan (Oxybutynin)Rivotril (Clonazepam) DropsRivotril Hydrochloride): 3977967-9Report Type:Expedited (15-DaCompany Report #PHBS2002IT08366 L/FU:F	Hepatotoxicity Foreign Baclofen (Baclofen) PS Literature Health Professional Other Literature Health Professional Other S 977960-6Report Type:Expedite(15-DaCompany Report #PHBS2002IT10106 L/FU:F Role Manufacturer PT Report Source Product Role Manufacturer Erythema Foreign Lioresal (Baclofen) PS Health Professional Other Ditropan (Oxybutynin) SS Rivotril (Clonazepam) Drops SS Omnic (Tamsulosin Hydrochloride) c : 3977967-9Report Type:Expedite(15-DaCompany Report #PHBS2002IT08365

Outcome	Duration	PT	Report Source	Product	Role Manufacturer	Route
Dose Hospitalizat: 37.5 MG/DAY,		Generalised Erythema	Foreign	Lioresal (Baclofen)	PS	ORAL
Initial or P	rolonged		Health			
ORAL						

	Professional	Ditropan		
	Other	(Oxybutynin)	SS	
7.5 MG/DAY		Rivotril		
		(Clonazepam)	SS	ORAL
ORAL				
		Omnic (Tamsulosin		
		Hydrochloride)	SS	ORAL
0.4		-		

0.1

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	Duration	PT	Report Source	Product	Role Manufacturer	Route
Dose Life-Threate	Duration ening	Drug Level Increased Loss Of Consciousness	_	Lioresal(Baclofen) Tablet	PS	ORAL
10 то 20						OUT
			Professional			
MG/DAY, ORAI	- -					
			Other	Primperan		
1				(Metoclopramide)	С	
				Calcium Carbonate	С	
1				Pantosin		
					C	
				Nitrol	C	
					С	
				Methycobal		
				. ,	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 Gender:Male Age: I/FU:I Outcome PTReport Source Product Role Manufacturer Route Dose Duration Life-Threatening Unevaluable Event Health Lioresal? Hospitalization -Professional Intrathecal Initial or Prolonged (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 PTRole Manufacturer Outcome Report Source Product Route Dose Duration Hospitalization -Accidental Overdose Foreign Lioresal (Baclofen) Initial or Prolonged Health Tablet Apathy PS ORAL 25 MG, BID, Professional Bradycardia ORAL Clonic Convulsion Other Lioresal "Novartis" Tablet Coma С Dyskinesia Botox (Botulinum Fatique Toxin Type A) С Grand Mal Convulsion Hypotonia Medication Error Miosis Pupillary Light Reflex Tests Abnormal Somnolence Tremor Date:09/25/02ISR Number: 3981956-8Report Type:Expedited (15-DaCompany Report #PHHO2001FR08069 Aqe:80 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Durati	on					
Hospitalization -	Incontinence	Foreign	Trileptal (Tril	eptal		
Initial or Prolonge	d Somnolence	Study	T22413+)	PS		ORAL
300 MG, BID,						

		Health			
ORAL		Professional	Zoloft (Sertraline		
		Other	Hydrochloride)	SS	
30 MG, TID,			Lioresal (Baclofen)	SS	
55 113, 112,			Mopral (Omeprazole)	С	
	umber: 3984603-4Report Type: Female I/FU:F	Expedited (15-DaCompany Rep	ort #PHHO2001FR08069		
Outcome	PT	Report Source	Product	Role	Manufacturer

Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - Initial or Prolonged	Incontinence Somnolence	Foreign Study	Trileptal (Trileptal T22413+)			
inicial of Plotonged	Doundlence	Health	Trileptal(Trileptal)	PS		ORAL
300 MG, BID,						
		Professional				
ORAL						
		Other	Zoloft (Sertraline			
			Hydrochloride)	SS		
			Lioresal (Baclofen)			
			Unknown	SS		
30 MG, TID						
			Mopral (Omeprazole)	С		

Freedom Of Information (FOI) Report

Date:10/02/02ISR Number: 3986831-0Report Type:Expedited (15-DaCompany Report #PHBS2002JP06406 Gender:Female Age:40 YR I/FU:F

Outcome Dose Duration	PT	Report Source	Product	Role Manufacturer	Route
Hospitalization - Initial or Prolonged 120 MG/DAY,	Drug Level Increased Epilepsy	Foreign Health	Lioresal(Baclofen)Ta blet	PS	ORAL
ORAL; SEE	Hypercapnia	Professional			
	Pyrexia	Other			
IMAGE					
	Respiratory Depression Respiratory Failure		Phenobarbital (Phenobarbital)	SS	ORAL
200 MG/D,			(_
ORAL; SEE					
IMAGE					
			Depakene	С	
			Benzalin Lactic Acid(Lacticf	C	
			Acid)	С	
			Ambroxol		
			Hydrochloride(Ambrox	-	
			ol Hydrochloride) Piracetam	C C	
Date:10/07/02ISR Numbe Age:52 YR Gender:Mal	r: 3989632-2Report Type:Expedi e I/FU:I	ted (15-DaCompany Repo	rt #PHBS2002AR11469		
Outcome Dose Duration	PT	Report Source	Product	Role Manufacturer	Route
Hospitalization - 10 MG, TID,	Activated Partial	Foreign	Lioresal (Baclofen)	PS	ORAL
Initial or Prolonged ORAL	Thromboplastin Time	Health			
	Abnormal	Professional	Heparin (Heparin)	C	
	Agitation Alanine Aminotransferase	Other	Acetylsalicylic Acid Omeprazole	C	
	Increased		(Omeprazole)	С	
	Aspartate		Alplax (Alprazolam)	C	
	Aminotransferase		Trapax Tablet	C	
	Increased		Folic Acid	C	
	Blood Alkaline		Calcium Carbonate	C	

Phosphatase Increased Blood Bilirubin Increased Confusional State Prothrombin Time Shortened Erythropoietin (Erythropoietni)

С

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		Cardiac Arrest	Literature	Dipotassium			
Life-Threate	ning	Depressed Level Of	Health	Clorazepate			
Hospitalizat	ion -	Consciousness	Professional	(Tranxene)			
Initial or P	rolonged	Grand Mal Convulsion		(Clorazepate			
Required		Intentional Misuse		Dipotassium)	PS		
Intervention	to			Amitriptyline	SS		
Prevent Perm	anent			Dextropropoxyphene	SS		
Impairment/D	amage			Oxybutynin	SS		
				Cyclobenzaprine	SS		
				Baclofen	SS		
				Cisapride	SS		
1				Omeprazole	SS		
				Diosmin	SS		
				Glycopyrronium			
				Bromide	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 Gender:Male Age:30 YR I/FU:I Outcome PTReport Source Product Role Manufacturer Route Dose Duration Hospitalization -Accidental Exposure Foreign Lamictal Tablet Initial or Prolonged Blood Pressure Systolic Health (Lamotrigine) ORAL PS500 MG SINGLE Professional Decreased DOSE ORAL Oxcarbazepine Tablet Therapeutic Agent Toxicity (Oxcarbazepine) SS ORAL 2400 MG SINGLE DOSE ORAL Baclofen Tablet (Baclofen) ORAL SS 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 Role Manufacturer Outcome PTReport Source Product Route Dose Duration Photosensitivity Reaction Diclofenac Other Foreign Health (Diclofenac) PS

UNK, UNK,

UNKNOWN

Professional

Other

Lioresal(Baclofen) Unknown SS Librium "Hoffman" (Chlordiazeoxide Hydrochloride) C

Dothiepin	
(Dosulepin)	

С

Date:10/15/02ISR Number: 3993753-8Report Type:Expedited (15-DaCompany Report #NSADSS2002032587 Age:57 YR Gender:Female I/FU:F

Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Death		Blood Glucose Increased Blood Ph Decreased Completed Suicide Intentional Misuse	Literature Health Professional	Tylenol With Codeine (Unspecified) (Acetaminophen/Codei 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 - INTRATHECAL DAILY	Therapeutic	Professional	(Baclofen Injection)	PS		
Initial or Prolonged INTRATHECAL	Medical Device					
	Complication					

Freedom Of Information (FOI) Report

Fragmin(Heparin-Frac
tion, Sodium Salt)

Nystatin(Nystatin)

SS

SS

ORAL

ORAL

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 Ma	nufacturer	Route
Dose Duration Hospitalization - Initial or Prolonged	Coma Intentional Misuse	Foreign Health	Lioresal (Baclofen) Tablet	PS		ORAL
40 TABLETS/D,	Miosis	Professional				
ORAL						
	Respiratory Depression Suicide Attempt	Other	Phenobarbital (Phenobarbital)	SS		
Date:10/17/02ISR Numbe Age:35 YR Gender:Mal	r: 3997059-2Report Type:Exped e I/FU:I	ited (15-DaCompany Re	eport #GRP02000157			
Age.35 ik Gender.Mai						
Outcome	PT	Report Source	Product	Role Ma	nufacturer	Route
Dose Duration		-				
Life-Threatening	Anaemia	Foreign	Dantamacrin(Dantrole			
Hospitalization -	Arthritis	Health	ne Sodium) Capsule,			
Initial or Prolonged ORAL	Beta Haemolytic	Professional	Unknownmg	PS		ORAL
	Streptococcal Infection	Other	Timonil(Carbamazepin			
1	Blister		e)	SS		ORAL
ORAL						
1	Candida Pneumonia		Lioresal "Novartis"			_
	Epidermolysis		(Baclofen)	SS		ORAL
ORAL						
	Erythema		Oxybutynin(Oxybutyni			0.0.3.1
ORAL	Pancytopenia		n)	SS		ORAL
UTAL	Peritonsillar Abscess		Tranxilium(Clorazepa			
	Photosensitivity Reaction		te Dipotassium)	SS		ORAL
ORAL	inclosensitivity reaction			55		OKAD
			Acimethin(Methionine			
)	SS		ORAL

ORAL

ORAL

ORAL

Date:10/24/02ISR Number Age:30 YR Gender:Male	: 3995588-9Report Type:Expedit I/FU:F	ed (15-DaCompany Repor	t #D0039382A			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - 500MG Single	Blood Pressure Systolic	Health	Lamictal	PS	Glaxo Wellcome	ORAL
Initial or Prolonged dose 1 DAY	Decreased	Professional				
2400MG Single	Drug Toxicity		Trileptal	SS		ORAL
dose 1 DAY			Lioresal	SS		ORAL
10MG Single			LIUIESAI	22		ORAL
dose 1 DAY			Keppra	SS		ORAL
2000MG Single						
dose 1 DAY						
Date:10/25/02ISR Number Age: Gender:Fema Outcome Dose Duration Hospitalization - Initial or Prolonged INTRATHECAL MCG, Di INTRATHECAL	PT Catheter Related Complication	ced (15-DaCompany Repor Report Source Health Professional	rt #20021200 Product Lioresal Intrathecal (Baclofen Injection)		Manufacturer	Route
Date:10/25/02ISR Number Age:38 YR Gender:Male	: 4000769-4Report Type:Expedit I/FU:I	ed (15-DaCompany Repor	t #EMADSS2002006188			
Outcome Other	PT Convulsion Drug Interaction	Report Source Foreign Health				
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Freedom Of Information (FOI) Report

Professional

_				Product	Role	Manufacturer	Route
Dose Dur:	ation			Topalgic Tramadol Hydrochloride) Deroxat (Paroxetine Hydrochloride) Lioresal (Baclofen) Neurontin (Gabapentin)	PS SS SS C		
	Number er:Male	: 4001488-0Report Type:Expo I/FU:I	edited (15-DaCompany Re	port #20021202			
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Life-Threatening Hospitalization INTRATHECAL Initial or Prolo INTRATHECAL Date:10/29/02ISR	- MCG, D. nged	Gastric Volvulus Intestinal Dilatation Post Procedural Complication Upper Gastrointestinal Haemorrhage Urinary Retention : 3998819-4Report Type:Expo	Health Professional edited (15-DaCompany Re	Lioresal Intrathecal (Baclofen Injection)		COMPANY-12081485	
Outcome	-	PT	Report Source	Product	Role	Manufacturer	Route
Dose Dura Hospitalization Initial or Prolo Daily dose:		Haematemesis Ulcer		Warfarin Sodium	PS	Bristol-Myers Squibb Company	ORAL
as per INR				Acetylsalicylic Acid Diclofenac Baclofen	SS SS SS		ORAL ORAL ORAL

	Folic Acid	С	ORAL
	Co-Amilofruse	С	ORAL
Daily dosage:			
5/40			
	Simvastatin	C	ORAL
	Epilim	C	ORAL
	Uniphyllin	С	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 Dose	Duration	PT	Report Source	Product	Role Manufacturer	Route
Other	Duración	Alanine Aminotransferase Increased	Foreign Health	Lioresal (Baclofen) Unknown	PS	ORAL
10 MG, TID,		Increaded	incuton			010111
		Aspartate	Professional			
ORAL						
		Aminotransferase	Other	Mormison	С	
		Increased		Stilnox (Zolpidem)	С	
		Gamma-Glutamyltransferase		Valium	С	
		Increased		Endone (Oxycodone		
				Hydrochloride) Pethidine	С	
				(Pethidine)	C	

Freedom Of Information (FOI) Report

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	Durati	PT	Report Source	Product	Role	Manufacturer	Route
Dose Disability Other 75 MG, TID;	Duration	Photosensitivity Reaction	Foreign Health	Diclofenac(Diclofena c) Unknown	PS		ORAL
			Professional				
ORAL			Other	Lioresal(Baclofen) Unknown	SS		ORAL
10 MG/DAY,					55		OTUIL
ORAL							
				Librium "Hoffman" (Chlordiazepoxide Hydrochloride)	С		
				Dothiepin (Dosulepin)	C		
)2ISR Number Gender:Fema	r: 4006150-6Report Type:Expedit ale I/FU:I	ed (15-DaCompany Repor	t #PHFR2002GB03463			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route

Dose	Duration					
Hospitalizat	ion -	Gastrointestinal Ulcer	Foreign	Diclofenac		
Initial or H	rolonged	Haematemesis	Health	(Diclofenac)	PS	ORAL
75 MG/DAY,						

Professional

Haemoglobin Decreased ORAL

	International Normalis	ed Other	Baclofen (Baclofen)	SS	ORAL
10 MG/DAY,					
	Ratio Increased				
ORAL					
			Warfarin (Warfarin)	SS	ORAL
ORAL					
			Aspirine		
			(Acetylsalicylic		00.01
			Acid)	SS	ORAL
75 MG/DAY,					
ORAL					
JIAL			Folic Acid	С	
			Co-Amilofruse	C	
			Simvastatin	C	
			Epilim	C	
			Uniphyllin "Napp"	C	
			Co-Codamol	-	
			(Paracetamol)	С	
	ISR Number: 4006957-5Report Type:	Expedited (15-DaCompany	Report #PHNU2002DE02752		
Age:65 YR Ge	ender:Female I/FU:F				
_ .					_ .
Outcome	PT	Report Source	Product	Role Manufacturer	Route
Dose D	Duration				

Dose	Duration					
Hospitaliz	zation -	Accidental Overdose	Foreign	Lioresal (Baclof	en)	
Initial or Prolo SEE IMAGE	-	Fatigue	Health	Tablet	PS	ORAL
		Hypertension	Professional Other			

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 Dose	Duration	РТ	Report Source	Product	Role Manufacturer	Route
Other 10 MG/DAY,	Duración	Fanconi Syndrome Acquired	Foreign	Lioresal (Baclofen)	PS	ORAL
ORAL		Renal Tubular Disorder	Health			
			Professional Other			

Date:11/06/02ISR Number: 4008526-XReport Type:Expedited (15-DaCompany Report #PHRM2002FR02640 Age:19 YR Gender:Male I/FU:I

Outcome Dose Duration	PT	Report Source	Product	Role Manufacturer	Route
Hospitalization - Initial or Prolonged SEE IMAGE	Neutropenia	Foreign Health	Lioresal (Baclofen) Tablet	PS	ORAL
		Professional Other	Fraxiparine (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 PTReport Source Role Manufacturer Outcome Product Route Dose Duration Cholangitis Other Foreign Lioresal (Baclofen) Cholelithiasis Health Tablet PS ORAL 25 MG, TID, Hepatic Steatosis Professional ORAL; 25 MG,

Other

TID, ORAL

Propra-Ratiopharm C

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Haematemesis	Health	Warfarin Sodium	PS	Bristol-Myers Squibb	
Initial or Prolonged Daily dose:	Haemoglobin Decreased	Professional			Company	ORAL
	International Normalised					
as per INR						
	Ratio Increased		Acetylsalicylic Acid	SS		ORAL
	Ulcer		Diclofenac	SS		ORAL
			Baclofen	SS		ORAL
			Folic Acid	С		ORAL
			Co-Amilofruse	С		ORAL
Daily dosage:						
5/40						
			Simvastatin	С		ORAL
			Epilim	С		ORAL
			Uniphyllin	С		ORAL
			Co-Codamol	С		ORAL

Date:11/11/02ISR Number: 4007050-8Report Type:Expedited (15-DaCompany Report #US-BRISTOL-MYERS SQUIBB COMPANY-12081485

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 -	Neutropenia	Foreign	Heparin-Fraction,		/
Initial or Prolonged		Other	Sodium Salt		/
			(Lovenox)	PS	ľ
SUBCUTANEOUS 40 MG	QD SC 5 WK				ľ
			Baclofen (Lioresal)	SS	ORAL
10 MG TID PO 13 DAY	Ч		· · ·		/

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	Duration	PT	Report Source	Product	Role Manufacturer	Route
Dose Other	Duración	Condition Aggravated Pyrexia	Foreign Health	Lioresal (Baclofen) Tablet	PS	ORAL
30MG/DAY,			Professional			
ORAL			Other	Metoclopramide Tavor Heparin	C C 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 Durat Hospitalization -	Drug Withdrawal Syndrome	Health	Zoloft (Sertraline		
Initial or Prolong	ged Grand Mal Convulsion	Professional	Hydrochloride)	PS	ORAL
ORAL					
Other	White Blood Cell Count		Baclofen (Baclofen)	SS	
	Increased		Klonopin		
			(Clonazepam)	SS	
3 MG (TID)			-		
			Atenolol	С	
			Fentanyl	C	
			Morphine	С	
			Simvastatin	С	

Date:11/18/02ISR Number: 4013896-2Report Type:Expedited (15-DaCompany Report #PHBS2002TW13256 Age:61 YR Gender:Male I/FU:I

Outcome Dose Duration	PT	Report Source	Product	Role Manufacturer	Route
Hospitalization - 5 MG, TID	Asthenia	Foreign	Baclofen(Baclofen)	PS	
Initial or Prolonged	Drug Toxicity Haemodialysis Hyporeflexia Hypotonia Nausea	Literature Health Professional Other			

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	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Dose Disability 10 MG/DAY,	Duracion	Fanconi Syndrome Acquired	Foreign	Lioresal (Baclofen)	PS		ORAL
		Renal Tubular Disorder	Health				
ORAL							
1			Professional	Valproic Acid			0.5.1.1
450 MG/DAY,			Other	(Valproic Acid)	SS		ORAL
ORAL							ļ
				Excergan			
				(Zonisamide)	С		1
				Rivotril	С		ļ
				Phenobal	С		
				Dantrium (Dantrolene			
				Sodium)	С		P

Mucodyne

Meptin (Procaterol Hydrochloride) С

С

Freedom Of Information (FOI) Report

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 Dose Duration	PT	Report Source	Product	Role Manufacturer	Route
Hospitalization - Initial or Prolonged 20 TABLETS,	Agitation Hypotension	Foreign Health	Lioresal (Baclofen) Tablet	PS	ORAL
	Intentional Misuse	Professional			
ONCE/SINGLE, ORAL	Mydriasis	Other			
	Suicide Attempt		Amitripyline (Amitriptyline)		
20 DF,			Tablet	SS	ORAL
ONCE/SINGLE,					
ORAL					
			Oxybutynin (Oxybutynin) Tablet	SS	ORAL
10 TABLETS,					
ONCE/SINGLE,					
ORAL					
			Diazepam (Diazepam) Tablet	SS	ORAL
10 TABLETS,			Tablet	55	
ONCE/SINGLE,					
ORAL					
Date:11/22/02ISR Number	: 4016036-9Report Type:Expedit	ed (15-DaCompany Repor	t #EMADSS2002006188		

Age:38 YR Gender:Male I/FU:F

Outcome Dose Duration

 \mathbf{PT}

Report Source Product

Hospitalization -	Convulsion	Foreign	Topalgic		
Initial or Prolonged	Drug Interaction	Health	(Unspecified)		
Other		Professional	(Tramadol		
			Hydrochloride)	PS	
300 MG, DAILY					
			Deroxat (Paroxetine		
			Hyrochloride)	SS	
20 MG, DAILY					
			Lioresal (Baclofen)	SS	
30 MG, DAILY					
			Neurontin		
			(Gabapentin)	С	
Date:11/26/02ISR Number	er: 4017585-XReport Type:Ex	pedited (15-DaCompany Re	eport #PHBS2002CL04226		
Age:57 YR Gender:Mal	le I/FU:F				
Outcome	PT	Report Source	Product	Role Manufacturer	Route
Dose Duration					
Other	Dulmonary Fibrogia	Foreign	Lioregal (Baclofen) Ta		

Other		Pulmonary Fibrosis Sarcoidosis	Foreign Consumer	Lioresal(Baclofen)Ta blet	e PS	ORAL
SEE IMAGE 1095 I	1095 DAY					
				Enalapril		
				(Enalapril)	С	
				Diazepam	С	

Date:12/02/	02ISR Number:	40205	521-3Report	Type:Expedited	(15-DaCompany	Report	#20021236
Age:	Gender:Male		I/FU:I				
Outcome		PT					
Death		Brain	Death				

Coma Hypotonia Pupil Fixed

Freedom Of Information (FOI) Report

		Ventricular Fibrillation					
Dose	Duration		Report Source	Product	Role	Manufacturer	Route
DOSE	Duración		Health	Lioresal Intrathecal			
INTRATHECAL	UNK MC	G,	Professional	(Baclofen Injection)	PS		
DAILY,							
INTRATHECAL							
Date:12/02/0)2ISR Number	: 4020792-3Report Type:Exped	ited (15-DaCompany Re	eport #20021235			
Age:	Gender:Male	I/FU:I					
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalizat Initial or P INTRATHECAL		Clonic Convulsion Muscle Spasticity G,	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		
DAILY,		Pneumonia					
INTRATHECAL							
				Tizanidine	C		
				Lorazepam Clonazepam	C C		
)2ISR Number Gender:Fema	: 4020794-7Report Type:Exped le I/FU:I	ited (15-DaCompany Re	eport #20021232			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other		Csf Bacteria Identified	Health	Lioresal Intrathecal			
INTRATHECAL	MCG, D		Professional	(Baclofen Injection)	PS		
INTRATHECAL		Drug Withdrawal Syndrome					
		Meningitis					
l							

Date:12/03/02ISR Number Age:22 YR Gender:Male	r: 4022059-6Report Type:Expedit e I/FU:F	ed (15-DaCompany Repor	ct #PHBS2002BR13602			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization -	Agitation	Foreign	Lioresal (Baclofen)			
Initial or Prolonged 20 TABLETS,	Heart Rate Increased	Health	Tablet	PS		ORAL
ONCE/SINGLE,	Hypotension	Professional				
ORAL	Intentional Misuse	Other				
	Mydriasis Suicide Attempt		Amitriptyline (Amitriptyline) Tablet	SS		ORAL
20 DF,						
ONCE/SINGLE,						
ORAL			Oxybutynin			
10 TABLETS,			(Oxybutynin) Tablet	SS		ORAL
ONCE/SINGLE,						
ORAL			Diazepam (Diazepam)			
10 TABLETS,			Tablet	SS		ORAL
ONCE/SINGLE,						
ORAL						
Date:12/09/02ISR Number Age:56 YR Gender:Male	r: 4020800-XReport Type:Direct e I/FU:I	Company Repor	rt #CTU 182317			
Outcome Life-Threatening Hospitalization -						
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1						

Freedom Of Information (FOI) Report

PT	Report Source	Product	Role	Manufacturer	Route
Asthenia Difficulty In Walking		Baclofen 2000.0 Ug/Ml	PS		
Dyspnoea UG/HR Medication Error					
Pharmaceutical Product Complaint					
nown I/FU:I					
PT	Report Source	Product	Role	Manufacturer	Route
Completed Suicide	Literature Health Professional	Hydrocodone/Acetamin ophen (Vicodin) (Hydrocodone/Acetami nophen)			
		Venlafaxine Baclofen	PS SS SS		
r: 4023117-2Report Type:Exp e I/FU:F		Venlafaxine Baclofen eport #PHNU2002DE03679	SS SS		
	edited (15-DaCompany Re Report Source	Venlafaxine Baclofen	SS SS	Manufacturer	Route
e I/FU:F		Venlafaxine Baclofen eport #PHNU2002DE03679	SS SS	Manufacturer	Route ORAL
2	Asthenia Difficulty In Walking Dyspnoea UG/HR Medication Error Pharmaceutical Product Complaint r: 4023061-0Report Type:Exp nown I/FU:I PT	Asthenia Difficulty In Walking Dyspnoea UG/HR Medication Error Pharmaceutical Product Complaint r: 4023061-OReport Type:Expedited (15-DaCompany Re nown I/FU:I PT Report Source Completed Suicide Literature Health	Asthenia Difficulty In Walking Dyspnoea UG/HR Medication Error Pharmaceutical Product Complaint PT Report Source Product Completed Suicide Literature Hydrocodone/Acetamin ophen (Vicodin)	Asthenia Difficulty In Walking Dyspnoea UG/HR Medication Error Pharmaceutical Product Complaint r: 4023061-0Report Type:Expedited (15-DaCompany Report #02P-163-0205269-00 nown I/FU:I PT Report Source Product Role Completed Suicide Literature Hydrocodone/Acetamin ophen (Vicodin)	Asthenia Difficulty In Walking Baclofen 2000.0 Ug/Ml PS Dyspnoea UG/HR Medication Error Pharmaceutical Product Complaint r: 4023061-0Report Type:Expedited (15-DaCompany Report #02P-163-0205269-00 nown I/FU:I PT Report Source Product Role Manufacturer Completed Suicide Literature Hydrocodone/Acetamin ophen (Vicodin)

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 Du Other	uration	Drug Interaction Muscle Spasticity	Foreign Health	Lioresal (Baclofen) Tablet	PS		ORAL
ORAL			nearen		10		Orun
			Professional Other	Dronabinol (Dronabinol)	SS		
CHANGING				· ·			ſ
DOSAGE							ſ
				Mydocalm "Strathmann" (Tolperisone Hydrochloride) Sirdalud Benzodiazepines	C C C		
Age:36 YR Gen	SR Number nder:Femal						
Outcome Dose Du	uration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization Initial or Pro 10 MG, TID,		Agranulocytosis Pyrexia	Foreign Health	Lioresal (Baclofen) Tablet	PS		
INTRAGASTRIC		White Blood Cell Count	Professional				
		Decreased	Other	Lovenox (Heparin-Fraction,			

Freedom Of Information (FOI) Report

Sodium Salt) Solution For Injection

SS

SUBCUTANEOUS 40 MG, QD;

SUBCUTANEOUS

Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization -	Haematemesis	Foreign	Baclofen(Baclofen)			
Initial or Prolonged 20 MG/DAY,	Haemoglobin Decreased	Health	Unknown	PS		ORAL
DRAL	Oesophagitis	Professional				
		Other	Diazepam Lactulose	C C		
Age:82 YR Gender:Fema					Marrieland	Dauta
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization -	Haematemesis	Foreign	Baclofen (Baclofen)			ORAL
Initial or Prolonged	Haemoglobin Decreased	Health	Unknown	PS		ORAL
Initial or Prolonged 5MG/DAY ,	Haemoglobin Decreased	Professional	Unknown	PS		ORAL
Initial or Prolonged 5MG/DAY ,	Haemoglobin Decreased		Unknown Lanzoprazole(Lanzopr azole) Amoxicillin	PS C C		URAL
Initial or Prolonged 5MG/DAY , ORAL	r: 4032190-7Report Type:Expe	Professional Other	Lanzoprazole(Lanzopr azole) Amoxicillin	С		URAL
Initial or Prolonged 5MG/DAY , DRAL Date:12/16/02ISR Number	r: 4032190-7Report Type:Expe	Professional Other	Lanzoprazole(Lanzopr azole) Amoxicillin	C C	Manufacturer	Route

Initial or Prol		driplegia	Professional	1b) Injection	PS
SUBCUTANEOUS Disability	SEE IMAGE			Baclofen (Baclofen)	SS
INTRATHECAL	INTRATHECA	L			
				Albuterol	С
				Tequin	
				(Gatifloxacin)	С
				Neurontin	
				(Gabapentin)	С
				Multivitamins	
				(Ergocalciferol,	
				Retinol, Panthenol)	С
				Mandelamine	
				"Park-Davis"	
				(Methenamine	
				Mandelate)	С
				Diovan "Novartis"	
				(Valsartan)	С
				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 Dose Duration	PT	Report Source	Product	Role Manufacturer	Route
Hospitalization - Initial or Prolonged 5MG QD ORAL	Haematemesis	-	Baclofen - Ipi Tablets	PS	ORAL
			Lansoprazole Amoxicillin	C C	

Freedom Of Information (FOI) Report

Date:12/20/	02ISR	Number:	4029155-8Report	Type:Direct
Age:	Gende	er:Female	e I/FU:I	

Company Report #CTU 183156

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Life-Threater	ning	Coma		Baclofen 10mg			
Required		Heart Rate Decreased		Upsher-Smith	PS	Upsher-Smith	ORAL
5MG ONCE ORAL	J						
Intervention	to	Hypotension		Compazine	С		
Prevent Perma	anent			Vicodin	С		
Impairment/Da	amage			Glipizide Xl	С		
				Isosorbide Er	С		
				Lovastatin	С		
				Methylphenidiate	С		

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 -	Asthenia	Foreign	Lioresal (Baclofen)		
Initial or Prolonged 12.5 MG, BID,	Depressed Level Of	Health	Tablet	PS	ORAL
	Consciousness	Professional			
ORAL; 10 MG,					
	Drug Level Above	Other			
BID, ORAL; 5	-				
	Therapeutic				
MG, BID, ORAL	-				
	Dysarthria		L-Thyroxin Henning		
	Fatigue		Berlin	С	
	Muscular Weakness		Dreisavit	C	
	Narcolepsy		Nexium Mups		
	Overdose		(Esomeprazole)	С	
	Reflux Oesophagitis		Lactulose	С	
	Vomiting		Mcp Hexal	С	
			Baldrian-Dispert		
			(Valeriana		
1			Officinalis Root)	C	

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Aphasia	Foreign	Sandoglobulin Or			
Initial or Prolonged	Disease Recurrence	Health	Placebo (Placebo			
	Epilepsy	Professional	Placebo)			
	Grand Mal Convulsion	Other	(Sandoglobulin Or			
	Multiple Sclerosis		Placebo)	PS		
INTRAVENOUS QMO,						
	Relapse					
INTRAVENOUS						
	Postictal State		Baclofen (Baclofen)			
	Pyrexia		Capsule	SS		
			Ds 103-282			
1			(Tizanidine			
			Hydrochloride)			
			Capsule	SS		
1			Neuromet			
			(Oxiracetam)	С		
			Orfiril (Valproate			
			Sodium)	С		

				rse Event Reporting Syste m Of Information (FOI) Re		RS)	
			1100d0		-Por c		
Date:01/06/0 Age:51 YR		: 4036977-6Report Type:Direct le I/FU:I	Company Re	port #CTU 183902			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other 10 MG 3 X A		Drug Ineffective Pharmaceutical Product		Baclofen 10 Mg Rosemont/Geneva	PS	Rosemont/Geneva	
DAY		Complaint					
Date:01/08/0 Age:50 YR		: 4038506-XReport Type:Direct I/FU:I	c Company Re	port #CTU 184078			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Life-Threate Hospitalizat 20 MG TID	ning	Drug Withdrawal Syndrome Hip Fracture		Baclofen 20 Mg Watson	PS	Watson	ORAL
Initial or P ORAL	rolonged	Road Traffic Accident					
Disability		Spinal Compression Fracture Syncope Tibia Fracture		Oxycontin Oxycodone Fibercon Sennacot Colace Benadryl	С С С С С С С С С		
		: 4040943-4Report Type:Expedi I/FU:F	ited (15-DaCompany Re	port #20010894			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Death		Blood Creatine Phosphokinase Increased	Health Professional	Lioresa (Baclofen Injection)	PS		
INTRATHECAL INTRATHECAL	967 MC	G DAILY Body Temperature					
INTRATHECAL		Increased		See B5	С		
		Csf Glucose Abnormal Csf Protein Abnormal Hypoaesthesia					

	Lung Disorder Post Procedural Complication						
Date:01/13/03ISR Number Age:51 YR Gender:Fema	: 4041205-1Report Type:Direct le I/FU:I		Company Report	t #CTU 184305			
Outcome	PT	Report	Source	Product	Role	Manufacturer	Route
Dose Duration Hospitalization - Initial or Prolonged LOMG 3X DAY	Difficulty In Walking Muscle Spasticity			Baclofen 10mg Rosemont	PS	Rosemont	
	Pharmaceutical Product Complaint			Baclofen 10mg Geneva	SS	Geneva	
Date:01/16/03ISR Number Age:49 YR Gender:Fema	: 4042953-XReport Type:Direct le I/FU:I		Company Report	t #CTU 184755			
Outcome Dose Duration	РТ	Report	Source	Product	Role	Manufacturer	Route
Hospitalization -	Dyspnoea			Baclofen - Watson -			
Initial or Prolonged 1T PO TID	Pharmaceutical Product			10mg Tabs	PS	Watson	ORAL
	Complaint Pharyngeal Oedema						

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 Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Death	Duración	Death	Literature Health	Aspirin (Formulation Unknown) (Aspirin)	PS		ORAL
ORAL							-
			Professional	Paracetamol (Formulation Unknown)			
ORAL				(Acetaminophen)	SS		ORAL
UIAL				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

Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other	Daración	Delusional Disorder, Persecutory Type Hallucination	Foreign Health Professional	Lioresal (Baclofen) Norvasc Sandocal "Novartis"	PS C		
		Hallucination	Professional	(Sodium) Stilnox (Zolpidem)	C C		
				Marcumar (Phenprocoumon)	С		
	3ISR Number Gender:Male	: 4050591-8Report Type:Direct I/FU:I	Company Report	t #CTU 185805			
N Contraction of the second se							
Outcome	Direction	PT	Report Source	Product	Role	Manufacturer	Route
	-	PT Anal Sphincter Atony Back Pain	Report Source	Product Enoxaparin-Lovenox- 100 Mg Aventis	Role PS	Manufacturer Aventis	Route
Dose Life-Threaten	ning ion - 100 MG	Anal Sphincter Atony Back Pain	Report Source	Enoxaparin-Lovenox-			Route
Dose Life-Threaten Hospitalizati SUBCUTANEOUS Initial or Pr	ning ion - 100 MG	Anal Sphincter Atony Back Pain EVERY	Report Source	Enoxaparin-Lovenox-			Route

Intervention to	Implant Site Infection	Drug In Pump Geigy	SS	Geigy
INTRATHECAL C	ONTINUOUS			
Prevent Permanent INTRATHECAL	Implant Site Reaction			
Impairment/Damage	Operative Haemorrhage Paraplegia Subdural Haematoma	Warfarin	С	

Date:02/05/03ISR Number: 4051268-5Report Type:Expedited (15-DaCompany Report #WAES 0208CHE00033 Age:72 YR Gender:Female I/FU:F

Outcome Dose Duration	PT	Report S	Source	Product	Role	Manufacturer	Route
Hospitalization -	Hypertension			Vioxx	PS	Merck & Co., Inc	ORAL
Initial or Prolonged 3 DAY	Stupor			Baclofen	SS		ORAL
5 2111				Deflazacort	SS		ORAL
				Acetaminophen	С		ORAL
				Amlodipine Besylate	С		ORAL
				Aspirin	С		ORAL
				Indapamide	С		ORAL
				Calcium			
				(Unspecified) And			
				Vitamin D			
				(Unspecified)	С		ORAL
				Cozaar	С		ORAL
				Hydrochlorothiazide			l
1				And Losartan			
				Potassium	С		ORAL

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 Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalizat 10 MG ORAL		Difficulty In Walking	Consumer	Baclofen	PS	Usp	ORAL
Initial or P	Prolonged	Muscle Spasticity	Other	Estrace	С		
				Lasix	С		
				Xanax	С		
				Effexor	С		
				Detrol	С		
				Loricet	С		
Date:02/14/(13ISR Number	: 4056899-4Report Type:Direct	Company Repor	+ #CTTI 186719			
	Gender:Male		company repor	t #CI0 100715			
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration			- ' 7			
Required		Areflexia		Lioresal			
Intervention		Coma		Intrathecal(Baclofen	20		
Prevent Perm		Hypotonia		Injection)	PS		
INTRATHECAL	400-42						
Impairment/I DAILY	Damage	Hypoventilation					
DATE		Irritability					
INTRATHECA		TTTCapiticy					
)3ISR Number Gender:Male	: 4065260-8Report Type:Expedit I/FU:I	ed (15-DaCompany Repor	t #HQWYE522020FEB03			
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration		-				
Death		Adverse Drug Reaction	Consumer	Infumorph (Morphine Sulfate, Injection)	PS		
INTRASPINAL				Baclofen (Baclofen)	SS		

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 Numbe	r: 4070019-1Report Type:Exped	lited (15-DaCompany Re	eport #20031317			
Date:03/04/03ISR Numbe Age:58 YR Gender:Mal	r: 4070019-1Report Type:Expected I/FU:I	lited (15-DaCompany Re	eport #20031317			
		lited (15-DaCompany Re	eport #20031317			
		lited (15-DaCompany Re Report Source	eport #20031317 Product	Role	Manufacturer	Route
Age:58 YR Gender:Mal	e I/FU:I			Role	Manufacturer	Route
Age:58 YR Gender:Mal Outcome	e I/FU:I			Role	Manufacturer	Route
Age:58 YR Gender:Mal Outcome Dose Duration	e I/FU:I PT	Report Source	Product		Manufacturer	Route
Age:58 YR Gender:Mal Outcome Dose Duration Hospitalization -	e I/FU:I PT Coma	Report Source Consumer	Product Lioresal		Manufacturer	Route
Age:58 YR Gender:Mal Outcome Dose Duration Hospitalization -	e I/FU:I PT Coma Drug Effect Decreased Hyperpyrexia	Report Source Consumer Health	Product Lioresal Intrathecal(Baclofen		Manufacturer	Route
Age:58 YR Gender:Mal Outcome Dose Duration Hospitalization - Initial or Prolonged	e I/FU:I PT Coma Drug Effect Decreased Hyperpyrexia	Report Source Consumer Health	Product Lioresal Intrathecal(Baclofen		Manufacturer	Route
Age:58 YR Gender:Mal Outcome Dose Duration Hospitalization - Initial or Prolonged	e I/FU:I PT Coma Drug Effect Decreased Hyperpyrexia	Report Source Consumer Health	Product Lioresal Intrathecal(Baclofen		Manufacturer	Route
Age:58 YR Gender:Mal Outcome Dose Duration Hospitalization - Initial or Prolonged INTRATHECAL DAILY	e I/FU:I PT Coma Drug Effect Decreased Hyperpyrexia	Report Source Consumer Health	Product Lioresal Intrathecal(Baclofen		Manufacturer	Route
Age:58 YR Gender:Mal Outcome Dose Duration Hospitalization - Initial or Prolonged INTRATHECAL DAILY	e I/FU:I PT Coma Drug Effect Decreased Hyperpyrexia ' Medical Device	Report Source Consumer Health	Product Lioresal Intrathecal(Baclofen		Manufacturer	Ro

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		
	50UG/D					
Initial or Prolonged	Asthenia	Health				
INTRATHECAL 11 MC						
Other	Catheter Related Complication	Professional				
	Clonic Convulsion					
	Deep Vein Thrombosis					
	Hypotonia					
	Migration Of Implant					
	Muscle Spasticity					
	Post Procedural					
	Complication					
	er: 4072935-3Report Type:Exp Le I/FU:F	edited (15-Dacompany R	eport #PHNU2002DE04194			
Age: Gender:Mal	1/F0.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,	Depressed Level Of	Other				
BID, ORAL	Depressed never of	Other				
	Consciousness		L-Thyroxin "Henning			
	Drug Level Above		Berlin"	С		
	Therapeutic		Dreisavit	C		
	Dysarthria		Nexium Mups	-		
	Fall		(Esomeprazole)	С		
	Fatigue		Lactulose	С		
	Haemodialysis		Mcp "Hexal"	С		
	Liver Disorder		Baldrian-Dispert			
	Muscular Weakness		(Valeriana			
	Narcolepsy		Officinalis Root)	С		
	Overdose					
	Reflux Oesophagitis					
	Renal Failure					

Age: Ge Outcome	nder:Fema	lle I/FU:F PT	Report Source	Product	Role Manufacturer	Route
	uration	L L	Report Bource	lioudee		Rouce
Other		Delusional Disorder,	Foreign	Lioresal(Baclofen)		
		Persecutory Type	Health	Unknown	PS	ORAL
ORAL						
		Hallucination	Professional	Norvasc	С	
			Other	Sandocal "Novartis"		
				Sodium	C	
				Stilnox (Zolpidem)	C	
				Marcumar(Phenprocoum		
				on)	С	

Date:03/17	/03ISR Number:	4077770-8Report	Type:Expedited	(15-DaCompany	Report	#2003009487	
Age:	Gender:Femal	e I/FU:I					
Outcome		PT					
Other		Alopecia					
		Arrhythmia					
		Blood Pressure In	creased				
		Cardiac Failure					
22-7119-200	5 12·15 DM						

Freedom Of Information (FOI) Report

Route

		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	С	
		Weight Increased		Taurine	С	
		5		All Other		
				Therapeutic Products	С	
				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 Dose Durat:	PT	Report Source	Product	Role Manufacturer	Route
Hospitalization -	Difficulty In Walking	Consumer	Baclofen Tablets,		
Initial or Prolonged 10 MG ORAL	ged Muscle Spasticity	Other	Usp	PS	ORAL
	Pharmaceutical Product		Estrace	С	
	Complaint		Lasix	C	
4			Xanax	C	
			Effexor	C	ļ
4			Detrol	C	
			Loricet	C	

Date:03/20/03ISR Number: 4080533-OReport Type:Expedited (15-DaCompany Report #20031307 Age: Gender: I/FU:I Outcome PT Report Source Product Role Manufacturer Dose Duration Required Drug Withdrawal Syndrome Foreign Lioresal Intrathecal

RequiredDrug Withdrawal SyndromeForeignLioresal IntrathecalIntervention toMedical DeviceHealth(Baclofen Injection)PSINTRATHECALDAILY,DAILY,DAILY,DAILY

Prevent Permanent INTRATHECAL	Complication	Professional			
Impairment/Damage	Pharmaceutical Product Complaint				
Date:03/20/03ISR Number Age:22 YR Gender:Male	: 4080569-XReport Type:Exped I/FU:I	ited (15-DaCompany Re	port #20031298		
Outcome Dose Duration	PT	Report Source	Product	Role Manufacturer	Route
Hospitalization -	Drug Withdrawal Syndrome	Health	Lioresal Intrathecal		
Initial or Prolonged	Heart Rate Increased	Professional	(Baclofen Injection)	PS	
INTRATHECAL INTRAT	HECAL				
	Post Procedural	Company			
	Complication	Representative			
	Pyrexia				
Date:03/20/03ISR Number Age:32 YR Gender:Fema	: 4080761-4Report Type:Exped le I/FU:I	ited (15-DaCompany Re	port #PHBS2003CH02731		
Outcome	PT				
Other	Abortion Spontaneous Complications Of Maternal				
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Freedom Of Information (FOI) Report

	Exposure To Therapeutic Drugs Maternal Drugs Affecting		Deve deve t		Doubo
Dose Duration	Foetus	Report Source	Product	Role Manufacturer	Route
20 Ma / DASI	Unintended Pregnancy	Foreign	Lioresal(Baclofen)	PS	
30 MG/DAY		Health Professional Other			
Date:03/26/03ISR Numbe: Age:80 YR Gender:Fema	r: 4083983-1Report Type:Exped: ale I/FU:I	ited (15-DaCompany Re	eport #2003CG00392		
Outcome Dose Duration	PT	Report Source	Product	Role Manufacturer	Route
Hospitalization - 10 MG QD PO	Abdominal Distension	Foreign	Zestril	PS	ORAL
Initial or Prolonged 20 MG QD PO	Abnormal Faeces	Health	Mopral	SS	ORAL
RESPIRATORY	Anorexia	Professional	Bricanyl	SS	
(INHALATION) 2 PUF:	C-Reactive Protein F DAILY Increased	Other			
10 MG QD PO	Cardioactive Drug Level		Lasilix	SS	ORAL
0.25 MG QD PO	Increased		Digoxine	SS	ORAL
50 MG TID PO	Drug Interaction		Rilutek	SS	ORAL
40 MG BID PO	Electrocardiogram St Segment Depression		Isoptine 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 160 MG QD PO	Decreased		Kardegic	SS	ORAL
RESPIRATORY	Renal Impairment		Atrovent	SS	
	Speech Disorder				

(INHALATION) 1PUFF DAILY

IH	Tongue Dry	Tongue Dry						
ΤΠ	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 Dose Durat	PT	Report Source	Product	Role Manufacturer	Route
Dose Durat Other 10 MG, TID,	Obsessive-Compulsive	Foreign	Baclofen (Baclofen)	PS	ORAL
ORAL	Personality Disorder	Health			
	Paranoia	Professional Other	Co-Codamol Folic Acid Risedronate Sodium (Risedronate Sodium) Perindopril (Perindopril) Aspirne Bumetanide (Bumetanide)	C C C C C	

Date:04/04/03ISR Number: 4090087-0Report Type:Expedited (15-DaCompany Report #PHNU2003DE01380 Age:70 YR Gender:Male I/FU:I

Outcome Dose I	Duration	PT	Report Source	Product	Role Manufacturer	Route
Hospitalization Initial or Property 50 MG/DAY,	on –	Drug Interaction Fatigue	Foreign Health	Lioresal (Baclofen) Tablet, 10mg	PS	ORAL
ORAL		Pain In Extremity	Professional			
		Weight Increased	Other	Neurontin (Gabapentin)	SS	
1800MG/DAY				Saroten "Bayer		

Freedom Of Information (FOI) Report

			Vital" (Amitriptyline Hydrochloride) L-Thyroxin "Henning Berlin" Candesartan (Candesartan) Oxybutynin (Oxybutynin)	ss c c c	Bayer Vital	
Date:04/04/03ISR Number Age:5 YR Gender:Male	: 4091000-2Report Type:Ex I/FU:I	pedited (15-DaCompany Re	eport #PHNU2003DE01333			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration Hospitalization - Initial or Prolonged 15 MG/DAY,	Coma Hypothermia	Foreign Health Professional	Lioresal (Baclofen) Tablet	PS		ORAL
ORAL		Other				
Date:04/07/03ISR Number Age:14 YR Gender:Male	: 4089788-XReport Type:Ex I/FU:I	pedited (15-DaCompany Re	eport #03-03-0381			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - INTRATHECAL 536-10	Clonic Convulsion	Literature	Baclofen	PS		
Initial or Prolonged INTRATHECAL 5 YR	Discomfort	Health				
	Dyspnoea Hyperpyrexia Medical Device Complication Muscle Spasticity Post Procedural Complication Respiratory Rate Increased	Professional				

	3ISR Number Gender:Fema	: 4091612-6Report Type:Expedit le I/FU:F	ed (15-DaCompany Repor	t #20021163			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other	Duración	Burning Sensation Feeling Cold	Health Professional	Lioresal? Intrathecal(Baclofen Injection)	PS		
INTRATHECAL	275 MC	G,			1.2		
DAILY,							
INTRATHECAL							
	3ISR Number Gender:Male	: 4092307-5Report Type:Expedit I/FU:I	ed (15-DaCompany Repor	t #20031346			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalizat Initial or P INTRATHECAL	ion -	Medication Error Respiratory Disorder AILY,	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		

INTRATHECAL

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 Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other	Duración	Insomnia Tooth Disorder	Foreign Other	Oxygesic 40 Mg(Oxycodone Hydrochloride) Cr Tablet	PS		ORAL
40 MG, TID,				Tablet	FD		UKAL
ORAL				Neurontin(Gabapentin			
600 MG, Q6H,)	SS		ORAL
ORAL				Baclofen(Baclofen)	SS		
30 MG, DAILY	,						
ORAL				Tramal	С		
		: 4092532-3Report Type:Expedit	ed (15-DaCompany Repor	t #PHNU2003DE00538			
Date:04/09/0	3ISR Number	: 4092532-3Report Type:Expedit	ed (15-DaCompany Repor	t #PHNU2003DE00538			
	3ISR Number Gender:Fema Duration	le I/FU:F PT	Report Source	Product	Role	Manufacturer	Route
Age:31 YR (Outcome Dose Other	Gender:Fema	le I/FU:F			Role PS	Manufacturer	Route ORAL
Age:31 YR (Outcome Dose	Gender:Fema	le I/FU:F PT Abortion	Report Source Foreign	Product Lioresal(Baclofen)		Manufacturer	
Age:31 YR (Outcome Dose Other	Gender:Fema	le I/FU:F PT Abortion Complications Of Maternal Exposure To Therapeutic Drugs Maternal Drugs Affecting Foetus	Report Source Foreign Health Professional	Product Lioresal(Baclofen)		Manufacturer	
Age:31 YR (Outcome Dose Other SEE IMAGE Date:04/09/03	Gender:Fema Duration	le I/FU:F PT Abortion Complications Of Maternal Exposure To Therapeutic Drugs Maternal Drugs Affecting Foetus	Report Source Foreign Health Professional Other	Product Lioresal(Baclofen) Tablet, 10mg		Manufacturer	
Age:31 YR (Outcome Dose Other SEE IMAGE Date:04/09/03	Gender:Fema Duration 3ISR Number	<pre>le I/FU:F PT Abortion Complications Of Maternal Exposure To Therapeutic Drugs Maternal Drugs Affecting Foetus Pregnancy : 4092915-1Report Type:Expedit</pre>	Report Source Foreign Health Professional Other	Product Lioresal(Baclofen) Tablet, 10mg	PS	Manufacturer	

		Health	(Baclofen Injection)	PS	
INTRATHECAL UNK	K MCG,	Professional			
DAILY,		PIOLESSIONAL			
INTRATHECAL					
Date:04/15/03ISR Num Age:9 YR Gender:	nber: 4095246-9Report Type:Exped I/FU:I	ited (15-DaCompany Re	eport #03-04-0444		
Outcome	PT	Report Source	Product	Role Manufacturer	Route
Dose Duratio	n				
Hospitalization - INTRATHECAL 99.	Accidental Overdose .8-777UG	Literature	Baclofen	PS	
Initial or Prolonged		Health			
Other	Coma	Professional	Ranidine	C	
	Delayed Recovery From		Scopolamine	С	I
	Anaesthesia				
	Haemodynamic Instability				
	Heart Rate Decreased				
4	Heart Rate Increased				
	Implant Site Reaction				
	Medical Device				
	Complication				
					, i i i i i i i i i i i i i i i i i i i

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 PTReport Source Product Role Manufacturer Route Duration Dose Other Cardiac Failure Foreign Lioresal (Baclofen) Health PS ORAL Dyspnoea Unknown ORAL Professional Other Date:04/17/03ISR Number: 4098157-8Report Type:Expedited (15-DaCompany Report #HQWYE640614APR03 Age: Gender: Female I/FU:I Report Source Product Role Manufacturer Outcome ΡТ Route Duration Dose Drug Withdrawal Syndrome Health Infumorph (Morphine Other Myocardial Infarction Professional Sulfate, Injection) PS INTRADISCAL Pharmaceutical Product (INTRASPINAL) INTRASPINAL 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 Report Source Role Manufacturer Outcome PTProduct Route Dose Duration Hospitalization -Decubitus Ulcer Health Infumorph (Morphine Loss Of Consciousness Professional Sulfate, Injection) Initial or Prolonged ΡS INTRADISCAL Rhabdomyolysis (INTRASPINAL) INTRASPINAL

Baclofen (Baclofen)

SS

INTRADISCAL

(INTRASPINAL) INTRASPINAL

Date:04/17/0 Age:	03ISR Number Gender:Male		Type:Expedited (15-DaCompany Report	#DEU-2002-0000223		
Outcome Dose	Duration	PT	Report Source I	Product	Role Manufa	acturer Route
Other	Duración	Insomnia Sleep Disorder Tooth Disorder	Other	Oxygesic 40 Mg (Oxycodone Hydrochloride) Cr Tablet	PS	ORAL
40 MG, TID,					- ~	
ORAL 600 MG, Q6H	Ι,			Neurontin (Gabapentin)	SS	ORAL
ORAL	,					
30 MG. DAIL	Ч		F	Baclofen	SS	ORAL
ORAL			,	Tramal	С	

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	a					
Hospitalization -	Coma	Health	Lioresal Intrathecal			
Initial or Prolonged	Overdose	Professional	(Baclofen Injection)	PS		
INTRATHECAL DAII	LY,					

INTRATHECAL

		FDA - Adverse	e Event Reporting Syste	m (AER	S)	
		Freedom C	of Information (FOI) Re	port		
Date:04/21/03ISR Number Age: Gender:Male	: 4099466-9Report Type:Expedit I/FU:I	ted (15-DaCompany Repor	t #20031364			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - Initial or Prolonged INTRATHECAL DAILY,	Decubitus Ulcer Loss Of Consciousness Overdose	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		
INTRATHECAL	Rhabdomyolysis		Morphine	С		
Date:04/24/03ISR Number Age:14 YR Gender:Male Outcome	: 4102658-3Report Type:Expedit I/FU:I PT	ted (15-DaCompany Repor Report Source	rt #ZANA001068 Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged ORAL	Clonic Convulsion Condition Aggravated	Literature Health	Zanaflex (Tizanidine Hydrochloride)	PS		ORAL
INTRATRACHEAL INTHC	Dyspnoea	Professional	Baclofen (Baclofen)	SS		
INIKAIKACHEAL	Hyperpyrexia Mechanical Complication Of Implant Medical Device Complication Muscle Spasms Respiratory Rate Increased		Lorazepam Clonazepam	C C		
Date:04/25/03ISR Number Age: Gender:	: 4101033-5Report Type:Direct I/FU:I	Company Repor	t #USP 55815			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other QUARTER TABS	Medication Error		Metoprolol	PS		
QUARTER TABS			Baclofen	SS		

utcome		PT	Report Source	Product	Role Manufacturer	Route
ose	Duration					
ther		Cardiac Failure	Foreign	Lioresal		
		Dyspnoea	Health	(Baclofen)Unknown	PS	ORAL
0 MG/DAY,						
			Professional			
RAL						
			Other	Lanoxin Drops	С	
				Sintrom	С	
				Tenoretic	С	

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Hospitalizati		Meningitis		Lioresal Intrathecal			
Initial or Pr	rolonged		Professional	(Baclofen Injection)	PS		
INTRATHECAL	MCG, D	AILY,					

INTRATHECAL

Intrethecal Morphine C

FDA - Adverse Event Reporting System (AERS) Freedom Of Information (FOI) Report Date:05/02/03ISR Number: 4107134-XReport Type:Expedited (15-DaCompany Report #20031364 Gender:Male I/FU:F Outcome PΤ Report Source Product Role Manufacturer Route Duration Hospitalization -Decubitus Ulcer Health Lioresal Loss Of Consciousness Professional Intrathecal(Baclofen Initial or Prolonged Overdose Injection) PS INTRATHECAL DAILY, Pharmaceutical Product INTRATHECAL Complaint Morphine С Rhabdomyolysis Date:05/02/03ISR Number: 4107135-1Report Type:Expedited (15-DaCompany Report #20031375 Gender:Male I/FU:I Age:34 YR Role Manufacturer Outcome PTReport Source Product Route Duration Hospitalization -Agitation Health Lioresal Initial or Prolonged Atrial Fibrillation Professional Intrathecal(Baclofen Injection) Required Confusional State PS INTRATHECAL 700 MCG, Intervention to Hallucination, Visual DAILY, Prevent Permanent Hyperpyrexia INTRATHECAL Impairment/Damage Hypertension Somnolence Tachycardia Tremor Date:05/02/03ISR Number: 4107136-3Report Type:Expedited (15-DaCompany Report #20031357 Gender:Female I/FU:F Outcome PTReport Source Product Role Manufacturer Route Duration Hospitalization -Depressed Level Of Health Lioresal Intrathecal Initial or Prolonged Consciousness Professional (Baclofen Injection) PS INTRATHECAL DAILY,

Age:

Dose

Dose

Age:

Dose

INTRATHECAL

Overdose

Nausea

Vomiting

Age: Gender:Ma		e:Expedited (15-DaCompany Re	50110 #FUD920031E4292			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Depression	Foreign	Lioresal(Baclofen)			
Initial or Prolonged	Mania	Health Professional Other	Solution	PS		
Date:05/07/03ISP Numbe	ar: 4109598-4Report Two	e:Fypedited (15-DaCompany P	2007t #HOWVE93132810003			
Age: Gender:Fer	nale I/FU:I	e:Expedited (15-DaCompany Re				_
Age: Gender:Fer Outcome		e:Expedited (15-DaCompany Re Report Source	eport #HQWYE931328APR03 Product	Role	Manufacturer	Route
Age: Gender:Fer Outcome Dose Duration	nale I/FU:I PT	Report Source	Product	Role	Manufacturer	Route
Age: Gender:Fer Outcome Dose Duration	nale I/FU:I	Report Source Health	Product Infumorph (Morphine		Manufacturer	Route
Age: Gender:Fer Outcome Dose Duration Other	nale I/FU:I PT	Report Source	Product	Role PS	Manufacturer	Route
Age: Gender:Fer Outcome Dose Duration Other	nale I/FU:I PT	Report Source Health	Product Infumorph (Morphine Sulfate, Injection)		Manufacturer	Route
Age: Gender:Fer Outcome	nale I/FU:I PT	Report Source Health	Product Infumorph (Morphine		Manufacturer	Route

INTRASPINAL

FDA - Adverse Event Reporting System (AERS) Freedom Of Information (FOI) Report Date:05/07/03ISR Number: 4109850-2Report Type:Expedited (15-DaCompany Report #20031379 Age: Gender:Male I/FU:I Outcome PTReport Source Product Role Manufacturer Route Duration Dose Treatment Noncompliance Health Lioresal Intrathecal Death Professional PS (Baclofen Inje) INTRATHECAL DAILY, INTRATHECAL Oral Baclofen С Date:05/12/03ISR Number: 4111021-0Report Type:Expedited (15-DaCompany Report #HQWYE64061APR03 Gender:Female I/FU:F Age: Role Manufacturer Report Source Product Outcome PTRoute Duration Dose Other Drug Withdrawal Syndrome Health Infumorph (Morphine Myocardial Infarction Professional Sulfate, Injection) PS INTRASPINAL Baclofen (Baclofen,) SS INTRA-UTERINE INTRASPINAL Date:05/14/03ISR Number: 4114069-5Report Type:Direct Company Report #CTU 193045 Gender:Female I/FU:I Age: Outcome PTReport Source Product Role Manufacturer Route Dose Duration Other Abnormal Behaviour Baclofen 5mg Bid X 7 Confusional State Days Then 10mg Bid PS 5MG BID X 7 Restlessness DAYS THEN Speech Disorder 10MG BID Urinary Tract Infection

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Agitation	Health	Lioresal Intrathecal			
Initial or Prolonged	Coma	Professional	(Baclofen Injection)	PS		
DAILY,						
Required	Headache					
INTRATHECAL						
Intervention to	Overdose					
Prevent Permanent	Swelling					
Impairment/Damage						
Date:05/15/03ISR Number Age: Gender:Male	: 4113334-5Report Type:Expedi- I/FU:I	ted (15-DaCompany Repo	rt #20031397			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration		-				
Hospitalization -	Affect Lability	Health	Lioresal Intrathecal			
Initial or Prolonged	Depression	Professional	(Baclofen Injection)	PS		
INTRATHECAL DAILY,						
INTRATHECAL						
Date:05/19/03ISR Number Age: Gender:Fema	: 4115291-4Report Type:Expedi le I/FU:I	ted (15-DaCompany Repoi	rt #PHFR2003GB01925			
Outcome	РТ	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Aphonia	Foreign	Lioresal(Baclofen)			
		Health	Tablet	PS		ORAL
5 MG, BID,						
		Professional				
ORAL						
		Other				

FDA - Adverse Event Reporting System (AERS) Freedom Of Information (FOI) Report Date:06/02/03ISR Number: 4122338-8Report Type:Expedited (15-DaCompany Report #20031387 Gender:Male Age: I/FU:I Outcome PTReport Source Product Role Manufacturer Route Dose Duration Life-Threatening Drug Withdrawal Syndrome Health Lioresal Intrathecal Migration Of Implant Professional (Baclofen Injection) ΡS DAILY, INTRATHECAL 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 Report Source Role Manufacturer Outcome PTProduct Route Dose Duration Hospitalization -Dizziness Haloperidol PS 2MG BID Initial or Prolonged Baclofen Syncope SS 10MG TID Guaifenesin С Atenolol С С Lorazepam Meclizine С С Venlafaxine Fosinopril С Hctz С С Fosinopril Date:06/04/03ISR Number: 4124610-4Report Type:Expedited (15-DaCompany Report #20031416 Gender:Male Aqe: I/FU:I Outcome PTReport 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

	03ISR Number Gender:Fema		8745-1Report Type:Expedit I/FU:I	ed (15-DaCompany Repor	<pre>st #PHBS2003BR05490</pre>			
Outcome Dose	Duration	PT		Report Source	Product	Role	Manufacturer	Route
Other		Facia	al Palsy	Foreign Consumer	Lioresal (Baclofen) Tablet	PS		ORAL
10 MG/DAY,				Other				
ORAL					Fluoxetine Hydrochloride (Fluoxetine Hydrochloride) Pyridoxine Hydrochloride Naprosyn Omeprazole (Omeprazole) Alprazolam (Alprazolam)	с с с с		
Date:06/13/0 Age:	03ISR Number Gender:Male		9705-7Report Type:Expedit I/FU:I	ed (15-DaCompany Repor	st #20031406			
Outcome Hospitalizat Initial or H			d Pressure Increased ce Failure					

Freedom Of Information (FOI) Report

Dose	Duration	Drug Withdrawal Syndrome Heart Rate Increased Hyperhidrosis	Report Source	Product	Role	Manufacturer	Route
	Daración	Muscle Spasms Muscle Spasticity	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		
INTRATHECAL	UNK MC		110100010101		10		
DAILY,							
INTRATHECAL							
)3ISR Number Gender:Male	r: 4130141-8Report Type:Exped e I/FU:I	lited (15-DaCompany Re	≥port #03-06-0687			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalizat Initial or F SEE IMAGE	cion -	Blood Pressure Increased Feeling Abnormal	Health Professional	Baclofen - Ipi Tablets	PS		ORAL
		High Density Lipoprotein Decreased Hypokalaemia Sinus Tachycardia					
)3ISR Number Gender:Male	r: 4130826-3Report Type:Exped e I/FU:I	lited (15-DaCompany Re	≥port #20031422			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalizat		Device Failure Lethargy Overdose	Health Professional	Lioresal Intrathecal(Baclofen Injection)	PS		
initerar or i		OVELUUSE			гIJ		
INTRATHECAL	MCG, I						
	MCG, I	DAILY, Somnolence					

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Hospitalizat:	ion –	Apnoeic Attack	Health	Lioresal Intrathecal			
Initial or Pr	colonged	Blood Pressure Decreased	Professional	(Baclofen Injection)	PS		
INTRATHECAL	DAILY	- · /					
		Catheter Related					
INTRATHECAL							
		Complication		Dilaudid	С		
		Drug Ineffective		Clonidine	С		
		Pain					
		Paralysis					
		Somnolence					
	3ISR Number Gender:Fema	: 4138389-3Report Type:Exped le I/FU:F	ited (15-DaCompany Re	eport #PHFR2003GB01925			
Age: (sender • rellia						
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration		-				
Other		Aphonia	Foreign	Lioresal(Baclofen)			
		-	Health	Tablet	PS		ORAL
5 MG, BID,							
			Professional				
ORAL							
			Other				

		FDA - Advers	se Event Reporting Syste	em (AERS)	
		Freedom	Of Information (FOI) Re	eport	
Date:06/30/03ISR Number Age:35 YR Gender:Fema	r: 4138358-3Report Type:Direct ale I/FU:I	Company Repc	ort #CTU 112871		
Outcome Dose Duration	РТ	Report Source	Product	Role Manufacturer	Route
1 TWICE A DAY	Dizziness Medication Error Nausea		Blacofen 10mg	PS	
Age:68 YR Gender:Fema					
Outcome Dose Duration	PT	Report Source	Product	Role Manufacturer	Route
Hospitalization - Initial or Prolonged	Dizziness Drug Interaction Eye Rolling	Foreign Study Health	Esidrix (Hydrochlorothiazide) Tablet	PS	ORAL
25 MG, QD,	Fall	Professional			
ORAL	Fall Hypertension Orthostatic Hypotension	Other	Baclofen (Baclofen, Baclofen)	SS	ORAL
25 MG, ORAL	Tremor		Benalapril (Enalapril) Tablet, 5mg	SS	ORAL
5 MG, QD ORAL			Doxepin (Doxepin)		•
75 MG, QD,			Capsule	SS	ORAL
ORAL			Celebrex Capsule Metoclopramide (Metoclopramide)	C	
			Solution	С	

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 Age:22 YR Gender:	r: 4148239-7Report Type:Expe I/FU:I	dited (15-DaCompany Re	eport #20031447			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Death	Death	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		
INTRATHECAL MCG, D)AILY,	1-0-000-0101	(10		
INTRATHECAL						
Age: Gender:Fema	r: 4149280-0Report Type:Expendent I/FU:I		eport #PHNU2003DE02530 Product	Dele	Manufacturer	Pouto
Outcome Dose Duration	21	Report Source	Product	Roie	Manulacturer	Route
Hospitalization - Initial or Prolonged 30 MG, QID,	Faecaloma Intestinal Obstruction	Foreign Health	Lioresal (Baclofen) Unknown	PS		
		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 PΤ Report Source Product Role Manufacturer Route Dose Duration Hospitalization -Depressed Level Of Foreign Lioresal Intrathecal Initial or Prolonged Consciousness Health \$Me(Baclofen)Ampoulr PS INTRATHECAL INTRATHECAL Professional Muscular Weakness Other Sleep Apnoea Syndrome Date:07/16/03ISR Number: 4150797-3Report Type:Expedited (15-DaCompany Report #PHNU2003DE02627 Age: Gender: Female I/FU:I Report Source Product Role Manufacturer Outcome ΡТ Route Duration Dose Diarrhoea Lioresal Foreign Other Incontinence (Baclofen) Health 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 Role Manufacturer Outcome PTReport Source Product Route Dose Duration Hospitalization -Drug Interaction Foreign Lioresal(Baclofen) Initial or Prolonged Fatigue Health Tablet, 10 Mg PS ORAL 50 MG/DAY, Pain In Extremity Professional ORAL Other Neurontin Weight Increased (Gabapentin) SS 1800 MG/DAY, Saroten "Bayer Vital" (Amitriptyline Hydrochloride) SS Bayer Vital L-Thyroxin "Henning Berlin" С Candesartan (Candesartan) С

(Oxybutynin) С Date:07/18/03ISR Number: 4152559-XReport Type:Expedited (15-DaCompany Report #20031457 Age:32 YR Gender:Male I/FU:I \mathbf{PT} Report Source Product Role Manufacturer Outcome Route Duration Dose Hospitalization -Health Lioresal Clonus Initial or Prolonged Drug Withdrawal Syndrome Professional Intrathecal(Baclofen Hyperreflexia Injection) ΡS INTRATHECAL 420 MCG, Hypertonia DAILY, Pruritus INTRATHECAL; Pyrexia 200 UG/DAY Tachycardia Baclofen (Baclofen) С Diazepam (Diazepam) С

Oxybutynin

Date:07/22/03ISR Number: 4154090-4Report Type:Expedited (15-DaCompany Report #PHNU2003DE02530 Age: Gender:Female I/FU:F

Outcome PT Hospitalization - Abdominal Distension Initial or Prolonged Constipation Gastrointestinal Motility

Freedom Of Information (FOI) Report

	Disorder					
	Intestinal Obstruction Vomiting					
Duratio		Report Source	Product	Role	Manufacturer	Route
Dose Duratio	on	Foreign	Lioresal (Baclofen)	PS		
SEE IMAGE		FULEIGII	LIULESAL (Bacioten)	ГÖ		
		Health Professional Other	Duragesic (Fentanyl) Sirdalud	SS C		
Date:07/28/03ISR Num Age: Gender:F	uber: 4157797-8Report Type:Expe Yemale I/FU:I	dited (15-DaCompany Re	eport #20031464			
Outcome Dose Duratic	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - Initial or Prolonged	Catheter Related Complication LLY,	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		
INTRATHECAL	Convulsion					
	Meningitis Mugala Specticity					
	Muscle Spasticity					
Date:07/30/03ISR Num Age: Gender:M	ber: 4160273-XReport Type:Expe	dited (15-DaCompany Re	eport #PHBS2003DE07067			
Age: Gender:M	ber: 4160273-XReport Type:Expe	dited (15-DaCompany Re Report Source	eport #PHBS2003DE07067 Product	Role	Manufacturer	Route
Age: Gender:M Dutcome Dose Duratic	aber: 4160273-XReport Type:Exped Male I/FU:I PT on	Report Source	Product	Role	Manufacturer	Route
Age: Gender:M Outcome Dose Duratic Life-Threatening	aber: 4160273-XReport Type:Exped Male I/FU:I PT on Autonomic Nervous System	Report Source Foreign	Product Lioresal Intrathecal	Role	Manufacturer	Route
Age: Gender:M Outcome Dose Duratic Life-Threatening Hospitalization -	aber: 4160273-XReport Type:Exper Male I/FU:I PT Autonomic Nervous System Imbalance	Report Source Foreign Literature	Product Lioresal Intrathecal \$Me (Baclofen)		Manufacturer	Route
Age: Gender:M Outcome Dose Duratic Life-Threatening Hospitalization - Initial or Prolonged	aber: 4160273-XReport Type:Exper Male I/FU:I PT Autonomic Nervous System Imbalance	Report Source Foreign	Product Lioresal Intrathecal	Role PS	Manufacturer	Route

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 \mathbf{PT} Hospitalization -Apnoea Initial or Prolonged Autonomic Nervous System Required Imbalance Intervention to Cardiac Failure Coagulopathy Prevent Permanent Drug Withdrawal Syndrome Impairment/Damage Hyperhidrosis 22-Aug-2005 12:15 PM Page: 175

Freedom Of Information (FOI) Report

Dose	Duration	Hypertension Hypertonia Hypotension	Report Source	Product	Role	Manufacturer	Route
		Myocardial Infarction Myopathy	Foreign Health	Lioresal Intrathecal (Baclofen Injection)	PS		
INTRATHECAL	1220 M	ICG, Pain	Professional				
DAILY,							
INTRATHECAL		Pneumonia					
		Pyrexia Renal Failure Tachycardia					
	3ISR Number Gender:	: 4160283-2Report Type:Exped: I/FU:F	ited (15-DaCompany Repo	rt #20031343			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Death	Daración	Cardiac Failure Pneumonia	Foreign Health	Lioresal Intrathecal (Baclofen Injection)	PS		
INTRATHECAL INTRATHECAL	, DAIL	Υ,	Professional				
	3ISR Number Gender:	: 4160943-3Report Type:Exped: I/FU:I	ited (15-DaCompany Repo	rt #20031470			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Life-Threater Hospitalizat	ning	Coagulopathy Coma	Literature Health	Lioresal Intrathecal(Baclofen			
Initial or P: INTRATHECAL Required		Drug Withdrawal Syndrome	Professional	Injection)	PS		
INTRATHECAL	to	Hypotension					
Intervention Prevent Perma Impairment/Da	anent	Hypotension Myopathy 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			I
Hospitalization -	Coma	Health	(Baclofen) Ampoule	PS		I
Initial or Prolonged	Device Failure Disseminated Intravascular Coagulation Drug Withdrawal Syndrome Hypotension Lung Disorder Muscle Rigidity Muscle Spasticity Rhabdomyolysis Tachycardia Urosepsis	Professional				

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 Dose Duration	PT	Report Source	Product	Role Manufacturer	Route
Hospitalization - Initial or Prolonged Other 12.5MG/2.5ML	Abdominal Pain Upper Accidental Overdose Aggression	Consumer	Baclofen (Watson Laboratories)(Baclof en) Tablet, 20mg	PS	ORAL
QAM, 5MG/ML	Dyskinesia				
QAM, JMG/ML	Electroencephalogram				
QHS, ORAL					
	Abnormal Hallucination Headache Insomnia Lethargy Medication Error Pruritus Respiratory Rate Decreased Scratch Screaming				
Date:08/04/03ISR Number Age:52 YR Gender:Male	: 4163552-5Report Type:Periodi I/FU:I	c Company Repor	t #0254-02(0)		
Outcome Dose Duration	PT	Report Source	Product	Role Manufacturer	Route
Life-Threatening Hospitalization - Initial or Prolonged 60 MG DAILY	Dehydration Grand Mal Convulsion	Foreign Health Professional	Baclofen Tablets (Unknown Strength) Usp (Danbury/Watson)	PS	ORAL
PO					
			Cannador	SS	ORAL
8 DF DAILY PO					
150 MG DAILY			Dantrolene	SS	ORAL

PO

Age:55 YR Gender:Male	: 4163554-9Report Type:Period I/FU:I	lic Company Repo	ort #0255-02(0)			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Life-Threatening Hospitalization - Initial or Prolonged 60 MG DAILY	Atrial Fibrillation Dehydration Grand Mal Convulsion Infection	Foreign Health Professional	Baclofen Tablets Usp (Unknown Strength) (Danbyry/Watson)	PS		ORAL
PO	Intection					
10 MG DAILY			Placebo Therapy	SS		ORAL
PO						
			Lansoprazole Viagra	C C		
			Viagia	C		
Date:08/06/03ISR Number Age: Gender:Male	: 4166353-7Report Type:Expedi I/FU:F	.ted (15-DaCompany Repo		C		
Age: Gender:Male Outcome		ited (15-DaCompany Repo Report Source		-	Manufacturer	Route
Age: Gender:Male	PT Accident	Report Source Health	ort #20031379 Product Lioresal Intrathecal	Role	Manufacturer	Route
Age: Gender:Male Outcome Dose Duration Death	PT Accident Atrophy	Report Source	ort #20031379 Product	Role	Manufacturer	Route
Age: Gender:Male Outcome Dose Duration Death	PT Accident Atrophy	Report Source Health	ort #20031379 Product Lioresal Intrathecal	Role	Manufacturer	Route

			FDA -	- Adverse !	Event Reporting System	n (AERS	S)	
			I	Freedom Of	Information (FOI) Rep	port		
	SR Number: nder:Femal	: 4166762-6Report Type:Direct le I/FU:I	Compa	any Report	#CTU 199720			
Outcome Dose Du	uration	PT	Report Source	e I	Product	Role	Manufacturer	Route
Other INTRATHECAL	5000MCG	Depressed Level Of G IT Consciousness		J	Baclofen Inj	PS		
Date:08/11/03IS Age:32 MON Ger		: 4167972-4Report Type:Periodi le I/FU:I	.c Compa	any Report	#03-03-0386			
Outcome Dose Du		PT	Report Source	e I	Product	Role	Manufacturer	Route
Dose Duration Hospitalization - Initial or Prolonged 75MG QD ORAL	Anorexia Coma	Consumer		Baclofen - Ipi Tablets	PS	Ipi	ORAL	
Date:08/12/03IS	SR Number:	Diarrhoea Hypoventilation Malaise Muscle Twitching Overdose Vomiting : 4166043-0Report Type:Expedit	ed (15-DaComp;		Tegretol Dilantin Aspirin Zyrtec Benadryl Vancomycin Zantac Gentamicin Zofran Lovenox Pulmicort #PHBS2003NL08166	0 0 0 0 0 0 0 0 0 0 0 0 0		
Age:8 YR Ger Outcome	nder:Unkno	own I/FU:I PT	Report Source	٩	Product	Role	Manufacturer	Route
	uration	Hypernatraemia Liver Function Test Abnormal	-		Lioresal	PS	Novartis Sector: Pharma	ORAL
		Pyrexia Restlessness Rhabdomyolysis						

Age: Gender:Male	e I/FU:I					
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - Initial or Prolonged	Blood Pressure Increased Muscle Spasticity	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		
INTRATHECAL 1200 M			- 2000mcg/Ml	P5		
DAILY,	Post Procedural					
INTRATHECAL	Complication					
	Pyrexia Reflexes Abnormal Urinary Tract Infection					
Date:08/14/03ISR Number Age:15 YR Gender:Male	r: 4168190-6Report Type:Exped	ited (15-DaCompany Re	eport #PHNU2003DE02970			
Outcome	РТ					
Other	Alanine Aminotransferase Increased					
	Aspartate					
	Aminotransferase Increased					
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Freedom Of Information (FOI) Report

Dose	Duration	Gamma-Glutamyltransferase Increased Liver Function Test Abnormal	Report Source	Product Lioresal	Role	Manufacturer Novartis Sector:	Route
UNK						Pharma	ORAL
ONK				Lioresal	SS	Novartis Sector: Pharma	ORAL
50mg/day							
Date:08/22/ Age:	03ISR Number Gender:	r: 4173452-2Report Type:Dired I/FU:I	ct Company Re	eport #CTU 200544			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
		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		
Age:73 YR	03ISR Number Gender:Fema				_		
Outcome Dose	Duration	РТ	Report Source	Product	Role	Manufacturer	Route
Hospitaliza Initial or UNKNOWN				Baclofen	PS	Novartis Sector: Pharma	
UNKNOWN	1500 m	Atrial Fibrillation ng/day		Acetaminophen	C		

		Creatinine Renal		Carbamazepine	C	
UNKNOWN	300 mg	/day				
		Clearance Increased		Glipizide	С	
UNKNOWN	5 mg/da	ay				
		Depressed Level Of		Meloxicam	С	
UNKNOWN	7.5 mg	, BID				
		Consciousness		Diazepam	С	
UNKNOWN	5 mg/da	-				
		Locked-In Syndrome		Zolpidime		
		Mental Impairment		Hemitartare	С	
UNKNOWN	10 mg/0	day				
		Proteinuria				
		Speech Disorder				
		Urinary Incontinence				
)3ISR Number Gender:Male	: 4178410-XReport Type:Exp I/FU:I	edited (15-DaCompany Re	eport #20031498		
Outcome		PT	Report Source	Product	Role Manufacturer	Route
Dose	Duration		-			
Life-Threate	ening	Cardiac Arrest	Health	Lioresal Intrathecal		
	5	Emotional Distress	Professional	(Baclofen Injection)	PS	
INTRATHECAL	MCG, D	AILY,				
		Loss Of Consciousness				
INTRATHECAL						
		Medication Error				
		Overdose				

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	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Dose Hospitalizat: 15 MG/DAY		Apathy	Foreign	Baclofen (Baclofen)	PS		
Initial or Pi	-	Atrial Fibrillation Back Pain Depressed Level Of	Literature Health Professional	Acetaminophen Carbamazepine Glipizide	C C		
		Consciousness Electroencephalogram	Other	(Glipizide) Meloxicam	С		I
		Abnormal Insomnia Locked-In Syndrome Mental Impairment		(Meloxicam) Diazepam Zolpidine Hemitartare	C C		
		Pain Proteinuria Speech Disorder Urinary Incontinence		(Zolpidem)	C		
Age:5 YR (3ISR Number: Gender:Male						
Outcome Dose	Duration	PT	Report Source	Product	Ro⊥e	Manufacturer	Route
Hospitalizat: Initial or Pr 15mg/day		Coma Hypothermia		Lioresal	PS	Novartis Sector: Pharma	ORAL
Other		Pneumonia Aspiration					
	3ISR Number: Gender:Femal	: 4176562-9Report Type:Direct le I/FU:I	Company Repor	rt #CTU 200904			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
	Duración	Pharmaceutical Product Complaint		Baclofen (Generic) For Lioresal	PS		ORAL
20MG 1 PO		-					
QHS, 10MG 1							
PIO TID, 10MC	G						l

Date:08/29/03ISR Number Age: Gender:Male	: 4179803-7Report Type:Exped I/FU:I	lited (15-DaCompany Re	eport #20031501			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - Initial or Prolonged	Drug Withdrawal Syndrome Medication Error	Health Professional	Lioresal Intrathecal(Baclofen			
INTRATHECAL DAILY,	Postoperative Infection		Injection)	PS		
INTRATHECAL						
Date:08/29/03ISR Number Age:13 YR Gender:Male	r: 4182478-4Report Type:Exped	lited (15-DaCompany Re	eport #2003UW10598			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization -	Dysphagia	Health	Iressa	PS		
Initial or Prolonged	Hallucination	Professional	Iressa	SS		
START DATE IS	Respiratory Arrest		Baclofen	SS		
PRIOR TO						
02-AUG-2003						
START DATE IS			Clonidine	SS		
PRIOR TO						
02-AUG-2003						
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1 BID PRN

		FDA - Adverse	e Event Reporting System	m (AER	LS)	
		Freedom O	Of Information (FOI) Rep	port		
START DATE IS			Methylphenidate	SS		
PRIOR TO						
02-AUG-2003						
START DATE IS			Lorazepam	SS		
PRIOR TO						I
02-AUG-2003				~~		I
START DATE IS			Zoloft	SS		I
PRIOR TO						I
02-AUG-2003			۲ ۲ ۲	00		I
START DATE IS			Benadryl	SS		
PRIOR TO						
02-AUG-2003						
Date:09/03/03ISR Number Age: Gender:Fema	r: 4184486-6Report Type:Expedit ale I/FU:I	ed (15-DaCompany Repor	't #20031508			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - Initial or Prolonged INTRATHECAL DAILY,	Back Disorder Catheter Related Complication	Health Professional	Lioresal (Baclofen Injection)	PS		
INTRATHECAL	Drug Withdrawal Syndrome Mental Status Changes Muscle Rigidity Muscle Spasticity Oedema Pyrexia Rebound Effect Stress		Oral Baclofen	С		

Date:09/08/03ISR Number: 4180743-8Report Type:Expedited (15-DaCompany Report #PHBS2003NL09276 Age:62 YR Gender:Female I/FU:I

PT Duration	Report Source	Product	Role	Manufacturer	Route
Drug Interaction Hypotonia		Baclofen	PS	Novartis Sector: Pharma	
12.5 mg, BID Muscle Twitching Muscular Weakness		Baclofen	SS	Novartis Sector: Pharma	
12.5 mg/d		Propofol	SS		
2.5 mg/kg/d		-			
5 mg/kg/d					
0.25 ug/kg/d					
10 ug/d					
0.6 mg/kg/d					
35 mg/d					
0.6 - 1.0		Isoflurane	SS		
8 mg/d					
7.5 mg, BID					
20 mg, QD			C		
25 ug, QD			C		
1500 mg/d		Cefuroxime	С		
600 mg/d		Clindamycin	С		
10 mg/d		Dexamethasone	С		
	Duration Prug Interaction Hypotonia 12.5 mg, BID Muscle Twitching Muscular Weakness 12.5 mg/d 2.5 mg/kg/d 0.25 ug/kg/d 0.25 ug/kg/d 10 ug/d 0.6 mg/kg/d 35 mg/d 0.6 - 1.0 8 mg/d 7.5 mg, BID 20 mg, QD 25 ug, QD 1500 mg/d 600 mg/d	Duration Drug Interaction Hypotonia 12.5 mg, BID Muscle Twitching Muscular Weakness 12.5 mg/d 2.5 mg/kg/d 35 mg/kg/d 0.6 mg/kg/d 35 mg/d 0.6 - 1.0 8 mg/d 7.5 mg, BID 20 mg, QD 25 ug, QD 1500 mg/d 600 mg/d	Duration Baclofen Hypotonia Baclofen 12.5 mg, BID Baclofen Muscular Weakness Propofol 12.5 mg/d Propofol 2.5 mg/kg/d Sufentanil 5 mg/kg/d Sufentanil 0.25 ug/kg/d Sufentanil 10 ug/d Atracurium 0.6 mg/kg/d Atracurium 35 mg/d Borliane 0.6 - 1.0 Morphine 8 mg/d Diazepam 7.5 mg, BID Diazepam 20 mg, QD Levothyroxine 25 ug, QD Vitamin B12 1500 mg/d Cefuroxime 60 mg/d Diazepam	Duration Baclofen PS Hypotonia Baclofen SS 12.5 mg, BD Muscule Twitching Baclofen SS 12.5 mg/d Propofol SS 12.5 mg/d Propofol SS 2.5 mg/kg/d Propofol SS 5 mg/kg/d Sufentanil SS 0.25 ug/kg/d Sufentanil SS 10 ug/d Atracurium SS 0.6 mg/kg/d Atracurium SS 0.6 mg/kg/d Atracurium SS 0.6 ng/kg/d Morphine SS 0.6 ng/kg/d Prednisone C 0.6 ng/kg/d Atracurium SS 0.6 ng/kg/d Morphine SS 0.6 ng/kg/d Prednisone C 0.6 ng/kg/d Evothyroxine C 2 ng, QD Evothyroxine C 2 ng, QD Cefuroxime C 1500 mg/d Cindamycin C 60 o mg/d Evothasone C	Duration HypotoniaBaclofenPSNovartis Sector: Pharma12.5 mg, BID Muscular WeaknessBaclofenSSNovartis Sector: Pharma12.5 mg/dPropofolSS2.5 mg/kg/dPropofolSS5 mg/kg/dSufentanilSS0.25 ug/kg/dSufentanilSS10 ug/dAtracuriumSS10 ug/dAtracuriumSS0.6 mg/kg/dIsofluraneSS35 mg/dIsofluraneSS0.6 mg/kg/dMorphineSS20 mg, QDPrednisoneC20 mg, QDLevothyroxineC25 ug, QDLevothyroxineC1500 mg/dGC600 mg/dCC

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 PTReport Source Product Role Manufacturer Route Dose Duration Hospitalization -Drug Toxicity Vancomycin Iv PS INTRAVENOUS 1 G IV Q12 Initial or Prolonged Mental Status Changes Baclofen 10 Mg Qid SS SEE IMAGE Required Renal Failure Acute Intervention to Prevent Permanent Impairment/Damage Date:09/09/03ISR Number: 4188462-9Report Type:Expedited (15-DaCompany Report #20031516 Gender:Male I/FU:I Age: Role Manufacturer Outcome PTReport Source Product Route Dose Duration Death Death Health Lioresal Professional 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 PTRole Manufacturer Outcome Report Source Product Route Duration Dose Blood Creatine Hospitalization -Health Lioresal Intrathecal Initial or Prolonged Phosphokinase Increased Professional (Baclofen Injection) PS INTRATHECAL DAILY, Drug Withdrawal Syndrome INTRATHECAL Muscle Spasticity Oral Baclofen С Pruritus Pyrexia Rebound Effect

Date:09/09/03ISR Number	: 4188465-4Report Type:Expe	dited (15-DaCompany Re	eport #20031512			
Age: Gender:Male	I/FU:I					
Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration Required Intervention to INTRATHECAL DAILY,	Respiratory Disorder Rhabdomyolysis	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		
Prevent Permanent INTRATHECAL Impairment/Damage						
Date:09/10/03ISR Number Age: Gender:Male	: 4188488-5Report Type:Experies I/FU:I	dited (15-DaCompany Re	eport #20031517			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Death	Death	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		
INTRATHECAL MCG, DA	AILY,					
INTRATHECAL						
Date:09/11/03ISR Number: Age:61 YR Gender:Male	: 4200753-1Report Type:Perio I/FU:I	odic Company Re	eport #2003163149US			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - Initial or Prolonged 10 MG, BID;	Renal Failure Acute	Health Professional	Bextra (Valdecoxib) Tablet	PS		ORAL
ORAL 365 DAY			Glucophage			
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		FDA - Adverse Event Rep	porting Syste	m (AERS)	
		Freedom Of Informat	ion (FOI) Re	port	
500 MG, BID;		(Metformi: Hydrochlo:		SS	ORAL
ORAL		Valium (D) iazepam)	SS	ORAL
UNK, UNK;					
ORAL		Paglafan	(Baclofen)	SS	
UNKNOWN	UNK, UNK, UNK				
UNKNOWN	UNK, UNK, UNK	Diovan (V	/alsartan)	SS	
		Zanaflex Hydrochlo:	(Tizanidine pride)	SS	ORAL
UNK, UNK;					
ORAL		Hydrocodo: (Hydrocodo		SS	
UNKNOWN	UNK, UNK, UNK	Niacin (N Acid)	Jicotinic	SS	ORAL
250 MG, QD;					
ORAL		Vasotec () Maleate)	Enalapril	SS	ORAL
10 UNK, UNK;					
ORAL			n Chloride		
8 UNK, BID;		(Potassium)	um Chloride)	SS	ORAL
ORAL					
		Tolterodi: L-Tartrat Ultram (T Hydrochlo: Protonix Lasix	ce Framadol	C C C C	
			(Amlodipine)	C C	

	03ISR Number Gender:Male	r: 4190173-0Report Type:Expedi e I/FU:I	ited (15-DaCompany Re	port #2003CG01252			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Required Intervention	ı to	Optic Neuropathy	Foreign Health	Marcaine Lioresal	PS		
Prevent Perm Impairment/D			Professional Other	"Ciba-Geigy" Catapressan	SS SS	Ciba-Geigy	
)3ISR Number Gender:Femal	r: 4195382-2Report Type:Direct ale I/FU:I	t Company Re	eport #CTU 202278			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
	Durucion	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 Gender:Female Aqe:64 YR I/FU:I Outcome PTReport Source Product Role Manufacturer Route Dose Duration Required Blood Calcium Baclofen PS 5 MG X 2 Intervention to Blood Chloride (ONLY) Blood Creatinine Prevent Permanent Impairment/Damage Blood Glucose Blood Potassium Blood Sodium Blood Urea Depressed Level Of Consciousness Haematocrit Mental Status Changes Pco2 Prescribed Overdose Date:09/24/03ISR Number: 4198354-7Report Type:Expedited (15-DaCompany Report #20031525 Aqe:38 YR Gender:Female I/FU:I Role Manufacturer PTReport Source Product Outcome Route Dose Duration Death Health Lioresal Death Intrathecal(Baclofen Professional Company Injection) PS INTRATHECAL UNK MCG, Representative DAILY, INTRATHECAL Date:09/24/03ISR Number: 4198922-2Report Type:Expedited (15-DaCompany Report #20031512 Age: Gender:Male I/FU:F Outcome PTReport Source Product Role Manufacturer Route Dose Duration Catheter Related Health Lioresal Intrathecal Required

Professional

(Baclofen Injection)

PS

Intervention to

INTRATHECAL

Complication

DAILY,

Prevent Permanent INTRATHECAL	Respiration Abnormal				
INTRATHECAL Impairment/Damage	Rhabdomyolysis Therapeutic Response Decreased		Oral Baclofen	С	
Date:09/29/03ISR Number Age: Gender:Fema	r: 4202431-1Report Type:Expe ale I/FU:I	edited (15-DaCompany Re	eport #20031523		
Outcome Dose Duration	PT	Report Source	Product	Role Manufacturer	Route
Required Intervention to Prevent Permanent	Constipation Drug Ineffective Dysarthria	Health Professional	Lioresal Intrathecal(Baclofen Injection)	PS	
INTRATHECAL MCG, I	DAILY,			-	
Impairment/Damage INTRATHECAL	Muscle Spasms				
	Pruritus Pyrexia				
Date:09/29/03ISR Number Age:50 YR Gender:Fema	r: 4202432-3Report Type:Expe ale I/FU:I	edited (15-DaCompany Re	eport #20031520		
Outcome Hospitalization - Initial or Prolonged	PT Anxiety Catheter Related Complication Drug Withdrawal Syndrome				
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Freedom Of Information (FOI) Report

Dese	Duur bir uu	Muscle Spasticity Nausea Pruritus	Report Source	Product	Role	Manufacturer	Route
Dose	Duration	Pyrexia Vomiting	Health Professional	Lioresal Intrathecal(Baclofen Injection)	PS		
INTRATHECAL	265 MG	2G,					
DAILY,							
INTRATHECAL	ı						
Age:64 YR Outcome	Gender:Unkı	r: 4203623-8Report Type:Exped nown I/FU:I PT	ited (15-DaCompany Reg Report Source	port #2003039929 Product	Role	Manufacturer	Route
Age:64 YR Outcome Dose Death		nown I/FU:I PT Cardio-Respiratory Arrest	Report Source Literature	Product Doxepin (Caps)		Manufacturer	
Age:64 YR Outcome Dose Death Other	Gender:Unkı	nown I/FU:I PT	Report Source	Product	Role PS	Manufacturer	Route ORAL
Age:64 YR Outcome Dose Death Other ORAL	Gender:Unkı	nown I/FU:I PT Cardio-Respiratory Arrest	Report Source Literature	Product Doxepin (Caps)		Manufacturer	
Age:64 YR Outcome Dose Death Other	Gender:Unkı	nown I/FU:I PT Cardio-Respiratory Arrest	Report Source Literature Health	Product Doxepin (Caps) (Doxepin)	PS	Manufacturer	ORAL
Age:64 YR Outcome Dose Death Other ORAL	Gender:Unkı	nown I/FU:I PT Cardio-Respiratory Arrest	Report Source Literature Health	Product Doxepin (Caps) (Doxepin) Baclofen (Baclofen) Quetiapine	PS SS SS	Manufacturer	ORAL

Date:10/07/03ISR Number: 4202376-7Report Type:Expedited (15-DaCompany Report #PHRM2003FR02525 Age:35 YR Gender:Female I/FU:I

Outcome		РТ	Report Source	Product	Role	Manufacturer	Route
Hospitalizati Initial or Pr		Cytolytic Hepatitis Hepatic Necrosis		Lioresal	PS	Novartis Sector: Pharma	ORAL
20 mg/day	07040мты			Di-Antalvic	SS		ORAL

6 DF/day 87840MIN

					- 1	c .	
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitaliz	zation -	Drug Ineffective	Consumer	Baclofen Tablets,			
Initial or 10 MG ORAI	r Prolonged L	Muscle Spasticity	Other	Usp	PS		ORAL
				Estrace	С		
				Lasix	С		
				Xanax	С		
			Effexor	С			
			Detrol	С			
				Loricet	С		
Date:10/05	1/03ISR Numbe	er: 4210085-3Report Type:Pe	riodic Company Re	eport #DCC 03-010 BAC			
Age:86 YR		nale I/FU:I		-	Role	Manufacturer	Route
Age:86 YR Outcome	Gender:Fem		eriodic Company Re Report Source	eport #DCC 03-010 BAC Product	Role	Manufacturer	Route
Age:86 YR		nale I/FU:I		Product Baclofen Tablets,	Role	Manufacturer	Route ORAL
Age:86 YR Outcome Dose	Gender:Fem	nale I/FU:I PT Confusional State	Report Source	Product		Manufacturer	
Age:86 YR Outcome Dose Other	Gender:Fem	nale I/FU:I PT Confusional State Somnolence	Report Source	Product Baclofen Tablets, Usp		Manufacturer	
Age:86 YR Outcome Dose Other 10 MG QID	Gender:Fem Duration	nale I/FU:I PT Confusional State Somnolence	Report Source	Product Baclofen Tablets, Usp Diovan	PS C	Manufacturer	
Age:86 YR Outcome Dose Other 10 MG QID	Gender:Fem Duration	nale I/FU:I PT Confusional State Somnolence	Report Source	Product Baclofen Tablets, Usp	PS C C	Manufacturer	
Age:86 YR Outcome Dose Other 10 MG QID	Gender:Fem Duration	nale I/FU:I PT Confusional State Somnolence	Report Source	Product Baclofen Tablets, Usp Diovan	PS C	Manufacturer	

			FDA - Adver	rse Event Reporting Syste	em (AEF	RS)	
			Freedor	n Of Information (FOI) Re	eport		
	SR Number: nder:Femal	4210088-9Report Type:Period Le I/FU:I	lic Company Rep	port #DCC 03-008 BAC20			
Outcome Dose D	uration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalizatio Initial or Pro 20 MG QD ORAL		Hallucinations, Mixed	Health Professional	Baclofen Tablets, Usp 20 Mg	PS		ORAL
Other				Zonegren Carbatrol Risperdal	C C C		
Age:57 YR Ge Outcome	nder:Male uration	4203687-1Report Type:Expedi I/FU:I PT Thrombocytopenia	ited (15-DaCompany Rep Report Source	port #PHNU2003DE03532 Product Lioresal	Role PS	Manufacturer Novartis Sector: Pharma	Route
Date:10/08/03I Age:35 YR Ge		4203695-0Report Type:Expedi Le I/FU:F	ited (15-DaCompany Rep	port #PHRM2003FR02525			
Outcome Dose D	uration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalizatio Initial or Pro 20 mg/day	n –	Cytolytic Hepatitis Hepatic Necrosis		Lioresal	PS	Novartis Sector: Pharma	ORAL
6 DF/day	87840MIN			Di-Antalvic	SS		ORAL
	SR Number: nder:	4207348-4Report Type:Direct I/FU:I	Company Rep	port #USP 080176			
Outcome Dose D	uration	PT	Report Source	Product	Role	Manufacturer	Route
		Medication Error		Baclofen Baclofen	PS SS		

	BISR Number Gender:Male	: 4207422-2Report Type:Expedi I/FU:I	ted (15-DaCompany Repo	ort #20031542			
Outcome Dose	Duration	РТ	Report Source	Product	Role	Manufacturer	Route
Death		Medication Error Overdose	Health Professional	Lioresal Intrathecal(Baclofen Injection)	PS		
INTRAVENOUS					PD		
							BOLUS
75 MCG, BOLUS	3						
EVERY 8							
MINUTES							
	3ISR Number Gender:Male	: 4205237-2Report Type:Expedi I/FU:I	ted (15-DaCompany Repo	ort #PHFR2003GB03795			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalizat:		Coma	Health	Baclofen	PS	Novartis Sector:	
Initial or Pi 5 mg, TID	rolonged	Musculoskeletal Stiffness	Professional			Pharma	
		Renal Impairment		Aspirine	С		
				Trimethoprim Salbutamol	C 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 Gender:Female Age: I/FU:I Outcome PΤ Report Source Product Role Manufacturer Route Dose Duration Other Convulsion Health Neurontin Professional (Gabapentin) PS Baclofen (Baclofen) OTHER SS OTHER Atenolol (Atenolol) С Bisacodyl С (Bisacodyl) Docusate Sodium (Docusate Sodium) С Vitamins С Magnesium Gluconate (Magnesium С Gluconate) Date:10/17/03ISR Number: 4210416-4Report Type:Expedited (15-DaCompany Report #PHFR2003GB03937 Gender:Female Age: I/FU:I PTRole Manufacturer Report Source Product Route Outcome Dose Duration Baclofen Confusional State PS Novartis Sector: Other Drug Withdrawal Syndrome Pharma 20 mg, TID Nightmare Date:10/20/03ISR Number: 4211969-2Report Type:Expedited (15-DaCompany Report #PHBS2003CA11214 Gender: Unknown Aqe: I/FU:I ΡТ Role Manufacturer Outcome Report Source Product Route Dose Duration Life-Threatening Convulsion Lioresal PS Novartis Sector: Hospitalization -Pyrexia Pharma ORAL 40 mg, BID Initial or Prolonged Sepsis

Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Required Intervention Prevent Perm INTRATHECAL Impairment/D DAILY,	n to manent UNK MC	Coagulopathy G,	Foreign Health Professional	Lioresal Intrathecal(Baclofen Injection)	PS		
INTRATHECAL							
	3ISR Number Gender:Male	: 4215104-6Report Type:Expedit I/FU:F	ed (15-DaCompany Repor	t #PHNU2003DE03532			
Outcome	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Dose Other	Duration	Thrombocytopenia		Lioresal	PS	Novartis Sector: Pharma	ORAL
20mg/day							
	3ISR Number Gender:Male	: 4213554-5Report Type:Expedit I/FU:F	ed (15-DaCompany Repor	t #PHFR2003GB03912			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Death Other	2424020	Colitis Death Diarrhoea		Lioresal	PS	Novartis Sector: Pharma	ORAL
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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 Daga	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration Death Hospitalization - 5 mg, TID	Cerebrovascular Accident Coma		Baclofen	PS	Novartis Sector: Pharma	
Initial or Prolonged	Musculoskeletal Stiffness Renal Impairment		Aspirine Trimethoprim Salbutamol Oxybutynin	C C C C		
Date:10/24/03ISR Numbe: Age:37 YR Gender:Fema	er: 4217495-9Report Type:Expedi male I/FU:F	ited (15-DaCompany Rej	port #PHBS2003JP06722			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration Hospitalization - Initial or Prolonged	Depressed Level Of Consciousness Muscular Weakness Sleep Apnoea Syndrome		Lioresal Intrathecal \$Me	PS	Novartis Sector: Pharma	ORAL
Date:10/24/03ISR Numbe: Age:84 YR Gender:Fema	er: 4217514-XReport Type:Direct male I/FU:I	t Company Rej	port #CTU 204544			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - Initial or Prolonged 20 MG BID -PO	Abasia Aphasia		Baclofen/Lioresal 20 Mg Ivax-Zenith	PS	Ivax-Zenith	ORAL
(4 DOSES)	Asthenia					
	Convulsion Drooling Feeding Disorder Gait Disturbance					

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Convulsion	Health	Lioresal			l
Initial or Prolonged	Dystonia	Professional	Intrathecal(Baclofen			
	Hypoglycaemia		Injection)	PS		
INTRATHECAL UNK I	MCG DAILY					
INTRATHECAL						
1			Glucose	С		
			Oral Baclofen	С		
			Antibiotics	С		
Date:10/28/03ISR Numbe	er: 4220492-0Report Type:Direct	Company Repo	ort #CTU 204679			
Age:62 YR Gender:Ma						
Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Life-Threatening	Blood Glucose Increased		Arsenic Trioxide			
	Drug Toxicity		0.25 Mg Kg	PS		
INTRAVENOUS 20 MG	G QD IV					
			Ascorbic Acid 1000	~~		
			Mg	SS		
ASCORBIC ACID						
IV						
			Baclofen	SS		
			Ativan	С		
			Pepcid	С		
			Prochloperazine	С		
			Darvocet	С		
22 August 2005 10.15 DM						

Freedom Of Information (FOI) Report

Lexapro	С
Norvasc	С
Remeron	С

Date:10/29/03ISR Number: 4221266-7Report Type:Expedited (15-DaCompany Report #PHBS2003US11591 Age:38 YR Gender:Female I/FU:I

Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalizat Initial or P	ion -	Angiogram Abnormal Blindness		Baclofen	PS	Novartis Sector: Pharma	ORAL
		Ocular Hyperaemia		Mexiletine			•
		Retinogram Abnormal		Hydrochloride	SS		ORAL
		Scotoma		Morphine Sulfate	С		ORAL
				Morphine Sulfate	С		
INTRATHECAL							
				Pentosan Polysulfate			
				Sodium	С		
UNKNOWN							
				Gabapentin	С		
UNKNOWN							
				Lorazepam	С		
UNKNOWN							
				Hydroxyzine			
				Hydrochloride	С		
UNKNOWN							
				Glimepiride	С		
UNKNOWN							
				Promethazine	-		
				Hydrochloride	С		
UNKNOWN							
				Lidocaine	a		
	205 05	,		Hydrochloride	С		
INTRAVENOUS	385.27	mg		Clonidine			
					a		
				Hydrochloride	С		
UNKNOWN				Methadone			
					a		
UNKNOWN				Hydrochloride	С		
OINTINOWIN				Fluoxetine			
				Hydrochloride	С		
UNKNOWN				inyar ochiror rae			
OTATCINO MATA				Trazodone	С		
UNKNOWN				1102000110			
OTATCINO MATA							

ate:10/29/03ISR Numbe	er: 4222057-3Report Type:Exped	ited (15-DaCompany Re	eport #03-10-1333		
ge: Gender:Mal		1004 (10 2400mpan/ 14			
outcome Duration	PT	Report Source	Product	Role Manufacturer	Rout
ospitalization -	Coma	Foreign	Baclofen - Ipi		
Initial or Prolonged	Musculoskeletal Stiffness	Other	Tablets	PS	
	Renal Impairment		Aspirin	С	
	-		Trimethoprim	С	
			Salbutamol	С	
			Oxybutynin	С	

Sucralfate

С

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 -	Anticonvulsant Drug Level
Initial or Prolonged	Below Therapeutic
Other	Aphasia
	Blood Pressure Increased
	Confusional State
	Heart Rate Increased
	Hypoventilation
	Intentional Misuse
	Intentional Self-Injury

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UNKNOWN

Freedom Of Information (FOI) Report

Dose D	vuration	Lethargy Loss Of Consciousness Miosis	Report Source	Product	Role	Manufacturer	Route
	alacion	Moaning Multiple Drug Overdose Productive Cough Pulmonary Oedema	Health Professional	Oxycontin Tablets(Oxycodone Hydrochloride) Cr Tablet	PS		ORAL
ORAL		Respiratory Rate Increased Somnolence Toxicologic Test Abnormal		Demerol (Pethidine Hydrochloride) Baclofen (Baclofen) Risperdal(Risperidon	SS SS		
				e) Dilantin (Phenytoin Sodium) Soma(Carisoprodol) Methadone(Methadone)	SS SS SS SS		
Date:11/05/03I Age:88 YR Ge		: 4227756-5Report Type:Direct I/FU:I	Company Repor	t #CTU 205260			
Outcome Dose D	uration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalizatio 10 MG QID PRN		Incoherent		Baclofen 10 Mg	PS		ORAL
Initial or Pro ORAL	longed	Medication Error					
		Somnolence		Asa Oxycodone	C C		
	SR Number nder:Male	<pre>Somnolence : 4229148-lReport Type:Expedit</pre>	ed (15-DaCompany Repor	Oxycodone			
Age:35 YR Ge Outcome	nder:Male	: 4229148-1Report Type:Expedit	ed (15-DaCompany Repor Report Source	Oxycodone	С	Manufacturer	Route
Age:35 YR Ge Outcome Dose D Life-Threateni Hospitalizatio	nder:Male Puration ng n -	: 4229148-1Report Type:Expedit I/FU:I PT Coma Convulsion		Oxycodone t #K200301699	С	Manufacturer	Route
Age:35 YR Ge Outcome Dose D Life-Threateni	nder:Male Puration ng n - 900 MG	: 4229148-1Report Type:Expedit I/FU:I PT Coma Convulsion	Report Source Literature	Oxycodone Tt #K200301699 Product Ketalar (Ketamine)	C Role	Manufacturer	Route

	Abnormal	900mg	SS
TRANSDERMAL	900 MG,		
	Overdose		
TRANSDERMAL			
	Postictal State	Amitriptyline	
		(Amitriptyline) 360mg	SS
TRANSDERMAL	360	3601119	22
MG, TRANSDERMA			
L			
		Lidocaine	
		(Lidocaine) 900mg	SS
TRANSDERMAL	900 MG,		
TRANSDERMAL			
		Ketoprofen(Ketoprofe	
		n) 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 Duratio	on					
Life-Threatening	Coma	Literature	Ketalar			
Hospitalization -	Convulsion	Health	(Ketamine)Injection			
Initial or Prolonged TRANSDERMAL 900	_	Professional	, 900 Mg	PS		
	Medication Error					
MG, TRANSDERMA						
	Overdose					
L						
			Baclofen (Baclofen)			
4						

			FDA - Advers	e Event Reporting System	m (AER	25)	
				Of Information (FOI) Rep			
	000 MC			900 Mg	SS		
TRANSDERMAL	900 MG	1					
TRANSDERMAL				Amitriptyline (Amitriptyline) 360			
TRANSDERMAL	360 MG	,		Mg	SS		
TRANSD3RMAL							
				Lidocaine (Lidocaine) 900 Mg	SS		
TRANSDERMAL	900,						
TRANSDERMAL				Ketoprofen			
TRANSDERMAL	1800, M	MG,		(Ketoprofen) 1800 Mg	SS		
TRANSDERMAL							
Age: Gene	R Number der:Male						
Outcome Dose Du:	ration	PT	Report Source	Product	Role	Manufacturer	Route
Other	Lation	Peptic Ulcer		Lioresal	PS	Novartis Sector: Pharma	
		: 4231764-8Report Type:Expedi le I/FU:I	ited (15-DaCompany Repo:	rt #2003UW14116			
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
	ration						
Required		Alopecia	Foreign	Xylocaine	PS		I
Intervention to		Angina Pectoris	Health	Baclofen	SS		
Prevent Permane 50 MG DAILY	nt	Arrhythmia	Professional	Neurontin	SS		ORAL
Impairment/Damag PO	де	Blood Pressure Increased	Other				
0.3		Cardiac Disorder		Nitrostat	SS		
0.3		Cardiac Failure		Atenolol	С		
		Cardiac Valve Disease		Avapro	C		

	Chest Pain		K-Lyte	C	
	Condition Aggravated		No Match	С	
	Disturbance In Atten	tion	Oxygen	C	
	Dizziness		Taurine	C	
	Electrolyte Imbalance	e			
	Heart Rate Increased				
	Hypotension				
	Memory Impairment				
	Myocardial Infarction				
	Pulmonary Hypertensi	on			
	Restlessness				
	Somnolence				
	Weight Decreased				
	Weight Increased				
Data:11/10/02190 N	umber: 1222596_2Penert Turn	e:Expedited (15-DaCompany Re			
Age:35 YR Gender		e.Expedited (15-Dacompany Re	eport #2003134306D3		
Age of it dender					
Outcome	PT	Report Source	Product	Role Manufacturer	Route
Dose Durat					
Life-Threatening	Areflexia	Literature	Ketoprofen	PS	
	RANSDERMAL				
Hospitalization -	Coma	Health			
(TRANSCUTANEO					
Initial or Prolong	ed Convulsion	Professional			
US)					
	Overdose		Amitriptyline	SS	
TRANSDERMAL T	RANSDERMAL				
(TRANSCUTANEO					
US)					
			Lidocaine	SS	
TRANSDERMAL T	RANSDERMAL				
(TRANSCUTANEO					
US)					
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FDA - Adverse Event Reporting System (AERS) Freedom Of Information (FOI) Report SS Ketamine TRANSDERMAL TRANSDERMAL (TRANSCUTANEO US) Baclofen SS TRANSDERMAL TRANSDERMAL (TRANSCUTANEO US) Date:11/13/03ISR Number: 4234531-4Report Type:Expedited (15-DaCompany Report #PHRM2003FR02941 Age:56 YR Gender:Male I/FU:I ΡТ Report Source Role Manufacturer Outcome Product Route Dose Duration Hospitalization -Gastric Ulcer Lioresal PS Novartis Sector: Gastrointestinal Initial or Prolonged Pharma ORAL 60 mg/day Haemorrhage Date:11/13/03ISR Number: 4236035-1Report Type:Expedited (15-DaCompany Report #KII-2003-0005736 Age:28 YR Gender:Female I/FU:I Outcome PTReport Source Product Role Manufacturer Route Dose Duration Hospitalization -Drug Screen Positive Study Morphine Initial or Prolonged Hyperhidrosis Health Sulfate(Similar To Other Hyperpyrexia Professional Nda 19-516)(Morphine Other Medication Error Sulfate) Unknown PS Multiple Drug Overdose Soma (Carisoprodol) SS SS Sinus Tachycardia Valium(Diazepam) Somnolence Ace Inhibitor Nos() SS White Blood Cell Count Antihistamine() SS Nortriptyline(Nortri ptyline) SS Biguandes() SS Anticonvulsant() SS Ssri() SS

Acetaminophen(Parace

SS

tamol)

Acetylsalicylic Acid	
(Acetylsalicylic	
Acid0	SS
Baclofen(Baclofen)	SS
Zanaflex(Tizanidine	
Hydrochloride)	SS

Date:11/13/03ISR Number: 4236056-9Report Type:Expedited (15-DaCompany Report #HQWYE6741310CT03 Age:63 YR Gender:Female I/FU:I

Outcome Dose Duration	РТ	Report Source	Product	Role Manufacturer	Route
Life-Threatening Hospitalization - 5 MG 1X PER 1	Dizziness Drug Interaction	Health Professional	Biso-Puren (Bisoprolol, Tablet)	PS	ORAL
Initial or Prolonged DAY 3 YR	Hiatus Hernia	Other			
	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		
30 DROPS, TID 1 YR			Tincture,) Nitrendipine	SS	ORAL
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		FDA - Adverse	Event Reporting Syste	em (AERS	3)	
		Freedom O	f Information (FOI) Re	port		
			(Nitrendipine,)	SS		ORAL
10 MG 2X PER						
1 DAY 1 YR						
Date:11/17/03ISR Number Age: Gender:Male	: 4236487-7Report Type:Expedit I/FU:I	ed (15-DaCompany Repor	t #20031567			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - Initial or Prolonged INTRATHECAL MCG,	Drug Withdrawal Syndrome Lethargy	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		
DAILY,	Muscle Spasticity					
INTRATHECAL						
Date:11/18/03ISR Number Age: Gender:Fema Outcome	: 4236827-9Report Type:Direct le I/FU:I PT	Company Repor Report Source	t #CTU 206287 Product	Role	Manufacturer	Route
Dose Duration Hospitalization -	Catheter Related		Lioresal Intrathecal			
Initial or Prolonged INTRATHECAL DAILY,	Complication		(Baclofen Injection)	PS		
INTRATHECAL	Muscle Spasticity					
	Pharmaceutical Product Complaint					
Date:11/18/03ISR Number Age: Gender:Fema	: 4236896-6Report Type:Direct le I/FU:I	Company Repor	t #CTU 206278			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration Required Intervention to INTRATHECAL MCG, D Prevent Permanent INTRATHECAL	Oedema Peripheral AILY		Lioresal Intrathecal (Baclofen Injection)	PS		
Impairment/Damage						

Date:11/18/03ISR Number Age: Gender:Fema	: 4236897-8Report Type:Direct le I/FU:I	Company Repor	t #CTU 206277		
Dutcome Dose Duration Hospitalization - Initial or Prolonged INTRATHECAL MCG, D		Report Source	Product Lioresal Intrathecal (Baclofen Injection)	Manufacturer	Route
INTRATHECAL					
Date:11/18/03ISR Number Age: Gender:Male	: 4236898-XReport Type:Direct I/FU:I	Company Repor	t #CTU 206276		
Dutcome Dose Duration Required Intervention to INTRATHECAL MCG, D Prevent Permanent INTRATHECAL Impairment/Damage	PT Condition Aggravated Device Failure MILY Muscle Spasticity	Report Source	Product Lioresal Intrathecal (Baclofen Injection)	Manufacturer	Route
Date:11/18/03ISR Number Age: Gender:Male	: 4236899-1Report Type:Direct I/FU:I	Company Repor	t #CTU 206275		
Dutcome Hospitalization - Initial or Prolonged	PT Clonus Device Failure Drug Withdrawal Syndrome Hypotension				
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Freedom Of Information (FOI) Report

Dose INTRATHECAI INTRATHECAI		Muscle Spasticity Muscle Twitching DAILY	Report	Source	Product Lioresal Intrathecal (Baclofen Injection)	Role PS	Manufacturer	Route
Date:11/18, Age:	/03ISR Number Gender:Male	r: 4236900-5Report Type:Direct e I/FU:I		Company Repor	t #CTU 206286			
Outcome Dose Hospitaliza Initial or INTRATHECAI DAILY, INTRATHECAI	Prolonged L UNK MC	PT Alcohol Withdrawal Syndrome CG, Device Failure	Report	Source	Product Lioresal Intrathecal (Baclofen Injection)	Role PS	Manufacturer	Route
Date:11/18, Age:	/03ISR Number Gender:Male	r: 4236901-7Report Type:Direct e I/FU:I		Company Repor	t #CTU 206285			
Outcome Dose Required Interventic INTRATHECAI Prevent Per DAILY, Impairment, INTRATHECAI	L UNK MC rmanent /Damage	PT Drug Effect Decreased Mechanical Complication CG. Of Implant	Report	Source	Product Lioresal Intrathecal (Baclofen Injection)		Manufacturer	Route
Date:11/18, Age:	/03ISR Number Gender:Male	r: 4236902-9Report Type:Direct e I/FU:I		Company Repor	t #CTU 206284			
Outcome Dose	Duration	PT	Report	Source	Product	Role	Manufacturer	Route

Hospitalization -	Agita				Lioresal Intrathecal			
Initial or Prolong INTRATHECAL U	ged Devic JNK MCG,	ce Failure			(Baclofen Injection)	PS		
	Muscl	e Spasticity						
DAILY,								
INTRATHECAL								
	Jumber: 4236 :Female	5903-0Report Type:Direct I/FU:I		Company Repor	t #CTU 206283			
	PT		Doport	Courses	Product	Dolo	Manufacturer	Pouto
Outcome Dose Durat			керогс	Source	Product	ROIE	Manuracturer	Route
Required Intervention to	Muscl	e Spasticity			Lioresal Intrathecal (Baclofen Injection)	PS		
INTRATHECAL U Prevent Permanent , INTRATHECAL	JNK MCG DAIL	ιΥ						
Impairment/Damage								
Date:11/18/03ISR N Age: Gender		5904-2Report Type:Direct I/FU:I		Company Repor	t #CTU 206282			
Outcome	PT		Report	Source	Product	Role	Manufacturer	Route
Dose Durat	-							
Required		cation Error			Lioresal Intrathecal	20		
Intervention to INTRATHECAL U	Musci JNK MCG DAIL	e Spasticity			(Baclofen Injection)	PS		
Prevent Permanent	JNK MCG DAIL	Ţ						
, 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 Gender:Female Age: I/FU:I Route Outcome PTReport Source Product Role Manufacturer Dose Duration Required Medical Device Lioresal Intrathecal Complication (Baclofen Injection) PS Intervention to INTRATHECAL UNK MCG, Medication Error Prevent Permanent DAILY, Impairment/Damage INTRATHECAL Date:11/18/03ISR Number: 4236907-8Report Type:Direct Company Report #CTU 206280 Gender:Female Aqe: I/FU:I Report Source Role Manufacturer PTProduct Route Outcome Dose Duration Medical Device Lioresal Intrathecal Hospitalization -Initial or Prolonged Complication (Baclofen Injection) PS INTRATHECAL UNK MCG, Overdose DAILY, Pharmaceutical Product INTRATHECAL Complaint Date:11/18/03ISR Number: 4236908-XReport Type:Direct Company Report #CTU 206279 Age: Gender:Male I/FU:I Report Source Role Manufacturer Outcome PTProduct Route Dose Duration Required Medical Device Lioresal Intrathecal Intervention to Complication (Baclofen Injection) ΡS INTRATHECAL UNK MCG, Prevent Permanent Muscle Spasticity DAILY, Impairment/Damage INTRATHECAL

Age:36 YR Gender:Mal	r: 4238788-5Report Type:Exped e I/FU:F	iited (15 bacompany K	20011 #20031495			
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 Numbe Age:64 YR Gender:	r: 4239065-9Report Type:Exped I/FU:I	lited (15-DaCompany Re	eport #2003-03851			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration		-				
Death	Death	Literature	Baclofen (Watson			
		Health	Laboratories)			
		Professional	(Baclofen) Tablet	PS		
			Clonazepam (Watson	10		
			Laboratories)			
			(Clonazepam) Tablet	SS		
			(CIONAZEPam) IADIEC	GG		

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 PΤ Report Source Product Role Manufacturer Route Dose Duration Required Hepatitis Acute Foreign Lioresal Health Intrathecal(Baclofen Intervention to Prevent Permanent Professional Injection) PS INTRATHECAL Impairment/Damage Date:11/21/03ISR Number: 4240662-5Report Type:Expedited (15-DaCompany Report #20031590 Age: Gender:Male I/FU:I Report Source Product Role Manufacturer Outcome PTRoute Dose Duration Health Lioresal Intrathecal Hospitalization -Erythema Meningitis Staphylococcal Professional (Baclofen Injection) PS Initial or Prolonged INTRATHECAL DAILY, Swelling INTRATHECAL Date:11/24/03ISR Number: 4239995-8Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0314709A Age:53 YR Gender:Male I/FU:I Role Manufacturer Outcome PTReport Source Product Route Dose Duration Glaxosmithkline Hospitalization -Dysaesthesia Clamoxyl PS ORAL 4 DAY Initial or Prolonged Hypochloraemia Laroxyl Drops Glaxosmithkline SS ORAL 5DROP Per day Lioresal Hyponatraemia SS ORAL 9UNIT Per day ORAL Pyrexia Neurontin SS 2UNIT Per day Rivotril Drops SS 7DROP per day Dantrium SS Glaxosmithkline ORAL **3UNIT** Per day Heptamyl С ORAL 3TAB Per day Diantalvic С Eductvl С

	Forlax	С	
	Oroken	С	
2 DAY			
	Rocephine	С	
INTRAVENOUS			
	Gentalline	С	Glaxosmithkline
INTRAVENOUS			

Date:11/24/03ISR Number: 4241863-2Report Type:Expedited (15-DaCompany Report #2003-04000 Age:64 YR Gender: I/FU:I

Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Death	Cardio-Respiratory Arrest		Baclofen (Watson Laboratories)(Baclof en) Tablet Doxepin (Watson Laboratories) (Doxepin Hydrochloride) Capsule Quetiapine (Quetiapine)	PS SS SS	Watson Laboratories	

Date:11/25/03ISR Number: 4242702-6Report Type:Expedited (15-DaCompany Report #2003117889 Age:53 YR Gender:Male I/FU:I

Outcome PT Hospitalization - Back Pain Initial or Prolonged Blood Bicarbonate Abnormal Blood Uric Acid Decreased

Freedom Of Information (FOI) Report

Dose	Duration	Dysaesthesia Heat Stroke Hypochloraemia	Report Source	Product	Role Manufacturer	Route
		Inappropriate Antidiuretic Hormone	Foreign Health	Neurontin (Gabapentin)	PS	ORAL
800 MG, ORAL		Antidiuretic Adriadie	nealth	(Gabapencin)	23	ORAL
		Secretion Pyrexia	Professional	Amoxicillin Trihydrate (Amoxicillin		
ORAL				Trihydrate)	SS	ORAL
URAL				Heptaminol Hydrochloride (Heptaminol		
563.4 MG,				Hydrochloride)	SS	ORAL
ORAL				Amitriptyline Hydrochloride (Amitriptyline		
				Hydrochloride)	SS	ORAL
ORAL						
90 MG, ORAL				Baclofen (Baclofen)	SS	ORAL
				Dantrolene Sodium (Dantrolene Sodium)	SS	ORAL
75 MG, ORAL				(Dancioiene Sodium)	35	ORAL
				Clonazepam (Clonazepam)	С	
				Dextropropoxyphene (Dextropropoxyphene)	С	
				Paracetamol (Paracetamol) Eductyl (Sodium Bicarbonate, Potassium	C	
				Bitartrate) Macrogol (Macrogol)	C C	
				Cefixime (Cefixime) Ceftriaxone (Ceftriaxone)	C C	

Date:11/28/03ISR Number Age:53 YR Gender:Male	er: 4244658-9Report Type:Expedi .e I/FU:I	ited (15-DaCompany Re	eport #FRP03000847		
Outcome Dose Duration	PT	Report Source	Product	Role Manufacturer	Route
Hospitalization -	Back Pain	Foreign	Dantrium (Dantrolene		
Initial or Prolonged 25 MG, 3/DAY,	Blood Osmolarity	Health	Sodium)Capsule, 25mg		ORAL
	Decreased	Professional			
ORAL					
	Blood Uric Acid Decreased Dysaesthesia	Other	Clamoxyl(Amoxicillin Trihydrate)	SS	ORAL
ORAL	· · · · ·				
I	Heat Stroke Hypochloraemia		Hept-A-Myl(Heptamino l Hydrochloride)	SS	ORAL
563.4 MG,	hypochioraemia			55	····
1	Hyponatraemia				
DAILY , ORAL					
I	Inappropriate Antidiuretic Hormone		Laroxyl(Amitriptylin e Hydrochloride)	SS	ORAL
5 MG, DAILY ,	Antialuretic Hormone		e Hydrochtoriae;	55	UKAL
J MG, DAILI ,	Secretion				
ORAL					
	Pyrexia		Lioresal		
1	Urine Sodium Abnormal		"Ciba-Geigy"(Baclofe		
90 MG DAILY			n)	SS	ORAL
90 MG DAIDI					
ORAL					
1			Neurontin(Gabapentin		
)	SS	ORAL
800 MG, DAILY					
, ORAL					
			Rivotril(Clonazepam)	SS	ORAL
0.7 MG ,					
DAILY ,ORAL					
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Freedom Of Information (FOI) Report

			Di-Antalvic(Dextropr opoxyphene Hydrochloride) Eductyl(Potassium Bitartrate, Sodium Bicarbonate) Forlax(Macrogol) Oroken(Cefixime)	SS SS SS		
2 DF, DAILY,			Rocephin(Ceftriaxone			
			Sodium)	SS		
INJECTION NOS			Gentamycin-Mp(Gentam icin Sulfate)	SS		
Age: Gender:Male						
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - Initial or Prolonged INTRATHECAL MCG, D	Meningitis AILY,	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		
INTRATHECAL						
Age:35 YR Gender:Male				Dele	Marufacturor	Douto
Outcome Dose Duration	PT	Report Source	Product	коте	Manufacturer	Route
Life-Threatening TRANSDERMAL 900 MG	Coma	Literature	Lidocaine	PS		
	Drug Level Above	Health				
TD	ml		And the day to all days	aa		
TRANSDERMAL 360 MG		Professional	Amitriptyline	SS		
TD	Drug Screen Positive					
TRANSDERMAL 900 MG	Overdose DAILY		Ketamine	SS		

TRANSDERMAL	900 MG	DAILY		Baclofen	SS		
TD							
TRANSDERMAL	1800 M	G DAILY		Ketoprofen	SS		
TD							
Date:12/08/03I Age:67 YR Ge		: 4247086-5Report Type:Expedit le I/FU:F	ced (15-DaCompany Report	t #PHNU2003DE03643			
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose D Death Other	uration	Condition Aggravated Drug Effect Decreased		Lioresal Intrathecal	PS	Novartis Sector: Pharma	
		Drug Ineffective Medication Error		Lioresal Intrathecal	SS	Novartis Sector: Pharma	
297ng/day							
		Muscle Spasticity Pneumonia		Lioresal Intrathecal	SS	Novartis Sector: Pharma	
297ng/day		Respiratory Failure					
	SR Number nder:Male	: 4247334-1Report Type:Expedit I/FU:F	ced (15-DaCompany Report	t #PHFR2003GB04243			
Outcome Dose D	uration	PT	Report Source	Product	Role	Manufacturer	Route

Lioresal

PS

Novartis Sector:

Pharma

22-Aug-2005 12:15 PM Page: 198 Oesophageal Rupture

Peptic Ulcer

Other

FDA - Adverse Event Reporting System (AERS) Freedom Of Information (FOI) Report Date:12/08/03ISR Number: 4248474-3Report Type:Direct Company Report #CTU 207682 Gender:Female Age:54 YR I/FU:I Outcome PTReport Source Product Role Manufacturer Route Dose Duration Life-Threatening Coma Intrathecal Baclofen Hospitalization -Drug Withdrawal Syndrome PS Medtronic Pump Initial or Prolonged Dyskinesia Disability Fatique Required Flushing Intervention to Heart Rate Increased Prevent Permanent Mydriasis Impairment/Damage Pupil Fixed Somnolence Date:12/08/03ISR Number: 4248588-8Report Type:Expedited (15-DaCompany Report #20031616 Gender:Male I/FU:I Age: Role Manufacturer Outcome PΤ Report Source Product Route Dose Duration Required Meningitis Health Lioresal Intrathecal Professional (Baclofen Injection) Intervention to PS INTRATHECAL UNG MCG, Prevent Permanent DAILY, Impairment/Damage INTRATHECAL Date:12/08/03ISR Number: 4248589-XReport Type:Expedited (15-DaCompany Report #20031620 Gender:Female I/FU:I Age: Role Manufacturer Outcome PTReport Source Product Route Dose Duration Lioresal Intrathecal Required Drug Withdrawal Syndrome Health Intervention to Pruritus Professional (Baclofen Injection) PSUNK MCG, Prevent Permanent Pyrexia DAILY, Impairment/Damage INTRATHECAL

Dose Duration Death Breath Holding Health Lioresal Intrathecal Professional (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 Dose Duration Hospitalization - Agitation Health Lioresal Intrathecal Initial or Prolonged Clonus Professional (Baclofen Injection) PS INTRATHECAL	
Outcome Dose Duration DeathPTReport SourceProductRoleManufacturerDeathBreath HoldingHealth ProfessionalLioresal Intrathecal (Baclofen Injection)PSINTRATHECALMCG, DAILY,INTRATHECALMCG, DAILY,Date:12/08/03ISR Number: 4248591-8Report Type:Expedited (15-DaCompany Report #20031615 Age: Infruition ProfessionalProductRoleManufacturerOutcomePTReport SourceProductRoleManufacturerOutcomePTReport SourceProductRoleManufacturerDose DorationDurationHealth ProfessionalLioresal Intrathecal (Baclofen Injection)PSFinitial or ProlongedINTRATHECALUNK MCG, Heart Rate IncreasedProfessionalKaclofen Injection)PSFinitial or ProlongedDAILY,UNK MCG, Heart Rate IncreasedProfessionalKaclofen Injection)PSFinitial or ProlongedDAILY,MCG Heart Rate IncreasedProfessionalKaclofen Injection)PSFinitial or ProlongedFinitial or ProlongedDAILY,MCG Heart Rate IncreasedMCG Heart Rate IncreasedFinitial or ProlongedFinitial or ProlongedFinitial or ProlongedFinitial or ProlongedFinitial or ProlongedMCG Heart Rate IncreasedHeart Rate IncreasedFinitial or ProlongedFinitial or ProlongedFinitial or ProlongedFinitial or ProlongedMCG Heart Rate IncreasedHeart Rate IncreasedHeart Rate IncreasedFinitial or ProlongedFinitial or Prolo	
Dose Duration Death Breath Holding Health Lioresal Intrathecal Professional (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 Dose Duration Hospitalization - Agitation Health Lioresal Intrathecal Initial or Prolonged Clonus Professional (Baclofen Injection) PS INTRATHECAL UNK MCG, Heart Rate Increased DAILY,	
Death Breath Holding Health Lioresal Intrathecal Professional (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 Dose Duration Hospitalization - Agitation Health Lioresal Intrathecal Initial or Prolonged Clonus Professional (Baclofen Injection) PS INTRATHECAL UNK MCG, Heart Rate Increased DAILY,	Route
Professional (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 Dose Duration Hospitalization - Agitation Health Lioresal Intrathecal Initial or Prolonged Clonus Professional (Baclofen Injection) PS INTRATHECAL UNK MCG, Heart Rate Increased DAILY,	
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 Dose Duration Hospitalization - Agitation Health Lioresal Intrathecal Initial or Prolonged Clonus Professional (Baclofen Injection) PS INTRATHECAL UNK MCG, Heart Rate Increased DAILY,	
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 Dose Duration Hospitalization - Agitation Health Lioresal Intrathecal Initial or Prolonged Clonus Professional (Baclofen Injection) PS INTRATHECAL UNK MCG, Heart Rate Increased DAILY,	
Age: Gender:Female I/FU:I Outcome PT Report Source Product Role Manufacturer Dose Duration Hospitalization - Agitation Health Lioresal Intrathecal Initial or Prolonged Clonus Professional (Baclofen Injection) PS INTRATHECAL UNK MCG, Heart Rate Increased DAILY,	
Age: Gender:Female I/FU:I Outcome PT Report Source Product Role Manufacturer Dose Duration Hospitalization - Agitation Health Lioresal Intrathecal Initial or Prolonged Clonus Professional (Baclofen Injection) PS INTRATHECAL UNK MCG, Heart Rate Increased DAILY,	
Dose Duration Hospitalization - Agitation Health Lioresal Intrathecal Initial or Prolonged Clonus Professional (Baclofen Injection) PS INTRATHECAL UNK MCG, Heart Rate Increased DAILY,	
Hospitalization - Agitation Health Lioresal Intrathecal Initial or Prolonged Clonus Professional (Baclofen Injection) PS INTRATHECAL UNK MCG, Heart Rate Increased DAILY,	Route
Initial or Prolonged Clonus Professional (Baclofen Injection) PS INTRATHECAL UNK MCG, Heart Rate Increased DAILY,	
INTRATHECAL UNK MCG, Heart Rate Increased DAILY,	
INTRATHECAL UNK MCG, Heart Rate Increased DAILY,	
Heart Rate Increased DAILY,	
DAILY,	
INTRATHECAL	
Pruritus	
Pyrexia	
Fylexia	
Date:12/08/03ISR Number: 4248790-5Report Type:Expedited (15-DaCompany Report #K200301829 Age:69 YR Gender:Female I/FU:I	
Outcome PT	
Hospitalization - Blood Potassium Decreased	
Initial or Prolonged Blood Sodium Decreased	
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Freedom Of Information (FOI) Report

Daga	Duration	Chest Pain Dehydration Left Ventricular Failure	Report Source	Product	Role	Manufacturer	Route
Dose	Duration	Renal Failure Acute Vomiting	Foreign Health Professional	Altace Capsules (Ramipril)Capsule, 5mg	PS		ORAL
10 MG, QD,			Other				-
ORAL							
				Prozac (Fluoxetine Hydrochloride) Capsule, 20 Mg	SS		ORAL
20 MG, QD,				2 · 3			
ORAL							
				Lioresal "Ciba-Geigy"(Baclofe n) Tablet, 10 Mg	SS		ORAL
40 MG, QD,				,, , ,	~~		
ORAL							
				Lexomil (Bromazepam) Tablet, 12 Mg	SS		ORAL
9 MG, ORAL							
				Corvasal (Molsidomine)			
				Tablet, 4 Mg Cordarone (Amiodarone	С		
				Hydrochloride)	~		
				Tablet Trinipatch (Glyceryl Trinitrate) Patch,	С		
				5mg	С		
Date:12/09/ Age:	03ISR Number Gender:Male	r: 4249963-8Report Type:Expedi I/FU:I	ted (15-DaCompany Rep	ort #20031628			
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Death		Cardio-Respiratory Arrest	Health Professional	Lioresal Intrathecal (Baclofen Injection) 500mcg/Ml	PS		
ͳ៱៲Ͳϲ៷ͲϤͼ·Ϲ៷ͳ				-			1

INTRATHECAL DAILY,

Date:12/10/03ISR Number: 4248881-9Report Type:Expedited (15-DaCompany Report #PHRM2003FR03170 Age:53 YR Gender:Male I/FU:I

Outcome Dose D	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalizatio Initial or Pro 90 mg/day	on –	Back Pain Blood Bicarbonate		Lioresal	PS	Novartis Sector: Pharma	ORAL
5760 MIN		Abnormal		Clamoxyl	SS		ORAL
		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 7 drops/day		Increased		Rivotril	SS		ORAL
		Dysaesthesia Heat Stroke		Di-Antalvic Eductyl	SS SS		ORAL
RECTAL		Hypochloraemia Hyponatraemia Inappropriate Antidiuretic Hormone Secretion Pyrexia		Forlax	SS		ORAL

Freedom Of Information (FOI) Report

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 40 mg/day	Blood Potassium Decreased Chest Pain		Lioresal	PS	Novartis Sector: Pharma	ORAL
	Dehydration		Prozac	SS		ORAL
20 mg/day	Hyponatraemia		Triatec			
	Left Ventricular Failure Renal Failure Acute		/Fra/	SS		ORAL
5 mg, BID			Lexomil	SS		ORAL
.25 DF, TID			Corvasal	С		ORAL
4 mg, TID			Cordarone			
200 mg OME			/Net/	С		ORAL
200 mg, QW5			Trinipatch	С		
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		Lioresal	PS	Novartis Sector:	
		Dermatitis Bullous				Pharma	ORAL
20 mg/day							/
		Peripheral Coldness		Zymafluor	С		ORAL
1		Peripheral Vascular		Lubentyl	С		ORAL
1		Disorder		-			
1		Raynaud'S Phenomenon					

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	Study Health Professional	Morphine Sulfate (Similar To Nda 19-516)(Morphine		0.0.0.1
9 MG, TID,	Consciousness Infection	Other	Sulfate) Unknown	PS	ORAL
ORAL SEE TEXT	Medication Error		Baclofen (Baclofen)	SS	
	Pyrexia		Ambien (Zolpidem Tartrate) Benzodiazepine	SS	
			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 Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalizat Initial or P Treated 2-3	tion -	Dermatitis Bullous Drug Interaction Pemphigoid	Health Professional	Lopril	PS	Geneva Pharmaceuticals, Inc. (Novartis)	ORAL
years		Pruritus					ļ
Treated for				Loxen	SS		ORAL
2-3 years				Lioresal	I		ORAL
0.5 tab per				DIOLEBAI	Ŧ		UNAL
day (0,5 DOS	έE						
X 3/D)				Seropram	I		ORAL
Treated for				Serobram	Ŧ		UKAL
2-3 years				Asasantine	т		ORAL
Treated for				Asasancine	I		ORAL
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Freedom Of Information (FOI) Report

Route

ORAL

2-3 years

outcome Jose I	Duration	PT	Report Source	Product	Role	Manufacturer
isability 2.5MG BID	Juracion	Muscle Twitching	Foreign	Baclofen	PS	Ipi
		Muscular Weakness	Literature			
AL						
			Health	Propofol	SS	
5MG/KG/HOUR			Professional			
)			1101Cbb10na1			
,			Other	Sufentanil	SS	
25UG/KG						
OUR(S)				Isoflurane		
				Inhalation Solution	SS	
.6-1.0 VOL%					22	
				Diazepam	С	
				Levothyroxine	С	
				Vitamin B 12		
				Injectable	С	
				Atracurium	С	
				Cefuroxime	С	
				Clindamycin	С	
				Dexamethasone	С	
				Morphine	С	
				Prednisone	С	

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		Hyperaemia	Health	Lioresal Intrathecal			
Intervention	to	Hypotension	Professional	(Baclofen			
Prevent Perma	nent	Rash Erythematous		Injection),			
Impairment/Da	mage	Respiratory Rate		500mcg/Ml	PS		
INTRATHECAL	100 MCG	<u>,</u>					

	Decreased					
DAILY,	Somnolence					
INTRATHECAL	Domine 20100					
	Tachycardia					
	per: 4254528-8Report Type:Exped	ited (15-DaCompany Re	eport #20031620			
Age: Gender:Fe	emale I/FU:F					
Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Required	Erythema	Health	Lioresal Intrathecal			
Intervention to	Meningitis Staphylococcal	Professional	(Baclofen Injection)	PS		
INTRATHECAL DAIL	•					
Prevent Permanent	Pruritus					
INTRATHECAL						
Impairment/Damage	Swelling					
10/15/00705						
Age:32 YR Gender:Ma	eer: 4254987-OReport Type:Exped le I/FU:I	ited (15-Dacompany Ke	eport #ZANAUUIIIZ			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration	1	-				
Life-Threatening	Drug Interaction	Health	Zanaflex (Tizanidine			
Other 36 MG ORAL	Haemolysis	Professional	Hydrochloride)	PS		ORAL
			Baclofen (Baclofen)	SS		
			Neurontin	a		
			(Gabapentin)	С		
			Ditropan (Oxybutynin)	С		
			(Oxybutynin) Prednisone	C		
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Freedom Of Information (FOI) Report

(Prednisone) C

Initial or Prolonged I	Coma Joss Of Consciousness	Consumer				
	verdose	Other	Oxycontin Tablets (Oxycodone Hydrochloride) Celebrex (Celecoxib) Baclofen (Baclofen) Ghb (Oxybate Sodium)	PS SS SS SS		
Date:12/17/03ISR Number: Age:18 YR Gender:Male	4271964-4Report Type:Peri I/FU:I	odic Company Re	eport #USA-2003-0009874			
Dutcome F Dose Duration	РТ	Report Source	Product	Role	Manufacturer	Route
±	oss 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: Age: Gender:Male	4255375-3Report Type:Expend I/FU:I	dited (15-DaCompany Re	eport #230032K03FRA			
Dutcome P Dose Duration	РТ	Report Source	Product	Role	Manufacturer	Route
Initial or Prolonged M SUBCUTANEOUS 44 MCG,		Foreign Consumer	Rebif (Interferon Beta)	PS		
S WEEKS,	Syncope	Health Professional				
SUBCUTANEOUS 2 YR		FIOLESSIONAL	Baclofen	SS		ORAL

FORMS, 3 IN 1

DAYS, PER			
ORAL	Vasobral	SS	
1 DOSAGE	VaSODIAL	55	ORAL
FORMS, 3 IN 1			
DAYS, PER			
ORAL	Modafinil	66	ORAL
3 DOSAGE	MODALIIII	SS	ORAL
FORMS, 3 IN 1			
DAYS, PER			
ORAL			
0.5 NOT	Zopiclone	SS	
REPORTED, 1			
IN 1 DAYS,			
NOT REPORTED		99	
NOT REPORTED,	Mianserin	SS	
1 IN 1 DAYS,			
NOT REPORTED		99	
NOT REPORTED,	Fenofibrate	SS	
1 IN 1 DAYS,			
NOT REPORTED			
NOT REPORTED,	Oxybutynin	SS	
2 IN 1 DAYS,			
NOT REPORTED			
NOT REPORTED,	Dantrolene Sodium	SS	
3 IN 1 DAYS,			
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Freedom Of Information (FOI) Report

NOT REPORTED

Date:12/18/	03ISR Number:	4255551-XReport	Type:Expedited	(15-DaCompany	Report	#2003117889
Age:53 YR	Gender:Male	I/FU:F				

		Demonth Garrier	Ducaluat	Dele Menufecture	Derte
Outcome Dose Duration	PT	Report Source	Product	Role Manufacturer	Route
Hospitalization -	Back Pain	Foreign	Neurontin		
Initial or Prolonged 800 MG, ORAL	Blood Osmolarity	Health	(Gabapentin)	PS	ORAL
	Decreased	Professional	Amoxicillin		
	Blood Uric Acid Decreased		Trihydrate		
	Dysaesthesia		(Amoxicillin		
	Heat Stroke		Trihydrate)	SS	ORAL
ORAL					
	Hypochloraemia		Amitriptyline		
	Hyponatraemia		Hydrochloride		
	Inappropriate		(Amitriptyline		
	Antidiuretic Hormone		Hydrochloride)	SS	ORAL
ORAL					
	Secretion		Dantrolene Sodium		0.0.0.1
	Pyrexia		(Dantrolene Sodium)	SS	ORAL
75 MG, ORAL			Baclofen (Baclofen)	SS	ORAL
90 mg, oral			Baciolen (Baciolen)	22	URAL
JU MG, UKAL			Heptaminol		
			Hydrochloride		
			(Heptaminol		
			Hydrochloride)	С	ORAL
563.4 MG,				-	
ORAL					
1			Clonazepam		
			(Clonazepam)	C	
			Dextropropoxyphene		
			(Dextropropoxyphene)	C	
			Paracetamol		
			(Paracetamol)	С	
			Eductyl (Sodium		
			Bicarbonate,		
			Potassium	a	
			Bitartrate)	C	
1			Macrogol (Macrogol)	C	
1			Cefixime (Cefixime) Ceftriaxone	C	
4			Certriaxone		

(Ceftriaxone)	С
Gentamicin	
(Gentamicin)	С

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 -	Aggression		Lioresal	PS	ORAL
Initial or Prolonged	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 Age:17 YR Gender:Male I/FU:I Company Report #CTU 208449

Outcome Life-Threatening Hospitalization -

Freedom Of Information (FOI) Report

Initial or Prolonged

Dogo	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Dose	DULALION	Accident Catheter Related		Baclofen-Intrathecal 4000.0 Ug/Ml	PS		
INTRATHECAL	40.6 U	G/HR Complication					
975.0 UG/D I	Т						
		Device Failure Drug Withdrawal Syndrome Medication Error Overdose Respiratory Arrest					
	3ISR Number Gender:Fema	: 4257661-XReport Type:Exped: le I/FU:I	ited (15-DaCompany Repo	rt #20031642			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalizat		Diplegia	Health	Lioresal Intrathecal			
Initial or P MCG, DAILY,	rolonged	Overdose	Professional	(Baclofen Injection)	PS		
INTRATHECAL		Therapeutic Response					
		Decreased Urinary Incontinence					
	3ISR Number Gender:Fema	: 4257663-3Report Type:Exped: le I/FU:F	ited (15-DaCompany Repo	rt #20031525			
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose Death	Duration	Bronchopneumonia	Health	Lioresal Intrathecal			
INTRATHECAL	MCG, D	•	Professional	(Baclofen Injection)	PS		
INTRATHECAL		Muscle Spasticity					
1		Panic Reaction					

	Number: 4257952-2Report Type:E r:Female I/FU:I	xpedited (15-DaCompany Re	port #S03-FRA-05163-01			
Outcome Dose Durat	PT tion	Report Source	Product	Role	Manufacturer	Route
Hospitalization -		Foreign	Seropram (Citalopram			,
Initial or Prolong		Health	Hydrobromide)	PS		,
	Pruritus	Professional Other	Lopril (Captoprol) Lioresal "Novartis"	SS		
1			(Baclofen)	SS	"Novartis"	ORAL
0.5 UNK TID						ľ
PO						
1			Loxen (Nicardipine			I
			Hydrochloride)	SS		,
			Dipyridamole	SS		ļ
	Number: 4257446-4Report Type:E r:Male I/FU:I	xpedited (15-DaCompany Re	≥port #PHFR2003GB04829			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Durat Other	Psychotic Disorder		Baclofen	PS	Novartis Sector: Pharma	
UNKNOWN						

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

PT	Report Source	Product	Role	Manufacturer	Route
Pemphigoid Pruritus		Lioresal	PS	Novartis Sector: Pharma	ORAL
		Loxen/Cardene	SS		ORAL
		Lopril	SS		ORAL
		Seropram	SS		ORAL
		Asasantin	SS		ORAL
	Pemphigoid	Pemphigoid	Pemphigoid Lioresal Pruritus Loxen/Cardene Lopril Seropram	Pemphigoid Pruritus Lioresal PS Loxen/Cardene SS Lopril SS Seropram SS	Pemphigoid Pruritus Lioresal PS Novartis Sector: Pharma Loxen/Cardene SS Lopril SS Seropram SS

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-Threater	ning	Glucose-6-Phosphate	Health	Zanaflex (Tizanidine			
Other		Dehydrogenase Deficiency	Professional	Hydrochloride)	PS		ORAL
36 MG ORAL							
		Haemolysis		Baclofen (Baclofen)	SS		
		Refusal Of Treatment By		Neurontin			
		Patient		(Gabapentin)	С		
				Ditropan			
				(Oxybutynin)	С		
				Predenisone			ľ
				(Prednisone)	С		l

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 Dur	ration						
Hospitalization	- (Coma		Lioresal	PS	Novartis Sector:	
Initial or Prolo	onged J	Fall				Pharma	ORAL
20 mg/day 2	2880 MIN						
Other	ŝ	Somnolence		Temesta	SS		
UNKNOWN		1440 MIN					ľ
	(Stupor		Floxapen	С		
INTRAVENOUS							

UNKNOWN	Insulin	C
	Actrapid	С
UNKNOWN	Benerva	С
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 Other	Duration	Alanine Aminotransferase Increased	Health Professional	Lioresal	PS	Novartis Sector: Pharma	ORAL
UNK							
		Aspartate Aminotransferase		Lioresal	SS	Novartis Sector: Pharma	ORAL
50mg/day							
		Increased 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 - Disorientation Initial or Prolonged Drug Interaction Other Mental Status Changes Pain

Freedom Of Information (FOI) Report

ose	Duration	Decreased Sinus Tachycardia	Report Source	Product	Role	Manufacturer	Route
	0 0	Somnolence	Study	Oxycodone			
			Health	Hydrochloride	PS		
			Professional Other	Fentanyl (Fentanyl) Amitriptyline	SS		
				(Amitriptyline)	SS		
				Ssri ()	SS		
				Baclofen (Baclofen)	SS		
				Gabapentin			
				(Gabapentin)	SS		
				Tramadol (Tramadol)			
				Cr Tablet	SS		
				Tolterodine			
				(Tolterodine)	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 D	Duration					ļ
Hospitalizatio	on –	Aggression		Lioresal	PS	ORAL
Initial or Pro	olonged	Agitation		Pirilene	С	ORAL
		Confusional State		Rimifon	С	ORAL
		Electroencephalogram		Rifampicin C Mopral C	С	ORAL
		Abnormal			C	ORAL
		Encephalopathy		Fozitec	C	ORAL
		Muscle Rigidity		Hemodialysis	C	Ì

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 Dura	ation					
Hospitalization -	- Pemphigoid	Consumer	Loxen Lp	PS	Roche	ORAL
Initial or Prolor	nged		Lioresal	SS		ORAL
			Lopril	SS		ORAL
			Seropram	SS		ORAL
			Asasantin	SS		ORAL

	04ISR Number: 4267133-4Report Type:Ex Gender:Female I/FU:I	xpedited (15-DaCompany R	eport #20031649		
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	С	
	Medical Device		Dexamethasone	С	
	Implantation				
	Proteus Infection				
	Urosepsis				
	-				

FDA - Adverse Event Reporting System (AERS) Freedom Of Information (FOI) Report Date:01/07/04ISR Number: 4267152-8Report Type:Expedited (15-DaCompany Report #US-SHR-03-019043 Gender:Male Aqe:62 YR I/FU:I Outcome PTReport Source Product Role Manufacturer Route Dose Duration Hospitalization -Coma Consumer Betaseron(Interferon Initial or Prolonged Injection Site Cellulitis Beta-1b) Pyrexia Betaseron(Interferon Beta -1b) Injection, 250uq PS SUBCUTANEOUS 8 MIU, EVERY 2 D, HS, SUBCUTANEOUS Baclofen (Baclofen) SS Date:01/13/04ISR Number: 4270791-1Report Type:Expedited (15-DaCompany Report #20041663 Gender:Male Age: I/FU:I Outcome PTReport Source Product Role Manufacturer Route Dose Duration Abdominal Distension Health Lioresal Intrathecal Hospitalization -Initial or Prolonged Agitation Professional (Baclofen Injection) PS INTRATHECAL DAILY, Anorexia INTRATHECAL Constipation Drug Withdrawal Syndrome Pyrexia Date:01/13/04ISR Number: 4271325-8Report Type:Expedited (15-DaCompany Report #20031610 Aqe: Gender:Male I/FU:F Outcome PTReport Source Product Role Manufacturer Route Dose Duration Hospitalization -Csf Culture Positive Health Lioresal Intrathecal Initial or Prolonged Implant Site Infection Professional (Baclofen Injection) PSINTRATHECAL DAILY, Meningitis INTRATHECAL Staphylococcal Infection

Age:							
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Required		Csf Bacteria Identified	Health	Lioresal			
Interventio	on to	Implant Site Infection	Professional	Intrathecal(Baclofen			
Prevent Per	rmanent	Meningitis		Injection)	PS		
INTRATHECAI	L DAILY	1					
Impairment, INTRATHECAI	-	Staphylococcal Infection					
				Antibiotics	С		
	/04ISR Numbe: Gender:Male	r: 4269940-0Report Type:Exped e I/FU:F	lited (15-DaCompany Re	eport #PHNU2003DE02970			
Age:15 YR Outcome	Gender:Male		lited (15-DaCompany Ro Report Source	eport #PHNU2003DE02970 Product	Role	Manufacturer	Route
Age:15 YR Outcome Dose		e I/FU:F PT		Product			Route
Age:15 YR Outcome	Gender:Male	e I/FU:F	Report Source	-	Role PS	Manufacturer Novartis Sector: Pharma	Route ORAL
Age:15 YR Outcome Dose	Gender:Male	e I/FU:F PT Alanine Aminotransferase	Report Source Health	Product		Novartis Sector:	
Age:15 YR Outcome Dose Other	Gender:Male	e I/FU:F PT Alanine Aminotransferase	Report Source Health	Product		Novartis Sector:	
Age:15 YR Outcome Dose Other	Gender:Male	e I/FU:F PT Alanine Aminotransferase Increased	Report Source Health	Product		Novartis Sector:	
Age:15 YR Outcome Dose Other	Gender:Male	e I/FU:F PT Alanine Aminotransferase Increased Aspartate	Report Source Health	Product		Novartis Sector:	
Age:15 YR Outcome Dose Other	Gender:Male	e I/FU:F PT Alanine Aminotransferase Increased Aspartate Aminotransferase	Report Source Health	Product		Novartis Sector:	
Age:15 YR Outcome Dose Other	Gender:Male	e I/FU:F PT Alanine Aminotransferase Increased Aspartate Aminotransferase Increased	Report Source Health	Product		Novartis Sector:	
Age:15 YR Outcome Dose Other	Gender:Male	e I/FU:F PT Alanine Aminotransferase Increased Aspartate Aminotransferase Increased Epstein-Barr Virus	Report Source Health	Product		Novartis Sector:	

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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 -	Condition Aggravated	Foreign	Triflucan		
Initial or Prolonged 1200 MG (TID)	Neutropenia	Health	(Fluconazole)	PS	
	Normochromic Normocytic	Professional	Baclofen (Baclofen)	SS	ORAL
ORAL					
	Anaemia Septic Shock White Blood Cell Count Decreased				

Date:01/16/04ISR Number: 4275310-1Report Type:Expedited (15-DaCompany Report #KII-2003-0006846 Age:53 YR Gender:Male I/FU:I

Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization -	Confusional State	Study	Oxycodone			
Initial or Prolonged	Drug Withdrawal Syndrome	Health	Hydrochloride			
	Flushing	Professional	(Similar To Nda			
	Hyperhidrosis	Other	20-553)(Oxycodone			
	Hypertension		Hydrochloride)	PS		ORAL
ORAL						
	Mental Status Changes		Morphine Sulfate			
	Overdose		(Similar No			
	Somnolence		Nda19-516) (Morphine			
	Tachycardia		Sulfate) Unknown	SS		ORAL
ORAL						
			Baclofen (Baclofen)	SS		ORAL
ORAL						
			Neurontin			
			(Gabapentin)	SS		
			Zinc (Zinc)	SS		
			Hydrochlorothiazide			
			(Hydrochlorothiazide	~~		
) Tablet	SS		
			Paxil ((Paroxetine	00		
			Hydrochloride)	SS		
			Vitamin A (Retinol)	SS		
			Vitamin C (Ascorbic	C		
4			Acid)	С		

Date:01/20/04ISR Number: Age:4 YR Gender:Femal	: 4274648-1Report Type:Expedite le I/FU:I	ed (15-DaCompany Report	c #PHFR2004GB00566			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization -	Bradycardia Hypothermia		Baclofen	PS	Novartis Sector: Pharma	ORAL
6m/day			Melatonin	С		ORAL
Date:01/20/04ISR Number: Age:17 YR Gender:Male	: 4281437-0Report Type:Periodic I/FU:I	c Company Report	t #PHBS2003US10785			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
	Hypertonia	Professional	Lioresal Intrathecal \$Me(Baclofen) Ampoule	PS		
INTRATHECAL INTRATH	IECAL		Impoure	10		

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 Durati	on				
Hospitalization -	Hypotension	Health	Lioresal Intrathecal		
Initial or Prolonge	ed Hypothermia	Professional	(Vaclofen Injection)	PS	
INTRATHECAL UN	IK MCG,				
	Hypotonia				
DAILY,					
	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 D Hospitalizatio Initial or Pro 5 mg, QD	Agitation Blood Bicarbonate		Lioresal	PS	Novartis Sector: Pharma	ORAL
3	Increased		Hemodialysis	С		
	Blood Creatinine Abnormal					
courses/week						ľ
	Blood Glucose Increased		Rimifon	С		ORAL
	Blood Urea Increased		Rifampicin	С		ORAL
900 mg/day						
	Coma		Inh	С		ORAL
	Confusional State		Triatec	С		ORAL
	Encephalopathy		Amlor	С		ORAL
	Haemoglobin Decreased		Pirilene	С		ORAL
750 mg/day						
	Muscle Rigidity		Mopral	С		ORAL
40 mg/day						
	Personality Change Due To		Fozitec	С		ORAL
0.5 tab/day						
	A General Medical					
	Condition					
	Toxic Induced					

Encephalopathy

Date:01/23/04ISR Number Age: Gender:Male	: 4279366-1Report Type:Expedit I/FU:F	ed (15-DaCompany Repor	t #230032K03FRA		
Outcome Dose Duration	PT	Report Source	Product	Role Manufacturer	Route
Hospitalization - Initial or Prolonged	Feeling Drunk Malaise 3 IN 1	Foreign Consumer	Rebif (Interferon Beta)	PS	
WEEKS	Syncope	Health			
SUBCUTANEOUS 2 YR		Professional			
2 DOSAGE			Baclofen	SS	ORAL
FORMS, 3 IN 1					
DAYS, PER					
ORAL			Vasobral	SS	ORAL
1 DOSAGE			VASODIAL	55	ORAL
FORMS, 3 IN 1					
DAYS, PER					
ORAL			Modafinil	99	ORAL
3 DOSAGE			MODALIIII	SS	ORAL
FORMS, 3 IN 1					
DAYS, PER					
ORAL			Zopiclone	99	
0.5 NOT			zopicione	SS	
REPORTED, 1					
IN 1 DAYS,					
NOT REPORTED			Mianserin	SS	
NOT REPORTED,			MIAIISELIII	55	
1 IN 1 DAYS					
NOT REPORTED			Fonofibrata	C C	
NOT REPORTED			Fenofibrate	SS	

Freedom Of Information (FOI) Report

Route

ORAL

Route

ORAL

ORAL

ORAL

1 IN 1 DAYS,					
NOT REPORTED			Que la transfer		
NOT REPORTED,			Oxybutynin	SS	
2 IN 1 DAYS,					
NOT REPORTED					
NOT REPORTED,			Dantrolene Sodium	SS	
3 IN 1 DAYS,					
NOT REPORTED					
Date:01/23/04ISR Number Age:76 YR Gender:Male	: 4279515-5Report Type:Exped I/FU:I	ited (15-DaCompany Re	port #DSA_23795_2004		
Outcome	PT	Report Source	Product	Role	Manufacturer
Dose Duration Hospitalization - Initial or Prolonged 10 MG BID PO	Coma Drug Interaction	Foreign Health	Temesta Lioresal	PS SS	
Other	Fall Somnolence	Professional Other	Floxapen Insulatard Actrapid Human Benerva	С С С	
Date:01/30/04ISR Number Age:27 YR Gender:Male	: 4281985-3Report Type:Exped I/FU:I	ited (15-DaCompany Re	port #PHBS2004CA01117		
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer
Other	Agitation Anger		Lioresal	PS	Novartis Sector: Pharma
1 tablet/day 4320 MIN	Antisocial Behaviour Constipation		Lioresal	SS	Novartis Sector: Pharma
1 tablet, BID 4320 MIN			Lioresal	SS	Novartis Sector: Pharma
1 tablet, TID 4320 MIN					

		Dysphagia Eye Disorder		Lioresal	SS	Novartis Sector: Pharma	ORAL
2 tablets,		rye Disorder				Pilatina	UKAL
Z LADICLD,		Hallucination					I
BID	4320 MIN						I
	1520 1111	Hyperhidrosis		Lioresal	SS	Novartis Sector:	I
		Insomnia		LICICDUI		Pharma	ORAL
2 tablets,						I HAL MA	Olum
		Lethargy					I
TID	2880 MIN						I
110	2000	Mood Swings		Lioresal	SS	Novartis Sector:	ŗ
		Paranoia		LIGICERI		Pharma	ORAL
1 tablet/day	5760 MIN	I di di di di di				I HAI MA	0101
1 000100,	0,00	Thyroid Function Test		Domperidone	С		I
UNKNOWN				Dom _F of Lotter	C		ſ
0111110.111		Abnormal					ſ
		Urine Output Decreased					I
Date:02/03/04 Age:51 YR G		: 4285825-8Report Type:Exp I/FU:I	edited (15-DaCompany R	eport #KII-2003-0007030			
Outcome		РТ	Report Source	Product	Role	Manufacturer	Route
Dose 1	Duration						ſ
Hospitalizati		Coma	Study	Ms Contin Tablets			I
Initial or Pro	olonged	Convulsion	Health	(Morphine Sulfate)			I
Other ORAL		Medication Error	Professional	Cr Tablet	PS		ORAL
		Muscle Spasms	Other				
			OCHICE	Oxycodone			
		Overdose	o chief	Oxycodone Hydrochloride			
				-			
		Overdose		Hydrochloride			
		Overdose		Hydrochloride (Similar To Nda	SS		
		Overdose		Hydrochloride (Similar To Nda 20-553) (Oxycodone	SS SS		ORAL
ORAL		Overdose		Hydrochloride (Similar To Nda 20-553) (Oxycodone Hydrocloride)			ORAL

Freedom Of Information (FOI) Report

Date:02/04/04ISR Number: 4284881-OReport Type:Expedited (15-DaCompany Report #PHRM2004FR00643 Age:37 YR Gender:Male I/FU:I

Outcome		РТ	Report Source	Product	Role	Manufacturer	Route
Dose Hospitalizati Initial or Pr 87840MIN		Anaemia Coma		Lioresal	PS	Novartis Sector: Pharma	ORAL
	57600MIN	Neutropenia		Triflucan	SS		ORAL
	57600MIIN	Septic Shock					

Date:02/04/04ISR Number: 4284882-2Report Type:Expedited (15-DaCompany Report #PHFR2003GB04829 Age:41 YR Gender:Male I/FU:F

Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other	Duracion	Delusion Hallucination, Auditory		Baclofen	PS	Novartis Sector: Pharma	ORAL
10 mg, QID							
4		Hallucination, Visual		Risperidone	С		ORAL
4 mg, QD		Psychotic Disorder		Bendrofluazide	С		ORAL
2.5 mg, QD		-					
8 mg, QD				Perindopril	С		ORAL
o mg, go				Metformin	С		
1 g, BID				Denialiteran	a		0.0.0.1
4 mg mane				Rosiglitazone	С		ORAL
				Diazepam	С		
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						
Hospitaliza	tion -	Escherichia Infection	Health	Lioresal			
Initial or Prolonged		Implant Site Infection Medical Device	Professional	Intrathecal(Baclofen Injection)	PS		
INTRATHECAL	MCG,	DAILY,					

		Complication					
INTRATHECAL							
		Meningitis					
		Post Procedural					
1		Complication					
		Pseudomonas Infection					
Date:02/09/0	4ISR Number	: 4289929-5Report Type:E:	xpedited (15-DaCompany Re	eport #PHBS2004BR011	.70		
	Gender:Fema			1			
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Other		Hyperaemia		Lioresal	PS	Novartis Sector:	
		Hypersensitivity				Pharma	ORAL
10 mg, BID					~		
	F 0	Skin Exfoliation		Higroton	C		
UNKNOWN	50 mg/	day			a		
TINIZATOUAN	200			Foraseq	С		
UNKNOWN	200 ug	/day			a		
	E0 ug/	darr		Puran T4	С		
UNKNOWN	50 ug/	day		Marax	С		
				maran	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						
Hospitalizati	on -	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 PΤ Report Source Product Role Manufacturer Route Dose Duration Required Disease Recurrence Health Lioresal Intrathecal Intervention to Fall Professional (Baclofen Injection) Prevent Permanent 500mcg/Ml Muscle Spasticity PSINTRATHECAL UNK MCG, Impairment/Damage Red Blood Cells Csf DAILY, Positive INTRATHECAL Reflexes Abnormal Date:02/10/04ISR Number: 4293965-2Report Type:Expedited (15-DaCompany Report #20041689 Gender:Female I/FU:I Age: Outcome PTReport Source Product Role Manufacturer Route Dose Duration Hospitalization -Cardio-Respiratory Arrest Health Lioresal Intrathecal Catheter Related Professional Initial or Prolonged (Baclofen Injection) PS INTRATHECAL DAILY, Complication INTRATHECAL Muscle Spasticity Date:02/18/04ISR Number: 4297296-6Report Type:Expedited (15-DaCompany Report #200410574FR Age:79 YR Gender:Male I/FU:I PTReport Source Role Manufacturer Outcome Product Route Dose Duration Hospitalization -Eczema Lovenox PS Aventis Pharmaceuticals Inc. Initial or Prolonged SUBCUTANEOUS Tegretol - Slow Release SS ORAL Prozac 20 Mg SS ORAL Mopral SS ORAL

Lioresal

Praxilene

Fludex 1.5 Mg Comprime Enrobe Lp SS

SS

С

ORAL

ORAL

			Motilium	С		
l l			Diffu K	С		ORAL
			Forlax	C		ORAL
						I
Date:02/18/04ISR Number Age: Gender:Male	: 4300236-4Report Type:Exped I/FU:I	ited (15-DaCompany Rep	ort #20041704			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization -	Device Failure	Health	Lioresal			,
Initial or Prolonged	Respiratory Failure	Professional	Inthrathecal			
Required	Upper Respiratory Tract		(Baclofen Injection)	PS		
INTRATRACHEAL MCG, D	DAILY,					
Intervention to	Infection					
INTRATHECAL						
Prevent Permanent			Iv Valium And Ativan	С		
Impairment/Damage						ļ
Date:02/19/04ISR Number Age:79 YR Gender:Male	: 4299078-8Report Type:Exped I/FU:I	lited (15-DaCompany Rer	ort #200412064GDDC			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization -	Eczema		Fludex	PS	Aventis	
Initial or Prolonged	ECZema		FIUCEA	FU	Pharmaceuticals Inc.	ORAL
Initial of reoringed			Lovenox	SS	Aventis	
I Contraction of the second					Pharmaceuticals Inc.	
SUBCUTANEOUS dose:	UNK					
			Prozac	SS		ORAL
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Freedom Of Information (FOI) Report

	Tegretol	SS	ORAL
dose: 2 DF	Mopral	SS	ORAL
dose: UNK			
	Lioresal	SS	
	Praxilene	C	
	Motilium	C	
	Diffu K	C	
	Forlax	C	
	Xyzal	С	

Date:02	2/20/0)4ISR	Number:	4301283-9Report	Type:Direct
Aqe:83	YR	Gende	er:Female	I/FU:I	

Company Report #CTU 212728

Age.03	IK	Gender • Feillare	T/FO.T	

Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Disability 5 MG PO TID	Duración	Aphasia		Baclofen	PS		ORAL
		Asthenia		Amlodipine	С		
		Depressed Level Of		Buffered Aspirin	С		
		Consciousness		Calcium /Vit D	С		
		Lethargy		Clonazepam	С		
		Mutism		Clopidogrel	С		
				Cyanocobalamin	С		
				Enoxaparin	С		
				Escitalopram	С		
				Furosemide	С		
					С		
				Gabapentin	С		
				Hydrochlorothiazide	С		
				Levothyroxine	С		
				Multivitamin	С		
				Nystatin	С		
				Simvastatin	С		
				Vitamin E	С		
				Acetaminophen	С		
				Diphenhydramine	С		
				Insulin Lispro			
				(Sliding Scale)	С		

Outcome		PT	Report Source	Product	Role Manufacturer	Route
Dose	Duration					
Life-Threate	ning	Bradycardia	Foreign	Baclofen - Ipi		
Other		Dizziness	Other	Tablets	PS	ORAL
80 MG ORAL						
1				Gabapentin	C	
1				Movicol	C	
1				Salbutamol	C	
1				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 - Hypotension Initial or Prolonged Hypothermia Hypotonia Implant Site Reaction Mental Status Changes Mouth Haemorrhage

Freedom Of Information (FOI) Report

Dose	Duration	Shock	Report Source	Product	Role	Manufacturer	Route
JUSE	Duración		Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		
INTRATHECAL	DAILY,			· · · · · ·			
INTRATHECAL							
)4ISR Number Gender:Male	: 4304452-7Report Type:Expe I/FU:I	dited (15-DaCompany Re	eport #04-02-0271			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other		Psychotic Disorder	Foreign Other	Baclofen Tablets - Ipi	PS	Ipi	ORAL
10MG QID ORA	AL .						
				Risperidone	С		
				Bendrofluazide	С		
				Perindopril	C		
				Metformin	С		
				Rosiglitazone Diazepam	C C		
)4ISR Number Gender:Male	: 4307179-0Report Type:Expe I/FU:I	dited (15-DaCompany Re	eport #PHRM2004FR00853			
		PT	Report Source	Product	Role	Manufacturer	Route
Outcome							
Outcome Dose	Duration						
	Duration	Headache	Foreign	Lioresal			
	Duration 50 UG,	Hyperhidrosis	Foreign Health	Lioresal (Baclofen)	PS		
Dose		Hyperhidrosis			PS		

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Life-Threater	-	Bradycardia		Baclofen		Novartis Sector:	
Other		Dizziness				Pharma	ORAL
80mg/day							
				Gabapentin	C		ORAL
300mg/day					~		
1 1				Movicol	С		ORAL
1 sachet/day					2		
				Salbutamol	С		
2.5ml/day					2		00.11
				Vitamin C	С		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 \mathbf{PT} Life-Threatening Arrhythmia Hospitalization -Blood Bicarbonate Initial or Prolonged Decreased Other Blood Calcium Decreased Blood Glucose Increased Blood Potassium Decreased Body Temperature Increased Depressed Level Of Consciousness Drug Screen Positive Electrocardiogram Qt

Freedom Of Information (FOI) Report

Dose Duration	Corrected Interval Prolonged Nausea Prothrombin Time	Report Source	Product	Role	Manufacturer	Route
	Prolonged Red Blood Cell Sedimentation Rate	Study Health Professional	Morphine Sulfate (Similar To Nda 19-516) (Morphine			
ORAL	Increased	Other	Sulfate)	PS		ORAL
UKAL	Respiratory Arrest Syncope Torsade De Pointes Ventricular Extrasystoles		Vistaril(Hydroxyzine Embonate) Benadryl (Diphenhydramine	SS		
	Ventricular Tachycardia Vomiting		(Diphemiydramine Hydrochloride) Metformin	SS		
	White Blood Cell Count Increased		(Metformin) Lipitor	SS		
			(Atorvastatin) Effexor (Venlafaxine	SS		
			Hydrochloride) Lasix (Furosemide)	SS SS		
			Potassium	22		
			(Potassium)	SS		
			Reglan			
			(Metoclopramide)	SS		
			Amfetamine			
			(Amfetamine)	SS		
			Ambien (Zolpidem			
			Tartrate)	SS		
			Acebutolol Hydrochloride			
			(Acebutolol			
			Hydrochloride)	SS		
			Baclofen (Baclofen) Nexium	SS		
			(Esomeprazole) Prilosec	SS		
			(Omeprazole)	SS		
			Quinine (Quinine)	SS		
			Promethazine			
			(Promethazine) Klonopin	SS		
			(Clonazepam) Wellbutrin (Amfebutamone	SS		
			Hydrochloride) Celexa (Citalopram	SS		

Hydrobromide) C

Date:03/02/04ISR Numbe Age: Gender:Fem	er: 4311152-6Report Type:Exped male I/FU:I	lited (15-DaCompany Re	eport #20041727		
Outcome	PT	Report Source	Product	Role Manufacturer	Route
Dose Duration					
Hospitalization -	Drug Withdrawal Syndrome	Health	Lioresal Intrathecal		
Initial or Prolonged	Migration Of Implant	Professional	(Baclofen Injection)	PS	
INTRATHECAL MCG,	DAILY,				
Required	Muscle Rigidity				
INTRATHECAL					
Intervention to	Muscle Spasticity		Baclofen	C	
Prevent Permanent	Pruritus				
Impairment/Damage	Pyrexia				

FDA - Adverse Event Reporting System (AERS) Freedom Of Information (FOI) Report Date:03/03/04ISR Number: 4312143-1Report Type:Expedited (15-DaCompany Report #20041729 Gender:Female Age: I/FU:I Outcome PTReport Source Product Role Manufacturer Route Dose Duration Hospitalization -Drug Withdrawal Syndrome Health Lioresal Intrathecal Initial or Prolonged Muscle Spasticity Professional (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 Report Source Product Role Manufacturer Outcome PTRoute Duration Dose Hospitalization -Aventis Eczema Lovenox PS Initial or Prolonged Psoriasis 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 С Motilium С Diffu K С ORAL Forlax С ORAL Date:03/04/04ISR Number: 4311492-0Report Type:Expedited (15-DaCompany Report #PHBS2004TW02803 Aqe:58 YR Gender:Male I/FU:I Outcome PTReport Source Product Role Manufacturer Route Dose Duration Hospitalization -Depressed Level Of Baclofen PSNovartis Sector: Consciousness Pharma

Initial or Prolonged Con UNKNOWN 5 mg, TID

Toxic Induced

Encephalopathy

Date:03/04/04ISR Number Age:76 YR Gender:Male	: 4311515-9Report Type:Expedi I/FU:I	ited (15-DaCompany Repor	t #PHBS2004TW02804			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - Initial or Prolonged UNKNOWN 10 mg,	Depressed Level Of Consciousness TID Neurotoxicity		Baclofen	PS	Novartis Sector: Pharma	
Age:50 YR Gender:Male Outcome	: 4311516-0Report Type:Expedi I/FU:I PT	ited (15-DaCompany Repor Report Source	rt #PHBS2004TW02802 Product	Role	Manufacturer	Route
Dose Duration Hospitalization - Initial or Prolonged	Agitation Blood Glucose Increased		Baclofen	PS	Novartis Sector: Pharma	
UNKNOWN 5 mg,			Triazolam	С		
UNKNOWN 0.25 m			11 18201811	C		

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						
Hospitalizat	ion -	Eczema		Lioresal	PS	Novartis Sector:	
Initial or P	rolonged					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	Dunchion	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Death		Device Failure	Health	Lioresal Intrathecal			
		Drug Ineffective	Professional	(Baclofen)	PS		
INTRATHECAL	SEE IM	AGE,					
		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 Duration

Product

Life-Threatening Hospitalization - INTRATHECAL 530	Cheyne-Stokes Respiration Respiratory Rate	Lioresal Inthratecal	PS	Novartis Sector: Pharma	
Initial or Prolonged	Decreased	Lioresal Inthratecal	SS	Novartis Sector: Pharma	
INTRATHECAL 585		Lioresal Clonazepam	SS C		ORAL
UNKNOWN		Depakene	C		
UNKNOWN		-			

Date:03/17/04ISR Number: 4320217-4Report Type:Expedited (15-DaCompany Report #ZANA001136 Age:24 YR Gender:Male I/FU:I

Outcome Dose Duration	PT	Report Source	Product	Role Manufacturer	Route
Hospitalization - Initial or Prolonged 12 MG DAILY	Bradycardia Drug Interaction	Foreign Health	Sirdalud (Tizanidine Hydrochloride)	PS	ORAL
ORAL	Hypotension	Professional			
	Hypotonia	Other	Lioresal (Baclofen)	SS	ORAL
30 MG DAILY	Malaise				
ORAL	Skin Infection		Myolastan (Tetrazepam)	SS	ORAL
75 MG DAILY			(letrazepam)	22	ORAL
ORAL					
			Ciflox (Ciprofloxacin)	SS	
1 G DAILY			Voltarene Lp (Diclofenac Sodium)	C	

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 Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - Initial or Prolonged 15 mg, TID 15840MIN	Anorexia General Physical Health		Lioresal	PS	Novartis Sector: Pharma	ORAL
15 Mg, 110 15640MIN	Deterioration Hypernatraemia Muscle Spasticity Somnolence					
Date:03/19/04ISR Number Age: Gender:Femal	: 4321930-5Report Type:Expedite le I/FU:F	ed (15-DaCompany Repor	t #20041729			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration Hospitalization – Initial or Prolonged INTRATHECAL MCG, DA	Drug Withdrawal Syndrome Muscle Spasticity AILY, Pyrexia	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		
	: 4322351-1Report Type:Expedite	ed (15-DaCompany Repor	t #ZANA001136			
Age:24 YR Gender:Male	I/FU:I					
Outcome Dose Duration	РТ	Report Source	Product	Role	Manufacturer	Route
Hospitalization - Initial or Prolonged 12 MG DAILY	Bradycardia Drug Interaction	Foreign Health	Sirdalud (Tizanidine Hydrochloride)	PS		ORAL
ORAL	Hypotension	Professional				
30 MG DAILY	Hypotonia	Other	Lioresal (Baclofen)	SS		ORAL
ORAL	Malaise					
ORAL			Myolastan			
75 MG DAILY			(Tetrazepam)	SS		ORAL

ORAL

1 G DAILY			Ciflox (Ciprofloxacin) Voltaren Lp Diclofenac Sodium)	SS C	
Date:03/22/04ISR Number Age:55 YR Gender:Male	r: 4321082-1Report Type:Direct e I/FU:I	Company Repo:	rt #CTU 214876		
Outcome Dose Duration	PT	Report Source	Product	Role Manufacturer	Route
Hospitalization -	Confusional State		Baclofen 10mg		
Initial or Prolonged 5 MG BID PRN	Fatigue		Tablets	PS	
	Mental Status Changes		Paracalitol	С	
1	Somnolence		Epoetin	C	
1			Ferrous Gluconate	C	
			Allopurinol	C	I
1			Warfarin	C	
1			Nephrovite	C	
1			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

Freedom Of Information (FOI) Report

	Musc	ular Weakness					
ose	Duration		Report Source	Product	Role	Manufacturer	Route
050	Duración		Foreign Literature Health	Baclofen (Watson Laboratories) (Baclofen) Tablet	PS	Watson Laboratories	ORAL
2.5 MG, E	BID,			(Bacioren) Tabiec	PD	Watson Laboratories	OKAL
			Professional				
DRAL			Other	Isoflurane (Isoflurane)	SS		OTHER
0.6 то 1.0)			(22		0111211
VOL%, OTHE	ER						
				Prednisone	С		
				Diazepam Levothyroxine	С		
				(Levothyroxine) Vitamin B12	С		
				Injection	С		
				Propofol (Propofol) Sufentanil	С		
				(Sufentanil) Cefuroxime	С		
				(Cefuroxime) Clindamycin	С		
				(Clindamycin)	С		
				Dexamethasone Atracurium	C		
				(Atracurium)	С		
				Morphine (Morphine)	С		

Date:03/24/04ISR Number: 4325382-0Report Type:Expedited (15-DaCompany Report #20031619 Age: Gender:Male I/FU:F

Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Death	Duración	Breath Holding	Health	Lioresal Intrathecal	Da		
INTRATHECAL	MCG,	Cardiac Disorder DAILY,	Professional	(Baclofen Injection)	P2		

INTRATHECAL

	4ISR Number Gender:Fema	: 4323641-9Report Type:Expe le I/FU:I	dited (15-DaCompany Rej	port #PHNU2004DE01249			
Outcome Dose	Duration	РТ	Report Source	Product	Role	Manufacturer	Route
Hospitalizat Initial or P UNKNOWN		Abdominal Pain Acidosis		Lioresal	PS	Novartis Sector: Pharma	
		Blood Ph Decreased Hypokalaemia Hyponatraemia Respiratory Failure Somnolence					
	4ISR Number Gender:	: 4330481-3Report Type:Experies I/FU:F	dited (15-DaCompany Rej	port #20031600			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Required Intervention INTRATHECAL	to	Hepatitis DAILY,	Foreign Health	Lioresal Intrathecal (Baclofen Injection)	PS		
Prevent Perm INTRATHECAL Impairment/D	anent		Professional				

FDA - Adverse Event Reporting System (AERS) Freedom Of Information (FOI) Report Date:03/29/04ISR Number: 4330679-4Report Type:Expedited (15-DaCompany Report #PHFR2003GB04316 Age: Gender:Male I/FU:F Outcome PΤ Report Source Product Role Manufacturer Route Duration Dose Cholelithiasis Health Baclofen Intrathecal Hepatitis Acute (Baclofen) Unknown PS Professional INTRATHECAL INTRATHECAL Other Date:03/29/04ISR Number: 4332202-7Report Type:Expedited (15-DaCompany Report #20041748 Age: Gender:Female I/FU:I ΡТ Role Manufacturer Report Source Product Outcome Route Duration Dose Lioresal Intrathecal Hospitalization -Cerebrospinal Fluid Health Professional (Baclofen Injection) Initial or Prolonged Leakage PS INTRATHECAL DAILY, Headache INTRATHECAL Lymphoedema Meningitis Date:03/30/04ISR Number: 4332873-5Report Type:Expedited (15-DaCompany Report #20041727 Gender: Female I/FU:F Aqe: Outcome PΤ Report Source Product Role Manufacturer Route Dose Duration Hospitalization -Drug Withdrawal Syndrome Health Lioresal Intrathecal Initial or Prolonged Pocket Erosion Professional (Baclofen Injection) PS INTRATHECAL MCG, DAILY, Required INTRATHECAL Oral Baclofen Intervention to С Prevent Permanent Impairment/Damage

Date:03/31/04ISR Number: 4328426-5Report Type:Expedited (15-DaCompany Report #PHBS2004SE04163 Age:89 YR Gender:Male I/FU:I

Outcome Dose	Duration	РТ	Report Source	Product	Role	Manufacturer	Route
Dose Death Other	Duration	Difficulty In Walking Drug Level Increased		Lioresal	PS	Novartis Sector: Pharma	
		Fatigue Intentional Misuse Pneumonia		Triobe	С		
	1ISR Number Gender:Fema	: 4330283-8Report Type:Exp le I/FU:I	edited (15-DaCompany Re	port #PHRM2004FR013	70		
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - Enitial or Prolonged .0 mg/day 5760 MIN	Cardiac Failure Confusional State		Lioresal	PS	Novartis Sector: Pharma	ORAL	
		Dyspnoea : 4330286-3Report Type:Exp	edited (15-DaCompany Re	port #PHBS2004SE041	63		
Age:89 YR (Gender:Male	I/FU:F					
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Death Other		Difficulty In Walking Drug Level Increased		Lioresal	PS	Novartis Sector: Pharma	ORAL
		Fatigue Intentional Misuse Pneumonia		Triobe	С		
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FDA - Adverse Event Reporting System (AERS) Freedom Of Information (FOI) Report Date:04/05/04ISR Number: 4334304-8Report Type:Expedited (15-DaCompany Report #20041774 Gender:Female Age: I/FU:I Outcome PTReport Source Product Role Manufacturer Route Dose Duration Hospitalization -Meningitis Streptococcal Health Lioresal Initial or Prolonged Wound Secretion Professional 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 PTReport Source Role Manufacturer Outcome Product Route Dose Duration Life-Threatening Autonomic Nervous System Health Lioresal Intrathecal Hospitalization -Imbalance Professional (Baclofen Injection) PS INTRATHECAL DAILY. Initial or Prolonged Blood Pressure INTRATHECAL Fluctuation Required Clonus Intervention to Prevent Permanent Convulsion Impairment/Damage Drug Withdrawal Syndrome Hypoxia Muscle Spasticity Pneumonia Pyrexia Rales Respiratory Distress Respiratory Failure Tachycardia Tremor Wheezing Date:04/08/04ISR Number: 4335915-6Report Type:Expedited (15-DaCompany Report #04-04-0494 Age:36 YR Gender:Male I/FU:I PTReport Source Product Role Manufacturer Outcome Route

Foreign

Baclofen Tablets -

Dose

Hospitalization -

Duration

Autonomic Nervous System

Initial or Prolonged 10MG HS ORAL	Imbalance	Other	Ipi	PS	Ipi	ORAL
	Blood Creatine Phosphokinase Increased Disorientation Drug Withdrawal Syndrome Muscle Rigidity		Amitriptyline	С		
Date:04/09/04ISR Number Age: Gender:Male	r: 4335860-6Report Type:Exped	ited (15-DaCompany Re	eport #PHFR2004GB01654			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - Initial or Prolonged 10 mg, TID	Anaemia Duodenal Ulcer		Baclofen	PS	Novartis Sector: Pharma	
	Haemorrhage					
Age:36 YR Gender:Male Outcome	PT	ited (15-DaCompany Re	eport #PHFR2004GB01655			
Hospitalization - Initial or Prolonged	Autonomic Nervous System Imbalance Blood Creatine					
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Freedom Of Information (FOI) Report

Dose	Duration	Phosphokinase Increased Disorientation Drug Withdrawal Syndrome Muscle Rigidity	Report Source	Product Baclofen		Manufacturer Novartis Sector:	Route
		Neuroleptic Malignant Syndrome		Baciolen	PS	Pharma	ORAL
10mg/nocte 50mg/nocte				Amitriptyline	С		ORAL
Date:04/09/0 Age:	04ISR Number Gender:Male	: 4336483-5Report Type:Direc	ct Company Re	eport #CTU 216356			
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose Disability	Duration	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:04/12/0 Age:	04ISR Number Gender:Male	: 4339539-6Report Type:Expect I/FU:I	lited (15-DaCompany Re	eport #20041771			
Outcome Dose	Duration	РТ	Report Source	Product	Role	Manufacturer	Route
Hospitalizat Initial or I INTRATHECAL	tion -	Enterococcal Infection Meningitis AILY,	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		
INTRATHECAL							

Date:04/13/04ISR Number: 4337273-XReport Type:Expedited (15-DaCompany Report #PHBS2004CA01117 Age:27 YR Gender:Male I/FU:F

Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other		Abnormal Behaviour Agitation		Lioresal	PS	Novartis Sector: Pharma	ORAL
1 tablet/day							
		Anger Antisocial Behaviour		Lioresal	SS	Novartis Sector: Pharma	ORAL
1 tablet, BID	D 4320 MIN						
		Depression Drug Hypersensitivity		Lioresal	SS	Novartis Sector: Pharma	ORAL
1 tablet, TID	D 4320 MIN	ſ					
		Dry Mouth Dysphagia		Lioresal	SS	Novartis Sector: Pharma	ORAL
2 tablets,							
		Eye Disorder					
BID	4320 MIN				~ ~		
		Hallucination Hyperhidrosis		Lioresal	SS	Novartis Sector: Pharma	ORAL
2 tablets,							
l		Infrequent Bowel					
TID	2880 MIN			T	20	Neccestia, Costoni	
		Movements Insomnia		Lioresal	SS	Novartis Sector: Pharma	ORAL
1 tablet/day							
UNKNOWN		Lethargy		Domperidone	C		
		Mood Swings Paranoia Thyroid Function Test Abnormal Urine Output Decreased					

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 Dose Duration	PT	Report Source	Product	Role Manufacturer	Route
Hospitalization - Initial or Prolonged ORAL	Acidosis Alanine Aminotransferase	Study Health	Oxycodone Hydrochloride	PS	ORAL
Other	Increased Anion Gap Increased	Professional Other	Hydrocodone W/Acetaminophen	SS	ORAL
ORAL	Alloli dap increased	Other	W/ACecaminophen	66	ULAL
	Aspartate		Baclofen (Baclofen)	SS	ORAL
ORAL	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				

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Death		Coma Device Failure Hypertonia	Foreign Health Professional	Lioresal Intrathecal (Baclofen Injection) 2000mcg/Ml	PS		
INTRATHECAL	MCG,						
INTRATHECAL							
		Proteus Infection Respiratory Failure Urosepsis		Antibiotics Dexamethasone	C C		

Date:04/21/04ISR Number: 4343187-1Report Type:Expedited (15-DaCompany Report #PHRM2004FR01508 Age:64 YR Gender:Male I/FU:I

Outcome	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalizati		Dermatitis Exfoliative		Lioresal	PS	Novartis Sector:	
Initial or Pr	-	Erythema				Pharma	ORAL
5 mg, TID	12960MIN						
		Pruritus		Augmentin Injection	SS		
INTRAVENOUS	1 g, TI	ID 11520MIN					
		Purpura		Pyostacine	SS		ORAL
1000 mg, BID	2880 MIN						
-		Rash Maculo-Papular		Gentalline	С		
INTRAVENOUS	1 DF, 7	_					
				Oflocet	С		ORAL
200 mg, BID	11520MIN						
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Freedom Of Information (FOI) Report

				Lovon	С		ORAL
150 mg/day				Loxen	C		ORAL
SUBCUTANEOU	10			Insulatard	С		
SUBCUIANEOU	22			Humalog	С		
SUBCUTANEOU	JS						
Date:04/21/ Age:	04ISR Numbe Gender:Fem	r: 4345636-1Report Type:Exped ale I/FU:I	ited (15-DaCompany Rep	port #20041811			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitaliza Initial or INTRATHECAI	ation - Prolonged	Blood Pressure Ambulatory Abnormal DAILY , Coma	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		
INTRATHECAL	_	Medication Error Overdose Somnolence					
Date:04/21/ Age:	04ISR Numbe Gender:Fem	r: 4345637-3Report Type:Exped ale I/FU:F	ited (15-DaCompany Rep	port #20041748			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitaliza Initial or INTRATHECAL	ation - Prolonged	Cerebrospinal Fluid Leakage DAILY, Lymphoedema	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		
INTRATHECAI	-	Meningitis					
Date:04/23/ Age:	04ISR Numbe Gender:Unk	r: 4344763-2Report Type:Exped nown I/FU:I	ited (15-DaCompany Rep	port #PHBS2004IE05132			
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose Other	Duration	Gastrointestinal Haemorrhage		Lioresal	PS	Novartis Sector: Pharma	ORAL

Age: Gender:Ma	er: 4349760-9Report Type:Exped: le I/FU:I					
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Death 5MG TID	Cerebrovascular Accident	Foreign	Baclofen-Ipi Tablets	PS	Ipi	
Other	Coma	Other	Aspirin	С		
	Musculoskeletal Stiffness		Trimethoprim	С		
	Renal Impairment		Salbutamol	С		
	Sudden Death		Oxybutynin	С		
	er: 4350043-1Report Type:Exped:	ited (15-DaCompany Re	port #PHFR2004GB01654			
Age:74 YR Gender:Ma Outcome	le I/FU:F PT	ited (15-DaCompany Re Report Source	eport #PHFR2004GB01654 Product	Role	Manufacturer	Route
Age:74 YR Gender:Ma Outcome Dose Duration	le I/FU:F PT		Product			Route
Age:74 YR Gender:Ma Outcome Dose Duration Hospitalization -	le I/FU:F PT Anaemia			Role PS	Novartis Sector:	
Age:74 YR Gender:Ma Outcome Dose Duration	le I/FU:F PT		Product			Route ORAL
Age:74 YR Gender:Ma Outcome Dose Duration Hospitalization - Initial or Prolonged	le I/FU:F PT Anaemia		Product		Novartis Sector:	
Age:74 YR Gender:Ma Outcome Dose Duration Hospitalization - Initial or Prolonged	le I/FU:F PT Anaemia Duodenal Ulcer		Product Baclofen	PS	Novartis Sector:	ORAL
Age:74 YR Gender:Ma Outcome Dose Duration Hospitalization - Initial or Prolonged 20 mg, TID 2.5 mg, BID	le I/FU:F PT Anaemia Duodenal Ulcer		Product Baclofen	PS	Novartis Sector:	ORAL
Age:74 YR Gender:Ma Outcome Dose Duration Hospitalization - Initial or Prolonged 20 mg, TID	le I/FU:F PT Anaemia Duodenal Ulcer Haemorrhage		Product Baclofen Oxybutynin	PS C	Novartis Sector:	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 PΤ Report Source Product Role Manufacturer Route Dose Duration Required Weight Decreased Health Lioresal Intrathecal (Baclofen Injection) Intervention to Professional PS INTRATHECAL MCG, DAILY, Prevent Permanent INTRATHECAL Impairment/Damage Date:04/29/04ISR Number: 4353011-9Report Type:Expedited (15-DaCompany Report #20041818 Gender: I/FU:F Aqe: PTReport Source Role Manufacturer Outcome Product Route Duration Dose Death Bradycardia Foreign Lioresal Intrathecal Cardiac Arrest (Baclofen Injection) PS Health INTRATHECAL DAILY, Pain Professional INTRATHECAL Procedural Complication Syncope Vasovagal Date:05/04/04ISR Number: 4353176-9Report Type:Direct Company Report #CTU 217952 Aqe:41 YR Gender:Female I/FU:I Outcome PTReport 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 Gender: I/FU:I Aqe: PTReport Source Product Role Manufacturer Route Outcome

Dose

Duration

Other		Atrioventricular Block		Baclofen	PS	Novartis Sector: Pharma	
				Dantrolene	С		
)4ISR Number Gender:Fema	r: 4356502-XReport Type:Exp ale I/FU:I	pedited (15-DaCompany R	eport #PHBS2004NL05381			
2	jenuer • r ema				¬ 1-		D
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
DOBE	Duración	Dysgeusia Parosmia	Health Professional	Lioresal (Baclofen) Solution For			
		Falobula	Other	Injection Nifedipine	PS		
				(Nifedipine) Amiloride	С		
1				W/Hydrochlorothiazid			
1				e (Amiloride)	C		
1				Tramadol (Tramadol)	С		
4				Carbamazepine (Carbamazepine)	С		
				(04104	C		
	94ISR Number Gender:Unkn	r: 4358475-2Report Type:Exp nown I/FU:F	pedited (15-DaCompany Re	≥port #PHBS2004IE05132			
Outcome Dose	Duration	РТ	Report Source	Product	Role	Manufacturer	Route
Other		Gastrointestinal Haemorrhage		Lioresal	PS	Novartis Sector: Pharma	ORAL
5 mg, BID		-					
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FDA - Adverse Event Reporting System (AERS) Freedom Of Information (FOI) Report Dantrolene С UNKNOWN UNK, UNK Date:05/17/04ISR Number: 4359226-8Report Type:Direct Company Report #CTU 218739 Aqe:61 YR Gender:Male I/FU:I Role Manufacturer PTReport Source Product Outcome Route Dose Duration Hospitalization -Mental Status Changes Baclofen PS 10 MG QID Initial or Prolonged Oxycodone С Fentanyl С Temazepam С Date:05/17/04ISR Number: 4359684-9Report Type:Direct Company Report #CTU 218832 Age:48 YR Gender:Female I/FU:I Outcome PTReport 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 Mylan SS 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 Role Manufacturer Outcome PTReport Source Product 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

С

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	Coma	Health	Lioresal Intratecal			
Hospitalization -	Depressed Level Of	Professional	(Baclofen) Solution			
Initial or Prolonged	Consciousness	Other	For Injection	PS		
INTRATHECAL INTRATH	HECAL					
	Drug Level Above		Lopril (Captopril)	С		
	Therapeutic		Nozinan			
	Escherichia Infection		(Levomepromazine			
	Implant Site Infection		Maleate)	С		
	Interstitial Lung Disease		Captea (Captopril,			
	Kussmaul Respiration		Hydrochlorothiazide)			
	Meningitis Bacterial		Tablet	С		
	Miosis					
	Musculoskeletal Stiffness					
	Pneumonia Aspiration					
	Shock					

FDA - Adverse Event Reporting System (AERS) Freedom Of Information (FOI) Report Date:05/17/04ISR Number: 4361020-9Report Type:Expedited (15-DaCompany Report #20041833 Age: Gender: I/FU:I Outcome PTReport Source Product Role Manufacturer Route Dose Duration Hospitalization -Catheter Related Foreign Lioresal Intrathecal Initial or Prolonged Complication Health (Baclofen Injection) PS INTRATHECAL DAILY, Device Failure Professional INTRATHECAL Drug Ineffective Meningitis Overdose Date:05/17/04ISR Number: 4362222-8Report Type:Expedited (15-DaCompany Report #20041833 Gender: I/FU:F Aqe: Role Manufacturer Outcome PTReport Source Product Route Dose Duration Hospitalization -Catheter Related Foreign Lioresal Intrathecal Initial or Prolonged Complication Health (Baclofen Injection) PS MCG, DAILY, INTRATHECAL Device Failure Professional 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 Report Source Product Role Manufacturer Outcome ΡТ Route Dose Duration Atrioventricular Block Baclofen Other PS Novartis Sector: Cardiac Arrest Pharma ORAL Convulsion Dantrolene SS ORAL Electrocardiogram Pr Prolongation

Outcome		PT		Report Source	Product	Role	Manufacturer	Route
Dose Dur	ration							
Hospitalization	-	Blood Creat:	inine	Health	Lioresal	PS	Novartis Sector:	
Initial or Prolo	nged	Increased		Professional			Pharma	ORAL
~	2880 MIN							
Other		Bradycardia			Temesta	SS		
UNKNOWN	1 mg/da	ay 144'	0 MIN					
		Coma			Floxapen	С		
INTRAVENOUS								
		Drug Intera	.ction					DRIP
6 g								
		Drug Level I	Decreased		Insulin	C		
UNKNOWN								
		Fall			Actrapid	C		
UNKNOWN								
		Somnolence			Benerva	C		
UNKNOWN								
		Stupor			Prednisone	C		
UNKNOWN	50 mg/d	lay						
					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 Dose Durat	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - Initial or Prolong 20 mg, TID	Anaemia	Health Professional	Baclofen	PS	Novartis Sector: Pharma	ORAL
	Duodenal Ulcer		Oxybutynin	С		ORAL
2.5 mg, BID	Haemorrhage		Rabeprazole	С		ORAL
10 mg/day	Nephrolithiasis		Ferrous Gluconate	С		ORAL
UNK, PRN			Lactulose	С		ORAL

Freedom Of Information (FOI) Report

Role Manufacturer

Route

Date:05/19	0/04ISR Number: 4	364533-9Report	Type:Expedited	(15-DaCompany	Report	#PHFR2004GB01886	
Age:	Gender:Unknown	I/FU:I					
Outcome	PI		Re	eport Source	F	Product	
Dose	Duration						

Duration				
	Atrioventricular Block	Health	Baclofen (Baclofe	n)
		Professional	Unknown	PS
		Other	Dantrolene	
			(Dantrolene)	С

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					
ORAL		Atrioventricular Block Cardiac Arrest	Foreign Health	Baclofen (Baclofen)	PS	ORAL
ORAL		Convulsion Electrocardiogram Pr	Professional Other	Dantrolene (Dantrolene)	SS	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 Du	uration						
Hospitalization	ı —	Chills	Health	Lioresal Intrathecal			
Initial or Prol	Longed	Confusional State	Professional	(Baclofen Injection)	PS		
INTRATHECAL	MCG,	DAILY,					
		Drug Withdrawal Syndrome					
INTRATHECAL							
		Hallucination					
		Medication Error					
		Muscle Spasms					
		Pyrexia					

Outcome	PT	Report Source	Product	Role Manufacturer	Route
Dose Duration					
Death	Drug Interaction	Foreign	Durogesic (Fentanyl)		
Hospitalization -	Encephalitis	Health	Patch	PS	
TRANSDERMAL 100 U	JG/HR,				
Initial or Prolonged	Insomnia	Professional			
TRANSDERMAL					
	Meningitis		Lioresal (Baclofen)		
	Myalgia		Tablets	SS	ORAL
10 MG, 3 IN 1					
	Refusal Of Treatment By				
DAY, ORAL					
	Patient		Voltaren (Diclofenac		
	Refusal Of Treatment By		Sodium)	С	
	Relative				
	Respiratory Depression				
Age: Gender:Ma	er: 4371696-8Report Type:Exped le I/FU:F	(
Outcome	PT	Report Source	Product	Role Manufacturer	
Dose Duration					Route
Hospitalization -					Route
	Blood Creatine	Health	Lioresal Intrathecal		Route
Initial or Prolonged	Blood Creatine Phosphokinase Increased	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS	Route
—	Phosphokinase Increased			PS	Route
Initial or Prolonged	Phosphokinase Increased			PS	Route
Initial or Prolonged	Phosphokinase Increased MCG,			PS	Route
Initial or Prolonged INTRATHECAL UNK N	Phosphokinase Increased MCG,			PS	Route
Initial or Prolonged INTRATHECAL UNK N	Phosphokinase Increased ACG, Drug Withdrawal Syndrome			PS	Route
Initial or Prolonged INTRATHECAL UNK M DAILY;	Phosphokinase Increased ACG, Drug Withdrawal Syndrome			PS	Route
Initial or Prolonged INTRATHECAL UNK M DAILY;	Phosphokinase Increased ACG, Drug Withdrawal Syndrome Hypertonia			PS	Route
Initial or Prolonged INTRATHECAL UNK M DAILY;	Phosphokinase Increased ACG, Drug Withdrawal Syndrome Hypertonia Muscle Spasticity			PS	Route
Initial or Prolonged INTRATHECAL UNK M DAILY;	Phosphokinase Increased ACG, Drug Withdrawal Syndrome Hypertonia Muscle Spasticity Pyrexia			ΡS	Route
Initial or Prolonged INTRATHECAL UNK M DAILY;	Phosphokinase Increased ACG, Drug Withdrawal Syndrome Hypertonia Muscle Spasticity Pyrexia			PS	Route

FDA - Adverse Event Reporting System (AERS) Freedom Of Information (FOI) Report Date:06/02/04ISR Number: 4371993-6Report Type:Expedited (15-DaCompany Report #PHBS2004SE06272 Gender:Male Age: I/FU:I Outcome PTReport Source Product Role Manufacturer Route Duration Dose Blood Alkaline Health Lioresal (Baclofen) PS Phosphatase Increased Professional Transaminases Increased Other Date:06/03/04ISR Number: 4369014-4Report Type:Expedited (15-DaCompany Report #PHNU2004DE01939 Age: Gender:Male I/FU:I Outcome РΤ Report Source Product Role Manufacturer Route Dose Duration Hospitalization -Hyponatraemia Lioresal Novartis Sector: PS Initial or Prolonged Inappropriate Pharma UNKNOWN Antidiuretic Hormone Secretion Pneumonia Date:06/03/04ISR Number: 4371662-2Report Type:Direct Company Report #CTU 220055 Aqe:60 YR Gender: I/FU:I PTRole Manufacturer Report Source Product Outcome Route Dose Duration Implant Site Reaction Hospitalization -Baclofen PS Medication Error Radiation Initial or Prolonged 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 PΤ Report Source Product Role Manufacturer Route Dose Duration Other Cardio-Respiratory Arrest Foreign Baclofen - Ipi Convulsion Other Tablets PS Ipi ORAL ORAL Electrocardiogram Pr Dantrolene SS ORAL ORAL Prolongation

Date:06/07/0 Age:	04ISR Number: Gender:Male	: 4375669-0Report T I/FU:I	ype:Expedite	ed (15-DaCompany	Report	#20041867			
Outcome Dose	Duration	РТ		Report Source		Product	Role	Manufacturer	Route
Other		Central Nervous Sy Infection	rstem	Health Professional		Lioresal (Baclofen Injection)	PS		
INTRATHECAL	DAILY,	White Blood Cell C	ount						
INTRATHECAL		Increased							
Date:06/08/(Age:)4ISR Number: Gender:	: 4374396-3Report T I/FU:I	'ype:Direct	Company	Report	: #CTU 220306			
Outcome Dose	Duration	PT		Report Source		Product	Role	Manufacturer	Route
Death	Duración	Cardiac Arrest Infusion Related R	eaction			Baclofen	PS		
)4ISR Number: Gender:Male	: 4375823-8Report T I/FU:I	'ype:Direct	Company	Report	: #CTU 220433			
Outcome Hospitalizat Initial or H									
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Freedom Of Information (FOI) Report

Other

Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duración	Multiple Drug Overdose		Morphine Baclofen	PS SS		
)4ISR Number Gender:Fema	: 4377999-5Report Type:Expe le I/FU:I	edited (15-DaCompany Re	eport #UKP04000167			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other		Atrioventricular Block Cardiac Arrest	Foreign Health	Dantrium (Dantrolene Sodium)	PS		ORAL
25 MG, 3/DAY	ζ,	Convulsion	Professional				
ORAL		Electrocardiogram Pr	Other	Baclofen (Baclofen)	SS		ORAL
ORAL		Prolongation					
	Gender:Male	: 4375216-3Report Type:Expe I/FU:F PT	Report Source	Product	Role	Manufacturer	Route
Dose Hospitalizat Initial or H 5 mg, TID		Dermatitis Exfoliative Erythema		Lioresal	PS	Novartis Sector: Pharma	ORAL
INTRAVENOUS	1 g, T	Pruritus		Augmentin Injection	SS		
1000 mg, BII		Purpura		Pyostacine	SS		ORAL
INTRAVENOUS	1 DF,	Rash Maculo-Papular TID 10080MIN		Gentalline	C		
200 mg, BID	11520MIN			Oflocet	C		ORAL
150 mg/day				Loxen	C		ORAL
SUBCUTANEOUS	5	8640 MIN		Insulatard Humalog	C C		
SUBCUTANEOUS	5	8640 MIN		παιιατογ	C		

100 mg/day			Tenormine	С		ORAL
			Zestril	С		ORAL
20 mg/day			Mediatensyl	С		ORAL
60 mg/day			Esidrex	С		ORAL
SUBCUTANEOUS	20160MIN		Lovenox	C		UITAL
	201001111					
Date:06/10/04ISR Number Age:41 YR Gender:Fema	r: 4375217-5Report Type:Exp ale I/FU:I	edited (15-DaCompany Re	port #PHFR2004GB02316			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration Other	Swollen Tongue		Baclofen	PS	Novartis Sector: Pharma	ORAL
5 mg, TID 5760 MII	N					
Date:06/10/04ISR Number Age:57 YR Gender:Unkr	r: 4375566-0Report Type:Exp nown I/FU:I	edited (15-DaCompany Re	port #PHHO2004DE07738			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
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						00.01
			Diclo-Phlogont Voltaren	SS SS		ORAL ORAL

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

Route
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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 -	Abnormal Behaviour	Study	Oxycontin		
Initial or Prolonged	Aggression	Health	Tablets(Oxycodone		
Other	Agitation	Professional	Hydrochloride) Cr		
	Anger	Other	Tablet	PS	ORAL
ORAL					
	Aspartate		Benzodiazepine		
	Aminotransferase		Derivatives ()	SS	ORAL
ORAL					
	Increased		Baclofen (Baclofen)	SS	ORAL
ORAL					
	Back Pain		Docusate Sodium		
	Blood Alkaline		(Docusate Sodium)	SS	

ORAL

Phosphatase Increased Blood Glucose Increased Blood Pressure Systolic Increased Blood Urea Increased 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

Marijuana (Cannabis)	SS
Tricyclic	
Antidepressants()	SS
Ultram (Tramadol	
Hydrochloride)	SS
Antiepileptics ()	SS

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	Duration	PT	Report Source	Product	Role Manufacturer	Route
Dose Other 400 MG, QD,	Duration	Blood Creatinine	Foreign	Lioresal	PS	ORAL
ORAL		Increased	Study			
ULAT		Creatinine Renal Clearance Decreased	Health Professional	Voltaren (Diclofenac Resinate)	SS	ORAL
ORAL			Other	Baclofen (Baclofen)	SS	ORAL
ORAL				Diclo-Phlogont		
ORAL				(Diclofenac Sodium)	SS	ORAL

Date:06/15/	04ISR Number:	4382009-XReport	Type:Expedited	(15-DaCompany	Report	#PHNU2004DE01939
Age:	Gender:Male	I/FU:I				

Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalizat Initial or F	tion -	Hyponatraemia Inappropriate Antidiuretic Hormone Secretion Pneumonia	Health Professional Other	Lioresal (Baclofen)	PS		
Age:56 YR)4ISR Number Gender:Male	: 4378730-XReport Type:Expedite I/FU:F				Manufashuman	Deute
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route

Hospitalization -	Hyponatraemia	Lioresal	PS	Novartis Sector:	
Initial or Prolonged	Inappropriate			Pharma	ORAL
80mg/day					
	Antidiuretic Hormone				
	Secretion				
	Pneumonia				

Date:06/16/04ISR Number Age:82 YR Gender:Male	r: 4382709-1Report Type:Expe e I/FU:I	edited (15-DaCompany Re	eport #D-04-023		
Outcome Dose Duration	PT	Report Source	Product	Role Manufacturer	Route
Hospitalization - 5 MG TID PO	Coordination Abnormal	Consumer	Baclofen 10 Mg; Usl	PS	ORAL
Initial or Prolonged	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 Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other	Duración	Blood Creatine Phosphokinase Increased		Baclofen	PS	Novartis Sector: Pharma	
UNKNOWN		Dystonia		Carbamazepine	SS		
UNKNOWN		Viral Infection		Trihexyphenidyl	SS		
UNKNOWN				Clonazepam	SS		
UNKNOWN				Tetrabenazine	С		
UNKNOWN							

Freedom Of Information (FOI) Report

UNKNOWN	Flurazepam	С
	Clobazam Pimozide	C C
TINIZATOLINI		

UNKNOWN

Date:06/18/0	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 Durati	on					
Death	Gastrointestinal Disorder	Health	Duramorph (Morphine			
Hospitalization -	Hypotension	Professional	Sulfate, Baxter)	PS	Baxter	
Initial or Prolonge	d Mental Status Changes		Baclofen	SS		
Required	Overdose		Ambien	С		
Intervention to	Pneumonia Aspiration		Amitriptyline	С		
Prevent Permanent	Pyrexia		Coumadin	С		
Impairment/Damage	Respiratory Failure		Ocybutynin	С		
			Valium	С		
			Lipitor	С		
			Macrodantin	С		
			Neurontin	С		
			Prozac	С		
			Zanaflex	С		
			Miralax	С		
			Peri-Colace	С		

Date:06/21/0 Age:	04ISR Number Gender:Male	: 4383929-2Report Type:Expe I/FU:F	dited (15-DaCompany R	eport #20041867			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other	Durución	Central Nervous System Infection	Health Professional	Lioresal (Baclofen Injection)	PS		
INTRATHECAL	DAILY,						
INTRATHECAL							

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose Di	uration						
Death		Drug Ineffective	Foreign	Lioresal Intrathecal			
		Drug Withdrawal Syndrome	Health	(Baclofen)	PS		
INTRATHECAL	TEST	DOSE;					
		Electroencephalogram	Professional				
INTRATHECAL		-1 -1					
		Abnormal	Other				
		Intracranial Pressure Increased					
		Medical Device					
		Complication					
		Sudden Death					
		Budden Beden					
Age: Ger	nder:Male				_	_	
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
	uration						
Hospitalization		Headache	Health	Lioresal			
Initial or Prol	Longed	Intentional Misuse	Professional	Intrathecal (Baclofen	Da		
	TINTIZ NAC	Suicide Attempt		Injection)	PS		
INTRATHECAL	UNK MC	.G ,					
DAILY,							
INTRATHECAL							
TRUKATIBCAD							
				Oral Baclofen	С		
				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 \mathbf{PT} Outcome Report Source Product Role Manufacturer Route Dose Duration Hospitalization -Coma Health Lioresal Initial or Prolonged Professional Intrathecal(Baclofen Csf Culture Positive Culture Wound Positive Injection) PS INTRATHECAL UNK MCG, Meningitis DAILY, Sepsis INTRATHECAL Staphylococcal Infection Streptococcal Infection Date:06/25/04ISR Number: 4387723-8Report Type:Expedited (15-DaCompany Report #20041903 Age: Gender:Male I/FU:I Outcome PΤ Report Source Product Role Manufacturer Route Dose Duration Required Burning Sensation Health Lioresal Dysgeusia Professional Intrathecal (Baclofen Intervention to Prevent Permanent Hypoaesthesia Injection) PSUNK MCG, INTRATHECAL Oedema Peripheral Impairment/Damage DAILY, Pain INTRATHECAL Dilaudid С Date:06/25/04ISR Number: 4387724-XReport Type:Expedited (15-DaCompany Report #20041860 Gender:Male Age: I/FU:F Outcome PΤ Report Source Product Role Manufacturer Route Dose Duration Required Catheter Related Health Lioresal Intervention to Complication Professional Intrathecal(Baclofen Prevent Permanent Confusional State Injection) PS INTRATHECAL UNK MCG, Impairment/Damage Convulsion 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 Gender:Male I/FU:I \mathbf{PT} Confusional State

Age:55 YR

Outcome Death Hospitalization -Crepitations Initial or Prolonged Decreased Appetite Dehydration Dyspnoea Hyperkalaemia Hyponatraemia Hypotension Hypoxia Infection Malignant Neoplasm Progression Neurological Symptom

Freedom Of Information (FOI) Report

Dogo	Duration	Oral Intake Reduced Renal Failure Acute Respiratory Distress	Report Source	Product	Role	Manufacturer	Route
Dose	Duración	Somnolence Urinary Tract Infection Enterococcal Urine Output Decreased	Study	Baclofen (Baclofen, Baclofen) Glivec (Sti571/Cgp57148b T35717+Caps) Capsule	PS		ORAL
500 MG, QD					55		01111
ORAL				Remeron (Mirtazapine)	SS		
				Lovenox (Heparin-Fraction, Sodium Salt) Thorazine	С		
				(Chlorpromazine Hydrochloride) Paxil (Paroxetine	С		
				Hydrochloride)	С		
Age:62 YR					Role	Manufacturer	Route
Age:62 YR Outcome Dose	Gender:Male	PT	Report Source	eport #US-SHR-03-019043 Product	Role	Manufacturer	Route
Date:06/28/0 Age:62 YR Outcome Dose Hospitalizat Initial or F	Gender:Male Duration	e I/FU:F			Role	Manufacturer	Route
Age:62 YR Outcome Dose Hospitalizat Initial or F	Gender:Male Duration tion - Prolonged	e I/FU:F PT Coma	Report Source	Product Betaseron (Interferon Beta-1b)		Manufacturer	Route
Age:62 YR Outcome Dose Hospitalizat Initial or F	Gender:Male Duration tion - Prolonged	e I/FU:F PT Coma Injection Site Cellulitis	Report Source	Product Betaseron (Interferon Beta-1b)		Manufacturer	Route
Age:62 YR Outcome Dose Hospitalizat Initial or F SUBCUTANEOUS	Gender:Male Duration tion - Prolonged S 8 MIU,	e I/FU:F PT Coma Injection Site Cellulitis	Report Source	Product Betaseron (Interferon Beta-1b)		Manufacturer	Route
Age:62 YR Outcome Dose Hospitalizat Initial or F SUBCUTANEOUS 2D, HS, SUBCUTANEOUS Date:06/28/0	Gender:Male Duration Lion - Prolonged 5 8 MIU,	 I/FU:F PT Coma Injection Site Cellulitis EVERY EVERY 	Report Source Consumer	Product Betaseron (Interferon Beta-1b) Injection, 250mcg Baclofen (Baclofen)	PS	Manufacturer	Route

Hospitalization -	Abdominal Pain Upper	Consumer	Neurontin		
Initial or Prolonged	Abnormal Behaviour		(Gabapentin)	PS	ORAL
ORAL					
Other	Condition Aggravated		Diazepam (Diazepam)	SS	
25 MG (2 IN 1					
	Drug Ineffective				
D)					
	Drug Interaction		Baclofen (Baclofen)	SS	
	Drug Withdrawal Syndrome		All Other		
	Feeling Abnormal		Therapeutic Products		
	Hallucination		(All Other		
	Medication Error		Therapeutic		
	Mental Disorder		Products)	SS	
	Pyrexia		Oxybutynin		
			Hydrochloride		
			(Oxybutynin		
			Hydrochloride)	C	
			Warfarin Sodium		
			(Warfarin Sodium)	C	
			Potassium		
			(Potassium)	C	
			Fluticasone		
			Propionate		
			(Fluticasone		
			Propionate)	C	
			Combivent		
			(Ipratropium		

			FDA - Adverse	Event Reporting Syste	m (AER	S)	
			Freedom O	f Information (FOI) Re	port		
				Bromide, Salbutamol Sulfate)	С		
Date:07/08/ Age:	04ISR Number Gender:	: 4392851-7Report Type:Expedit I/FU:I	ced (15-DaCompany Repor	t #PHBS2004JP08731			
Outcome	Durati	РТ	Report Source	Product	Role	Manufacturer	Route
Dose Other	Duration	Deep Vein Thrombosis		Lioresal	PS	Novartis Sector: Pharma	
	04ISR Number Gender:Male	: 4395433-6Report Type:Expedit I/FU:I	ced (15-DaCompany Repor	t #PHRM2004FR02278			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other	Duración	Arrhythmia Bradycardia	Health Professional	Lioresal	PS	Novartis Sector: Pharma	ORAL
35 mg/day		Dyspnoea					
Date:07/13/ Age:	04ISR Number Gender:	: 4395441-5Report Type:Expedit I/FU:F	ted (15-DaCompany Repor	t #PHBS2004JP08731			
Outcome	Duration	РТ	Report Source	Product	Role	Manufacturer	Route
Dose Hospitaliza Initial or : Other	tion -	Deep Vein Thrombosis	Health Professional	Lioresal	PS	Novartis Sector: Pharma	
	04ISR Number Gender:Male	: 4406641-XReport Type:Expedit I/FU:F	ced (15-DaCompany Repor	t #REFE00204002334			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Life-Threat 10 MG DAILY	ening	Blood Pressure Decreased	Foreign	Cannador (Cannador)	PS		ORAL
PO, 10 MG		Circulatory Collapse	Study				

	Pulse Absent	Health			
DAILY PO					
30 MG DAILY	Sinus Bradycardia	Professional	Baclofen (Baclofen)	SS	ORAL
		Other			
PO					
Age:50 YR Gender:Fem	r: 4406642-1Report Type:Exp ale I/FU:F	edited (15-Dacompany Re	eport #DRONUU2U4UU2327		
Outcome Dose Duration	PT	Report Source	Product	Role Manufacturer	Route
Other	Circulatory Collapse	Foreign	Marinol (Dronabinol)	PS	ORAL
2.5 MG BID,					
PO	Confusional State	Study			
	Somnolence	Health	Amitripytline		
200 MG DAILY	Speech Disorder	Professional	(Amitriptyline)	SS	ORAL
200 MG DAILI		Other			
PO					
70 MG DAILY			Baclofen (Baclofen)	SS	ORAL
PO			Tizanidine		
			(Tizanidine)	SS	ORAL
32 MG DAILY					
PO					
£ 0					

Freedom Of Information (FOI) Report

Date:07/20/04ISR Number: 4402845-0Report Type:Direct Age:78 YR Gender:Female I/FU:I Company Report #CTU 223124

Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Life-Threater 5 MG PO TID X	ning	Abnormal Dreams		Baclofen	PS		ORAL
3 D , 10 MG	-	Coma					
		Dysphagia					
TID X 3D, 20		Hallucination					
MG TID X 2 D		Oral Intake Reduced		Sinemet	С		
		Physical Examination Abnormal Speech Disorder		Zoloft	C		
	ISR Number Gender:Male	: 4403689-6Report Type:Expedit I/FU:I	ed (15-DaCompany Repor	t #PHFR2004GB02844			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other	Duración	Peptic Ulcer		Baclofen	PS	Novartis Sector: Pharma	
20 mg, BID							
		: 4407380-1Report Type:Expedit	ed (15-DaCompany Repor	t #PHBS2004US09673			
Age:32 YR G	Gender:Male	I/FU:I					
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Life-Threater Other		Haemoglobin Decreased Haemolysis	Health Professional	Baclofen	PS	Novartis Sector: Pharma	
				Zanaflex \$El	SS	r nar ma	ORAL
36 mg/d				Neurontin	С		
UNKNOWN				Ditropan	С		
UNKNOWN							

04ISR Number	: 4413959-3Report Type:Exped	ited (15-DaCompany Re	eport #PHBS2004JP08731			
Gender:	I/FU:F					
Duration	PT	Report Source	Product	Role	Manufacturer	Route
tion - Prolonged	Deep Vein Thrombosis	Health Professional Other	Lioresal (Baclofen)	PS		
04ISR Number Gender:	: 4414463-9Report Type:Exped I/FU:I	ited (15-DaCompany Re	eport #2004-DE-03937GD			
Duration	PT	Report Source	Product	Role	Manufacturer	Route
Anomaly	Drug Exposure During Pregnancy	Foreign Literature	Ibuprofen (Ibuprofen)	PS		
NE IU	Ventricular Septal Defect		Paracetamol			
NE IU						
NE IU			Baclofen (Baclofen)	SS		
NE IU						
		ited (15-DaCompany Re	eport #20031586			
Gender Male						
tion - Prolonged	Bruxism Catheter Related Complication					
12:15 PM	Device Failure					
	Gender: Duration tion - Prolonged 04ISR Number Gender: Duration Anomaly NE IU NE IU NE IU NE IU NE IU 04ISR Number Gender:Male tion - Prolonged	Gender: I/FU:F PT Duration tion - Deep Vein Thrombosis Prolonged 04ISR Number: 4414463-9Report Type:Exped Gender: I/FU:I PT Duration Anomaly Drug Exposure During Pregnancy NE IU NE IU NE IU NE IU 04ISR Number: 4414651-1Report Type:Exped Gender:Male I/FU:I 04ISR Number: 4414651-1Report Type:Exped Gender:Male I/FU:I	Gender: I/FU:F PT Report Source Duration Deep Vein Thrombosis Health Prolonged Professional Other 04ISR Number: 4414463-9Report Type:Expedited (15-DaCompany Regender: I/FU:I 04ISR Number: 4414463-9Report Type:Expedited (15-DaCompany Regender: 04ISR Number: 4414651-9Report Type:Expedited (15-DaCompany Regender: Duration PT Report Source Duration Pregnancy Literature NE IU Ventricular Septal Defect NE IU NE IU NE IU PT 04ISR Number: 4414651-1Report Type:Expedited (15-DaCompany Regender:Male 0FT FT tion - Bruxism Prolonged Catheter Related Complication Device Failure	Duration tion - Prolonged FT Report Source Product Dep Vein Thrombosis Health Professional Other Lioresal (Baclofen) 04ISR Number: 4414463-9Report Type:Expedited (15-DaCompany Report #2004-DE-03937GD I/FU'I Product 04ISR Number: 4414463-9Report Type:Expedited (15-DaCompany Report #2004-DE-03937GD I/FU'I Product 04ISR Number: 4414651-9Report Type:Expedited (15-DaCompany Report #2004-DE-03937GD Pregnancy Product NE IU Progenancy Ibuprofen (Ibuprofen) NE IU Ventricular Septal Defect Paracetamol (Paracetamol) NE IU Jiazepam (Diazepam) NE IU Baclofen (Baclofen) NE IU FT Proluct FT Procetamol Outst I/FU'I Baclofen (Baclofen)	Gender: I/FU:F PT Report Source Product Role Duration Deep Vein Thrombosis Health Lioresal (Baclofen) PS Prolonged Deep Vein Thrombosis Health Lioresal (Baclofen) PS OdISR Number: 4414463-9Report Type:Expedited (15-DaCompany Report #2004-DE-03937GD Content Role Ouration PT Report Source Product Role Nanomaly Drug Exposure During Foreign Ibuprofen PS NE IU Ventricular Septal Defect Paracetamol SS NE IU Ioazepam (Diazepam) SS NE IU Baclofen (Baclofen) SS NE IU SS Baclofen (Baclofen) SS NE IU PT Baclofen (Baclofen) SS NE IU PT PT Baclofen (Baclofen) SS NE IU PT PT Baclofen (Baclofen) SS NE IU PT PT Baclofen (Baclofen) SS NE IU PT<	Gender:I/FU:FPTReport SourceProductRoleManufacturerDurationDeep Vein ThrombosisHealth Professional OtherLioresal (Baclofen)PSD04ISK Number:4114463-9Report Type:Expedited (15-DaCompany Report #2004-DE-03937GD OtherPSO04ISK Number:FTReport SourceProductRoleGender:I/FU:IPTReport SourceProductRoleDuration AnomalyPrug Exposure During PregnancyForeign LiteratureIbuprofen (Ibuprofen)PSNEIUVentricular Septal DefectParacetamol (Paracetamol)SSNEIUIUSSBaclofen (Baclofen)SSNEIUI/FU:ISSSSO4ISK Number:4114651-1Report Type:Expedited (15-DaCompany Report #20031586 Gender:MaleI/FU:ISSO4ISK Number:1/FU:IFT Bruxism Complication Device FailureSS

Freedom Of Information (FOI) Report

		Granuloma Muscle Rigidity	Deport Courgo	Decidence	Polo	Manufacturor	Douto
Dose	Duration		Report Source	Product	коте	Manufacturer	Route
	Daracron		Health Professional	Lioresal Intrathecal(Baclofen Injection)	PS		
INTRATRACHEAL	DAILY,						
INTRATHECAL							
	ISR Number ender:Fema	: 4414672-9Report Type:Expedit le I/FU:I	ted (15-DaCompany Repor	t #20041759			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Required	Duration	Meningitis	Health	Lioresal			
Intervention	to		Professional	Intrathecal(Baclofen			
Prevent Perma	nent			Injection)	PS		
INTRATHECAL Impairment/Da	mage						
Age:20 YR G Outcome	ISR Number ender:Fema Duration	: 4414673-0Report Type:Expedit le I/FU:I PT	ted (15-DaCompany Repor Report Source	rt #20041923 Product	Role	Manufacturer	Route
Death	Duración	Death	Health Professional	Lioresal Intrathecal9baclofen Injection)	PS		
INTRATHECAL	DAILY,				FD		
INTRATHECAL							
	ISR Number ender:Male	: 4422425-0Report Type:Expedit I/FU:I	ted (15-DaCompany Repor	t #PHBS2004US09673			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Life-Threaten		Glucose-6-Phosphate Dehydrogenase Deficiency	Foreign Health	Zanaflex \$El (Tizanidine			
i i i i i i i i i i i i i i i i i i i							

36 MG/D	Haemoglobin Decreased	Professional	Hydrochloride)	PS	ORAL
20 MG/D	Haemolysis	Other	Baclofen (Baclofen) Neurontin	SS	
			(Gabapentin) Ditropan (Oxybutynin	C	
			Hydrochloride)	С	
Date:08/10/04ISR	Number: 4425814-3Report Type:Expe	edited (15-DaCompany R	leport #2004033685		

Age:43 YR Gender:Female I/FU:F

Outcome Dose	Duration	РТ	Report Source	Product	Role Manufacturer	Route
Death Other ORAL		Completed Suicide Drug Level Above	Foreign Health	Neurontin (Gabapentin)	PS	ORAL
		Therapeutic Intentional Misuse Muscle Relaxant Drug Level Above Therapeutic Victim Of Homicide	Professional	Baclofen (Baclofen)	SS	

FDA - Adverse Event Reporting System (AERS) Freedom Of Information (FOI) Report Date:08/12/04ISR Number: 4426046-5Report Type:Expedited (15-DaCompany Report #04-08-1139 Age: Gender:Male I/FU:I Outcome PΤ 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 Aqe:32 YR Gender:Female I/FU:I Report Source Product Role Manufacturer Outcome PTRoute Dose Duration Health Lioresal Hospitalization -Drug Ineffective Drug Tolerance Decreased Professional Intrathecal(Baclofen Initial or Prolonged Required Fluid Retention Injection) PS MCG, DAILY, Intervention to Muscle Spasms INTRACHECAL Prevent Permanent Pyrexia Impairment/Damage Seroma Date:08/19/04ISR Number: 4429617-5Report Type:Expedited (15-DaCompany Report #PHRM2004FR02278 Aqe:66 YR Gender:Male I/FU:F Role Manufacturer Outcome PTReport Source Product Route Dose Duration Arrhythmia Lioresal PS Other Novartis Sector: Bradycardia Pharma ORAL 45 mg/day Lioresal Dyspnoea SS Novartis Sector: Pharma ORAL 30 mg/day

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Amnesia	Health	Zanaflex (Tizanidine			
Initial or Prolonged	Blood Creatine	Professional	Hydrochloride)	PS		ORAL
4 MG ORAL						
Other	Phosphokinase Increased	Other	Copaxone (Glatiramer			
1	Carotid Artery Stenosis		Acetate)	SS		
SUBCUTANEOUS 20 MG	DAILY,					
1	Confusional State					
SUBCUTANEOUS						
1	Delirium		Baclofen (Baclofen)	SS		ORAL
14 TO 20 MG						
	Encephalopathy					
TABLETS, ORAL						
	Mental Status Changes					
	Overdose					
	Pain In Extremity					
	Urinary Tract Infection					
	r: 4431077-5Report Type:Exped	ited (15-DaCompany Re	eport #PHBS2004IE10906			
Age: Gender:Male	e I/FU:I					
Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Dyskinesia		Lioresal	PS	Novartis Sector:	
Initial or Prolonged	Infection				Pharma	ORAL
240 mg/day						
	Muscle Spasticity		Lioresal	SS	Novartis Sector:	
					Pharma	ORAL
180 mg/day						
4						

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		Baclofen	PS	Novartis Sector:	
	Increased				Pharma	ORAL	
		Creatinine Renal		Sti 571 Vs Ifn-Alpha			
		Clearance Decreased		+ 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 Numb Age: Gender:Fe	er: 4441115-1Report Type:Direc male I/FU:I	t Company Rep	port #CTU 226232			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - Initial or Prolonged 10 MG TID PO	Convulsion		Baclofen 10 Mg Tablet	PS		ORAL
	on: 4440504 Openent Three Dene	ited (15 Decomposer Dec				
Age: Gender:Fe	er: 4440504-9Report Type:Exped male I/FU:I	itted (15-DaCompany Rep	port #PHBS2004GB11400			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route

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	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Dose Other	Duración	Depressed Level Of Consciousness	Health Professional	Baclofen	PS	Novartis Sector: Pharma	
UNKNOWN							
		Dizziness Tachycardia		Tizanidine Hydrochloride	SS		
UNKNOWN							
				Nortriptyline			
				Hydrochloride	SS		
UNKNOWN				Gabapentin	SS		
UNKNOWN							
				Phenelzine	SS		
UNKNOWN							
				Ketorolac	SS		
UNKNOWN					~~		
INTERNAL				Bethanechol	SS		
UNKNOWN				Olanzapine	SS		
UNKNOWN				Oranzapriic	55		

			FDA - Adverse	e Event Reporting Syste	em (AER	₹S)	
			Freedom (Of Information (FOI) Re	port		
	04ISR Number: Gender:	: 4442884-7Report Type:Direct I/FU:I	Company Repor	rt #CTU 226404			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalizat Initial or F	tion -	Mental Status Changes		Baclofen	PS		
	04ISR Number Gender:Fema	: 4444808-5Report Type:Direct le I/FU:I	Company Repor	rt #CTU 226505			
Outcome	Dunchion	РТ	Report Source	Product	Role	Manufacturer	Route
Dose Hospitalizat 20 MG TID PC Initial or F	C	Psychotic Disorder		Baclofen	PS		ORAL
Date:09/13/0 Age:50 YR		: 4448171-5Report Type:Expedit I/FU:I	ed (15-DaCompany Repor	rt #PHRM2004FR02721			
Outcome Dose	Duration	РТ	Report Source	Product	Role	Manufacturer	Route
Hospitalizat Initial or F 20 mg, TID	tion -	Alanine Aminotransferase Increased		Lioresal	PS	Novartis Sector: Pharma	ORAL
100 mg, 5QD	17280MIN	Aspartate Aminotransferase Increased Blood Alkaline Phosphatase Increased Cytolytic Hepatitis Gamma-Glutamyltransferase Increased		Di-Hydan	SS		ORAL
	04ISR Number: Gender:Femal	: 4448423-9Report Type:Expedit le I/FU:F	ed (15-DaCompany Repor	rt #PHBS2004ZA11247			
Outcome		ΡΨ	Report Source	Product	Role	Manufacturer	Route

Product

Route

Hospitalization - UNK,	Agitation	Lioresal	PS
Initial or Prolonged	Blood Chloride Increased		
ONCE/SINGLE 1440 MIN			
	Blood Lactate	Benzodiazepines	SS
	Dehydrogenase Increased	Barbiturates	SS
	Blood Sodium Decreased	Tricyclic	
	Blood Urea Decreased	Antidepressants	SS
	Circulatory Collapse	-	
	Coma		
	Coordination Abnormal		
	Excitability		
	Extraocular Muscle		
	Disorder		
	Nystagmus		
	Overdose		
	Pco2 Decreased		
	Respiratory Disorder		

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 Dura	tion					
Hospitalization -	Pyrexia	Health	Lioresal Intrathecal			
Initial or Prolon	ged	Professional	(Baclofen) Unknown	PS		
INTRATHECAL	600 NG/DAY;					
		Other				
150 NG/DAY;						
INTRATHECAL						

Freedom Of Information (FOI) Report

Valproate Sodium (Valproate Sodium) C Topamax (Topiramate) C Sodium Chloride (Sodium Chloride) C

: 4450580-5Report Type:Expedit le I/FU:F	ed (15-DaCompany Repor	t #20041964			
PT Convulsion Muscle Spasticity AILY, Sepsis	Report Source Health Professional	Product Lioresal Intrathecal (Baclofen Injection)		Manufacturer	Route
: 4454305-9Report Type:Direct I/FU:I	Company Repor	t #CTU 227407			
PT	Report Source	Product	Role	Manufacturer	Route
Mental Status Changes		Baclofen	PS		
: 4457242-9Report Type:Expedit I/FU:I	ed (15-DaCompany Repor	t #PHFR2004GB03536			
PT	Report Source	Product	Role	Manufacturer	Route
Extrapyramidal Disorder Facial Spasm		Baclofen	PS	Novartis Sector: Pharma	
Muscle Spasms		Benzhexol	С		
	<pre>le I/FU:F PT Convulsion Muscle Spasticity AILY, Sepsis : 4454305-9Report Type:Direct I/FU:I PT Mental Status Changes : 4457242-9Report Type:Expedit I/FU:I PT Extrapyramidal Disorder Facial Spasm</pre>	le I/FU:F PT Report Source Convulsion Health Muscle Spasticity Professional ALLY, Sepsis : 4454305-9Report Type:Direct Company Repor I/FU:I PT Report Source Mental Status Changes : 4457242-9Report Type:Expedited (15-DaCompany Repor I/FU:I PT Report Source Extrapyramidal Disorder Facial Spasm	PTReport SourceProductConvulsion Muscle Spasticity ALLY, SepsisHealth ProfessionalLioresal Intrathecal (Baclofen Injection)ALLY, SepsisProfessional(Baclofen Injection)ALLY, SepsisCompany Report Professional(Baclofen Injection)ALLY, SepsisCompany Report #CTU 227407PTReport SourceProductMental Status ChangesBaclofenet 4457242-9Report Type:Expedited (15-DaCompany Report #PHFR2004GB03536 I/FU:IProductPTReport SourceProductPTReport SourceProductPTReport SourceProductPTReport SourceProductPTReport SourceProductPTReport SourceProductPTReport SourceProductExtrapyramidal Disorder Facial SpasmBaclofen	PT Report Source Product Role Convulsion Health Lioresal Intrathecal Muscle Spasticity Professional (Baclofen Injection) PS AILY, Sepsis Company Report #CTU 227407 I/FU:I PT Report Source Product Role Mental Status Changes Baclofen PS : 4457242-9Report Type:Expedited (15-DaCompany Report #PHFR2004GB03536 I/FU:I PT Report Source Product Role Extrapyramidal Disorder Report Source Product Role	le I/FU:F Report Source Product Role Manufacturer PT Report Source Product Role Manufacturer Convulsion Health Lioresal Intrathecal PS Muscle Spasticity Professional (Baclofen Injection) PS AILY, Sepsis Company Report PS * 4454305-9Report Type:Direct Company Report #CTU 227407 PS PT Report Source Product Role Mental Status Changes Baclofen PS * 4457242-9Report Type:Expedited (15-DaCompany Report #PHFR2004GB03536 PS I/FU:I Report Source Product Role PT Report Source Product Role

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Drug Exposure During	Foreign	Baclofen	PS	Ipi	
TRANSPLACENTAL TRAN	SPLANCENT					
	Pregnancy	Health				
AL						
TRANSPLACENTAL TRAN	Foetal Distress Syndrome SPLACENTA	Professional	Diazepam	SS		
	Forceps Delivery	Other				
L						
	Pregnancy					
	er: 4465123-XReport Type:Exped	areed (15 Dacompany no				
Age:41 YR Gender:Ma Outcome	le I/FU:F PT	Report Source	Product	Role	Manufacturer	Route
Age:41 YR Gender:Ma Outcome Dose Duration	le I/FU:F PT		Product	Role		Route
Age:41 YR Gender:Ma Outcome	le I/FU:F PT Abdominal Distension		-		Novartis Sector:	
Age:41 YR Gender:Ma Outcome Dose Duration Other	le I/FU:F PT		Product	Role		Route ORAL
Age:41 YR Gender:Ma Outcome Dose Duration	le I/FU:F PT Abdominal Distension Abdominal Pain Upper		Product Lioresal	Role PS	Novartis Sector: Pharma	
Age:41 YR Gender:Ma Outcome Dose Duration Other	le I/FU:F PT Abdominal Distension Abdominal Pain Upper Chest Wall Pain		Product	Role	Novartis Sector: Pharma Novartis Sector:	ORAL
Age:41 YR Gender:Ma Outcome Dose Duration Other 1 tablet/day	le I/FU:F PT Abdominal Distension Abdominal Pain Upper		Product Lioresal	Role PS	Novartis Sector: Pharma	
Age:41 YR Gender:Ma Outcome Dose Duration Other	le I/FU:F PT Abdominal Distension Abdominal Pain Upper Chest Wall Pain		Product Lioresal	Role PS	Novartis Sector: Pharma Novartis Sector:	ORAL
Age:41 YR Gender:Ma Outcome Dose Duration Other 1 tablet/day	le I/FU:F PT Abdominal Distension Abdominal Pain Upper Chest Wall Pain Fatigue		Product Lioresal Lioresal	Role PS SS	Novartis Sector: Pharma Novartis Sector: Pharma	ORAL
Age:41 YR Gender:Ma Outcome Dose Duration Other 1 tablet/day	le I/FU:F PT Abdominal Distension Abdominal Pain Upper Chest Wall Pain Fatigue Flatulence		Product Lioresal Lioresal	Role PS SS	Novartis Sector: Pharma Novartis Sector: Pharma Novartis Sector:	ORAL
Age:41 YR Gender:Ma Outcome Dose Duration Other 1 tablet/day 2 tablets/day	le I/FU:F PT Abdominal Distension Abdominal Pain Upper Chest Wall Pain Fatigue Flatulence		Product Lioresal Lioresal	Role PS SS	Novartis Sector: Pharma Novartis Sector: Pharma Novartis Sector:	ORAL
Age:41 YR Gender:Ma Outcome Dose Duration Other 1 tablet/day 2 tablets/day	le I/FU:F PT Abdominal Distension Abdominal Pain Upper Chest Wall Pain Fatigue Flatulence		Product Lioresal Lioresal Lioresal	Role PS SS SS	Novartis Sector: Pharma Novartis Sector: Pharma Novartis Sector:	ORAL
Age:41 YR Gender:Ma Outcome Dose Duration Other 1 tablet/day 2 tablets/day 4 tablets/day	le I/FU:F PT Abdominal Distension Abdominal Pain Upper Chest Wall Pain Fatigue Flatulence		Product Lioresal Lioresal Lioresal	Role PS SS SS	Novartis Sector: Pharma Novartis Sector: Pharma Novartis Sector:	ORAL

		FDA - Adverse	e Event Reporting Syste	em (AER	RS)	
		Freedom C	Of Information (FOI) Re	port		
Date:10/04/04ISR Number Age:92 YR Gender:Male	r: 4468030-1Report Type:Direct	Company Repor	rt #CTU 228709			
Outcome Dose Duration Other	PT Confusional State Somnolence	Report Source	Product Baclofen	Role PS	Manufacturer	Route
	Tremor					
Date:10/06/04ISR Number Age: Gender:Fema	r: 4471331-4Report Type:Expedit ale I/FU:I	ed (15-DaCompany Repor	ct #M2004-1416			
Outcome Dose Duration	РТ	Report Source	Product	Role	Manufacturer	Route
Other	Complication Of Delivery -PLACENT	Foreign	Diazepam	PS		
AL	Drug Exposure During	Other				
	Pregnancy Foetal Distress Syndrome Pregnancy		Baclofen	SS		
Date:10/06/04ISR Number Age:47 YR Gender:Male	r: 4471369-7Report Type:Expedit e I/FU:I	ed (15-DaCompany Repor	ct #20042012			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - Initial or Prolonged	Abdominal Rigidity Arrhythmia DAILY,	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		
Required INTRATHECAL	Cyanosis					
Intervention to	Device Failure Drug Withdrawal Syndrome					
Prevent Permanent						

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration	'n					
Hospitalization -	Myocardial Infarction	Consumer	Rebif (Interferon			
Initial or Prolonged		Health	Beta)	PS		
1		Professional	Baclofen (Baclofen)	SS		
1			Beta Blocker (Beta			
			Blocking Agents)	С		
1			Aspirine			
1			(Acetylsalicylic			
1			Acid)	С		
1						

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 - Condition Aggravated Initial or Prolonged Decreased Activity Device Failure Dyspnoea Dystonia Hyperreflexia Hypertonia Muscle Spasms Post Procedural Complication

Freedom Of Information (FOI) Report

Dose Duration	Respiratory Distress Stridor Vocal Cord Disorder	Report Source	Product	Role	Manufacturer	Route
		Literature	Baclofen	PS		
INTRATHECAL 165-18	80U/DAY	Health				
INTRATHECAL 8 MOI	N	Professional				
Date:10/12/04ISR Numbe: Age:19 YR Gender:	r: 4476484-XReport Type:Expedi I/FU:I	ted (15-DaCompany Repo	rt #2004070485			
Outcome Dose Duration	РТ	Report Source	Product	Role	Manufacturer	Route
Death	Completed Suicide Intentional Misuse	Literature Health	Gabapentin (Gabapentin)	PS		ORAL
ORAL						
ORAL		Professional	Baclofen (Baclofen)	SS		ORAL
ORAL			Oxybutynin (Oxybutynin)	SS		ORAL
Date:10/13/04ISR Numbe Age:82 YR Gender:Male	r: 4505129-5Report Type:Period e I/FU:I	lic Company Repo	rt #D-04-023			
Outcome Dose Duration	РТ	Report Source	Product	Role	Manufacturer	Route
Hospitalization - 5 MG TID; PO	Coordination Abnormal	Consumer	Baclofen 10 Mg; Usl	PS		ORAL
Initial or Prolonged	Hallucination		Alprazolam	С		
_	Loss Of Consciousness		Aricept	С		
	Pneumonia		Neurontin	С		
			Oxycontin	С		
			Trazadone	С		
			Endocet	С		
			Morphine Pca Intrathecal	С		
1						

Date:10/13/04ISR Number Age:8 YR Gender:Femal	: 4505130-1Report Type:Period: le I/FU:I	ic Company Repor	t #DCC 04-005			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration Hospitalization - ORAL 4 YR	Drug Withdrawal Syndrome	Consumer	Baclofen	PS		ORAL
Initial or Prolonged						
Date:10/18/04ISR Number: Age:14 YR Gender:Male	: 4480401-6Report Type:Expedit	ted (15-DaCompany Repor	t #20042004			
Age.14 ik Genuer.mare	1/F0-1					
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization -	Medical Device	Health	Lioresal Intrathecal			
Initial or Prolonged	Complication	Professional	(Baclofen Injection)	PS		
INTRATHECAL DAILY,						
INTRATHECAL	Meningitis					
Date:10/18/04ISR Number: Age:14 YR Gender:Male	: 4480402-8Report Type:Expedit	ted (15-DaCompany Repor	t #20042004			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration		1.1				
Hospitalization -	Incision Site	Health	Lioresal Intrathecal	DC		
Initial or Prolonged INTRATHECAL DAILY,	Complication	Professional	(Baclofen Injection)	PS		
INTRATHECAL	Medical Device					
	Complication					
	Meningitis					
	Wound Drainage					
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		FDA - Adverse	e Event Reporting System	m (AER:	دs)	
		Freedom C	Of Information (FOI) Re	port		
Date:10/20/04ISR Number Age:63 YR Gender:Fema	r: 4483529-XReport Type:Direct ale I/FU:I	Company Repor	rt #CTU 230115			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other	Convulsion ONCE IT Respiratory Distress		Baclofen	PS		
Date:10/25/04ISR Number Age:13 YR Gender:Fema	r: 4483836-0Report Type:Expedit ale I/FU:I	ed (15-DaCompany Repor	:t #PHRM2004FR03161			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
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 Duphalac	SS SS		ORAL ORAL
			Efferalgan	C		ORAL
10 mg, QD			Mopral	C		ORAL
Date:10/25/04ISR Number Age:44 YR Gender:Fema	r: 4485343-8Report Type:Direct ale I/FU:I	Company Repor	rt #CTU 230381			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - Initial or Prolonged	Dysarthria Lethargy		Lioresal Intrathecal 2000mcg/Ml Medtrinoc	PS	Medtrinoc	
INTRATRACHEAL INTRAT	'RACH		Medtrinoc	PS	Meatrinoc	

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration -	on Catheter Related	Health	Lioresal Intrathecal			
Initial or Prolonge		Professional	(Baclofen Injection)	PS		
INTRATHECAL						
	Lung Infection Meningitis Staphylococcal Infection White Blood Cell Count Increased	1				
Date:10/26/04ISR Num Age: Gender:1	mber: 4488597-7Report Type:Ez Male I/FU:I	spedited (15-DaCompany Re	eport #20042018			
Outcome Dose Duratio	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - Initial or Prolonge	Catheter Related	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		
INTRATHECAL	Implant Site Infection					
	Meningitis Staphylococcal Infection	1				
Date:10/28/04ISR Nu Age:58 YR Gender:1	mber: 4488183-9Report Type:Ez Male I/FU:I	pedited (15-DaCompany R	eport #PHNU2004DE03651			
Outcome Hospitalization - Initial or Prolonge	PT Bradycardia d Bradypnoea					
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Dose	Duration	Hypotonia Intentional Misuse Loss Of Consciousness Myoclonic Epilepsy Sopor	Report Source	Product Lioresal	Role PS	Manufacturer Novartis Sector: Pharma	Route ORAL
15 DF,		50001				FIIALIIIA	UITAL
ONCE/SINGLE	1440 MIN						
	ISR Number ender:Fema	: 4492023-1Report Type:Expedi le I/FU:I	ted (15-DaCompany Re	port #PHNU2004DE03427			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
INTRATHECAL	750 NG	Drug Withdrawal Syndrome Medication Error , OD	Health Professional	Lioresal Intrathecal (Baclofen) Unknown	PS		
		Pyrexia	Other	Beta Blocking Agents (No Ingredients/Substanc es)	С		
Date:11/01/04 Age:22.5 YR G		: 4491269-6Report Type:Direct I/FU:I	Company Re	port #CTU 230853			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Life-Threaten 40 MG PO Q 6		Apnoea		Baclofen	PS		ORAL
Required H [2 DOSES]		Oxygen Saturation					
Intervention 1.5 MG PO Q6	to	Decreased		Clonazepam	SS		ORAL
Prevent Perma H [2 DOSES]	inent	Procedural Complication					
Impairment/Da	umage	Respiratory Depression Scar					

Hydrochlo Paracetam Lidocaine (Lidocain Baclofen Amantadin Hydrochlo (Amantadi Hydrochlo All Other	<pre>(Fentanyl) SS (Oxycodone oride, mol) SS e he) SS (Baclofen) SS ne oride ine oride ine oride) SS r tic Proudcts er tic) SS</pre>	

Route

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 Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - Initial or Prolonged INTRATHECAL SEE IM	Decreased Appetite Device Failure MAGE	Health Professional	Lioresal Intrathecal (Baclofen) Ampoule	PS		
	Dyskinesia Muscle Spasticity Pyrexia Rash Generalised Rash Pruritic Respiratory Rate Decreased Sleep Disorder	Other	Rivotril (Clonazepam) Tablet	SS		
Date:11/02/04ISR Number Age: Gender:Male	r: 4493386-3Report Type:Expedi I/FU:I	ted (15-DaCompany Repo	rt #20042048			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization -	Clonus	Health	Lioresal Intrathecal			
Initial or Prolonged INTRATHECAL DAILY,	Convulsion	Professional	(Baclofen Injection)	PS		
INTRATHECAL	Hyperhidrosis					
INIKAINECAL	Intestinal Obstruction Medication Error Muscle Spasms Pyrexia					
Date:11/05/04ISR Number Age:53 YR Gender:Male	r: 4498419-6Report Type:Expedi e I/FU:I	ted (15-DaCompany Repo	rt #2004083821			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - Initial or Prolonged 1200 MG (1	Blood Glucose Fluctuation Diabetes Mellitus	Foreign Health	Neurontin (Gabapentin)	PS		ORAL
,	Dizziness	Professional				
D), ORAL	Drug Ineffective		Lisinopril			

	Drug Interaction	(Lisinopril)	SS
20 MG (1 D)			
	Fall Grand Mal Convulsion	Hydrochlorothiazide	
	Hypoglycaemia	(Hydrochlorothiazide	SS
12.5 MG (1 D)	nypogrycaciiia	1	55
	Status Epilepticus	Baclofen (Baclofen)	SS
5 MG (1 D)			
		Pantoprazole Sodium (Pantoprazole	
		Sodium)	SS
20 MG (1 D)			
		Interferon Beta	SS
SUBCUTANEOUS	1 AMPULE (2	(Interferon Beta)	55
D),			
SUBCUTANEOUS			
50DC01ANE005		Amitriptyline	
		Hydrochloride	
		(Amitriptyline	
		Hydrochloride)	С
		Carbamazepine	a
		(Carbamazepine) Zopiclone	С
		(Zopiclone)	С
1			

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						
Hospitalizati	.on –	Meningitis	Health	Lioresal			
Initial or Pr	colonged		Professional	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 Death OROPHARINGEAI	Duration	Blood Pressure Abnormal		Tylenol 3	PS		
		Cardio-Respiratory Arrest Coma		Acetaminophen/Hydroc odone	SS		
OROPHARINGEAI	J						
		Completed Suicide		Acetaminophen/Hydroc			
		Heart Rate Increased		odone	SS		
OROPHARINGEAI	ച						
		Intentional Misuse		Amitriptyline	SS		
OROPHARINGEAI	ച						
		Loss Of Consciousness		Baclofen	SS		
		Oxygen Saturation		Zolpidem	SS		
		Decreased		Valdecoxib	SS		
		Pupil Fixed		Escitalopram	SS		
		Status Epilepticus		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	I					

	Blood Pressure Increased		Morphine	SS		
OROPHARINGEAL						
	Coma		Lorazepam	SS		
OROPHARINGEAL						I
	Completed Suicide		Baclofen	SS		I
	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 Numbe Age:29 YR Gender:Mal	er: 4501993-4Report Type:Exped Le I/FU:F	ited (15-DaCompany Rep	port #PHHO2004AU04534			
Age:29 YR Gender:Mal Outcome		ited (15-DaCompany Reg Report Source	port #PHHO2004AU04534 Product	Role	Manufacturer	Route
Age:29 YR Gender:Mal Outcome Dose Duration	le I/FU:F PT		Product			Route
Age:29 YR Gender:Mal Outcome Dose Duration Hospitalization -	le I/FU:F PT Encephalopathy			Role PS	Novartis Sector:	Route
Age:29 YR Gender:Mal Outcome Dose Duration	le I/FU:F PT Encephalopathy Loss Of Consciousness		Product Baclofen	PS		
Age:29 YR Gender:Mal Outcome Dose Duration Hospitalization - Initial or Prolonged	le I/FU:F PT Encephalopathy Loss Of Consciousness Metabolic Encephalopathy		Product		Novartis Sector:	Route ORAL
Age:29 YR Gender:Mal Outcome Dose Duration Hospitalization -	le I/FU:F PT Encephalopathy Loss Of Consciousness Metabolic Encephalopathy		Product Baclofen	PS	Novartis Sector:	
Age:29 YR Gender:Mal Outcome Dose Duration Hospitalization - Initial or Prolonged	le I/FU:F PT Encephalopathy Loss Of Consciousness Metabolic Encephalopathy		Product Baclofen	PS	Novartis Sector:	
Age:29 YR Gender:Mal Outcome Dose Duration Hospitalization - Initial or Prolonged	le I/FU:F PT Encephalopathy Loss Of Consciousness Metabolic Encephalopathy		Product Baclofen	PS	Novartis Sector:	

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 Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - Initial or Prolonged 0.2 MG PO	Alanine Aminotransferase Increased	Foreign Health	Harnal (Tamsulosin)	PS		ORAL
	Aspartate Aminotransferase	Professional Other	Dantrium (Dantrolene Sodium)	SS		ORAL
25 MG PO	Increased 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 Hepatic Function Abnormal		Vitamedin (Benfotiamine/B6/B12) Diazepam (Diazepam)	C C		ORAL

Date:11/22/04ISR Number: 4506572-0Report Type:Expedited (15-DaCompany Report #PHRM2004FR03161 Age:13 YR Gender:Female I/FU:F

Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - Initial or Prolonged	Abdominal Distension Blood Amylase Increased		Lioresal	PS	Novartis Sector: Pharma	ORAL
10 mg, TID 1460 DAY				~ ~		
	C-Reactive Protein		Depakine	SS		ORAL
500 mg, TID						
	Increased		Theralene	SS		ORAL
10 mg, QD 365 DAY						
	General Physical Health		Smecta	SS		ORAL
	Deterioration		Duphalac	SS		ORAL
	Leukocytosis		Efferalgan	С		ORAL
	Lipase Increased		Mopral	С		ORAL
10 mg, QD						
	Pancreatic Necrosis Pancreatitis					
	Pyrexia					

Date:11/29/04ISR Numbe Age:77 YR Gender:Mal	r: 4514790-0Report Type:Direct e I/FU:I	Company Rep	ort #CTU 233075		
Outcome Dose Duration	PT	Report Source	Product	Role Manufacturer	Route
Other	Asthenia Confusional State Hypotension		Baclofen	PS	
					I
Age:13 YR Gender:Fema Outcome	r: 4512867-7Report Type:Expedia ale I/FU:F PT	ted (15-DaCompany Repo Report Source	ort #FR-ABBOTT-04P-056-0 Product	0279415-00 Role Manufacturer	Route
Age:13 YR Gender:Fema Outcome Dose Duration Hospitalization - Initial or Prolonged	ale I/FU:F				Route ORAL ORAL
Age:13 YR Gender:Fema Outcome Dose Duration Hospitalization - Initial or Prolonged 4 YR	ale I/FU:F PT General Physical Health Deterioration Pancreatitis		Product Depakine Tablets	Role Manufacturer PS	ORAL
Age:13 YR Gender:Fema Outcome Dose Duration Hospitalization - Initial or Prolonged	ale I/FU:F PT General Physical Health Deterioration Pancreatitis		Product Depakine Tablets Baclofen	Role Manufacturer PS SS	ORAL ORAL

Omeprazole

Paracetamol

Paracetamol

Paracetamol

Phenobarbital

Lactulose

С

С

С

С

С

С

ORAL

ORAL

ORAL

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INTRAVENOUS

INTRAVENOUS

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Date:11/30/04ISR Number: 4513292-5Report Type:Expedited (15-DaCompany Report #PHBS2004NL15786 Age:64 YR Gender:Female I/FU:I

Outcome		РТ	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Death		Aortic Occlusion		Lioresal	PS	Novartis Sector:	
Hospitalizati	on -	Hepatic Encephalopathy				Pharma	ORAL
Initial or Pr	colonged	Hepatic Enzyme Increased		Nitrofuranaoine	SS		
		Nausea		Acenocoumarol	С		
		Somnolence		Paracetamol	С		
				Simvastatin	С		ł
				Paroxetin	С		

Date:12/06/04ISR Number: 4519660-XReport Type:Expedited (15-DaCompany Report #PHFR2004GB04326 Age:51 YR Gender:Female I/FU:I

Outcome Dose	Duration	РТ	Report Source	Product	Role	Manufacturer	Route
Other	Duración	Periorbital Oedema		Baclofen	PS	Novartis Sector: Pharma	ORAL
10 mg, BID	5760 MIN			Pregabalin	SS		ORAL
75 mg, BID							UKAL
UNKNOWN	350mg	nocte		Trazodone	С		
UNKNOWN	50 mg,			Tramadol	С		
	50 mg,			Cetirizine	С		
UNKNOWN				Omeprazole	С		
UNKNOWN	20mg/d	ay		Lactulose	С		
UNKNOWN	15ml n	octe					
UNKNOWN	1-2 bi	d		Naproxen	C		
				Gabapentin	С		
300 mg, TID				Nefopam	С		
UNKNOWN	600 mg	, TID					

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
	Duration						
Other		Cerebrovascular Accident		Lioresal	PS	Novartis Sector:	
10mg/day	4320 MIN	Communication Disorder				Pharma	ORAL
I Ullig/day	4320 MIN	Disturbance In Attention		Mst	С		
		Speech Disorder		Neurontin	C		
		SPeccel Diperder		Tetra-Saar	C		
				Saroten "Bayer	-		
				Vital"	С		
	ISR Number ender:Male	: 4521297-3Report Type:Expec I/FU:I	lited (15-DaCompany R	eport #PHBS2004US16080			
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
	Duration						
Other		Catheter Related Complication		Lioresal Intrathecal	PS	Novartis Sector: Pharma	
INTRATHECAL	1985 ma						
		Drug Ineffective		Lioresal Intrathecal	SS	Novartis Sector: Pharma	
INTRATHECAL	270 mcg	g/day					
	ISR Number ender:Male	: 4521298-5Report Type:Expec I/FU:I	lited (15-DaCompany R	eport #PHBS2004US16083			
Outcome		РТ					
Other		Chills					
		Device Failure					
		Diarrhoea					
		Dysgeusia					
		Hyperhidrosis					
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Freedom Of Information (FOI) Report

		Lacrimation Increased Nausea			- 1		
Dose	Duration	Pain	Report Source	Product	Roie	Manufacturer	Route
Dose	Duración	Parosmia Yawning		Lioresal Intrathecal	PS	Novartis Sector: Pharma	
INTRATHECAL	129.6	ug/day		Morphine	С		
)4ISR Number Gender:Unkn	: 4521299-7Report Type:Expection I/FU:I	lited (15-DaCompany Re	port #PHBS2004US16084			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other	Duración	Hypertonia Speech Disorder		Lioresal Intrathecal	PS	Novartis Sector: Pharma	
INTRATHECAL		Speech Disorder				Pilarilla	
)4ISR Number	: 4521303-6Report Type:Exped	lited (15-DaCompany Re	port #PHBS2004US16086			
)4ISR Number Gender:Unkn Duration	: 4521303-6Report Type:Expection I/FU:I PT	lited (15-DaCompany Re Report Source	port #PHBS2004US16086 Product	Role	Manufacturer	Route
Age: Outcome	Gender:Unkn	lown I/FU:I				Manufacturer Novartis Sector: Pharma	Route
Age: Outcome Dose Other INTRATHECAL Date:12/08/0	Gender:Unkn Duration)4ISR Number	own I/FU:I PT Device Failure Drug Withdrawal Syndrome : 4521304-8Report Type:Expect	Report Source	Product Lioresal Intrathecal		Novartis Sector:	Route
Age: Outcome Dose Other INTRATHECAL Date:12/08/0 Age:49 YR	Gender:Unkn	Nown I/FU:I PT Device Failure Drug Withdrawal Syndrome : 4521304-8Report Type:Exped le I/FU:I	Report Source dited (15-DaCompany Re	Product Lioresal Intrathecal port #PHBS2004US16088	PS	Novartis Sector: Pharma	
Age: Outcome Dose Other INTRATHECAL Date:12/08/0 Age:49 YR Outcome	Gender:Unkn Duration)4ISR Number Gender:Fema	own I/FU:I PT Device Failure Drug Withdrawal Syndrome : 4521304-8Report Type:Expect	Report Source	Product Lioresal Intrathecal	PS	Novartis Sector:	Route
Age: Outcome Dose Other INTRATHECAL Date:12/08/0 Age:49 YR	Gender:Unkn Duration)4ISR Number	Nown I/FU:I PT Device Failure Drug Withdrawal Syndrome : 4521304-8Report Type:Exped le I/FU:I	Report Source dited (15-DaCompany Re	Product Lioresal Intrathecal port #PHBS2004US16088	PS Role	Novartis Sector: Pharma	

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration				-		
Hospitalization - 600 mg, QD 397 DAY	Coma Y	Health	Glivec	PS		ORAL
Initial or Prolonged	Encephalopathy Loss Of Consciousness Pneumonia Aspiration Sepsis Somnolence	Professional	Clofen	SS		
	r: 4525886-1Report Type:Expe	edited (15-DaCompany Re	port #PHNU2004DE04093			
Age: Gender:Male Outcome	r: 4525886-1Report Type:Expe	edited (15-DaCompany Re Report Source	port #PHNU2004DE04093 Product	Role	Manufacturer	Route
Age: Gender:Male Outcome Dose Duration Other	r: 4525886-1Report Type:Expe e I/FU:I		-	Role PS	Manufacturer Novartis Sector: Pharma	Route ORAL
Age: Gender:Male Outcome Dose Duration	r: 4525886-1Report Type:Expe e I/FU:I PT Condition Aggravated		Product		Novartis Sector:	

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	Dunation	РТ	Report Source	Product	Role	Manufacturer	Route
Dose Hospitalizat Initial or P UNKNOWN		Acute Respiratory Failure Blood Creatine g/day Phosphokinase Increased Bradycardia Coma Hypertension Intentional Misuse Suicide Attempt		Baclofen	ΡS	Novartis Sector: Pharma	
	4ISR Number Gender:Male	: 4525895-2Report Type:Expedit I/FU:I	ed (15-DaCompany Report	t #PHBS2004PL16419			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalizat Initial or P UNKNOWN	ion -	Acute Respiratory Failure Blood Creatine /day Phosphokinase Increased Bradycardia Coma Hypertension Intentional Misuse Suicide Attempt		Baclofen	ΡS	Novartis Sector: Pharma	
	4ISR Number Gender:Male	: 4525898-8Report Type:Expedit I/FU:I	ed (15-DaCompany Report	t #PHBS2004PL16418			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalizat Initial or P UNKNOWN	ion -	Acute Respiratory Failure Blood Creatine g/day Phosphokinase Increased Bradycardia Coma Intentional Misuse Suicide Attempt		Baclofen	ΡS	Novartis Sector: Pharma	

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 -	Acute Respiratory Failure		Baclofen	PS	Novartis Sector:	
Initial or Prolonged	Bradycardia				Pharma	
UNKNOWN 400 m	ng/day					
	Coma					
	Intentional Misuse					
	Suicide Attempt					
Date:12/14/04ISR Numbe Age:41 YR Gender:Fem	er: 4526301-4Report Type:Exped male I/FU:I	ited (15-DaCompany Re	eport #PHBS2004PL164:	22		
Outcome	PT					
Hospitalization -	Acute Respiratory Failure					
Initial or Prolonged	Blood Creatine					I
	Phosphokinase Increased					
	Coma					

Hypertension

Intentional Misuse

Freedom Of Information (FOI) Report

Suicide Attempt Report Source Product Role Manufacturer Route Duration Dose Baclofen PS Novartis Sector: Pharma 300 mg/day UNKNOWN Date:12/14/04ISR Number: 4526304-XReport Type:Expedited (15-DaCompany Report #PHBS2004PL16423 Age:15 YR Gender:Male I/FU:I Outcome PTReport Source Product Role Manufacturer Route Dose Duration Hospitalization -Coma Baclofen PS Novartis Sector: Initial or Prolonged Intentional Misuse Pharma UNKNOWN 250 mg/day Suicide Attempt Date:12/14/04ISR Number: 4526314-2Report Type:Expedited (15-DaCompany Report #PHBS2004PL16424 Age:55 YR Gender:Female I/FU:I Report Source Role Manufacturer Outcome PTProduct Route Duration Dose Hospitalization -Acute Respiratory Failure Baclofen PS Novartis Sector: Blood Creatine Initial or Prolonged Pharma UNKNOWN 250 mg/day Phosphokinase Increased Coma Intentional Misuse Suicide Attempt Date:12/14/04ISR Number: 4526315-4Report Type:Expedited (15-DaCompany Report #PHBS2004PL16431 Age:28 YR Gender:Male I/FU:I Outcome PTReport Source Product Role Manufacturer Route Dose Duration Hospitalization -Blood Creatine Baclofen PS Novartis Sector: Initial or Prolonged Phosphokinase Increased Pharma 200 mg/day UNKNOWN Coma Intentional Misuse

Suicide Attempt

Date:12/14/04ISR Number: 4526316-6Report Type:Expedited (15-DaCompany Report #PHBS2004PL16430 Aqe:16 YR Gender:Female I/FU:I Outcome Report Source Product Role Manufacturer PTRoute Dose Duration Hospitalization -Baclofen Novartis Sector: Coma ΡS Initial or Prolonged Intentional Misuse Pharma UNKNOWN 240 mg/day Suicide Attempt Date:12/14/04ISR Number: 4526317-8Report Type:Expedited (15-DaCompany Report #PHBS2004PL16433 Age:25 YR Gender:Male I/FU:I РT Product Role Manufacturer Outcome Report Source

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Hospitalizati	lon –	Blood Creatine		Baclofen	PS	Novartis Sector:	
Initial or Pr	colonged	Phosphokinase Increased				Pharma	
UNKNOWN		g/day					
		Coma					
		Intentional Misuse					
		Suicide Attempt					

FDA - Adverse Event Reporting System (AERS) Freedom Of Information (FOI) Report Date:12/14/04ISR Number: 4528903-8Report Type:Expedited (15-DaCompany Report #20042095 Gender:Female Age: I/FU:I Outcome PTReport Source Product Role Manufacturer Route Dose Duration Hospitalization -Asthenia Health Lioresal Intrathecal Initial or Prolonged Professional (Baclofen Injection) Lethargy 2000mcg/Ml Mental Status Changes PSINTRATHECAL 524.7 MCG, Pyrexia DAILY, INTRATHECAL Date:12/15/04ISR Number: 4527203-XReport Type:Expedited (15-DaCompany Report #PHBS2004PL16435 Aqe:30 YR Gender:Male I/FU:I Outcome Role Manufacturer PTReport Source Product Route Dose Duration Hospitalization -Blood Creatine Baclofen PS Novartis Sector: Initial or Prolonged Phosphokinase Increased 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 ΡТ Role Manufacturer Outcome Report Source Product Route Dose Duration Hospitalization -Acute Respiratory Failure Baclofen PS Novartis Sector: Blood Creatine Initial or Prolonged Pharma 200 mg/day UNKNOWN Phosphokinase Increased 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 Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - Initial or Prolonged	Acute Respiratory Failure Blood Creatine g/day Phosphokinase Increased Coma Intentional Misuse Suicide Attempt		Baclofen	PS	Novartis Sector: Pharma	
Date:12/15/04ISR Numbe Age:53 YR Gender:Mal Outcome	r: 4527208-9Report Type:Exped: e I/FU:I PT	ited (15-DaCompany Re	port #PHBS2004PL16438			
Hospitalization - Initial or Prolonged	Acute Respiratory Failure Blood Creatine Phosphokinase Increased Bradycardia Coma					
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Freedom Of Information (FOI) Report

Dose	Duration	Intentional Misuse Suicide Attempt	Report Source	Product		Manufacturer	Route
UNKNOWN	200 mg	/day		Baclofen	PS	Novartis Sector: Pharma	
)4ISR Number Gender:Fema	: 4527209-0Report Type:Exp le I/FU:I	edited (15-DaCompany Re	port #PHBS2004PL164	39		
Outcome	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Dose Hospitalizat Initial or P UNKNOWN	cion -	Coma Intentional Misuse /day Suicide Attempt		Baclofen	PS	Novartis Sector: Pharma	
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
	le I/FU:I				Manufacturer	Route	
	Prolonged	Blood Creatine Phosphokinase Increased		Baclofen	PS	Novartis Sector: Pharma	
Initial or P UNKNOWN		Phosphokinase Increased		Baclofen	PS		
UNKNOWN	Prolonged 150 mg 04ISR Number	Phosphokinase Increased /day Bradycardia Coma Hypertension Intentional Misuse Suicide Attempt : 4527211-9Report Type:Expe	∋dited (15-DaCompany Re				
UNKNOWN Date:12/15/0 Age:48 YR Outcome	Prolonged 150 mg 04ISR Number Gender:Fema	Phosphokinase Increased /day Bradycardia Coma Hypertension Intentional Misuse Suicide Attempt : 4527211-9Report Type:Expe	edited (15-DaCompany Re Report Source		43		Route
UNKNOWN Date:12/15/0 Age:48 YR	Prolonged 150 mg 04ISR Number Gender:Fema Duration tion -	Phosphokinase Increased /day Bradycardia Coma Hypertension Intentional Misuse Suicide Attempt : 4527211-9Report Type:Expe le I/FU:I	Report Source	port #PHBS2004PL164	43	Pharma	Route

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 Life-Threate: Hospitalizat 300 mg,	-	Bradycardia Coma		Lioresal	PS	Novartis Sector: Pharma	ORAL
Initial or P:	nitial or Prolonged NCE/SINGLE	Intentional Misuse					
UNCE / DINULE		Mydriasis Suicide Attempt					
	4ISR Number Gender:Male	4527520-3Report Type:Exper I/FU:I	dited (15-DaCompany Repor	ct #PHBS2004PL16421			
Outcome		PT					
Hospitalizat Initial or P		Blood Creatine Phosphokinase Increased Coma Intentional Misuse					
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Freedom Of Information (FOI) Report

		Davahatia Digondor					
		Psychotic Disorder Suicide Attempt					
		Dateras meent	Report Source	Product	Role	Manufacturer	Route
Dose	Duration				- ~		
				Baclofen	PS	Novartis Sector: Pharma	
UNKNOWN	400 mg,	/day				FILLING	
		: 4528559-4Report Type:Expe	dited (15-DaCompany Re	eport #PHNU2004DE04185			
Age:	Gender:Male	I/FU:I					l
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration	_					I
Other		Ammonia Increased Depressed Level Of		Lioresal	PS	Novartis Sector: Pharma	ORAL
10 mg, TID		Debressed Dever of				Filatina	UKAL
10 <u>)</u> ,		Consciousness		Tetrazepam	С		
		Gamma-Glutamyltransferase		Antibiotics	С		
		Increased		Heparin	С		
		Hepatic Enzyme Increased Hepatocellular Damage					
Date:12/20/ Age:	04ISR Number Gender:Male	: 4535940-6Report Type:Expe I/FU:I	dited (15-DaCompany Re	eport #20042105			
Outcome	00	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration				-		- · -
Hospitaliza		Meningitis	Health	Lioresal Intrathecal	50		
Initial or INTRATHECAL			Professional	(Baclofen Injection)	P.S		
Other		Allı,					
INTRATHECAL	1						I
	04ISR Number Gender:Fema	: 4532668-3Report Type:Expe le I/FU:I	dited (15-DaCompany Re	eport #PHRM2004FR03639			
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose							
	Duration						
Other	Duration	Abasia		Tegretol	PS	Novartis Sector:	
		Abasia Drug Interaction		Tegretol	PS	Novartis Sector: Pharma	
Other 200 mg, BID				Tegretol	PS		

Facial Palsy	Lioresal	SS	ORAL
Date:12/21/04ISR Number: 4532686-5Report Type:Expedited (15-DaCor	mpany Report #PHRM2004FR03670	0	
Age:53 YR Gender:Female I/FU:I			

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Durati Hospitalization - Initial or Prolonge 30 mg, TID	Arthritis		Lioresal	PS	Novartis Sector: Pharma	ORAL
	Pneumonia Aspiration		Athymil	SS		ORAL
60 mg/day						
	Sepsis Subileus		Lioresal	SS	Novartis Sector: Pharma	ORAL
60 mg/day						
			Urbanyl	C		ORAL
			Keppra	С		ORAL
			Imovane	C		ORAL
7.5 mg, QD						
			Rifadine	C		ORAL
600 mg, BID				-		
			Bactrim Forte	C		
INTRAVENOUS			T access acc	G		
			Lovenox Tazocilline	C C		
INTRAVENOUS			Tazocititie	C		
INIRAVENOUS			Ciflox	С		
UNKNOWN			CILION	C		
			Perfalgan	С		
INTRAVENOUS			rerrargan	C		

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	С		ORAL
200 mg, PRN 30 gtt, PRN			Metoclopramide	C		ORAL
50 gcc, 110						

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 - SEE IMAGE	Condition Aggravated	Consumer	Baclofen	PS	Watson Labaoratories	ORAL
Initial or Prolonged Other	Drug Ineffective For Unapproved Indication Muscle Spasticity Nephrolithiasis Paraesthesia		Nexium (Esomeprazole) Multivitamins	C C		

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						
Hospitalizat	ion -	Dizziness	Foreign	Esidrix(Hydrochlorot			
Initial or Pr	rolonged	Drug Interaction	Study	hiazide) 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 Metoclopramide (Metoclopramide)	C	
			Solution	C	

Date:01/06/05ISR Number: 4546300-6Report Type:Expedited (15-DaCompany Report #PHBS2002CL09569 Age:41 YR Gender:Male I/FU:F

Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other	Duración	Abdominal Distension Abdominal Pain		Lioresal	PS	Novartis Sector: Pharma	ORAL
1 tablet/day		Abdominal Pain Upper		Lioresal	SS	Novartis Sector:	
2 tablets/day	7	Chest Wall Pain				Pharma	ORAL
		Fatigue Flatulence		Lioresal	SS	Novartis Sector: Pharma	ORAL
4 tablets/day	7						
		Haematochezia Somnolence		Lioresal	SS	Novartis Sector: Pharma	ORAL
20 mg/day		Urinary Incontinence		Diazepam	С		
UNKNOWN							

FDA - Adverse Event Reporting System (AERS) Freedom Of Information (FOI) Report С Losec PRN Date:01/07/05ISR Number: 4624543-0Report Type:Periodic Company Report #234705K04USA Gender:Female Aqe:53 YR I/FU:I PTReport Source Role Manufacturer Product Route Duration Joint Swelling Consumer Rebif (Interferon Oedema Peripheral Beta) PS Baclofen SS Date:01/13/05ISR Number: 4552753-XReport Type:Direct Company Report #CTU 236599 Gender:Male Aqe:17 YR I/FU:I PTReport Source Product Role Manufacturer Route Duration Catheter Related Life-Threatening Intrathecal Baclofen Hospitalization -Complication Pump 400 Mcg Per Medtronics Initial or Prolonged Device Failure Day PS Medtronics INTRATHECAL 400 MCG Drug Withdrawal Syndrome Required Intervention to Surgery INTRATHECA

Prevent Permanent Impairment/Damage

UNKNOWN

Outcome

Outcome

Dose

DAILY

Dose

Date:01/18/05ISR Number: 4555354-2Report Type:Direct Company Report #CTU 237033 Aqe:35 YR Gender:Female I/FU:I Role Manufacturer Outcome PTReport Source Product Route Dose Duration Other Blood Glucose Decreased Novolog Novonordisk PS Novonordisk SUBCUTANEOUS 66 UNITS OVER

> Baclofen 10mg SS

ORAL

SUBCUTANEOUS

24 HOURS

Drug Interaction

	Gender:	I/FU:I		eport #PHFR2004GB04658			
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Hospitaliza		Coma	Health	Lioresal (Baclofen)			
Initial or	Prolonged	Escherichia Infection	Professional	Solution For			
		Incoherent	Other	Injection	PS		
		Pyrexia					
		Therapy Non-Responder					
Date:01/19/ Age:	/05ISR Number Gender:Male	r: 4555426-2Report Type:Expe e I/FU:I	edited (15-DaCompany Re	eport #PHBS2005US00800			
Outcome		РТ	Report Source	Product	Polo	Manufacturer	Route
Dose	Duration	PI	Report Source	Product	ROIE	Manufacturer	Route
Hospitaliza		Arnold-Chiari		Tegretol	PS	Novartis Sector:	
Initial or		Malformation		iegrecor	FD	Pharma	
UNKNOWN	300 mg					FIIALIIIA	
ONICIOWIN	500 mg	Brain Herniation		Baclofen Intrathecal	QQ		
INTRATHECAI	г.	Brain nermacion		bacioren intratiletar	55		
11,11011110CA		Drooling					
In Internet in Chi		Drooling Dysarthria					
		Dysarthria					
		Dysarthria Facial Palsy					
CA.		Dysarthria Facial Palsy Hypokinesia					
		Dysarthria Facial Palsy Hypokinesia Joint Contracture					
		Dysarthria Facial Palsy Hypokinesia Joint Contracture Shunt Malfunction					
		Dysarthria Facial Palsy Hypokinesia Joint Contracture					
		Dysarthria Facial Palsy Hypokinesia Joint Contracture Shunt Malfunction					

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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 Hospitalization - 50 mg/day		on	Alanine Aminotransferase Increased		Lioresal	PS	Novartis Sector: Pharma	ORAL
Initial or Pr 117 DAY	colonge	d	Aspartate		Bactrim Forte	SS		ORAL
1 DF, BID	300	DAY	Aminotransferase Increased		Viracept "Roche" Combivir	SS SS		ORAL ORAL
10080MIN	300	DAI	Blood Lactate		Lysanxia	SS		ORAL
10080MIN			Dehydrogenase Increased		Fumafer	SS		ORAL
500 mg, BID	214	DAY	Bone Marrow Depression		Depakine Chrono	SS		ORAL
4 mg/day			Prothrombin Level		Coversyl	SS		ORAL
			Decreased		Aspegic	С		ORAL

Date:01/19/05ISR Number: 4558591-6Report Type:Expedited (15-DaCompany Report #2004056018 Age: Gender:Female I/FU:F

Outcome Dose	Duration	РТ	Report Source	Product	Role	Manufacturer	Route
Other		Abnormal Behaviour Adverse Event Amnesia Economic Problem Feeling Hot Granuloma Heart Rate Increased	Consumer Health Professional	Neurontin (Gabapentin) Morphine (Morphine) All Other Non-Therapeutic Products (All Other Non-Therapeutic	PS SS		

Н	Hot Flush		Products)	SS	
H	Ayperhidrosis		Baclofen (Baclofen)	SS	ſ
	Inadequate Analgesia				
	Insomnia				ſ
L	Loss Of Consciousness				ſ
	Medical Device				ſ
	Complication				ſ
	Nerve Injury				ſ
-	Dedema				, , ,
	Pain				ſ
	Speech Disorder				, , ,
	Spinal Disorder				
W	Neight Increased				, I
Date:01/21/05ISR Number: Age:9 YR Gender:Male	4578905-0Report Type:Periodic I/FU:I	Company Repor	t #PHBS2003US13735		
	PT T	Report Source	Product	Role Manufacturer	Route
Dose Duration					
	1 1		Liorseal Intrathecal		
Initial or Prolonged		Professional	\$Me(Baclofen) Ampoule	PS	
INTRATHECAL INTRATHE	CAL.		Ampoure	-5	

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 PTReport Source Product Role Manufacturer Route Dose Duration Hospitalization -Meningitis Health Liorseal Intrathecal Initial or Prolonged Pyrexia Professional \$Me(Baclofen) Swelling Ampoule PS INTRATRACHEAL INTRATHECAL Date:01/21/05ISR Number: 4578909-8Report Type:Periodic Company Report #PHBS2004US01509 Gender:Female Aqe:65 YR I/FU:I Role Manufacturer РΤ Report Source Product Outcome Route Duration Dose Confusional State Liorseal Intrathecal Health Other Drug Ineffective Professional \$Me(Baclofen) Drug Withdrawal Syndrome Ampoule PS INTRATHECAL INTRATHECAL Hypertonia Pruritus Date:01/21/05ISR Number: 4578911-6Report Type:Periodic Company Report #PHBS2004US07423 Age:40 YR Gender:Male I/FU:I Role Manufacturer Outcome PTReport Source Product Route Dose Duration Liorseal Intrathecal Hospitalization -Cerebrospinal Fluid Health Initial or Prolonged Professional Leakage \$Me(Baclofen) Muscle Spasticity PS Ampoule INTRATHECAL INTRATHECAL Date:01/21/05ISR Number: 4578912-8Report Type:Periodic Company Report #PHBS2004US07475 Age: Gender:Male I/FU:I Outcome PΤ Report Source Product Role Manufacturer Route Dose Duration Other Drug Ineffective Health Lioresal Intrathecal Professional \$Me(Baclofen) Ampoule PS INTRATHECAL INTRATHECAL

	5ISR Number Gender:Male		13-XReport Type:Periodic I/FU:I	c	Company Report	#PHBS2004US07476			
Outcome Dose	Duration	PT		Report	Source	Product	Role	Manufacturer	Route
Other	Durucion	Muscle	Spasticity	Health Profess	ional	Lioresal Intrathecal \$Me(Baclofen)			
INTRATHECAL	INTRATI	HECAL				Ampoule	PS		
Date:01/21/05 Age:24 YR (16-5Report Type:Periodic I/FU:I	2	Company Report	#PHBS2004US07483			
Outcome Dose	Duration	PT		Report	Source	Product	Role	Manufacturer	Route
Hospitalizati Initial or Pr	ion -	Muscle	Spasticity	Health Profess	ional	Lioresal Intrathecal \$Me(Baclofen)			
INTRATHECAL	INTRATI	HECAL				Ampoule	PS		
Date:01/21/05 Age:16 YR (18-9Report Type:Periodic I/FU:I	C	Company Report	#PHBS2004US07485			
Outcome Hospitalizati Initial or Pi			Spasticity oskeletal Stiffness						
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Freedom Of Information (FOI) Report

	Pruritus					
Dose Duratio	าก	Report Source	Product	Ro⊥e	Manufacturer	Route
		Health Professional	Lioresal Intrathecal \$Me(Baclofen) Ampoule	PS		
INTRATHECAL INT	RATHECAL		Ampoure	FD		
Date:01/21/05ISR Num Age: Gender:M	ber: 4578919-0Report Type:Peri Male I/FU:I	odic Company Re	eport #PHBS2004US07572			
Outcome Dose Duratio	PT	Report Source	Product	Role	Manufacturer	Route
Other	Confusional State Convulsion	Health Professional	Lioresal Intrathecal \$Me(Baclofen)			
INTRATHECAL INT	Headache RATHECAL		Ampoule	PS		
	Hypertonia Hypotension		Tegretol (Carbamazepine)	С		
	Infection Pruritus		Valium (Diazepam) Demerol (Pethidine	С		
	Urinary Tract Infection		Hydrochloride)	С		
Date:01/21/05ISR Num	ber: 4578920-7Report Type:Peri	.odic Company Re	eport #PHBS2004US08489			
Age:34 YR Gender:F		_	-			
Outcome Dose Duratio	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - Initial or Prolonged	Condition Aggravated Hypertonia Muscle Spasticity	Health Professional	Lioresal Intrathecal \$Me(Baclofen) Ampoule	PS		
INTRATHECAL INT	RATHECAL Pain					
Date:01/21/05ISR Num Age:47 YR Gender:F	ber: 4578921-9Report Type:Peri 'emale I/FU:I	odic Company Re	eport #PHBS2004US08491			
Outcome	РТ	Report Source	Product	Role	Manufacturer	Route
Dose Duratio Other	n Hypertonia	Health	Lioresal Intrathecal			

INTRATHECAL IN	TRATHECAL	Professional	\$Me (Baclofen) Ampoule	PS	
Date:01/21/05ISR Nu Age:10 YR Gender:	mber: 4578922-0Report Type:Pe Male I/FU:I	eriodic Company Re	port #PHBS2004US08492		
Outcome	PT	Report Source	Product	Role Manufacturer	Route
Dose Durati Other	on Hypertonia Muscle Rigidity	Health Professional	Lioresal Intrathecal &Me(Baclofen) Ampoule	PS	
Date:01/21/05ISR Nu Age:68 YR Gender:	mber: 4578923-2Report Type:Pe Male I/FU:I	eriodic Company Re	port #PHBS2004US08555		
Outcome Dose Durati	PT	Report Source	Product	Role Manufacturer	Route
Hospitalization - Initial or Prolonged	Drug Ineffective	Health Professional	Lioresal Intrathecal &Me(Baclofen) Ampoule	PS	
INTRATHECAL IN	TRATHECAL				

FDA - Adverse Event Reporting System (AERS) Freedom Of Information (FOI) Report Date:01/21/05ISR Number: 4578924-4Report Type:Periodic Company Report #PHBS2004US08645 Gender:Female Age:14 YR I/FU:I Outcome PΤ Report Source Product Role Manufacturer Route Dose Duration Other Overdose Health Lioresal Intrathecal Professional &Me(Baclofen) Respiratory Distress PS Ampoule INTRATHECAL INTRATHECAL Date:01/21/05ISR Number: 4578925-6Report Type:Periodic Company Report #PHBS2004US08719 Age:47 YR Gender:Male I/FU:I ΡТ Role Manufacturer Report Source Outcome Product Route Dose Duration Drug Ineffective Lioresal Inthratecal Hospitalization -Health Muscle Spasticity (Baclofen) Ampoule Initial or Prolonged Professional PS INTRATHECAL INTRATHECAL Date:01/21/05ISR Number: 4578926-8Report Type:Periodic Company Report #PHBS2004US08720 Age:46 YR Gender:Male I/FU:I Role Manufacturer РΤ Report Source Outcome Product Route Dose Duration Hospitalization -Drug Ineffective Health Lioresal Inthratecal Initial or Prolonged Muscle Spasticity Professional (Baclofen) Ampoule PS INTRATHECAL INTRATHECAL Date:01/21/05ISR Number: 4578927-XReport Type:Periodic Company Report #PHBS2004US08811 Gender:Female Age:50 YR I/FU:I Role Manufacturer Outcome PTReport Source Product Route Dose Duration Hospitalization -Drug Ineffective Health Lioresal Intrathecal Initial or Prolonged Professional &Me(Baclofen) Ampoule PS INTRATHECAL 200 UG/DAY,

INTRATHECAL

Outcome		PT	Boport Courgo	Product	Polo	Manufacturer	Pouto
Dose	Duration	PI	Report Source	Product	ROIE	Manulacturer	Route
Other		Hypotonia	Health Professional	Lioresal Intrathecal &Me(Baclofen) Ampoule	PS		
INTRATHECAL	INTRAT	HECAL					
Date:01/21/ Age:	05ISR Number Gender:Male	: 4578929-3Report Type:Per I/FU:I	riodic Company Re	eport #PHBS2004US08961			
Outcome	Durahim	PT	Report Source	Product	Role	Manufacturer	Route
Dose Other	Duration	Muscle Spasticity	Health Professional	Lioresal Intrathecal &Me(Baclofen) Ampoule	PS		
INTRATHECAL	INTRAT	HECAL		Ampoure	15		
	05ISR Number Gender:Fema	: 4578930-XReport Type:Per le I/FU:I	ciodic Company Re	port #PHBS2004US08965			
Outcome	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Dose		Dizziness Overdose	Health Professional	Lioresal Intrathecal &Me(Baclofen)			
Dose Other		01010000		Ampoule	PS		

			rse Event Reporting Syste			
					(5)	
		Freedo	m Of Information (FOI) Re	eport		
Date:01/21/05ISR Numbe Age:44 YR Gender:Mal	r: 4578931-1Report Type:Per e I/FU:I	iodic Company Re	port #PHBS2004US09117			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - Initial or Prolonged	Condition Aggravated Muscle Spasms THECAL Pain	Health Professional	Lioresal Intratecal (Baclofen) Ampoule	PS		
Date:01/21/05ISR Numbe Age:11 YR Gender:Mal	r: 4578932-3Report Type:Per e I/FU:I	iodic Company Re	port #PHBS2004US09118			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - Initial or Prolonged	Lethargy Overdose THECAL Vomiting	Health Professional	Lioresal Intrathecal (Baclofen) Ampoule	PS		
Date:01/21/05ISR Numbe Age: Gender:Mal	r: 4578933-5Report Type:Per e I/FU:I	iodic Company Re	port #PHBS2004US09253			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other	Drug Ineffective	Health Professional	Lioresal Intrathecal \$Me(Baclofen) Ampoule	PS		
INTRATHECAL INTRA	THECAL		Ampoure	15		
Date:01/21/05ISR Numbe Age:61 YR Gender:Mal	r: 4578935-9Report Type:Per e I/FU:I	iodic Company Re	port #PHBS2004US09254			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other	Muscle Spasticity	Health Professional	Lioresal Intrathecal Me (Baclofen) Ampoule	PS		
INTRATHECAL INTRA	THECAL					

Date:01/21/0 Age:47 YR		: 4578936-0Report Type I/FU:I	e:Periodic Company Repor	t #PHBS2004US10136			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other		Drug Ineffective Overdose Sedation	Health Professional	Lioresal Intrathecal Me (Baclofen) Ampoule	PS		
INTRATHECAL	INTRATI	HECAL		-			
	5ISR Number Gender:Male	: 4578943-8Report Type I/FU:I	e:Periodic Company Repor	t #PHBS2004US10137			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other	Duracion	Drug Ineffective	Health Professional	Lioresal Intrathecal Me (Baclofen)			
INTRATHECAL	INTRATI	HECAL		Ampoule	PS		
	5ISR Number Gender:Male	: 4578944-XReport Type I/FU:I	e:Periodic Company Repor	t #PHBS2004US10138			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other	Duración	Drug Ineffective	Health Professional	Lioresal Intrathecal Me (Baclofen)	Da		
INTRATHECAL	975 UG,	/DAY,		Ampoule	PS		
INTRATHECAL							
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		FDA - Adverse Event Reporting System (AERS)							
		Freedo	om Of Information (FOI) Re	port					
Date:01/21/05ISR Number Age: Gender:Fema	: 4578945-1Report Type:Perio le I/FU:I	dic Company Re	eport #PHBS2004US10139						
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route			
Hospitalization - Initial or Prolonged	Muscle Spasticity	Health Professional	Lioresal Intrathecal Me (Baclofen)	DQ					
INTRATHECAL 600 UG	/DAY,		Ampoule	PS					
INTRATHECAL									
			Clonidine Dilaudid	C					
			(Hydromorphone Hydrochloride)	С					
Date:01/21/05ISR Number Age: Gender:Male Outcome Dose Duration Other INTRATHECAL INTRAT	PT Drug Withdrawal Syndrome Loss Of Consciousness	dic Company Re Report Source Health Professional	eport #PHBS2004US10140 Product Lioresal Intrathecal Me (Baclofen) Ampoule	Role	Manufacturer	Route			
INIKAINECAL INIKAI.	necal		Dilaudid (Hydromorphone Hydrochloride)	С					
Date:01/21/05ISR Number Age: Gender:Male	: 4578949-9Report Type:Perio I/FU:I	dic Company Re	eport #PHBS2004US10141						
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route			
Other	Muscle Spasms	Health Professional	Lioresal Intrathecal Me (Baclofen) Ampoule	PS					
INTRATHECAL INTRAT	HECAL		TWEPOULC	10					

Date:01/26/05ISR Number: 4560776-XReport Type:Expedited (15-DaCompany Report #FR-SOLVAY-00205000157 Age:42 YR Gender:Male I/FU:I

Outcome	Derest		PT	Report Source	Product	Role Manufacturer	Route
Dose Life-Threate Daily dose: 4		.on	Alanine Aminotransferase		Coversyl	PS	ORAL
Dally dose: 4 Hospitalizat: milligram(s)			Increased				ļ
Initial or Pr Daily dose:	rolonge	≥d	Aspartate		Bactrim	SS	ORAL
unknown	117	DAY	Aminotransferase				
		DAI	Increased		Combivir	SS	ORAL
Daily dose: 2			Blood Lactate				ļ
dosage form	300	DAY	Dehydrogenase Increased		Viracept	SS	ORAL
Daily dose:			Bone Marrow Depression				
unknown			Prothrombin Level		Depakine	SS	ORAL
Daily dose:			Decreased				
1000			Decreased				
milligram(s)	214	DAY			·'	20	
SUBCUTANEOUS	Da	ily (dose:		Lioresal	SS	
50							
milligram(s)							
SUBCUTANEOUS	Da	ily (dose:		Aspegic	С	
unknown							
Daily dose:					Lysanxia	С	ORAL
unknown	0	MON					
Daily dose:					Fumafer	С	ORAL
unknown							

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		Report	bourde	1100000	1010		nouce
Life-Threatening 1TAB Twice	Alanine Aminotransferase			Combivir	PS	Glaxosmithkline	ORAL
Other	Increased DN						
per day 10 MG	Anaemia			Viracept	SS		ORAL
	Aspartate			Bactrim Fort	SS	Glaxosmithkline	ORAL
4 MON	Aminotransferase			Depakine Chrono	SS		ORAL
500MG Twice					55		oranz
Jaco 7 Ma	Increased						
per day 7 MG	ON Blood Lactate			Coversyl	SS		ORAL
4MG Per day							
EOMC more do	Dehydrogenase Increased			Lioresal	SS		ORAL
50MG per day	Bone Marrow Depression			Aspegic	С		ORAL
	Leukopenia			Lysanxia	C		ORAL
	Prothrombin Level			Fumafer	C	Glaxosmithkline	ORAL
	Decreased						-
	Thrombocytopenia						
Date:01/26/05ISR Numbe Age:15 MON Gender:Mai	er: 4566398-9Report Type:Direct le I/FU:I		Company Repor	t #CTU 238039			
Outcome	PT	Report	Source	Product	Role	Manufacturer	Route
Dose Duration							
Life-Threatening	Apnoeic Attack			Baclofen 1mg/1ml			
Hospitalization -	Coma			Clinical			
Initial or Prolonged	Depressed Level Of Consciousness			Apothecaries	PS	Clinical Apothecaries	
parenteral 5mg						Apolliecaries	
FARENTERAL SMG	Dry Mouth						
PARENTERAL							
	Dyspnoea			Valium	С		
	Dysuria			Phenobarbital	C		
	Hypotonia			Pepcid	С		
	Lethargy			-			
	Mental Status Changes						
	Moaning						
1	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 Sc	ource	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		ļ
I	Hepatic Enzyme Increased			Acenocoumarol	С		
	Nausea			Paracetamol	С		
	Somnolence			Simvastatin	С		
				Paroxetin	С		
Age:42 YR Gender:Fem	r: 4601997-7Report Type:Period ale I/FU:I		50mF	t #ACO_0019_2004			
Outcome	PT	Report Sc	ource	Product	Role	Manufacturer	Route
Dose Duration							
Hospitalization - DF	Accidental Overdose	Consumer		Zanaflex	PS		
Initial or Prolonged DF	Coma			Baclofen	SS		

DF

		FDA - Adverse Event Reporting System (AERS)								
		Freedom	Of Information (FOI) Re	eport						
Date:02/02/05ISR Number Age:58 YR Gender:Male	: 4578098-XReport Type:Direct I/FU:I	Company Repo	rt #CTU 238907							
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route				
	Oedema Peripheral		Baclofen 10mg	PS						
Date:02/07/05ISR Number Age:37 YR Gender:Fema	: 4571548-4Report Type:Expedit le I/FU:F	ed (15-DaCompany Repo	rt #PHBS2003JP06722							
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route				
Hospitalization - Initial or Prolonged	Depressed Level Of Consciousness Muscular Weakness Sleep Apnoea Syndrome		Lioresal	PS	Novartis Sector: Pharma	ORAL				
Date:02/07/05ISR Number Age: Gender:Male Outcome Dose Duration	: 4576705-9Report Type:Expedit I/FU:I PT	ed (15-DaCompany Repo Report Source	rt #20052152 Product	Role	Manufacturer	Route				
Life-Threatening	Convulsion	Health	Lioresal Intrathecal							
Hospitalization - INTRATHECAL MCG, D	Loss Of Consciousness AILY.	Professional	(Baclofen Injection)	PS						
Initial or Prolonged INTRATHECAL	Muscle Spasticity									
Required	Sepsis		Oral Baclofen	С						
Intervention to Prevent Permanent Impairment/Damage	Treatment Noncompliance		Iv Valium	С						
Date:02/08/05ISR Number Age:42 YR Gender:Male	: 4575062-1Report Type:Expedit I/FU:I	ed (15-DaCompany Repo	rt #PERI0020500157							
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route				
Hospitalization - 300 DAY	Blood Lactate		Combivir	PS	Glaxosmithkline	ORAL				
Initial or Prolonged UNKNOWN 4MG Pe	Dehydrogenase Increased r day		Coversyl	SS						

	Bone Marrow Depression	Bactrim	SS	Glaxosmithkline
	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	1					ŗ
Hospitalization -	Alanine Aminotransferase		Lioresal	PS	Novartis Sector:	ŗ
Initial or Prolonged	Increased				Pharma	ŗ
	Aspartate		Coversyl	SS		ŗ
4 mg, QD						ŗ
	Aminotransferase		Bactrim	SS		ŗ
	Increased		Viracept	SS		ŗ
	Blood Lactate		Combivir	SS		ŗ
	Dehydrogenase Increased		Depakine Chrono	SS		I
	Bone Marrow Depression					
	Prothrombin Level					
	Decreased					

Freedom Of Information (FOI) Report

Date:02/09/05ISR Number: 4577751-1Report Type:Expedited (15-DaCompany Report #2004AL000561 Age:61 YR Gender:Female I/FU:F

Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Death Hospitalizat Initial or P:	ion -	Blood Pressure Increased Coma Completed Suicide	Literature Health Professional	Kadian (Morphine Sulfate Sustained Release) Capsules,			
PO		Heart Rate Increased		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		Capital And Codeine Oral Suspension (Acetaminophen/Codei			
		Respiratory Rate Increased		ne Oral Suspension), 120/12 Per 5	SS	Alpharma	ORAL
PO		mercusea		120/12 101 3	60	11pilar ma	0
				Ibuprofen Oral Suspension Usp, 100 Mg/5 Ml (Otc)			
PO				(Alpharma)	SS	Alpharma	ORAL
PO				Ibuprofen Oral Suspension Usp, 100 Mg/5 Ml (Rx)			
				(Alpharma)	SS	Alpharma	ORAL
PO				Baclofen	SS		ORAL
PO				Bactoren	22		UKAL
				Aluminium/Magnesioum Hydroxide	SS		ORAL
PO					20		
PO				Cocaine	SS		ORAL

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	Foreign	Viracept (Tablet)			
		Increased	Health	(Nelfinavir			

	Aplastic Anaemia	Professional	Mesilate)	PS	ORAL
ORAL					
	Aspartate		Bactrim		
	Aminotransferase		(Sulfamethoxazole,		
	Increased		Trimethoprim)	SS	ORAL
ORAL					
	Biopsy Bone Marrow		Zidovudine		
	Abnormal		W/Lamivudine		
	Blood Creatinine Abnormal		(Lamivudine,		
	Blood Lactate		Zidovudine)	SS	ORAL
2 IN 1 D,					
	Dehydrogenase Increased				
ORAL					
	Prothrombin Time		Ergenyl Chrono		
	Shortened		(Valproate Sodium,		
	Treatment Noncompliance		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

Freedom Of Information (FOI) Report

	Increased Blood Lactate Dehydrogenase Increased Bone Marrow Depression	Report Source	Product	Role Manufacturer	Route
Dose Duration					
	Prothrombin Time Ratio		Depakine Chrono		
010 514	Decreased		Tablets	PS	ORAL
213 DAY			Destaular		0.0.7.7
115 DAY			Bactrim	SS	ORAL
115 DAY			Nelfinavir Mesilate	SS	ORAL
			Nellinavir Mesilate Nelfinavir Mesilate	SS	URAL
			Nelfinavir Mesilate	SS	
			Nelfinavir Mesilate	SS	ORAL
			Zidovudine	~~	01010
			W/Lamivudine	SS	ORAL
			Zidovudine		
			W/Lamivudine	SS	
			Perindopril	SS	ORAL
			Baclofen	SS	ORAL
			Acetylsalicylate		
			Lysine	С	
UNKNOWN					
			Prazepam	C	ORAL
5 DAY				a.	
5 DAY			Ferrous Fumarate	С	ORAL
Date:02/11/05ISR Numbe Age: Gender:Mal	r: 4583757-9Report Type:Exped e I/FU:I	ited (15-DaCompany Re	eport #20052173		
Outcome Dose Duration	PT	Report Source	Product	Role Manufacturer	Route
Hospitalization - Initial or Prolonged	Drug Withdrawal Syndrome Muscle Spasticity	Health Professional	Lioresal Intrathecal (Baclofen Injection)	D.C.	
Required INTRATHECAL 180 M	Pruritus		720 Mcg/Ml	PS	
INTRATHECAL 180 M Intervention to	Pyrexia				
DAILY,	ryicala				
Prevent Permanent					
INTRATHECAL					
Impairment/Damage			Morphine Sulfate	С	

Date:02/11/05ISR Number: 4583845-7Report Type:Expedited (15-DaCompany Report #2005022019 Age:29 YR Gender:Male I/FU:I

Outcome	РТ	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
—	Cystitis	Consumer	Neurontin			1
Initial or Prolonged 600 MG (200	Depression		(Gabapentin)	PS		ļ
Other	Diarrhoea					1
MG, 3 IN 1 D)						, I
1	Disturbance In Attention		Baclofen (Baclofen)			ļ
1	Drug Interaction		(Baclofen)	SS		ļ
130 MG	-					
	Hallucination		Paracetamol	С		
1	Hypotension		Ibuprofen	С		
1	Insomnia		Vicodin (Hydrocodone			
	Neuralgia		Bitartrate,			ļ
1	Pain In Extremity		Paracetamol)	С		
	Psychotic Disorder					
	Sensory Disturbance					I
	Social Avoidant Behaviour					ļ
1	Syncope					I

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

Freedom Of Information (FOI) Report

Impairment/Damage

Dose	Duration	РТ	Report Source	Product	Role	Manufacturer	Route
DOSE	Duración	Dysuria Medical Device	Health Professional	Lioresal Intrathecal	Da		
INTRATHECAL	DAILY,	Medical Device	Processional	(Baclofen Injection)	PS		
		Complication					
INTRATHECAL							
		Medication Error Muscle Spasms Neck Pain Pain Pyrexia		Fentanyl	С		
	5ISR Number Gender:Male	: 4582767-5Report Type:Expedite I/FU:F	ed (15-DaCompany Report	t #PERI0020500157			

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Hospitaliza 300 DAY	tion -	Alanine Aminotransferase		Combivir	PS	Glaxosmithkline	ORAL
Initial or 1	Prolonged	Increased		Coversyl	SS		
UNKNOWN	4MG Per	r 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					Ĩ
		Prothrombin Level					
		Decreased					
		Transaminases Increased					
							Ĩ

Date:02/15/05ISR Number: 4587494-6Report Type:Expedited (15-DaCompany Report #2005024115 Age:42 YR Gender:Male I/FU:I

Hospitalization -	Alanine Aminotransferase	Health	Viracept (Tablet)	
Initial or Prolonged	Increased	Professional	(Nelfinavir	
	Aspartate		Mesilate)	PS
	Aminotransferase		Perindopril	
	Increased		(Perindopril)	SS
4 MG				
	Blood Lactate		Bactrim	
	Dehydrogenase Increased		(Sulfamethoxazole,	
	Bone Marrow Depression		Trimethoprim)	SS
	Prothrombin Level		Zidovudine	
	Decreased		W/Lamivudine	
			(Lamivudine,	
			Zidovudine)	SS
			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	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Dose Other		Depressed Level Of Consciousness		Lioresal	PS	Novartis Sector: Pharma	ORAL
10 mg, QD							0D
(pulverized)	1440 MIN						
1 mg, QD				Risperdal	SS		ORAL
(pulverized)	1440 MIN						
22-Aug-2005 Page: 270	12:15 PM						

Freedom Of Information (FOI) Report

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 I Death Other UNKNOWN	Duration	Abdominal Mass Confusional State		Baclofen	PS	Novartis Sector: Pharma	
		Death Drug Ineffective Eructation Faecaloma Faeces Hard Haematemesis Insomnia Nausea		Chlorpromazine Metoclopramide Senna Hydromorphone Lidocaine	C C C C C		
		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 Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other	Duración	Abnormal Behaviour Amnesia	Consumer Health	Neurontin (Gabapentin)	PS		
900 MG (1 D)			nearen	(Gabapenein)	10		
		Dysstasia	Professional	Morphine (Morphine)	SS		
INTRATHECAL	9 MG (1	l D), Feeling Hot					
INTRATHECAL							
		Granuloma Heart Rate Increased Hot Flush Hyperhidrosis Insomnia		Baclofen (Baclofen) All Other Non-Therapeutic Products (All Other Non-Therapeutic	SS		
		Loss Of Consciousness Medical Device		Product) Bupivacaine	SS		
		Complication Mental Disorder		(Bupivacaine)	С		

	Nerve Injury Oedema Pain Speech Disorder Unevaluable Event Weight Increased					
Date:02/17/05ISR Number Age: Gender:Male	r: 4590494-3Report Type:Exped: e I/FU:F	ited (15-DaCompany Re	eport #20052173			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - Initial or Prolonged	Condition Aggravated Drug Withdrawal Syndrome	Health Professional	Lioresal Intrathecal (Baclofen Injection)			
Required INTRATHECAL 180 MC	Muscle Spasticity CG,		720 Mcg/Ml	PS		
Intervention to DAILY,	Pruritus					
Prevent Permanent INTRATHECAL	Pyrexia					
Impairment/Damage			Morphine Sulphate	С		

	FDA - Adverse Event Reporting System (AERS)							
		Freedo	m Of Information (FOI) Re	eport				
Date:02/18/05ISR Number Age: Gender:Male	: 4587005-5Report Type:Exped I/FU:I	ited (15-DaCompany Rej	port #PHBS2005US02266					
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route		
Hospitalization - Initial or Prolonged INTRATHECAL 180 ug	Drug Withdrawal Syndrome Muscle Spasticity		Baclofen Intrathecal	PS	Novartis Sector: Pharma			
Other	Pruritus Pyrexia		Morphine Sulfate	С				
Date:02/18/05ISR Number Age: Gender:Male	: 4587088-2Report Type:Exped I/FU:I	ited (15-DaCompany Re	port #PHNU2005DE00987					
Outcome	PT	Report Source	Product	Role	Manufacturer	Route		
Dose Duration Life-Threatening	Cardiovascular Disorder Coma		Lioresal Intratecal	PS	Novartis Sector: Pharma			
INTRATHECAL 50000 ONCE/SINGLE								
UNCE/SINGLE	Respiratory Failure		Timonil Sirdalud	C C				
Date:02/22/05ISR Number Age:67 YR Gender:Fema	: 4588705-3Report Type:Exped le I/FU:I	ited (15-DaCompany Rej	port #PHFR2005GB00884					
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route		
Hospitalization - Initial or Prolonged			Baclofen	PS	Novartis Sector: Pharma	ORAL		
10mg/day 8640 MIN 10 mg, QD 124 DAY			Amitriptyline	С		ORAL		
10 mg, QD 124 DAY 30 mg, QD			Lansoprazole	С		ORAL		
2 ug, QW2			Alfacalcidol	С		ORAL		

Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - 20 MG PO TID Initial or Prolonged	Depressed Level Of Consciousness		Baclofe	PS		ORAL
	Myoclonus					
Date:02/25/05ISR Number Age:53 YR Gender:Male	: 4596237-1Report Type:Expedit I/FU:I	ced (15-DaCompany Repor	t #20052206			
Outcome Dose Duration	РТ	Report Source	Product	Role	Manufacturer	Route
Hospitalization - Initial or Prolonged INTRATHECAL DAILY,	Device Failure Pruritus	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		
Required INTRATHECAL	Pyrexia					
Intervention to Prevent Permanent Impairment/Damage	Respiratory Depression					
Date:02/25/05ISR Number Age: Gender:Male	: 4596238-3Report Type:Expedit	ced (15-DaCompany Repor	t #20052207			
Outcome Hospitalization -	PT Catheter Related					
Initial or Prolonged	Infection Csf Bacteria Identified Incision Site Complication					
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Freedom Of Information (FOI) Report

	Staphylococcal Infection	Depart Course	Dreduct	Dele	Manufacturer	Douto
Dose Duratio	an	Report Source	Product	ROIE	Manulacturer	Route
		Health	Lioresal Intrathecal			
		Professional	(Baclofen Injection)	PS		
INTRATHECAL DA	ILY,					
INTRATHECAL						
Date:03/02/05ISR Nu Age:32 YR Gender:	mber: 4598828-0Report Type:Expe Female I/FU:I	dited (15-DaCompany Re	eport #230610K05USA			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Convulsion	Consumer	Rebif (Interferon			
Initial or Prolonge	d Meningitis Chemical		Beta)	PS		
44 MCG, 3 IN	Muscle Spasms					
1 WEEKS	MUSCLE Spasms					
I WEEKS	Thrombosis Urinary Tract Infection		Lioresal (Baclofen)	SS		
Age:60 YR Gender:						
Age:60 YR Gender: Outcome	Female I/FU:F PT	dited (15-DaCompany Re Report Source	port #PHNU2004DE02948 Product	Role	Manufacturer	Route
Age:60 YR Gender: Outcome Dose Duratio	Female I/FU:F PT on	Report Source	Product	Role	Manufacturer	Route
Age:60 YR Gender: Outcome Dose Duration Hospitalization -	Female I/FU:F PT on Apnoea	Report Source Health	Product Baclofen Intrathecal	Role	Manufacturer	Route
Age:60 YR Gender: Outcome Dose Duratio	Female I/FU:F PT on Apnoea d Coma	Report Source Health Professional	Product Baclofen Intrathecal (Baclofen) Solution		Manufacturer	Route
Age:60 YR Gender: Outcome Dose Duration Hospitalization - Initial or Prolonged	Female I/FU:F PT on Apnoea d Coma Device Failure	Report Source Health	Product Baclofen Intrathecal	Role	Manufacturer	Route
Age:60 YR Gender: Outcome Dose Duration Hospitalization - Initial or Prolonged	Female I/FU:F PT on Apnoea d Coma Device Failure KNOWN;	Report Source Health Professional	Product Baclofen Intrathecal (Baclofen) Solution		Manufacturer	Route
Age:60 YR Gender: Outcome Dose Duration Hospitalization - Initial or Prolonged	Female I/FU:F PT on Apnoea d Coma Device Failure	Report Source Health Professional	Product Baclofen Intrathecal (Baclofen) Solution		Manufacturer	Route

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Durati	lon	-				
Hospitalization -	Alanine Aminotransferase		Septra			ļ
Initial or Prolonge	ed Increased		Tablets/Septra Ds			ļ
	Aspartate		Tablets	PS	King	ŗ
1	Aminotransferase				Pharmaceuticals,	ľ
	Increased				Inc.	ŗ
	Blood Lactate		Combivir	SS		ORAL
UNK, UNK						ľ
	Dehydrogenase Increased		Coversyl	SS		ŗ
4 mg, qd						ľ
	Bone Marrow Depression		Viracept "Agouron"	SS		ŗ
4	Prothrombin Level		Depakine Chrono	SS		ŗ
4	Decreased		Lioresal			ļ
4			"Ciba-Geigy"	SS		ļ
4						
4						ļ
4						ļ
Date:03/03/05ISR N1	umber: 4598974-1Report Type:Expe	edited (15-DaCompany R	(eport #PHFR2004GB04658			
			- I			

Age:56 YR Gender:Male I/FU:F

Outcome]	PT	Report Source	Product	Role	Manufacturer	Route
Dose Dura	ation						
Life-Threatening	(Coma	Health	Lioresal Intrathecal			
Hospitalization -	- 1	Escherichia Infection	Professional	(Baclofen) Solution			
Initial or Prolor	nged I	Incoherent	Other	For Injection	PS		
INTRATHECAL	UNKNOWN	;					
	I	Meningitis Bacterial					

INTRATHECAL

Freedom Of Information (FOI) Report

Date:03/03/05ISR Number: 4599601-XReport Type:Expedited (15-DaCompany Report #20052215 Age: Gender:Male I/FU:I Outcome PΤ Report Source Product Role Manufacturer Route Dose Duration Hospitalization -Catheter Related Health Lioresal Intrathecal Initial or Prolonged Infection Professional (Baclofen Injection) PS INTRATRACHEAL DAILY, Meningitis Required INTRATHECAL Intervention to Muscle Spasticity Staphylococcal Infection Prevent Permanent Impairment/Damage Date:03/03/05ISR Number: 4600073-7Report Type:Expedited (15-DaCompany Report #PHNU2005DE00987 Gender:Male I/FU:I Age: Role Manufacturer Outcome PTReport Source Product Route Dose Duration Life-Threatening Cardiovascular Disorder Health Lioresal Intratecal Professional Coma (Baclofen) Ampoule PS 50000 UG, Medication Error Other ONCE/SINGLE Respiratory Failure Timonil (Carbamazepine) С Sirdalud (Tizanidine Hydrochloride) С Date:03/04/05ISR Number: 4600418-8Report Type:Expedited (15-DaCompany Report #K200500263 Age:42 YR Gender:Male I/FU:I ΡТ Role Manufacturer Outcome Report Source Product Route Dose Duration Hospitalization -Alanine Aminotransferase Health Septra Initial or Prolonged Increased Professional Tablets/Septra Ds Aspartate Other Tablets(Trimethoprim Aminotransferase , Sulfamethoxazole) Increased Tablet 80/400 Mg PS Blood Lactate Combivir Dehydrogenase Increased (Lamivudine, Bone Marrow Depression Zidovudine) Tablet SS ORAL

ORAL

	Prothrombin Level Decreased	Coversyl (Perindopril Erbumine) 4 Mg	SS	
4 MG, QD			00	
		Viracept "Agouron" (Nelfinavir		
		Mesilate) Depakine Chrono	SS	Agouron
		(Valproate Sodium, Valproic Acid) Lioresal	SS	
		"Ciba-Geigy" (Baclofen)	SS	Ciba-Geigy
Date:03/07/05ISR Numbe Age: Gender:Mal	r: 4602460-XReport Type:Expedited (15-Da0 e I/FU:I	Company Report #20052192		
Outcome	PT			
Hospitalization -	Blister			
Initial or Prolonged Required	Blood Creatine Phosphokinase Increased			
Intervention to	Drug Withdrawal Syndrome			
Prevent Permanent	Enzyme Abnormality			
Impairment/Damage	Hepatic Enzyme Increased Hyperhidrosis			
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Freedom Of Information (FOI) Report

Dose	Duration	Medical Device Complication Muscle Rigidity Pyrexia Tachypnoea	Report Source Health Professional	Product Lioresal Intrathecal(Baclofen Injection) 2000	Role	Manufacturer	Route
INTRATHECAL	300 MC	G		Mcg/Ml	PS		
DAILY,							
INTRATHECAL							
Date:03/08/0 Age:76 YR (: 4603736-2Report Type:Direct I/FU:I	Company Repor	t #CTU 242303			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalizat 20 MG PO QID	ion -	Lethargy		Baclofen 20 Mg	PS		ORAL
Initial or P MG Q AM 2 MG Q HS		Mental Status Changes Treatment Noncompliance		Lorazepam 1 Mg	SS		
Date:03/08/0 Age:54 YR (: 4604280-9Report Type:Direct I/FU:I	Company Repor	t #CTU 242244			
Outcome Dose	Duration	РТ	Report Source	Product	Role	Manufacturer	Route
Life-Threater 25 MG PO QHS	ning	Loss Of Consciousness		Amitriptyline 25 Mg	PS		ORAL
23 MG FO QUS		Suicide Attempt		Baclofen	SS		
	5ISR Number Gender:Fema	: 4606114-5Report Type:Expedit le I/FU:F	ed (15-DaCompany Repor	t #US014707			
Outcome Dose	Duration	РТ	Report Source	Product	Role	Manufacturer	Route

Drug Interaction	Study	Provigil	PS	ORAL
Grand Mal Convulsion QOD	Consumer	Betaseron	SS	
		Prednisone	SS	
		Baclofen	99	
		Bactoren		
		Synthroid	C	
	Grand Mal Convulsion	Grand Mal Convulsion Consumer	Grand Mal Convulsion Consumer Betaseron OD Prednisone Baclofen	Grand Mal Convulsion Consumer Betaseron SS Prednisone SS Baclofen SS

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						
Hospitalizat	ion -	Cystitis	Consumer	Neurontin			
Initial or Pa	rolonged	Depression	Health	(Gabapentin)	PS		
UNKNOWN	600 MG	(200					
Other		Diarrhoea	Professional				
MG, 3 IN 1							
		Disturbance In Attention					
D), UNKNOWN							
		Hallucination		Baclofen (Baclofen)	SS		
UNKNOWN	130 MG						
		Hypotension					
(UNKNOWN)							
		Insomnia		Paracetamol			
		Social Avoidant Behaviour		(Paracetamol)	С		
				Ibuprofen			
				(Ibuprofen)	С		
				Vicodin (Hydrocodone			
				Bitartrate,			
				Paracetamol)	С		
				Ciprofloxacin	-		
				(Ciprofloxacin)	С		

Freedom Of Information (FOI) Report

Role Manufacturer

Route

Product

Date:03/10/05ISR Number: 4608969-7Report Type:Expedited (15-DaCompany Report #2004-BP-11398YA Age:41 YR Gender:Male I/FU:F

Outcome

 \mathbf{PT}

		Hefere beare	1200000		
Dose Duration					
Hospitalization - 0.2 MG (NR)	Alanine Aminotransferase	Foreign	Harnal (Tamsulosin)	PS	ORAL
Initial or Prolonged PO	Increased	Health			
Other	Aspartate Aminotransferase	Professional	Dantrium (Dantrolene Sodium) (Nr)	SS	ORAL
25 MG (NR) PO					
	Increased 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,			,		01012
· · · · · · · · · · · · · · · · · · ·	Gamma-Glutamyltransferase				
TID) PO	4				
	Increased Liver Disorder		Vitamedin (Benfotiamine/B6/B12		
	Lymphocyte Stimulation) (Nr)	С	
	Test Positive		Diazepam (Diazepam)		
	Malaise		(Nr)	C	
Date:03/14/05ISR Numbe: Age:73 YR Gender:Male	r: 4609508-7Report Type:Direct e I/FU:I	Company Repo	rt #CTU 243164		
Outcome Dose Duration	РТ	Report Source	Product	Role Manufacturer	Route
Hospitalization - 10 MG TID	Mental Status Changes		Baclofen	PS	
Initial or Prolonged			Dexamethasone	SS	
			Tramadol	SS	
1-2 TID					
			Oscal	С	
			Asa	С	
			Clonidine	С	
			Docusate	C	
			Guaifenesin	C	
			Isosorbide	C	
			Lisinopril	C	
			Zocor Mitemin F	C	
			Vitamin E	C	

Report Source

Metoprolol C

Date:03/15/05ISR Number: 4608733-9Report Type:Expedited (15-DaCompany Report #PHNU2005DE00955 Age:80 YR Gender:Female I/FU:F

Outcome Dose	Duration	РТ	Report Source	Product	Role	Manufacturer	Route
Other	2 42 4 0 2 0 1	Coma Depressed Level Of		Lioresal	PS	Novartis Sector: Pharma	ORAL
10 mg, BID		-					
5.		Consciousness		Risperdal	SS		ORAL
1 mg, QD	5760 MIN			-			
				Risperdal	SS		ORAL
1				Durogesic	С		
SUBCUTANEOUS	UNK, UN	NK		-			
1				Zolpidem	С		ORAL
1				Ramipril	С		ORAL

Date:03/16/05ISR Number: 4612639-9Report Type:Expedited (15-DaCompany Report #20052232 Age: Gender:Male I/FU:I

Outcome	PT
Hospitalization -	Abasia
Initial or Prolonged	Catheter Related
Required	Complication
Intervention to	Drug Withdrawal Syndrome
Prevent Permanent	Granuloma
Impairment/Damage	Hypertonia

Freedom Of Information (FOI) Report

		Hypotonia Spinal Column Stenosis		Duradurat	D - 1 -	Manual	Deute
Dose	Duration		Report Source	Product	Role	Manufacturer	Route
	Daración		Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		
INTRATHECAL	MCG, D	AILY,					
INTRATHECAL							
	5ISR Number Gender:	: 4615398-9Report Type:Expe I/FU:F	dited (15-DaCompany Re	eport #2004070485			
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration		_				
Death		Completed Suicide Intentional Misuse	Literature Health	Gabapentin (Gabapentin)	PS		ORAL
ORAL		Intentional Misuse	nearth	(Gabapenein)	FD		ORAL
			Professional	Baclofen (Baclofen)	~~		0.5.1.5
ORAL				(Baclofen)	SS		ORAL
				Oxybutynin (Oxybutynin) (Oxybutynin)	SS		ORAL
ORAL				(/ /			
	5ISR Number Gender:Fema	: 4614907-3Report Type:Expe le I/FU:I	dited (15-DaCompany Re	eport #PHBS2005TW03936			
		PT	Report Source	Product	Role	Manufacturer	Route
	Duration						
Outcome Dose Hospitalizat Initial or P 5 mg, TID	ion -	Confusional State Disorientation		Baclofen	PS	Novartis Sector: Pharma	ORAL

Outcome Dose Duration Hospitalization - Initial or Prolonged	PT Cerebral Artery Embolism Headache Hyperacusis Photophobia	Report Source	Product Baclofen	Role PS	Manufacturer Novartis Sector: Pharma	Route
Date:03/23/05ISR Number Age: Gender:Fema Outcome	: 4622248-3Report Type:Direct le I/FU:I PT	Company Repor Report Source	t #CTU 244040 Product	Role	Manufacturer	Route
Dose Duration Hospitalization - INTRATHECAL 1250 M Initial or Prolonged IT	Medication Error	Acport Source	Baclofen	PS	nanuraccurer	nouce
			Elavil Levoxyl Cozaar Lipitor Protonix	C C C C 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 Aqe:38 YR Gender:Female I/FU:I Report Source Product Role Manufacturer Outcome PTRoute Duration Dose Hospitalization -Cerebral Artery Embolism Baclofen Intrathecal PS Novartis Sector: Initial or Prolonged Headache Pharma INTRATHECAL Hyperacusis Photophobia Date:03/24/05ISR Number: 4617784-XReport Type:Expedited (15-DaCompany Report #PHBS2005CA01725 Age:55 YR Gender:Female I/FU:F Outcome \mathbf{PT} Report Source Product Role Manufacturer Route Duration Dose Disability Hypersensitivity Lioresal PS Novartis Sector: Muscular Weakness Pharma ORAL 20 mg/day 63360MIN Hydrochlorothiazide С 25 mg, QD UNKNOWN Diazepam С ORAL 5 mg, TID Didrocal С 20160MIN Calcium С Date:03/24/05ISR Number: 4617871-6Report Type:Expedited (15-DaCompany Report #PHBS2005CA01725 Age:55 YR Gender:Female I/FU:F Outcome DТ Report Source Product Role Manufacturer Route

Ouccome		P1	Report Source	Product	ROIE	Manulacturer	Roule
Dose Disability	Duration	Hypersensitivity		Lioresal	PS	Novartis Sector:	
Dibability		Muscular Weakness		Littebai	10	Pharma	ORAL
20 mg/day	63360MIN						
				Hydrochlorothiazide	С		
UNKNOWN	25 mg,	QD					
_				Diazepam	С		ORAL
5 mg, TID					_		
0.01 (0.4737				Didrocal	С		
20160MIN					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 Death	Duration	Cardiac Failure Chromaturia		Lioresal	PS	Novartis Sector: Pharma	ORAL
100 mg/day							
		Dyspnoea Exertional		Amfetamine	С		
		Nervous System Disorder		Morphine	С		
		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
Hospitalizatio	-	Blood Alkaline		Lioresal	PS	Novartis Sector:	0.0.0.1
Initial or Pro 15 mg, TID	oronded	Phosphatase Increased				Pharma	ORAL
,		Blood Lactate		Dafalgan	SS		ORAL
500 mg, 6QD	2880 MIN						
		Dehydrogenase Increased		Fraxiparine	С		
SUBCUTANEOUS	0.4 ml,	QD					
		Gamma-Glutamyltransferase		Duphalac	С		ORAL
10 g, 6QD							
		Increased					
		Hepatitis					
		Transaminases Increased					

Freedom Of Information (FOI) Report

Route

Date:04/01/05ISR Number: 4628396-6Report Type:Expedited (15-DaCompany Report #20052246 Age: Gender:Male I/FU:F Outcome PTReport Source Product Role Manufacturer Dose Duration Hospitalization -Cystitis Health Lioresal Intrathecan Professional (Baclofen Injection) Initial or Prolonged Drug Withdrawal Syndrome ΡS INTRATRACHEAL MCG, DAILY, Failure Of Implant Required INTRATHECAL Intervention to Heart Rate Increased Prevent Permanent Hypertonia Impairment/Damage Muscle Spasms Muscle Spasticity Pelvic Abscess Sepsis Date:04/04/05ISR Number: 4626071-5Report Type:Expedited (15-DaCompany Report #PHNU2005DE01513

Age: Gender:Female I/FU:I

Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
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 Gender:Male Aqe: I/FU:I Role Manufacturer Outcome PTReport Source Product Route Dose Duration Hospitalization -Muscle Spasticity Health Lioresal Initial or Prolonged Pyrexia Professional Intrathecal(Baclofen Underdose Injection)500mcg/Ml PS

INTRATHECAL 198 MCG,

DAILY,

INTRATHECAL

Initial or Prolonged Pyro Undo INTRATHECAL 198 MCG, DAILY,	cle Spasticity exia erdose	Report Source Health Professional	Product Lioresal Intrathecal (Baclofen Injection) 500 Mcg/Ml	Role PS	Manufacturer	Route
Hospitalization - Muse Initial or Prolonged Pyre Unde	exia		(Baclofen Injection)	PS		
Initial or Prolonged Pyro Undo INTRATHECAL 198 MCG, DAILY,	exia		(Baclofen Injection)	PS		
Unde INTRATHECAL 198 MCG, DAILY,		Professional		PS		
INTRATHECAL 198 MCG, DAILY,						
INTRATHECAL						
Age: Gender:Male Outcome PT Dose Duration	I/FU:I	Report Source	Product	Role	Manufacturer	Route
	g Withdrawal Syndrome	Health	Lioresal Intrathecal			
-	chema	Professional	(Baclofen Injection)	PS		
INTRATHECAL MCG, DAILY						
-	lant Site Infection					
INTRATHECAL						
Mus	cle Spasticity					
	2 Procedural					
	plication					
	exia					
-	phylococcal Infection					

Freedom Of Information (FOI) Report

Date:04/11/05ISR Number: 4632024-3Report Type:Expedited (15-DaCompany Report #PHBS2005JP04814 Age:63 YR Gender:Male I/FU:I

Outcome Dose Duration	РТ	Report Source	Product	Role	Manufacturer	Route
Hospitalization - Initial or Prolonged 15 mg/day 2880 MIN	Depressed Level Of Consciousness		Lioresal	PS	Novartis Sector: Pharma	ORAL
			Lasix	С		ORAL
80 mg/day			Zantac	С		ORAL
150 mg/day			Amlodin	С		ORAL
10 mg/day			Anplag	С		ORAL
200 mg/day			Calcium Carbonate	C		ORAL
3 g/day						
3 df/day			Neurovitan	С		ORAL
750 mg/day			Renagel	С		ORAL
			Cilostate	С		ORAL
50 mg/day			Diovan	С		ORAL
80 mg/day			Alfarol	С		ORAL
0.5 ug/day						
40 mg/day			Tryptanol	С		ORAL
400 mg/day			Tegretol	С		ORAL

Date:04/11/	05ISR Number:	4633096-2Report	Type:Direct	Company	Report	#CTU	245806
Age:46 YR	Gender:Female	e I/FU:I					

Outcome		PT	Report Source	Product	Role Manufacturer	Route
Dose	Duration					
20 MG 3 TIM	БС	Chest Pain		Baclofen	PS	ORAL
ZU MG 3 IIM	60	Pain In Extremity				
A DAY ORAL		2				
				Wellbutrin 300 Mg	SS	ORAL
300 MG 1 TI	ME					

A DAY ORAL					
			Vioxx Celebrex Bextra	C C C	
Date:04/11/05ISR Number Age: Gender:Male	: 4635229-0Report Type:Exped: I/FU:F	ited (15-DaCompany Re	port #20052246		
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer
Hospitalization - Initial or Prolonged Required INTRATHECAL DAILY,	Cystitis Drug Withdrawal Syndrome Heart Rate Increased	Health Professional	Lioresal Intrathecal(Baclofen Injection)	PS	
Intervention to INTRATHECAL	Hypertonia				
Prevent Permanent Impairment/Damage	Medical Device Complication Medication Error Muscle Spasticity				
	Pelvic Abscess Pyrexia Urosepsis				
Date:04/13/05ISR Number Age:36 YR Gender:Male	: 4635614-7Report Type:Exped: I/FU:I	ited (15-DaCompany Rej	port #KII-2005-0015781		
Dutcome Life-Threatening Hospitalization - Initial or Prolonged Other	PT Acidosis Agitation Bowel Sounds Abnormal Bradycardia Cardiac Arrest Coma Disorientation				
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Route

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Freedom Of Information (FOI) Report

Dose	Duration	Prolonged Hypertension Intentional Misuse Mydriasis	Report Source	Product	Role	Manufacturer	Route
Dose	Duración	Pupillary Reflex Impaired Somnolence	Study Health Professional	Morphine Sulfate (Similar To Nd 19-516) (Morphine	Þđ		0.5.11
ORAL			Other	Sulfate) Unknown	PS		ORAL
				Clonazepam(Clonazepa m)	SS		ORAL
ORAL							
ORAL				Baclofen(Baclofen)	SS		ORAL
				Methocarbamol(Methoc arbamol)	SS		ORAL
ORAL				Gabapentin(Gabapenti n)	SS		

Date:04/18/05ISR Number: 4638119-2Report Type:Expedited (15-DaCompany Report #PHRM2005FR01234 Age:70 YR Gender:Female I/FU:I

Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - Initial or Prolonged	Abasia Alanine Aminotransferase		Lioresal	PS	Novartis Sector: Pharma	ORAL
10 mg, TID 15840MIN	Increased		Zaldiar	SS		ORAL
	Aspartate		Xanax	С		ORAL
	Aminotransferase		Anafranil	С		ORAL
25 mg, BID	Increased Cerebral Atrophy Confusional State Escherichia Urinary Tract Infection		Dafalgan	С		ORAL

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration Other	Hallucination Muscle Spasms		Baclofen	PS	Novartis Sector: Pharma	
UNKNOWN					I Harma	
	Paranoia		Dantrolene	С		
UNKNOWN						
Date:04/22/05ISR Number Age:17 YR Gender:Fema	r: 4642762-4Report Type:Expedi ale I/FU:I	ted (15-DaCompany Repor	ct #PHEH2005US04344			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other	Mental Status Changes		Zelnorm	PS	Novartis Sector: Pharma	
			Klonopin	I		
			Keppra	I		
			Baclofen	I		
ארה אווו			Ativan	I		
UNK, PRN			Depakote	I		
			Prevacid	I		
Date:04/25/05ISR Number Age:63 YR Gender:Male	: 4643634-1Report Type:Expedi I/FU:F	ted (15-DaCompany Repor	ct #PHBS2005JP04814			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - Initial or Prolonged 15 mg/day 2880 MIN	Depressed Level Of Consciousness I		Lioresal	PS	Novartis Sector: Pharma	ORAL
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Freedom Of Information (FOI) Report

	Lasix	C	ORAL
80 mg/day	Zantac	С	ORAL
150 mg/day			
10 mg/day	Amlodin	C	ORAL
200 mg/day	Anplag	С	ORAL
	Calcium Carbonate	C	ORAL
3 g/day	Neurovitan	С	ORAL
3 df/day	Renagel	С	ORAL
750 mg/day			
50 mg/day	Cilostate	С	ORAL
	Diovan	С	ORAL
80 mg/day	Alfarol	С	ORAL
0.5 ug/day	Tryptanol	С	ORAL
40 mg/day			
400 mg/day	Tegretol	С	ORAL

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-Threate	ning	Alanine Aminotransferase Increased	Foreign Health	Viracept (Tablet) (Nelfinavir			
		Aplastic Anaemia	Professional	Mesilate)	PS		ORAL
ORAL							
		Aspartate		Bactrim			
		Aminotransferase		(Sulfamethoxazole,			
		Increased		Trimethoprim)	SS		ORAL
ORAL							
		Blood Creatinine Abnormal		Zidovudine			
		Blood Lactate		W/Lamivudine			
		Dehydrogenase Increased		(Lamivudine,			
		Blood Urea Decreased		Zidovudine)	SS		ORAL
(2 IN 1 D),							
		Bone Marrow Depression					

ORAL

	Epilepsy	Ergenyl Chrono		
	Prothrombin Level	(Valproate Sodium,		
	Decreased	Valproic Acid)	SS	ORAL
(2 IN 1 D),				
	Prothrombin Time			
ORAL				
	Shortened	Perindopril		
	Treatment Noncompliance	(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 Dose Duratic	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duratic Hospitalization - Initial or Prolonged 30 mg, QID	Delirium		Baclofen	PS	Novartis Sector: Pharma	ORAL
	Heart Rate Increased		Gabapentin	C		ORAL
400 mg, TID	Overdose		Oxycodone	С		ORAL
60 mg, TID	Pyrexia		Celecoxib	С		ORAL
100 mg, BID	Self-Injurious Ideation		Nifedipine	С		ORAL
60 mg/day	Suicide Attempt		Omeprazole	С		ORAL
20 mg/day	-		Tizanidine	С		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

Freedom Of Information (FOI) Report

		Fatigue Flatulence Haematochezia	Report Source	Product	Role	Manufacturer	Route
Dose Du	ration	Pigmentation Disorder Somnolence		Lioresal	PS	Novartis Sector: Pharma	ORAL
1 tablet/day		Urinary Incontinence		Lioresal	SS	Novartis Sector: Pharma	ORAL
2 tablets/day						Pilalilla	ORAL
				Lioresal	SS	Novartis Sector: Pharma	ORAL
4 tablets/day				Lioresal	SS	Novartis Sector: Pharma	ORAL
20 mg/day							01012
UNKNOWN				Diazepam	С		
				Losec	С		
UNKNOWN	PRN						
Age: Gen Outcome	der:Male ration - onged MCG, DA	: 4651510-3Report Type:Expedit I/FU:F PT Catheter Related Complication AILY, Device Failure Dizziness Migration Of Implant Vision Blurred	ed (15-DaCompany Repor Report Source Health Professional	t #20052273 Product Lioresal Intrathecal (Baclofen Injection)		Manufacturer	Route
	R Number der:Femai	: 4652397-5Report Type:Expedit le I/FU:I	ed (15-DaCompany Repor	t #20052321			
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose Du Hospitalization Initial or Prol INTRATHECAL		Device Malfunction Respiratory Failure G,	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		

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 Durati	ion					
Life-Threatening	Amnesia	Foreign	Lioresal Intrathecal			
Hospitalization -	Coma	Health	(Baclofen Injection)	PS		
INTRATHECAL MC	CG, DAILY,					
Initial or Prolonge	ed 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 Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
		Hallucination Muscle Spasms	Health Professional	Baclofen (Baclofen) Dantrolene	PS		
		Paranoia	Other	(Dantrolene)	С		

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 Dece	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration Life-Threatening Hospitalization - INTRATHECAL 50000	Cardiovascular Disorder Coma	Foreign Health	Lioresal Intratecal (Baclofen) Ampoule	PS		
Initial or Prolonged ONCE/SINGLE	Convulsion	Professional				
INTRATHECAL	Depressed Level Of	Other				
INIKAINECAL	Consciousness Disorientation Hypotension Incorrect Dose Administered Memory Impairment Muscle Spasticity Respiratory Failure		Timonil (Carbamazepine) Sirdalud (Tizanidine Hydrochloride)	C		
Date:05/02/05ISR Number Age: Gender:Male	: 4653037-1Report Type:Exped: I/FU:F	ited (15-DaCompany Rej	port #20052279			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - Initial or Prolonged INTRATHECAL MCG, D	•	Health Professional	Lioresal Intrathecal (Baclofen Injection)	PS		
INTRATHECAL	Device Failure					
	Drug Withdrawal Syndrome Haematemesis Lethargy Melaena Overdose		Miralax Mobic	C C		
	Pyrexia					
Date:05/12/05ISR Number Age:41 YR Gender:Male	: 4660527-4Report Type:Exped:	ited (15-DaCompany Rej	port #PHBS2002CL09569			

Other		Abdominal Distension	Lioresal	PS	Novartis Sector:	
ł		Abdominal Pain Upper			Pharma	ORAL
1 tablet/day						
		Chest Wall Pain	Lioresal	SS	Novartis Sector:	
		Choking Sensation			Pharma	ORAL
2 tablets/day						
		Fatigue	Lioresal	SS	Novartis Sector:	
1		Flatulence			Pharma	ORAL
4 tablets/day						
1		Haematochezia	Lioresal	SS	Novartis Sector:	
1		Pigmentation Disorder			Pharma	ORAL
20 mg/day						
		Somnolence	Diazepam	С		
UNKNOWN						
1		Urinary Incontinence	Losec	С		
UNKNOWN	PRN	-				
1						

Date:05/12/05ISR Number: 4660535-3Report Type:Expedited (15-DaCompany Report #PHNU2005DE01924 Age:48 YR Gender:Female I/FU:I

Outcome Dose	Duration	РТ	Report Source	Product	Role	Manufacturer	Route
Other		Blood Chloride Decreased Blood Sodium Decreased		Lioresal	PS	Novartis Sector: Pharma	ORAL
7200 MIN		Delusional Disorder, Persecutory Type		Detrusitol Spasmex	C 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 Gender:Female Age: I/FU:I Outcome PTReport Source Product Role Manufacturer Route Dose Duration Other Hallucination Foreign Baclofen PS Muscle Spasms Other Baclofen SS Paranoia Dantrolene С Date:05/20/05ISR Number: 4669855-XReport Type:Expedited (15-DaCompany Report #20052351 Age: Gender: Female I/FU:I Outcome ΡТ Report Source Product Role Manufacturer Route Dose Duration Implant Site Reaction Health Lioresal Intrathecal Required Inflammation Professional (Baclofen Injection) Intervention to PS INTRATHECAL MCG, DAILY, Prevent Permanent Mass INTRATHECAL Impairment/Damage Date:05/23/05ISR Number: 4669589-1Report Type:Expedited (15-DaCompany Report #PHNU2005DE01956 Gender:Female I/FU:I Age: Role Manufacturer PTReport Source Product Outcome 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 Gender:Male Age: I/FU:I Outcome PTReport Source Product Role Manufacturer Route Duration Dose Cholestasis Foreign Lioresal Health (Baclofen) Professional Ampoule PSINTRATHECAL 1 MG/KG/DAY, Other

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 Hospitalizat:	Duration ion -	Colitis	Foreign	Baclofen	PS	ORAL
2.5 MG MANE Initial or Pi ORAL	rolonged		Other			
Disability						

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 -	Agitation	Study	Hydromorphone Hcl		
Initial or Prolonged	Bowel Sounds Abnormal	Health	(Similar To Nda		
Other	Coma	Professional	21-044)		
	Disorientation	Other	(Hydromorphone		
	Hypotension		Hydrochloride)	PS	ORAL
ORAL					
	Mydriasis		Methadone		
	Tachycardia		(Methadone)	SS	ORAL
ORAL					
			Gabapentin		
			(Gabapentin)	SS	ORAL
ORAL					
			Amitriptyline		
			(Amitriptyline)	SS	ORAL
ORAL					
			Baclofen (Baclofen)	SS	ORAL
ORAL					
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Freedom Of Information (FOI) Report

Benzodiazepine Derivatives ()	SS	ORAL
Antiepileptics()	SS	ORAL
Warfarin (Warfarin)	SS	ORAL
	Derivatives () Antiepileptics()	Derivatives () SS

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 2.5mg Mane; Disability 5mg Nocte	Colitis		Baclofen	PS	Novartis Sector: Pharma	ORAL

Date:05/26/05ISR Number: 4674600-8Report Type:Expedited (15-DaCompany Report #PHBS2005JP04814 Age:63 YR Gender:Male I/FU:F

Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - Initial or Prolonged 5 mg, TID 2880 M	Depressed Level Of Consciousness		Lioresal	PS	Novartis Sector: Pharma	ORAL
			Lasix	С		ORAL
80 mg/day			Zantac	С		ORAL
150 mg/day			Amlodin	С		ORAL
10 mg/day			Anplag	С		ORAL
UNK , UNK			Calcium Carbonate	С		ORAL
UNK, UNK			Neurovitan	С		ORAL
3 df/day			illar ov i call	C		ORAL
			Renagel	С		ORAL
UNK, UNK			Cilostate	С		ORAL
UNK, UNK			-			

	Diovan	C	ORAL
UNK, UNK	Alfarol	С	ORAL
UNK, UNK	Tryptanol	С	ORAL
UNK, UNK	Tegretol	С	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 Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other	Duración	Hallucination Muscle Spasms		Baclofen	PS	Novartis Sector: Pharma	ORAL
40 mg/day		-					/
		Paranoia		Senna	С		ľ
2 tabs nocte							
				Dantrolene	С		ļ
UNKNOWN				Valproate Sodium	С		ORAL
400 mg/day				Valpioace Boaram	C		Olum

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 -	Atrioventricular Block
Initial or Prolonged	First Degree
Other	Blood Pressure Systolic
	Increased
	Convulsion
	Depressed Level Of
	Consciousness
	Drug Ineffective
	Hypokalaemia
	Hypotension
	Intentional Misuse

Freedom Of Information (FOI) Report

Dose	Dose Duration	Multiple Drug Overdose Simple Partial Seizures Sinus Bradycardia	Report Source Study	Product Morphine Sulfate	Role	Manufacturer	Route
			Health Professional Other	(Similar To Nda 19-516) (Moprhine Sulfate) Other	PS		ORAL
60 MG, SEE							
TEXT, ORAL				Baclofen (Baclofen)	SS		ORAL
ORAL				Bacioren (Bacioren)	20		OKAL
)5ISR Number Gender:Male	: 4679421-8Report Type:Expedi I/FU:F	ted (15-DaCompany Repor	t #1996AS00236			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other		Blood Pressure Decreased		Naropin	PS		
EPIDURAL	DOSE :	20 MG 1 DAY Bundle Branch Block Cardiac Septal Defect Convulsive Threshold Lowered Drug Level Increased Drug Toxicity Grand Mal Convulsion Incorrect Route Of Drug Administration Sinus Tachycardia Tachycardia		Baclofen Imipramine Hydrochloride Diazepam	SS C		
)5ISR Number Gender:Fema	: 4679967-2Report Type:Expedi le I/FU:F	ted (15-DaCompany Repor	t #PHNU2005DE01956			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other	Duracion	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	С	ORAL
40 mg/day		Torem	С	ORAL
5 mg, QD		Acetylsalicylic Acid	С	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 Life-Threaten Hospitalizati	5	Blood Creatinine Increased		Baclofen	PS	Novartis Sector: Pharma	ORAL
40 mg, QD							
Initial or Pr	colonged	Drug Level Increased		Tizanidine	SS		ORAL
36mg/day Other		Epilepsy		Gabapentin	SS		
UNKNOWN	400 mg,	BID					
		Glasgow Coma Scale		Bendrofluazide	С		ORAL
2.5mg/day							
		Abnormal					
		Hallucination					
		Loss Of Consciousness					
		Overdose					l
		Renal Failure Acute					
		Urinary Tract Infection					

Freedom Of Information (FOI) Report

Date:06/03/05ISR Number: 4680697-1Report Type:Expedited (15-DaCompany Report #1999AU14180 Age:13 YR Gender:Male I/FU:F

Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other	Duración	Bundle Branch Block		Ropivacaine	PS		
EPIDURAL	DOSE:	20 mg		-			
		Grand Mal Convulsion		Baclofen	SS		
		Tachycardia		Imipramine	SS		
Date:06/03/0	05ISR Number	: 4684546-7Report Type:Exped:	ited (15-DaCompany Re	port #20052367			
Age:	Gender:	I/FU:I					
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Hospitalizat		Cardiac Enzymes Increased	Health	Lioresal Intrathecal			
Initial or H	Prolonged	Loss Of Consciousness	Professional	(Baclofen Injection)	PS		
INTRATHECAL	MCG, I	DAILY,					
Required		Urosepsis	Company				
INTRATHECAL							
Intervention	n to		Representative				
Prevent Perr	manent						
Impairment/I	Damage						
Date:06/06/(Age:)5ISR Number Gender:Male	r: 4682607-XReport Type:Exped: I/FU:F	ited (15-DaCompany Re	port #PHNU2004DE04093			
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Other		Condition Aggravated Confusional State		Lioresal	PS	Novartis Sector: Pharma	ORAL
5 mg, BID						r mar ma	orum
		General Physical Health		Lioresal	SS	Novartis Sector:	
		Deterioration				Pharma	ORAL
2.5 mg, BID							
		Nausea		Trileptal "Novartis"	С		
900mg/day							
		· · ·					

Vomiting

Outcome	PT		Report Source	Product	Role	Manufacturer	Route
Dose Duration Hospitalization - Initial or Prolonged OROPHARINGEAL	Dyskinesia Vomiting						
OROPHARINGEAL	0	DAY		Tramadol Hydrochloride	SS		
OROPHARINGEAL	б	DAY		Baclofen	SS		
OROPHARINGEAL	б	DAY		Asprin	С		
OROPHARINGEAL				Frusemide	C		
OROPHARINGEAL				Senna	C		
OROPHARINGEAL				Semia	C		
Date:06/07/05ISR Number Age: Gender:Male			ited (15-DaCompany Repor	t #PHFR2005GB02015			
Outcome	PT		Report Source	Product	Role	Manufacturer	Route
Dose Duration Other	Confusional Creatinine F			Baclofen	PS	Novartis Sector: Pharma	
UNKNOWN 10 mg,						Fliatina	

Renal Impairment

Sedation

Freedom Of Information (FOI) Report

Date:06/07/05ISR Number: 4684072-5Report Type:Expedited (15-DaCompany Report #PHBS2005IE07820 Age:42 YR Gender:Female I/FU:I

Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other	DULALION	Asthenia Bradycardia		Lioresal	PS	Novartis Sector: Pharma	ORAL
5 mg		Syncope		Lithium	С		
Date:06/07/0 Age:	05ISR Number Gender:Male	r: 4685227-6Report Type:Exped	ited (15-DaCompany Re	port #05-06-0968			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other 10 MG TDS	Duración	Confusional State	Foreign	Baclofen -Ipi	PS		
		Renal Impairment Sedation	Other				
		Sedacion					
Age:17 YR Outcome	Gender:Male	: 4687999-3Report Type:Exped	lited (15-DaCompany Re Report Source	port #20052372 Product	Role	Manufacturer	Route
Age:17 YR	Gender:Male Duration tion -	r: 4687999-3Report Type:Exped e I/FU:I			Role	Manufacturer	Route
Age:17 YR Outcome Dose Hospitalizat	Gender:Male Duration tion - Prolonged	r: 4687999-3Report Type:Exped E I/FU:I PT Blood Pressure Decreased Blood Test Abnormal Catheter Related	Report Source Health	Product Lioresal	Role PS	Manufacturer	Route
Age:17 YR Outcome Dose Hospitalizat Initial or F Required	Gender:Male Duration tion - Prolonged MCG, E n to	r: 4687999-3Report Type:Exped E I/FU:I PT Blood Pressure Decreased Blood Test Abnormal Catheter Related	Report Source Health	Product Lioresal Intrathecal(Baclofen		Manufacturer	Route

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose Hospitaliza Initial or		Alanine Aminotransferase Increased		Lioresal	PS	Novartis Sector: Pharma	ORAL
Inicial Of	riorongea	Aspartate		Iuvacor	С	1 Har ma	ORAL
UNKNOWN		nopareace		14/4001	C		
		Aminotransferase		Oxygen	С		
		Increased		Seretide	С		
UNK, UNK							
		Asthenia		Ventoline	С		
		Blood Alkaline		Meteospasmyl	С		ORAL
PRN		Phosphatase Increased Blood Bilirubin Increased Chromaturia Chronic Hepatitis Cytolytic Hepatitis Faeces Discoloured Jaundice Pruritus					
Date:06/15/ Age:63 YR		: 4691421-0Report Type:Expedit le I/FU:I	ced (15-DaCompany Repor	rt #KII-2005-0016870			
Outcome		PT					
Other		Abnormal Behaviour Anger					

Freedom Of Information (FOI) Report

	5	Cerebral Ischaemia Confusional State Drug Ineffective	Report Source	Product	Role	Manufacturer	Route
Dose	Duration	Hostility Hypertension Somnolence Thinking Abnormal	Study Health Professional Other	Oxycontin Tablet (Oxycodone Hydrochloride) Cr Tablet	PS		ORAL
HS, ORAL				Flexeril (Cyclobenzaprine Hydrochloride)	SS		ORAL
SEE TEXT,				hydrochioride)	66		ORAL
ORAL				Amitriptyline (Amitriptyline)	SS		ORAL
SEE TEXT,							
ORAL				Baclofen (Baclofen)	SS		ORAL
DAILY, ORAL				······································			
Date:06/17/(Age:	05ISR Number Gender:	: 4695697-5Report Type:Direc I/FU:I	ct Company Re	eport #CTU 251410			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other	Duracion	Drug Dispensing Error Medication Error		Baclofen	PS		
Date:06/20/0 Age:	05ISR Number Gender:Fema	: 4696318-8Report Type:Expedule I/FU:I	lited (15-DaCompany Re	eport #2005087341			
Outcome	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Dose Hospitaliza Initial or D Other		Blood Pressure Abnormal Chest Pain Drug Ineffective Heart Rate Irregular Hepatic Cyst Mobility Decreased	Consumer	Bextra (Valdecoxib) Celebrex (Celecoxib) Baclofen (Baclofen) Vioxx (Rofecoxib) Rebif (Interferon Beta)	PS SS SS SS		

	Nausea Spinal Cord Injury		(Clarithromycin) Skelaxin	SS		
I			(Metaxalone)	SS	SS	
Date:06/21/05ISR Number Age: Gender:Fema	: 4698265-4Report Type:Exped le I/FU:F	lited (15-DaCompany Re	eport #20052321			
Outcome Dose Duration	РТ	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, DA Intervention to INTRATHECAL Prevent Permanent Impairment/Damage	AILY,					
Date:06/22/05ISR Number Age:42 YR Gender:Fema	: 4697061-1Report Type:Exped le I/FU:I	lited (15-DaCompany Re	eport #PHRM2005FR01836			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other	Accidental Overdose Hypotonia		Lioresal	PS	Novartis Sector: Pharma	ORAL
150 mg 1440 MIN	Salivary Hypersecretion		Lioresal	SS	Novartis Sector:	
30 mg/day	Somnolence				Pharma	ORAL

Freedom Of Information (FOI) Report

Baclofen

Ciprofloxacin

Bendrofluazide

SS

С

С

ORAL

	Topalgic "Houde"	C	ORAL
	Spasfon	C	
UNKNOWN			
	Microlax	C	
RECTAL			

Date:06/22/05ISR Number Age: Gender:Unkn	: 4698580-4Report Type:Exped nown I/FU:F	ited (15-DaCompany Re	port #20052367		
Outcome	PT	Report Source	Product	Role Manufacturer	Route
Dose Duration					
Hospitalization -	Autonomic Nervous System	Health	Lioresal		
Initial or Prolonged	Imbalance	Professional	Intrathecal(Baclofen		
Required	Disease Progression	Company	Injection)	PS	
INTRATHECAL DAILY,					
Intervention to INTRATHECAL	Loss Of Consciousness	Representative			
Prevent Permanent	Multiple Sclerosis				
	-				
Impairment/Damage	Myocardial Infarction Orthostatic Hypotension Urosepsis				
Date:06/22/05ISR Number Age: Gender:Fema	: 4699427-2Report Type:Exped le I/FU:I	ited (15-DaCompany Re	port #ACO_0169_2005		
Outcome	PT	Report Source	Product	Role Manufacturer	Route
Dose Duration					
Hospitalization - 36 MG PO	Epilepsy	Foreign	Zanaflex	PS	ORAL
Initial or Prolonged	Glasgow Coma Scale	Health	Gabapentin	SS	ORAL

Professional

Other

40	MG	PO

800 MG PO

Hallucination Intentional Misuse Loss Of Consciousness Overdose Renal Failure Acute Urinary Tract Infection

Abnormal

Date:06/27/05ISR Number: 4700189-0Report Type:Expedited (15-DaCompany Report #PHBS2005JP04814 Age:63 YR Gender:Male I/FU:F

Outcome Dose Durati	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - Initial or Prolonge	Depressed Level Of		Lioresal	PS	Novartis Sector: Pharma	ORAL
			Lasix	С		ORAL
80 mg/day			Zantac	С		ORAL
150 mg/day			Amlodin	С		ORAL
10 mg/day			Anplag	С		ORAL
200 mg/day			Calcium Carbonate	С		ORAL
3 g/day			Neurovitan	C		ORAL
3 df/day						
750 mg/day			Renagel	С		ORAL
100 mg/day			Cilostate	С		ORAL
80 mg/day			Diovan	С		ORAL
			Alfarol	С		ORAL
0.5 ug/day			Tryptanol	С		ORAL
40 mg/day			Tegretol	С		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 - Areflexia Initial or Prolonged Drug Dispensing Error Other Dry Mouth

Freedom Of Information (FOI) Report

		Enuresis Medication Error Psychomotor Skills	Report Source	Product	Role	Manufacturer	Route
Dose	Duration	Impaired	nepolo Scalco	Lioresal	PS	Novartis Sector:	
1 - 0		Somnolence				Pharma	ORAL
150 mg	1440 MIN			Lioresal	SS	Novartis Sector: Pharma	ORAL
10 mg, 6QD					a		0.5.1.1
				Topalgic "Houde" Spasfon	C C		ORAL ORAL
				Microlax	C		Oldin
RECTAL				Lovenox	С		
	5ISR Number Gender:Male Duration	: 4707038-5Report Type:Expedi I/FU:I PT	ted (15-DaCompany Repor Report Source	rt #PHBS2005CN09312 Product	Role	Manufacturer	Route
DOBC							
Other	Duracion	Glaucoma		Lioresal	PS	Novartis Sector: Pharma	ORAL
Other 120 to 160	Duración	Glaucoma		Lioresal	PS		
	Duración	Glaucoma		Lioresal	PS		
120 to 160 mg/day Date:07/07/0		: 4708591-8Report Type:Expedi	ted (15-DaCompany Repo		PS		
120 to 160 mg/day Date:07/07/0 Age: Outcome	5ISR Number Gender:Fema	: 4708591-8Report Type:Expedi	ted (15-DaCompany Repor Report Source				
120 to 160 mg/day Date:07/07/0 Age:	5ISR Number Gender:Fema Duration ion -	: 4708591-8Report Type:Expedi le I/FU:I PT Drug Withdrawal Syndrome Muscular Weakness		ct #PHFR2005GB02359		Pharma	ORAL

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						,
Hospitaliza	ation -	Convulsion		Rifadine	PS	Aventis	
Initial or	Prolonged	Drug Effect Decreased				Pharmaceuticals Inc.	ORAL
1		Drug Level Below		Artane	SS		ORAL
1		Therapeutic		Oflocet	SS		ORAL
1		Drug Level Decreased		Depakine	SS		ORAL
1		Postictal State		Lioresal	SS		I
4							

INTRATHECAL

Date:07/07/05ISR Number: 4708859-5Report Type:Expedited (15-DaCompany Report #2005087341 Age: Gender:Female I/FU:F

rer Route	Manufacturer	Role	Product	Report Source	PT	come
						e Duration
		PS	Bextra (Valdecoxib)	Consumer	Blood Pressure	pitalization -
			Celebrex	Health	Fluctuation	tial or Prolonged
				Professional	Chest Pain	ler
		SS	(Celecoxib)		Drug Ineffective	
			Baclofen		Heart Rate Irregular	
		SS	(Baclofen)		Hepatic Cyst	
			Vioxx		Multiple Sclerosis	
		SS	(Rofecoxib)		Nausea	
			Rebif			
		SS	(Interferon Beta)			
			Biaxin			
		SS	(Clarithromycin)			
			Skelaxin			
		SS SS	(Celecoxib) Baclofen (Baclofen) Vioxx (Rofecoxib) Rebif (Interferon Beta) Biaxin (Clarithromycin)		Chest Pain Drug Ineffective Heart Rate Irregular Hepatic Cyst Multiple Sclerosis	_

Freedom Of Information (FOI) Report

(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 Dura	ation					
Hospitalization	- Blood Pressure	Consumer	Bextra (Valdecoxib)	PS		
Initial or Prolo	nged Fluctuation	Health	Celebrex (Celecoxib)	SS		
Other	Chest Pain	Professional	Baclofen (Baclofen)	SS		
	Drug Ineffective		Vioxx (Rofecoxib)	SS		
	Heart Rate Irregula	ır	Rebif (Interferon			
	Hepatic Cyst		Beta)	SS		
	Multiple Sclerosis		Biaxin			
4	Nausea		(Clarithromycin)	SS		
4			Skelaxin			
			(Metaxolone)	С		

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:	
	Bra	Bradycardia				Pharma	ORAL
		Syncope		Lithium	С		

Date:07/11/05ISR Number: 4711302-3Report Type:Expedited (15-DaCompany Report #05-07-1153 Age:49 YR Gender:Female I/FU:I

Outcome Dose	Duration	PT	Report Source	Product	Role Manufacturer	Route
Hospitalization - Initial or Prolonged 10MG TID ORAL	lon - rolonged	Blood Creatine Phosphokinase Increased		Baclofen - Ipi Tablets	PS	ORAL
		Chest Pain Hypoaesthesia Oral Mitral Valve Prolapse Palpitations Paraesthesia Oral				

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Adhesion		Lioresal	PS	Novartis Sector:	
Initial or Prolonged 25 mg, TID	Asthenia				Pharma	ORAL
Disability INTRATHECAL	Motor Dysfunction		Lioresal Intrathecal	SS		
	Oedema					
Age:81 YR Gender:Male		dited (15-DaCompany Re	20010 #1111020030510/10			
Age:81 YR Gender:Male Outcome	e I/FU:I PT		-pore #1111020030510710			
Age:81 YR Gender:Male Outcome Hospitalization -	e I/FU:I		-pore #1111020030510710			
Age:81 YR Gender:Male Outcome	e I/FU:I PT Adrenal Adenoma		-pore #1111020030510710			
Age:81 YR Gender:Male Outcome Hospitalization -	PT Adrenal Adenoma Bladder Mass Dehydration Haematuria		-pore #1111020030510710			
Age:81 YR Gender:Male Outcome Hospitalization -	PT Adrenal Adenoma Bladder Mass Dehydration		-pore #1111020030510710			

Freedom Of Information (FOI) Report

Dose Durati	Sedation Syncope Urinary Tract Infection on	Report Source	Product	Role	Manufacturer	Route
			Baclofen	PS	Novartis Sector: Pharma	
INTRAVENOUS Do	uble-blind		Zoledronic Acid Vs Placebo	SS	Pharma	
INTRAVENOUS DC			Ativan Pentoxifylline Lasix Calcium Carbonate Vitamin D	SS SS SS C C		
Date:07/13/05ISR Nu Age:45 YR Gender:	umber: 4714224-7Report Type:Di Female I/FU:I	rect Company Re	eport #CTU 253147			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Durati Hospitalization - Initial or Prolonge	Difficulty In Walking		Baclofen	PS C		
	Complication		Neurontin Tylenol	C C		
Date:07/15/05ISR Nu Age:14 YR Gender:	mber: 4715316-9Report Type:Ez Female I/FU:I	pedited (15-DaCompany Re	eport #FR-ABBOTT-05P-056	-0305095	5-00	
Outcome Dose Durati	PT .on	Report Source	Product	Role	Manufacturer	Route
Hospitalization -	Convulsion		Depakine Tablets	PS		ORAL
Initial or Prolonge			Rifampicin	SS		ORAL
UNKNOWN	Drug Interaction		Morphine	С		
UNKNOWN	Drug Level Decreased		Morphine	С		
			Morphine	С		
UNKNOWN				_		0537
			Ofloxacin Baclofen	I I		ORAL
INTRATHECAL 12	5 mg daily		200102011	-		

through

implantable					
intrathecal					
pump			Trihexyphenidyl Hydrochloride	I	
Date:07/15/05ISR Number Age: Gender:Male	: 4715673-3Report Type:Direct I/FU:I	Company Repor	rt #CTU 253397		
Outcome Dose Duration	PT	Report Source	Product	Role Manufacturer	Route
Hospitalization - INTRATHECAL 1400 MC Initial or Prolonged 24 HOURS	Device Failure G OVER Hypotension		Lioresal	PS	
Required INTRATHECA	Lethargy				
Intervention to Prevent Permanent Impairment/Damage	Loss Of Consciousness Overdose Urinary Retention				
Date:07/19/05ISR Number Age: Gender:Male	: 4719507-2Report Type:Expedit I/FU:I	ed (15-DaCompany Repor	rt #20052426		
Outcome Hospitalization - Initial or Prolonged					
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Freedom Of Information (FOI) Report

SS

ORAL

Rifadine

Required						
Intervention to				_		
Prevent Permanent	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration	7 - then is	Health	Lioresal			
Impairment/Damage	Asthenia Diplegia	Professional	Intrathecal(Baclofen			
	Granuloma	FIOLESSIONAL	Injection) 2000			
	OFAIIAFOINA		Mcg/Ml	PS		
INTRATHECAL MCG,	DAILY,		2.			
INTRATHECAL						
	r: 4720549-1Report Type:Exped	lited (15-DaCompany Re	eport #20052419			
Age: Gender:Mal	e I/FU:I					
Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration		-				
Hospitalization -	Atrial Fibrillation	Health	Lioresal	PS		
	100 MCG,					
Initial or Prolonged	Catheter Related	Professional				
DAILY,						
Required INTRATHEC	Complication					
Intervention to	Drug Withdrawal Syndrome					
Prevent Permanent	Dysphonia					
Impairment/Damage	Fluid Retention					
2	Hallucination					
	Mental Status Changes					
	Muscle Spasticity					
	Post Procedural					
	Complication					
	Pruritus Pulmonary Embolism					
	Screaming					
	Screaming					
Data:07/22/05.50 Numba	x. 4700520 VDepert Trme. Frme	lited (15 Declements D	Sout HID INIEGO 20050700			
Age:14 YR Gender:Fem	r: 4722538-XReport Type:Expec ale I/FU:I	iited (15-Dacompany Re	2001C #02-000FOC-200507008	52		
Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration		-				
Hospitalization -	Convulsion		Oflocet	PS		ORAL
Initial or Prolonged	Drug Interaction		Artane	SS		ORAL
			Diffe dia a	<u> </u>		

Drug Level Below

INTRATRACHEAL	Therapeutic		Lioresal	SS	
INIRAIRACHEAL	Postictal State		Depakine	I	ORAL
Date:07/25/05ISR Numbe Age: Gender:Mal	er: 4726181-8Report Type:Ex	pedited (15-DaCompany R	eport #20052437		
Outcome	PT	Poport Courgo	Product	Role Manufacturer	Route
Dose Duration	PI	Report Source	Product	ROLE Manufacturer	KOULE
Hospitalization -	Gait Disturbance	Foreign	Lioresal Intrathecal		
Initial or Prolonged DAILY,	Generalised Oedema	Health	(Baclofen Injection)	PS	
	Hypotonia	Professional			
INTRATHECAL					
	Laboratory Test Abnormal				
Date:07/25/05ISR Numbe Age: Gender:Mal	er: 4726243-5Report Type:Ex .e I/FU:F	pedited (15-DaCompany R	eport #PHBS2005AT09514		
Age: Gender mar					
Outcome	PT	Report Source	Product	Role Manufacturer	Route
Dose Duration					
Hospitalization -	Adhesion	Foreign	Lioresal Intrathecal		
Initial or Prolonged	Asthenia	Health	(Baclofen) Ampoule	PS	
	ATHECAL				
Disability	Brain Oedema	Professional	Lioresal (Baclofen)		0.5.7.7
	Motor Dysfunction	Other	Tablet	SS	ORAL
25 MG, TID					
ORAL	Muscular Weakness				
ORAL	Oedema				
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Freedom Of Information (FOI) Report

Age:	Gender:	I/FU:I					
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Other		Delusion		Lioresal	PS	Novartis Sector:	
100 150		Psychotic Disorder				Pharma	ORAL
100-150 mg,							
daily							
	05ISR Number Gender:Fema	r: 4727384-9Report Type:Dir ale I/FU:I	ect Company R	eport #CTU 254537			
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration			- 1 6	5.0		
Hospitaliza [PAST WEEK]		Drug Toxicity		Baclofen	PS		
Initial or		Mental Status Changes		Lipitor	С		
	1101011904			Glipizide	C		
				Zemplar	C		
				Epogen	С		
				Insulin	С		
				Prevacid	С		
				Vicodin	С		
				Trazodone	С		
				Plavix	С		
				Pro-Med	C		
	05ISR Number Gender:Fema	r: 4727426-0Report Type:Dir ale I/FU:I	ect Company R	eport #CTU 254510			
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Hospitaliza		Hypotension		Hydromorphone 20	5.0		
Initial or		Hypoventilation		Mg/Ml	PS		
INTRATHECAL	. 20 MG/	ML, 4					
MG DAILY IT	,	Hypoxia					
NG DAIDI II		Lethargy					
		ncentar Al					
[דיטאט האנא ו							
[LONG TERM]		Respiratory Depression		Baclofen 140 Mg /Ml	SS		

IT [LONG

TERM]

Somnolence

Ambien	С
Propoxyphene	С
Singulair	С
Promethazine	С
Lamictal	С
Zanaflex	С
Paxil	С
Neurotin	С
Zetia	С
Nexium	С
Maxide	С
Dicyclomine	С
Patanol	С
Nasonex	С
Diazepam	С
Clarinex	С
Coumadin	С

Date:08/01/05ISR Number: 4730631-0Report Type:Expedited (15-DaCompany Report #PHHO2005US10718 Age:81 YR Gender:Male I/FU:F

Outcome PT Hospitalization - Adrenal Adenoma Initial or Prolonged Bladder Mass

Freedom Of Information (FOI) Report

Dogo	Dehydration Haematuria Hypotension	Report Source	Product	Role	Manufacturer	Route
Dose Duratic	Mental Status Changes Sedation		Baclofen	PS	Novartis Sector: Pharma	
	Syncope		Zoledronic Acid Vs			
	Urinary Tract Infection		Placebo	SS		
INTRAVENOUS Dou	ble-blind					
			Ativan	SS		
			Pentoxifylline	SS		
			Lasix	SS		
			Calcium Carbonate	С		
			Vitamin D	С		
Age:56 YR Gender:M				- 1		-
Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duratio						
Hospitalization -	Body Temperature	Study	Oxycodone			
Initial or Prolonged		Health	Hydrochloride			
Other	Confusional State	Professional	(Similar To Nda			
	Hypertension	Other	20-553) (Oxycodone			0.7.7.7
	Lethargy		Hydrochloride)	PS		ORAL
ORAL	Tremor		Tramadol (Tramadol)	SS		ORAL
ORAL	ITEMOL			66		ORAL
			Acetaminophen With			
			Propoxyphene			
			(Acetaminophen With			
1			Propoxyphene)	SS		ORAL
ORAL						•
			Baclofen (Baclofen)	SS		ORAL
ORAL						
	ber: 4733088-9Report Type:Di	rect Company Re	eport #CTU 254843			
Age:80 YR Gender:№	Iale I/FU:I					
Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duratio		Report Bource	1100000	1.010		
Hospitalization -	Dyskinesia		Baclofen	PS		ORAL
5 MG PO TID						

Initial or Prolonged 60 MG PO Q 12	Fall		Promethazine	SS	ORAL
Required H	Mental Status Changes				
Intervention to PRN	Pain		Diphenhydramine	SS	
Prevent Permanent Impairment/Damage			Morphine Hydrocodone/Apap	SS C	
Date:08/01/05ISR Numbe: Age:49 YR Gender:Male	e: 4733092-0Report Type:Direct	Company Repor	rt #CTU 254840		
Outcome Dose Duration	PT	Report Source	Product	Role Manufacturer	Route
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

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	Adrenal Adenoma		Baclofen	PS	Novartis Sector:	
Death Hospitalization -	Anaemia		Baciolen	PS	Pharma	
Hospitalization - Initial or Prolonged	Bladder Cancer		Zoledronic Acid Vs		Pilarilla	
inicial of Florongea	Bladder Mass		Placebo	SS		
INTRAVENOUS Double			FIACEDO	22		
INTRAVENOUS DOUDIE	Confusional State		Ativan	SS		
	Dehydration		Pentoxifylline	SS		
	General Physical Health		Lasix	SS		
	Deterioration		Calcium Carbonate	C		
	Haematocrit Decreased		Vitamin D	C		
	Haematuria			-		
	Haemoglobin Decreased					
	Hypokalaemia					
	Hyponatraemia					
	Hypotension					
	Mental Status Changes					
	Sedation					
	Syncope					
	Urinary Tract Infection					

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Other		Abdominal Distension Gastrointestinal Disc	order	Lioresal	PS	Novartis Sector: Pharma	
5 mg							
l				Lioresal	SS	Novartis Sector: Pharma	
5 mg TID							
l							
	05ISR Number: Gender:	: 4747946-2Report Type I/FU:I	e:Expedited (15-DaCompany Rep	ort #US-ABBOTT-05	P-163-0307987	-00	
		5			- 1		

Outcome		PT	Report Source	Product	Role Manufacturer	Route
Dose	Duration					
Hospitalizat	tion -	Convulsion		Vicodin	PS	
Initial or H	Prolonged	Convulsion Neonatal		Baclofen	SS	
Other		Drug Exposure During		Etanercept	SS	
		Pregnancy				
		Neonatal Respiratory				
		Distress Syndrome				
		Premature Baby				
		Premature Labour				
1		Respiratory Distress				
1						

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